Questionnaire 1 (Clarification) Exemption 17 of RoHS Annex IV

Lead in solders of portable emergency defibrillators (category 8)

Requested validity: Until the end of 2025

1. 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 some information is 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 26 August 2020 latest.

2. Questions

1. How long is the field time of defibrillators before they are either checked and/or replaced?

   The battery and pads in defibrillators have a shelf life which is typically between 2 to 5 years, depending on the model. Both of these components require periodic replacement. Usually, defibrillators remain in use in the field until they stop functioning correctly. This is usually shown by internal test or routine checks and the identified faults cannot be repaired. Typically, products are guaranteed for 5-10 years but may be active in service for 15 years or more. Maintenance checks are typically annually or as needed and some parts are replaced every 2 years. An example operating instructions is provided to illustrate these timescales.

2. You mention the ongoing conversion of new models to lead-free solders:

   a. What is the current share of lead-free models in the product range and as market share?

      For COCIR members, the proportion that are lead-free is approximately 10% of models, so 90% still require lead-based solders.

   b. Are these models used in all environments?

      There are limitations to the types of use environments for some defibrillators. Some models have been designed (including the use of lead-solder for shock and vibration) to be used in emergency responder vehicles intended for harsher use scenarios including the back of a vehicle and falling off a stretcher used in emergency settings. Whereas hospital versions of defibrillators are intended to sit on a stable cart, so experience some vibration and jolts, but are less likely to be dropped. Other environments that defibrillator models have been design for include the use in battlefield, commercial aircraft, marine environments and helicopters.

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

c. How many ongoing approval procedures are there for new equipment using lead-free solders?

To "qualify" Class III Medical Device there are a minimum of three phases of testing required to be conducted and each phase may require more than one round of testing. Each round of testing at each phase consists of approximately 140 tests.

COCIR is aware of two approvals which are in progress for an existing product lines, which span multiple products. There is the potential for additional approvals which are underway which COCIR have been unable to confirm due to limited timeframes. Furthermore, there are activities which include the evaluation, scoping and planning for other product lines and related accessories which are ongoing.

3. You justify the exemption among other things with undesirable price increases for the customers. Most other devices have been shifted to lead-free in the past almost two decades without any remarkable price increases observed, which is plausible, since the soldered parts (printed circuit boards, etc.) are only a very small portion of the total production cost, and the cost increase due to lead-free soldering adds a small percentage to this already small portion. What is the average price increase you expect and how would it be prohibitive for purchasing defibrillators?

We explained in the exemption renewal request that take up of new defibrillators will be dependent on availability and price, where a lower price would encourage more to be purchased. Price is not affected by choice of solder alloy as the difference in metal price is insignificant compared to the price of a defibrillator. Product price will however depend on the cost of development of new lead-free designs. As a Class III Medical Device, defibrillators face significantly greater barriers to market than typical EEE devices; examples of the additional effort include clinical trials which may be required due to significant changes, global approvals and validation and approvals from notified bodies where extensive reliability and trials are required.

Lead-free solders tend to be more brittle and therefore adds considerably more design and testing efforts to create reliable lead solder-free printed circuit board assemblies that will withstand road and stretcher vibrations and 30-inch drops. Furthermore, defibrillators are designed to be as light and small as possible without compromising reliability. Therefore, in order to install additional shock and vibration buffering, layout inside the defibrillator and the overall size of the defibrillator is included in the design changes.

Manufacturers believe that price increases are inevitable, but would be higher if there are no profits from sales of existing lead-soldered models to help fund R&D. The price increase will be based on the design expenses of the new boards as well as the costs of the new and more robust components. So either way, the cost of the lead-free defibrillator will still be higher. If safe and effective replacements are not qualified then manufacturers could be forced to withdraw some models from the EU market temporarily until development can be completed, or as a worst-case scenario withdraw products permanently.

4. You estimate that the transition to lead-free solders will be completed and approvals granted by the end of 2025. Please explain further the assumptions you have made for this estimate.

