QuestionnaireExemption Request No. 9

"Lead in solders and solderable coatings used on non-magnetic components and circuits that are intended to be used in magnetic fields or are associated with circuits that are intended to be used inside strong magnetic fields"

Background

The Öko-Institut together with Fraunhofer IZM has been appointed for the technical assistance in reviewing the requests for exemptions from the requirements of the RoHS Directive 2011/85/EU (RoHS II) by the European Commission. You have submitted the above mentioned request for exemption which has been subject to a first completeness and understandability check.

As a result we have identified that there is some information missing and a few questions to clarify before we can proceed with the online consultation on your request. Therefore we kindly ask you to reformulate your request taking the following points into consideration.

Questions

1. You claim that less than 100 kg of lead is put on the market in Europe in solders and finishes related to the exemption request. Please substantiate this calculation:
   a) Which types of equipment would use this exemption (MEG, MRI, …), Predominantly MRI as scanners and as coils, although very small numbers are used in NMR (a chemical analysis instrument), so also need this exemption for the same technical reasons. MEG does not use very powerful magnetic fields although the sensors are sensitive to any magnetic materials so magnetic materials are also avoided in this equipment. MEG is not covered by this exemption request.
   b) How much lead per printed circuit board/circuitry? RF coils: A head coil represents an average coil, it has been measured in the production process and contains 18.16 grams of lead. MRI Scanner: Contains typically 63 PCB circuits (average 2.5 grams of lead each) and one Bodycoil: (average 4,5 grams of lead each), total 162 grams.
   c) How many circuits per device? MRI scanner contains 63 PCB circuits plus one Bodycoil
   d) How many of such devices are sold annually worldwide and in the EU? RF coils: World sales 20,000, 30% of sales are in the EU, 6000 RF coils on the EU market

per year. MRI scanners: World market 2600 scanners per year, of which 780 scanners in the EU market.

e) How much lead would be used in this exemption in equipment put on the market in Europe and worldwide? Total for MRI scanners and RF coils: 250kg lead per year in EU (30% of market). Worldwide

2. Your research has shown that metals with even very small magnetic susceptibility degrade the image quality. Please provide evidence for this best related to components containing small quantities of nickel.

a. The relation to RoHS is that using lead-free solder necessitates nickel layers on objects that are soldered with this lead-free solder.

b. Nickel is a ferro-magnetic material. Having nickel close to the imaging volume can therefore negatively influence image quality.

c. The imaging method most sensitive for B0-inhomogeneity is FatSat. The specification for successful fat suppression is maximum 1.0 ppm. We go through great efforts to realize this homogeneity in a large volume so that image quality is good and the commercial requirements are fulfilled. The extra inhomogeneity caused by the presence of magnetic material in a coil or whatever soldered connection in the neighborhood shall be a fraction of this 1.0 ppm -> Maximum is 0.25 ppm for all components together.

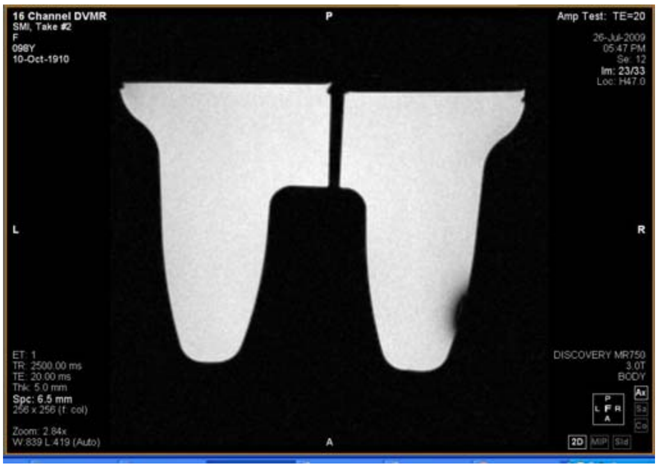
d. An example circuit is about 45 mm from the patient. An object making 0.25 ppm at 1.5 T (i.e. 0.375 μT) at 45 mm distance perpendicular to its magnetization direction corresponds with a magnetic moment of 3.4E-4 Am^2. This follows from the simple field formula for a magnetic point dipole. In a direction perpendicular to the magnetic moment m, the formula becomes $B=(\mu 0m)/(4\pi r^3)$. Well, assuming the nickel saturates at 0.5 T, such a magnetic moment corresponds with a volume of 0.9E-9 m^3 because Volume=m/Msat, with Msat expressed in A/m. This is 7 mg. So for this circuit, if this were the only contribution to inhomogeneity, we could allow 7 mg.

e. However, certain soldered connections in the coils are as close as 5 mm to the patient. In this case the allowed quantity of nickel is a factor (5/45)^3 less because the field scales with third power of distance. This becomes 10 μg (provided there are no other magnetic components).

