Questionnaire 3, Request for Renewal of RoHS Annex IV Exemption 27

"*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, or

Requested renewal period: 7 years

Abbreviations and Definitions

MRI	magnet resonance imaging

Background

The Oeko-Institut and Fraunhofer IZM have been appointed within a framework contract[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 a request and additional information which has been subject to evaluation. The information COCIR has referred has been reviewed and as a result we have identified that further information is required to evaluate the exemption request against the exemption criteria of RoHS Art. 5(1)(a)/(b).

We ask you to kindly answer the below questions until 24 February 2020.

Questions

1. The current exemption 27 has a broader scope than your requested renewed exemption. It includes a part *(b) magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy"*. Just to avoid misunderstandings, please let us know whether you intentionally dropped part b) of the current exemption in your renewal request.

   When the exemption was initially requested, the scope of the RoHS Directive was not yet clear. The FAQ where only published in 2014. As the scope of the definition of "large scale fixed installation" was not clear, we extended the scope of the exemption also to particle therapy installations. Given the interpretation of LSFI in the EC FAQ on RoHS we are confident that particle therapy installations, that weights several hundred tons are not in the

[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.

scope of RoHS Directive, and therefore we decided to drop the corresponding part of the exemption wording.

2. You calculated the total amount of lead being used under exemption 27 with around 200 kg per year in the EU assuming that the amount of lead has doubled from around 100 kg in 2006. In your application in 2011 and the related questionnaires you indicate 250 kg per year in the EU already. Please kindly explain the deviation.

   There is significant uncertainty over the amount of lead used because MRI manufacturers do not routinely measure the quantity of solder that they use. MRI manufacturers can only make estimates and these vary depending on when these estimates are made. 200kg and 250kg are both within the margins of uncertainty.

3. You stated that “One model of MRI can be used to examine all parts of the body using many different MRI coils, each MRI coil is used to examine a unique body part or a subset of body parts […]. To image the entire body, multiple MRI coils are needed.”

   Does your above statement mean:

   a. A single MRI device contains several different sending/receiving coils which are activated depending on the respective body part to be examined?

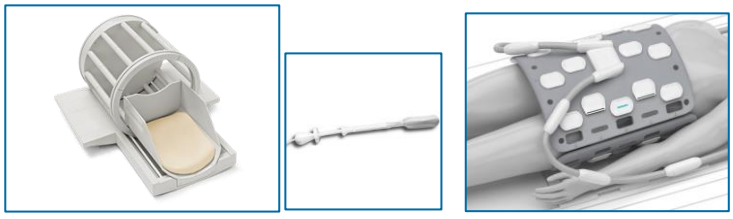
      A single MRI scanner is supplied without coils as these are sold separately to hospitals. Each type of coil is plugged into the MRI scanner when it is being used and then disconnected. Coils are located adjacent to the patient’s body or limbs and connected by wires to the scanner. They are stored elsewhere when not needed, far from the MRI as they could interfere with the image quality. Coils are very different in shape and function, from endorectal coils to full body coils.

      From COCIR Members websites:

      https://www.siemens-healthineers.com/magnetic-resonance-imaging/options-and-upgrades/coils

      https://services.gehealthcare.com/gehcstorefront/c/ACC_CTG_L2_MR_08

      https://www.usa.philips.com/healthcare/solutions/magnetic-resonance/coils-overview



Head endorectal body

b. These coils can be exchanged for other ones, e.g. to allow examinations of body parts that cold not yet be examined, or to replace defect coils, or install improved versions of the already available ones?

Faulty coils may be replaced, but most coils are sold to hospitals as additional coils and so are not replacements. These will therefore not benefit from the exclusion of Article 4.4a. Note that spare parts are defined by Article 3.27 as a: “separate part of an EEE that can replace a part of an EEE”. Hospitals purchase sets according to the kind of examinations they need to perform, but they can always expand their capabilities by buying new ones for other body parts.

c. MRI devices are constructed to apply different coils, which, however, must not all be actually contained in the device, meaning there is space left for additional coils if needed?

Yes.

4. How long will send/receiving coils be used in MRI devices in the EU (!) until they are technically outdated and will therefore be replaced by modern ones for technical reasons even though they might still be functional?

Each coil design is specific to the model of MRI that it is designed. They should last the lifetime of the MRI scanner, but may be replaced if a fault develops.

