Questionnaire 4

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] 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 ask you to kindly answer the below questions until 17 March 2020 latest.

Questions

1. You state in your answer to question 6 b) of the previous questionnaire that exemption 27 is also needed for other lead-free circuit of MRI. We are not sure how to interpret this statement:
   a. Would exemption 27 of Annex IV still be required for those other applications in new MRI devices even if lead-free coils were available for those new MRI devices?
   Yes. Substitution of lead in solders of other MRI circuits is described in section 6 page 11 and in sections 7 (A) and (B). Replacement of lead solders in coils will require the design of new MRI that can utilize new coil designs, whereas replacing lead solders in other MRI circuits depends on component manufacturers developing suitable non-magnetic components that can be soldered with lead-free. Although the availability of non-magnetic components that manufacturers claim can be soldered using lead-free solders is increasing (especially passives), until 100% of components used can be lead-free soldered without reliability issues, this exemption will continue to be needed for these circuits.

[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.

Any new circuit board assembly converted to lead free is based on the availability of the newer “lead free” solderable components as they become available needs analysis, partial redesign and qualification for reliability and to ensure the geometry of the solder pads on the printed circuit board allows a secure connection with lead free solder. Design rules for secure connections are different for lead free solder which is less forgiving due to a lower flow capability forming joints. Each converted circuit board needs to be tested in the application of the MRI which is a vibration rich environment causing severe mechanical stress.

Circuit boards cannot be converted to leaf-free before all the required lead free solderable components are available. Each circuit needs conversion and reliability evaluations to replace lead. Component replacement activity must precede the printed circuit board conversion as only when 100% of suitable components are available can boards be redesigned. The conversion of a single circuit board can take 1 year time with 2 to 4 dedicated engineers.
Additionally, cables subject to flexing and bending still utilize lead solder in some applications. Both circuit boards and cables need to be shown manufacturable, reliable and durable without lead

b. If so, why can’t the solutions that enable designing lead-free coils be applied to substitute or eliminate lead in MRI-circuits and other MRI applications besides coils?

Coils use relatively few types of components and new designs can be made with greatly reduced numbers of solder bonds and both of these changes enable greater reliability of coils to be achieved. Other MRI circuits are highly complex with large numbers of electronic components and solder bonds. Some components are not available in the lead-free solderable version but some other components cannot be soldered using lead-free solders without reliability issues.
Semiconductors are usually available only as magnetic versions as only a few applications, such as MRI and NMR requires non-magnetic versions (very small number of applications).
Design of new semiconductors (ICs) is very expensive (up to $10s millions each - $40M for a new flip chip) so IC manufacturers will not make non-magnetic lead-free versions for the very small numbers needed.
Non-magnetic components such as inductors, electrolytic capacitors, diodes or transformers cannot be integrated like passives. Such components are specifically manufactured for the MRI OEMs. Even when lead-free solderable versions become available, reliability is still an issue, especially due to the vibration experienced in MRI.

All the elements reported in the dossier for exemption 15 / 15a by the umbrella project support the problems indicated here with the availability of semiconductors and the lack of lead-free solderable alternatives that can be just substituted as drop-in replacements without requiring a complete redesign of the MRI. New ICs are rarely drop-in replacements

As a last consideration, it is useful to mention that some of the high power diodes that are used are specific to MRI and in applications in sectors that are excluded from RoHS such as aerospace and military. As such sectors are excluded from RoHS, they are made using lead solders and the small volume used for medical applications does not encourage this high-power diode market to change to lead-