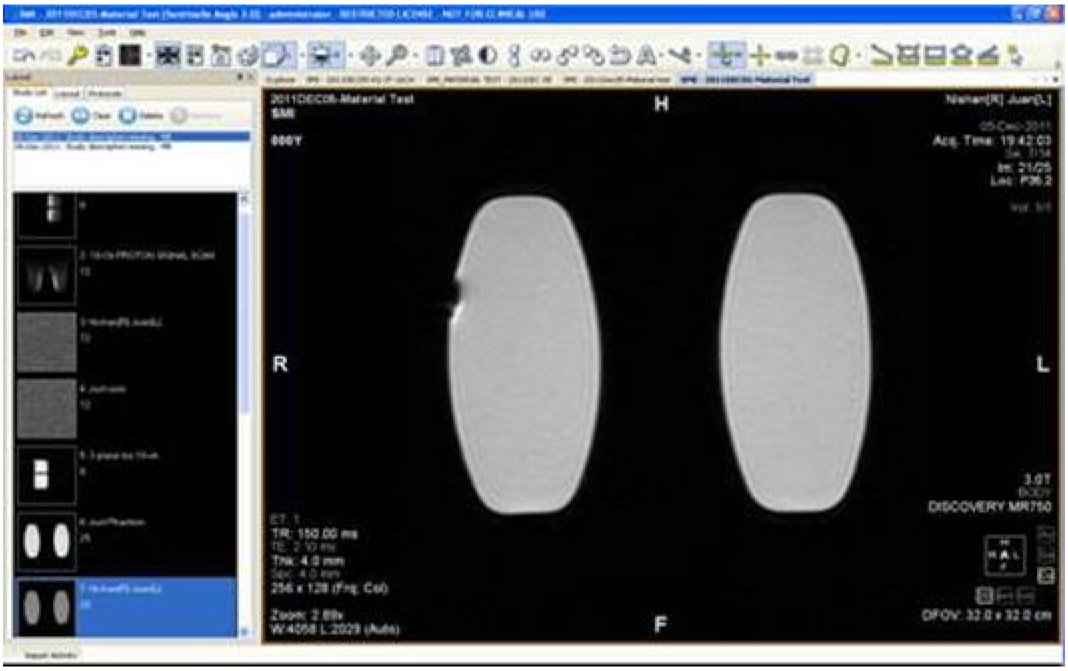
f. The effect of various nickel components on the image quality is shown in the attachment on Magnetic Component B0 distortion. One hi-low intensity variation (phase transition) corresponds with 0.25ppm.

The effect of small amounts of nickel can be seen visually by the following.

Below is an image of a breast phantom acquired with a 16ch breast coil. This coil employed pre-amplifiers which had a voltage regulator containing nickel. The loss of image apparent in the lower right hand corner is due to the field distortion caused by the pre-amp.



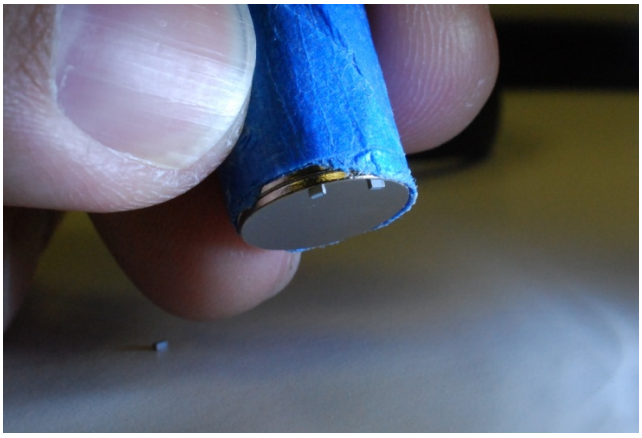
The image below demonstrates a loss of image on the upper left due to nickel on capacitor terminations.



3. You say that not all components you use are available without lead and without nickel in the termination coatings. Which components are these and why are they not available without nickel and lead? '

All components are without nickel wherever possible for the reasons explained above. These components are usually coated with lead solder or alternatively are validated to only be used with solders that are in the lead based temperature range and not the non-lead based temperature range. In addition, many of these components have wires that connect to the component body part, where lead is also used for that termination inside the component. Examples of these components include leaded capacitors made by Sprague, variable capacitors made by Voltronics, diodes made by Alpha, inductors made by JW Miller, RF connectors made by Amphenol, etc. We are the only industry that actually asks for no nickel coating, and that is easily replaced by lead/tin solder on the terminations.