This transition is predicated on the assumptions that new designs prove to be reliable and function as expected during validation testing and that new models are approved. This will, allow older designs which include lead solder to be withdrawn from the EU market by this date.

Timing is based on the re-design that includes multiple components, the install process of the components and size limitations inside the defibrillator. There are many of these devices to re-design and a finite number of design and test engineers available, causing some of the devices to be re-designed in sequence. Furthermore, the regulatory submission cycles/approvals of significant changes can take between 16 and 18 months. The extension to 2025 was to allow time for all of the defibrillator devices to be re-designed, tested and approved.

5. The cited research results on the reliability of lead-free solders are 10 years and older.

    a. Have you included current research results? Which ones?

Intensive research into lead-free solders began when the RoHS Directive was originally adopted in 2002. This early work showed that all lead-free alloys are different to lead-based solders and are not drop-in replacements. Some suitable lead-free alloys had been developed by 2006 for products that were in scope of RoHS at that time, but these alloys still had reliability concerns and so research has continued. Until about 2010, most research was carried out and published by Universities and industry consortia, but since then, further research, based on this published knowledge has been carried out primarily by individual manufacturers for their own product designs and this work has not been published as it is regarded as confidential. Medical device manufacturers are still carrying out research into lead-free soldered designs in those applications where RoHS exemptions still allow the use of lead-solders and this will end only when proven reliable substitutes have been developed.

b. Some properties are, of course, inherent to the lead-free solders that have been available in the past almost 20 years. Nevertheless, even the automotive industry, which also has very high reliability requirements since electronics operates in very harsh environments, changed to lead-free soldered printed circuit boards and replaced lead in most other applications as well, despite of the properties of lead-free solders which you reference as a reason for continuation of using lead solders. In the light of these developments, we understand that defibrillators are highly important and must be reliable, but we kindly ask you to explain how the requirements for defibrillators go beyond those of other branches that basic properties of lead-free solders prevent the shift to lead-free solders.

Defibrillators are different to most other types of electrical product and also automotive. The most important difference is that if any single solder bond in a defibrillator were to fail, a person is likely to die. Solder bond reliability is further compromised by the hostile environments in which defibrillators are used. Unlike the automotive industry, drop shock performance is a critical parameter as during defibrillators' normal operations, they could easily experience drops from 1m or above. It is foreseeable that defibrillators can be transported in helicopters and in ambulances where they suffer from severe vibration or be located at locations where they experience large temperature fluctuations, high humidity, marine environments or are used in factories where they may be exposed to corrosive chemicals. All of these types of situations represent a range of harsh environments which are experienced by relatively few types of products and of these, none have the same, very high reliability requirement. It is for these reasons that development of lead-free defibrillators is taking a longer time than most other products.

- Defibrillators contain multiple aluminum electrolytic capacitors in PCBAs. Most of the types of aluminum electrolytic capacitors used in defibrillators do not meet the higher lead-free solder temperature requirement. In some defibrillators, eight Aluminum Electrolytic capacitors (used in 23 location) are questionable due that they cannot withstand the higher lead-free reflow temperature requirement (This part meets the peak reflow, but not the dwell time requirements). The component suppliers do not recommend using the components beyond the supplier recommended reflow profiles. There are no replacements available for these eight components in the market that are specified to be compatible to be with the lead-

free reflow soldering process. The only option is to use these parts beyond the supplier recommended reflow profile which may cause reliability issues long term for patient use. If aluminum electrolytic capacitors are heated to above their recommended temperature profile, the electrolyte will vaporize and will be lost which will shorten the useful life of the component and the defibrillator may not work in an emergency situation.

- For Automotive design, there are automotive standards at component level and there are many commercial off-the shelf components available in the marked that meet these standards. These components, by default, ensure they can withstand the environments found with automotive use. This helps to upgrade/re-design the automotive circuits faster. However, Medical devices do not have such standards at component level. Hence, customized reliability testing is required for components used in Medical devices to ensure that all components will be able to withstand environments experienced during emergency response situations.