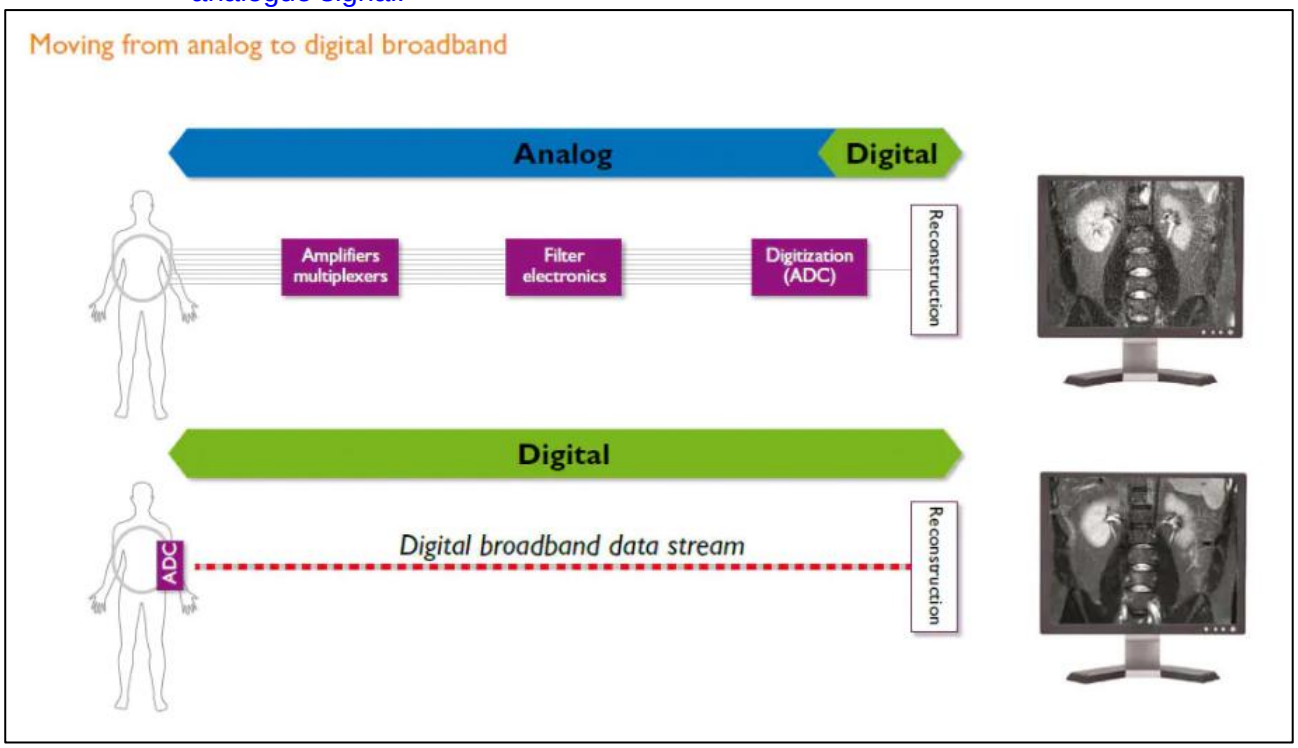
free. Such sectors are very unlikely to move to lead free due to high reliability risk just because lead-free is needed for of a few MRIs.

2. You mention digital coils in your answers to the previous questionnaire stating that digital coils would not need exemption 27 either.
   a. Could you kindly give us some insights into the differences between the current lead-containing, the newly designed lead-free coils, and the digital coils?

   New coils are being developed using lead free solutions, both digital and analogic ones. As we explained, the process takes time as:
   - there are lots of different coils
   - old installed MRIs need their own types of coils
   - When new coils are designed, they are now being designed lead free

   Again we have to highlight the economic unfeasibility of redesigning old coils just to be lead-free. For some old design, the market volume could be as low as 100 units and EU hospitals would not be able to pay for this redesign work in the form of what would be an extremely high price for these coils and so the only acceptable solution for a MRI manufacturer is to discontinue the coil, with the consequences for hospitals already described so far. New MRI are typically €1 million so EU hospitals will not replace their existing MRI just to obtain some different types of coils.

   Digital coils are different from analog coils as the analog signal (from the patient) is digitalized inside the coils so the coil transmits digital data to the MRI instead of an analogue signal.