Another example is LM431 adjustable precision Zener shunt Regulator in 4-bump micro SMD package A-size capacitors (Note there are two issues with the A size cap, one is the use of nickel in the terminations and the second is the use of magnetic Neodymium oxide in the component.)



4. You describe that some of your members carried out soldering experiments with bad results. Most of these insufficient results seem to be very typical for transition to lead-free if there is no or little experience only with lead-free soldering. The use and processing of lead-free materials is not a drop-in lead solution. Other branches experienced and solved the same or very similar problems.

The MRI environment is very harsh compared to other industries: e.g. high vibration levels caused by interaction of the strong magnet and gradient field. See attached reliability comparison of components in report DHF131208 "Mechanical vibration tests on RF screen capacitors"*. The selected capacitors are wired capacitors for reliability and are hand-soldered. Note that poor solder connections cause image quality deterioration due to RF spiking under vibrating.

MR scanners are expected to be in service with clients for at least 10 years. To simulate actual vibration levels for at least 10 years service, the typical vibration levels used for MR environment reliability tests are:

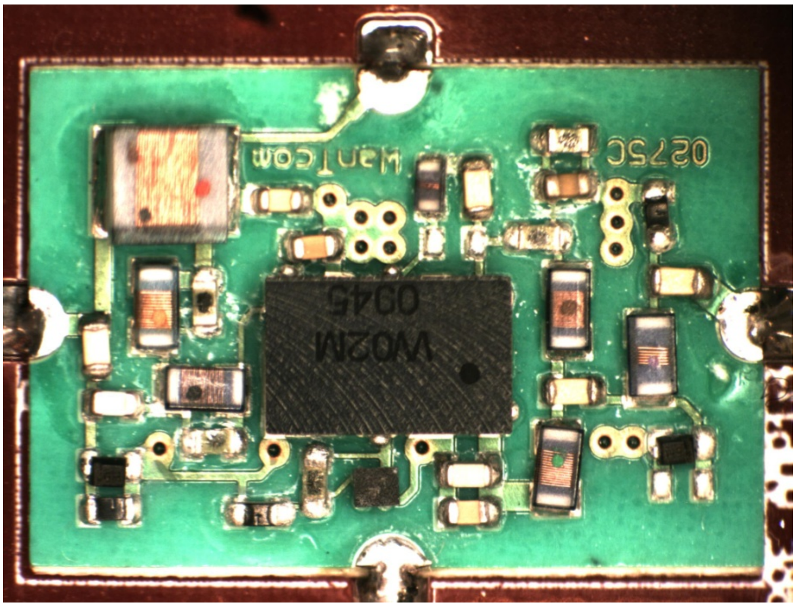
- Vibration levels up to 70 grms for 180hrs, corresponding to 19,000 hours MRI scan time, this is far worse then automotive, see attachment on Vibration levels*.

- Number of temperature Cycles (=number of exams on patients) is 6300/year covering 90% of MRI used in the EU. This is far worse than automotive, comparable with space, see attached report IPC-9701A*.

One manufacturer use wired components to withstand the vibration levels. Such capacitors contain lead because two soldering temperatures for capacitors with leads are needed. An HMP solder (high melting point) for connection of the ribbons or wires to the capacitor and an LMP solder (Low Melting Point) for soldering the capacitor in the application. The HMP solder contains mostly more than 85% lead. This is covered by exemption 7a (lead in high melting temperature type solders until 1st July 2021). However, it was concluded by a PCB supplier (Jabil - a major EMS company) - the Novocaps capacitors used in DHF131208 are incompatible with the RoHS soldering process. Refer to their comments in the document attached*.

a) Did the manufacturers adapt and optimize the designs and processing as well as the lead-free material selection for the tests? Circuit designs and reflow profiles suitable for lead-free processes have been used and adjusted wherever possible to improve reliability but with limited success so far. Manufacturers also need to determine and minimise the magnetic properties and the proton signal from alternative materials.