5. You mention in your exemption request that research on non-magnetic components has been conducted since 2014. Please let us know details of this research work including the status of non-magnetic components for lead-free soldering, and explain why such efforts were not started in 2011 already when the RoHS Directive was published officially.

When the RoHS 2 was published in 2011, companies where already working on finding alternatives. Since before 2011, component manufacturers have been developing non-magnetic components that are better able to be soldered using lead-free solders and several manufacturers claim that their non-magnetic resistors, capacitors, etc can be soldered with lead-free solders. COCIR members have been evaluating these components, but lead-free circuits cannot be built until all of the components required are available as versions that can be soldered with lead-free solders. In our exemption renewal request, we stated that trials by COCIR member companies with lead-free soldered circuits were unreliable and failed prematurely. As demonstrate in several COCIR studies (for instance in the one supplied to Oeko for the consultation on the assessment of 7 new substances under RoHS) substituting substances in medical devices takes considerable time. MRI coils constitute a very critical application, as any change affecting diagnostic capability is not acceptable. Companies worked since 2011 to develop exemption request dossiers for 14 applications, including exemption 27, that were submitted between 2012 and 2013. The research on exemption 27 showed that there were no viable alternatives. Therefore,

immediately after, companies dedicated their resources to develop alternative designs (please note that new designs are always motivated by developing better coils, not just by removing a few grams of lead). It is also important to remember that companies' resources are dedicated to R&D digital coils that, in a near future, will bring incredible benefits to patients, highly increasing diagnostic capabilities. Designing classic coils with lead-free alternatives (see next question) diverts resources from digital coils development and other innovations. As explained in the dossier, designing, testing and approving a new coil is a lengthy time-consuming process which would take many years and occupy design engineers who would otherwise be developing new innovative life-saving medical devices.

6. You state in your application that manufacturers "[…] only recently have been able to produce a small number of coil designs without lead solders by not using discrete components."

    a. We assume that these coils were new coil designs, not redesigned older ones. Is this correct?

    Yes. It is a completely different design. The process is lengthy, and resource intensive. It must also be considered that not all coils are compatible with all MRI models from the same manufacturer. New coils are compatible with all new MRI models, but for older MRIs (the service life can be as long as 15 years) old coils should be available to allow hospitals to use their MRIs for diagnosis.

    b. Could these coils be produced RoHS-compliant without using exemption 27 and hence would make this exemption obsolete for new coil designs?

    Exemption 27 will not be needed anymore once enough new lead free coils will be available for all applications and all MRI models installed. As long as old MRI models will be installed, exemption 27 would be needed, otherwise such MRIs would be made obsolete. The substitution rate of old MRIs is not something companies can control and as the COICR report on the "Age Profile of installed medical imaging equipment 2018" shows, the substitution rate is decreasing due to budget cuts in healthcare systems. Note that exemption 27 is also needed for other lead-free circuit of MRI as well as coils as explained in our renewal request.

    c. If not, please let us know where and why exemption 27 was still required for those new coil designs.

    Exemption 27 is not required for new design coil that are still a small percentage of the total needed by EU hospitals to keep providing healthcare. The introduction of digital coils for new MRIs would probably not need exemption 27 as well. For the moment, new coil designs cannot be used with the currently available range of MRI and so without exemption 27 for coils, EU hospitals could not buy additional coils for their MRI scanners and so their patients could not be treated.

7. You explained that effects of distortions in the magnetic field cannot be compensated by the signal evaluation software, even if the distortions are “constant”, i.e. occurring systematically e.g. caused by the use of components with nickel. Please explain in more detail why this is not possible.

   The theory behind image reconstruction using fast Fourier transformation is extremely complex. New model-based reconstruction algorithm, or the introduction of deep convolutive neural networks are increasing the complexity. Since the 70’s when MRI was introduced, any magnetic material could not be introduced in the MRI field. If any software solution could be possible, it would have been adopted long time ago. We also refer to the exemption request for DEHP in plastic parts of coils. The noise generated by the proton signal of different plasticizers and polymers cannot be compensated.

   Anyway we have to note that introducing on purpose interference and distortion in the image, leaving to software to correct it with the unavoidable creation of noise and artifacts is unacceptable from an ethical perspective, even if it was technically possible. The life of patients depends on the correct and timely diagnosis. Companies have spent 50 years to bring MRI imaging to the actual level of precision and any future development must only focus on providing better healthcare to patients.

Please note that answers to these questions are to be published as part of the available information relevant for the stakeholder consultation to be carried out 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.