The RF-receiver coil is the first element of a complex electronic chain by which the MR signal is amplified, digitized, decoded, and transferred to the main computer system for processing into the final MR image.

The detected MR signal shares several features with the transmitted RF-pulse: 1) Both contain a carrier wave centered at the Larmor frequency; 2) important imaging information (position,

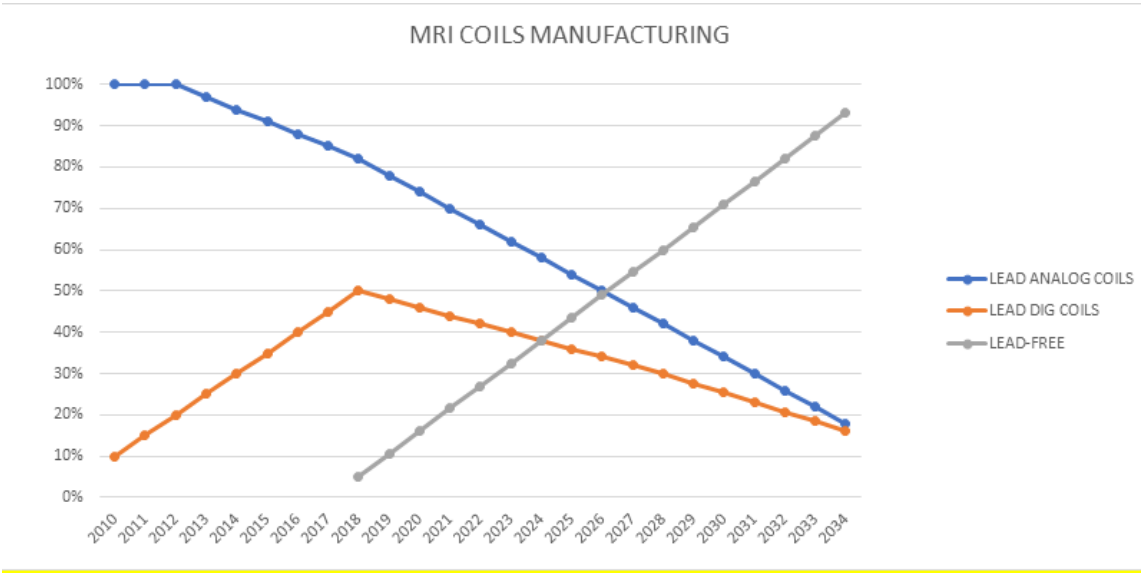
intensity, etc) is modulated into the carrier wave; 3) a chain of electronic elements must be used to amplify, digitize, and decode the information.

The basic components of the RF-receiver chain are:
Coil Decoupling → Preamplification → ADC → Demodulation → Image Processing

Preamplification. The MR signal detected by the RF coil is extremely weak (on the order of millivolts). To prevent contamination by environmental noise, the signal is immediately amplified close to the RF coil by a device called a low-noise preamplifier (also called an LNP or "preamp").

***In most current (but older) systems**, this amplified analog signal is then sent via long shielded cables from the scanner into an RF-processing unit in the adjacent equipment room where it is digitized.*
***The newest MR systems** employ small high frequency analog-to-digital converters (ADCs) in close proximity to the coils and send the digitized data to the next room **via fiber-optic cables**.*

Digital coils have performance advantages over analogue and so many of the recently developed coils for new types of MRI are digital. Originally, since about 2010, these were designed using lead-based solders as the reliability of lead-free designs could not be ensured. Recently new designs of analogue and digital coils are being developed with lead-free solders and as older models of MRI are phased out and replaced, the proportion of coils made using lead-free solders will gradually increase, as shown in the hypothetical graph below (note that COCIR does not have actual data as this is proprietary to individual manufacturers).



Digital coils cannot be used with old MRIs for the obvious reason that the old MRI expect an analogue signal from the coil to process it, not a stream of digital data. Old MRIs are connected to coils via shielded electric cables while new MRIs use fiber optic cables.