   Why can high thermal mass components not be soldered selectively instead of using reflow solder processes to avoid overheating, as other branches do to enable lead-free soldering? High thermal mass components can be selectively soldered as a separate process. The concern mentioned on page 8 is that for reflow soldering, the time that small components are at soldering temperature depends on the component with the highest thermal mass. A solution is to solder larger components separately and many components are individually hand soldered. However hand soldering of large non-magnetic components can also difficult as explained on page 9 (paragraph below table). Selective soldering may be an option for large components:



The above MRI PCB assembly is 10mm by 15mm (overall dimensions). Selectively soldering components of differing thermal mass is possible with relatively large leaded components but would be difficult with the small surface mount components and population densities employed in circuits such as the above pre-amplifier.

b) You say that low temperature solders are not a solution as at lower temperatures the wetting time is much longer and so the component termination is in contact with liquid solder for a longer period. Lower melting point solders should have better wetting properties at lower temperatures. Please provide evidence for your claim. In general, wetting times are proportional to temperature and so as temperature decreases, wetting is slower. This is why Syfer state that their MLCCs can be at 240°C for up to 20 seconds but only 7 seconds at 260°C (see table on page 8). This is also shown by Figure 3 in http://www.asahisolder.com/Publication/Comparative.pdf . Wetting times at lower temperatures are also significantly affected by the time taken for the flux to remove the air formed oxide film. The rate of oxide removal depends on the activity of the flux and the temperature. As temperature decreases, the rate of reaction between flux activators and oxide decreases. For most chemical reactions, reaction rates halve for a 10°C temperature decrease. The use of more aggressive fluxes can accelerate wetting to some extent but are not used for electrical circuitry because if traces of corrosive material remain, corrosion will occur leading to early failure. It is usually difficult or impossible to remove all traces of flux residues so the use of low activity no-clean fluxes has become the norm.

c) You state that the intermetallic phases are thicker in case of lead-free soldering and that this creates reliability problems. Other branches solved this problem with optimized soldering processes. Why should this be impossible in this case despite of the non-magnetic component issues? The most common way to minimise intermetallic thickness is by using a nickel barrier layer which cannot be used for this application.

5. You put forward whisker generation as a specific problem of lead-free soldering. Is there any PROVEN case of a failure due to whiskers besides space applications? Missiles, nuclear power station in USA and pacemakers in USA (details from NASA website http://nepp.nasa.gov/WHISKER/). Note that most manufacturers never publicise failures of their products so although we have heard anecdotal evidence of failures, there is very little published.

6. We would like to propose a different wording for the exemption: Lead in solders and terminal finishes of non-magnetic components on printed circuit boards used in magnetic fields of at least XXX Tesla in YYY

   Justification of our proposal:

   The magnetic field is the reason to use non-magnetic components, which are a crucial argument for the exemption. Circuits just attached to other circuits used in magnetic fields either do not need such components, or are included in our wording proposal if they are exposed to a strong magnetic field.

   The term "strong magnetic field" is not defined and thus should be specified to avoid abuse of the exemption. The exemption should be restricted to specific equipment for the same reason.

   a) Please let us know whether you agree with our wording proposal or otherwise comment.

   b) Please specify XXX and YYY in the proposed wording.

The MRI with the weakest magnet on the EU market is 0.3Tessla so 50% of this would be 0.15 Tessla. This would give a definition:

Lead in solders and terminal finishes of non-magnetic components on electrical circuits used in magnetic fields of at least 0.3 Tesla in MRI system

However, the definition "Lead in solders and solderable coatings used on non-magnetic components and electrical circuits that are intended to be used within at least 50% of the specified main magnetic field of MRI" is more restrictive as this would limit lead use only to areas within MRI that experience at least 50% of the specified maximum field strength. So for example, in a 3.0 Tessla MRI's field, the field strength is 3.0 Tessla only at certain locations next to the magnet and the strength decreases away from the magnet. Distortion of MRI images occurs mainly when magnetic components are within the magnetic field and a limit of 50% of the maximum field strength would be suitable. With this approach, lead is exempted only in the minimum magnetic fields with the following field strength, e.g.

50%	**Specified magnet strength**
0.15 Tesla	0.3T MRI system
0.30 Tesla	0.6T MRI system
0.50 Tesla	1.0T MRI system
0.75 Tesla	1.5T MRI system
1.50 Tesla	3.0T MRI system
3.50 Tesla	7.0T MRI system

Note: We prefer the term 'circuits' over 'printed circuit boards' as MR devices generally contain also other components that shall not contain magnetic material, e.g. connectors and cable traps. We use a percentage of the main magnetic field of MRI to restrict the scope of the exemption.

See also confidential additional information for further details to answer Qu. 2.

Magnetic component distortion Examples

***See confidential attachments for further details to answer Qu. 4.**

DHF131208 "Mechanical vibration tests on RF screen capacitors

Vibration levels Bodycoil RFscreen

Jabil report

IPC-9701A