Questionnaire 5

Request for renewal of exemption 27 of RoHS Annex IV, “*Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors, which are used in-magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment“*, for 7 years

##### Abbreviations and Definitions

MRI magnet resonance imaging

Pb lead

##### Background

The Oeko-Institut and Fraunhofer IZM have been appointed within a framework contract[[1]](#footnote-1) for the evaluation of applications for the renewal of exemptions currently listed in Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.

COCIR has submitted information as to the renewal of the above-mentioned exemption. This information has been reviewed and as a result we have identified that some information is missing. Against this background, the questions below are intended to clarify some aspects concerning your request.

We would appreciate your quick answer until 23 March 2020 latest.

##### Questions

Introductory remark:

The below questions refer **only to newly designed** coils and MRI devices, **not** to the redesign of currently lead-soldered coils and other MRI equipment.

1. You say that all newly designed coils will be produced without lead solders, mostly as digital coils.
	1. In the answers to the previous questionnaire you mention active components like semiconductors etc. as one reason why MRI equipment circuitry other than coils cannot be soldered lead-free. We assume that at least digital coils contain semiconductors as well. If so, how did you solve the problems with the semiconductors, diodes, etc. which you mention in the answers to the last questionnaire?

All coils contain semiconductors (at least one). These are not available as non-magnetic versions, so harmful interference with image quality is avoided by minimization of the amount of nickel (by careful component selection) and by circuit design, followed by extensive testing.

* 1. Based on the above, could you please kindly explain again why the approaches used for the coils cannot be used for MRI equipment circuitry – other than in coils - as well even if they contain more components including semiconductors etc.?
	We do **not** ask about the use of non-magnetic components or the integration of non-magnetic components **unless** this was part of the approach for the lead-free coils as well. If this was the case, please kindly also explain how you solved the availability issue for non-magnetic components for lead-free soldering and the reliability issues related to such components as you explained in the previous information.

The approaches used for coils can also used for MRI equipment circuitry other than coils, with the same consideration given to minimize the quantity of magnetic material in the components that are used. Capacitors, resistors and inductors are only recently available as non-magnetic lead-free solderable versions and so these are now being used. Interference effects from magnetic materials are minimized by careful design and testing to ensure it does not impact the image quality and reliability of MRI.

For example, if small amounts of magnetic material are spaced evenly around the magnet, their effect can be cancelled out (this approach is used in PET/MRI that was granted exemption 32, although this exemption is no longer required). Due to the greater complexity of MRI circuitry in comparison to coils, as well as environmental effects of low temperatures and severe vibration the transition to lead free requires more time to complete.

1. You said that the certification of new products is one of the time consuming steps towards lead-free coils. We conclude from this that all new coil designs require certification by a notified body, and that the same applies to newly designed MRI equipment other than coils.

Since you state that all new coil designs will be produced without using lead solders, those new coil designs can be required to be lead-free if they are certified after a certain date.

As to the possibilities of producing newly designed MRI equipment other than coils with lead-free soldered devices, we would normally only make proposals for the future exemption 27 after we have a full understanding of the matter from your answers to the above questions related to the MRI equipment other than coils. For time reasons we would like to raise it now already: If the approaches for lead-free coils can be used for other circuitry as well, and new MRI equipment needs to be certified as well, new MRI equipment designs other than coils could be required to be lead-free if they are certified after a certain date.

The current suggestion of the exemption wording, which is under discussion by COCIR members is as follows (alterations highlighted in red):

* + 1. *Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors of MRI non-integrated coils certified for the first time before 30 June 2020 [Or the date of publication].*
		2. *Lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors in MRI equipment including integrated coils and other than separately sold coils, which are used in-magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment certified for the first time under EU medical device legislation before 30 June 2024.*

*Certification means Notified Body approval under either the Medical Device Directive or Medical Device Regulation, whichever occurs first.*

To avoid the date being published for (A) that is before the date of publication of

The Commission Delegated Directive to renew this exemption, the publication date could be used instead.

Designing of new models of MRI has been underway for many years (since about 2014) and has been undergoing system testing. The next step is reliability testing of new MRI designs which should be starting soon and expected to take up to 2 years if no failures are found. Non-magnetic components that could be soldered with lead-free solders were not available in 2014 (when exemption 27 was originally granted), so this work could not start earlier.

Although it is planned to start reliability testing of new MRI designs soon, if this testing identifies poor reliability, further redesign work would be needed followed by more testing. Due to this potential outcome an expiry date of 2024 is suggested as this will allow sufficient time for additional testing if required.

Although the transition to lead free is already underway, due to the limited number of qualified engineers additional time is required to complete testing.

The “X” for the expiry date in part B) would depend on the technical situation with the MRI equipment other than coils.

The intention of the above exemption wording is to restrict the exemption to those applications for which the avoidance of lead is still scientifically and technically impracticable. At the same time, the reference to the certification would avoid that you would have to redesign old equipment making sure that the restriction of lead only applies to new designs, and you could continue supplying “old” coils for use in older MRI equipment.

Please let us know your comments to the above proposal.

**Please note that answers to these questions are to be published as part of the available information for 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.**

1. The contract is implemented through Framework Contract No. FWC ENV.A.2/FRA/2015/0008 of 27/03/2015, led by Oeko-Institut e.V. [↑](#footnote-ref-1)