Even in case this could be possible, the MRI software would need to be modified. Such modification would potentially require a new certification. In addition redeveloping software for old MRI models is again not feasible from an economic perspective. OEM will simply discontinue the product, leaving hospitals in a dire situation.

b. We understand from your answer that the current coils will step by step be fully replaced by digital coils. Is this correct?
New coils, weather digital or analogic will transition to lead-free solutions.

In principle most coils will be developed as digital versions, but there may be specific coils where the difference in performance between the analog and the digital version may not be worthwhile, and some coils will remain analogic as conversion is not possible due to their small dimension. Anyway the transition requires older models of MRI to be replaced by newer designs. It is both the MRI and its associated coils that have to be redesigned, not just the coils.
This is where technology goes, always in the direction of better performances for patients. Designing a new model of MRI is a huge task taking many years plus time needed for testing and approvals, so the times-scale for having only digital coils will be long. With time all new MRIs will be designed to use mainly digital coils (there are some exceptions such as Multi Nuclei coils and very small coils that cannot be digital) and the production of old analogue lead-solder containing coils will be reduced, eventually just to service old installed MRIs. Considering MRIs are used for 10 to 15 years, the process will take some time, definitely longer than the 7 years maximum duration of exemptions. Also, MRI manufacturers need time to replace their existing models which due to their complexity, will also take a long time before all current models (and associated coils) can be replaced

c. If so, could you please let us know the time frame until all coils would be available in digital form?

A few types of coil may always be analogue (see previous question). The timescale to replace lead will be at least 15 years for both analogue and digital coils as shown in the graph in answer to Q2a. We can expect that for at least 10-15 years there will still be the need to deliver lead-soldered analogue coils for use with installed MRIs as well as spare parts. Unfortunately, additionally supplied coils do not fit the definition of spare parts (which need to be replacements) that was defined keeping in mind domestic appliances and ICT. This exemption would not be necessary if the definition of spare parts is revised for medical imaging devices (and probably for capital investment equipment in general).

d. Can digital coils be used with older MRIs and with MRIs designed for the later generation lead-free coils, or must the MRI devices from the beginning be designed together with the digital coils to function properly?

Digital coils cannot be used with old MRIs for the obvious reason that the old MRI expect an analogue signal from the coil to process it, not a stream of digital data. Old MRIs are connected to coils via shielded electric cables while new MRIs use fiber optic cables". Of course different proprietary technologies are developed by different companies.

Regarding the possibility to use lead free coils for old MRIs, this is possible in theory but not in practice:

- This is not a simple re-design, it is a new design of an old coil for an old MRI that requires all the testing and re-certification. Also, reliability is not ensured.

Previously poor reliability of lead-free coils has been found as was reported in the original exemption request, so this can take a significantly long time.

- The process is costly and time consuming and uneconomic as redesigning old coils with limited market to just support the old installed base makes no sense. The prices for coils that would have to be paid by hospitals would be prohibitively high so that hospitals would not be able to afford them and so could not treat patients. And therefore, such coils would probably be discontinued without this exemption. This means that patients could not be scanned, or that different, less specific coils will have to be used: for instance, a full body coil for a prostate scan will deliver a less detailed image with the risk of unproper detection of the anomaly.
- Diverting engineers to redesign old coils instead of designing new digital coils for new MRIs makes no sense for a medical company that is supposed to use its resources to provide better diagnostic to patients. The harm to human health caused by a few grams of lead in coils (and which is decreasing every year) is likely to be much smaller than not being able to MRI scan thousands of patients, while forcing a medical company to delay the development and delivery of better medical technology has the potential to affect millions of patients every year. Any new MRI scans up to 9000 patients per year with the best technology available. For each MRI that is delayed, 9000 patients are scanned with old technologies that may not always ensure the best possible diagnosis.

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.