- In addition, many component suppliers offer automotive standard certified components but do not offer Class III Medical device certified components. This is again limiting the components choices for class III device owners.

6. We understood in earlier exemption reviews that the medical industry produces highly complex machines like MRTs, PETs, etc. where the redesign may take years. Compared to those devices, defibrillators seem to be much less complex. Against the background that it was official since 2011 that medical devices are included into the scope of the RoHS Directive, could you please let us know why those redesigns have not yet happened in the past nine years?

   The time taken to convert a medical device made with lead solders to a lead-free medical device depends on many factors. By 2014, many lead-free soldered medical devices had been developed including X-ray imaging, but lead solders are still needed in MRI and in a few other applications permitted by RoHS exemptions. Most medical devices are used in hospitals where the environment is relatively benign. Reliability is especially uncertain when bonds are exposed to cyclic stresses due to large temperature changes, drop shocks and vibration, which can occur with defibrillators, but is not an issue with medical devices located in hospitals, clinics or in homes. These reliability concerns are especially important with defibrillators because if a fault occurs, the defibrillator will not function and as a result, the patient is likely to die. This severe result of failure does not occur with most other types of medical device. Failure of MRI or PET could stop the equipment from working which will prevent patients being diagnosed, but immediate death is unlikely.

   The differences in regulatory requirements also impact the qualification timescales. Defibrillators are Class III medical devices and as such require a significantly higher regulatory burden to place and keep on the market compared with Class II medical devices like the imaging systems referenced.

   Imaging systems like the ones referenced are operated by radiologists and imaging technicians who are trained and run those machines regularly if not continuously. Automated External Defibrillators (AED) devices are intended to be operated by lay users with no previous training, while in a chaotic and nerve-racking situation. Manufacturers expend a large amount of effort into developing and testing user interfaces in an iterative manner in order to achieve an optimal level of usability.

7. The new EU MDR (medical device regulation) must be observed:

   a. How long does an approval procedure for a new model actually take only for EU countries, if it requires around 2 years for a global approval?

Based on notified body communications and previous experience with notified body review times, a notified body review of a new medical device submission under the new EU MDR regulations can take between 12 to 18 months.

b. How many ongoing procedures are there?

For COCIR member companies only, 90% of their products will need to be redesigned to produce lead-free products. These are at different stages of development, some being in the design stage, others being tested or being submitted for approval. One company has currently two at the re-design stage.

8. You explain the typical development time of new designs with 6-8 years. The table on page 11 describes the individual aspects.

a. The rewriting of software is indicated with one year. Why is the use of newer microprocessors so challenging that such a long period is necessary?

Complete circuit redesign is usually necessary as lead-free versions of previously used components are often not available. As a consequence this will probably mean that newer and different microprocessors are used which requires the software to be rewritten. Software used in medical devices must meet the requirements of IEC 62304 entailing considerable documentation.

The one-year timescale given for software writing in the table of page 11 includes validation testing of the circuit to ensure that the software performs correctly under all foreseeable circumstances and conditions. There are many variables that need to be considered, such as patient's age, size, weight, medical conditions, user behavior, environmental conditions, factors that affect circuit tests, etc., and there are a very large number of combinations of these variable, each of which must be thoroughly assessed. If a defect occurs, then the software will need to be amended. Experience has shown that allowing one year for this phase is reasonable. Another limitation on the time needed is the number of available trained engineers who are able to be tasked which such redesign which can delay this work.

b. Which of the phases can run in parallel, e.g. reliability testing and rewriting the software?

Some aspects of the circuit design and software rewrite may be able to run in parallel but the majority of phases have to happen sequentially. For example, if the software was still in development while the reliability testing was being undertaken, critical implications could be missed and the overall reliability undermined.

It is a requirement of Class III medical devices that the validation tests be conducted on Production-Equivalent product, so this is inevitably sequential.

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.