Questionnaire for Further Clarification

Exemption Request "LeadinsoldersforPositronEmissionTomography detectorsanddataacquisitionunitsinstalledin Magnetic Resonance Imaging equipment"

Non-confidential version.

Background

The Öko-Institut together with Fraunhofer IZM has been appointed within a framework contractfor the evaluation of applications for granting,renewing or revoking an exemption to be included in or deleted from Annexes III and IV ofthe new RoHS Directive 2011/65/EU (RoHS 2)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 stakeholder consultation on your request. Therefore we kindly ask you to provide answers for the following questions and to reformulate your request if necessary.

Questions

1. You state that besides for MRI, this exemption would be needed for PET as well. PET does not use strong magnetic fields. You justify your exemption request with the vibrations resulting from the strong magnetic field.
    a) Does this exemption request refer to medical devices that combine MRI and PET in one device? **YES**
    b) In case a) does not apply, why is this exemption needed for PET? Or is there another source of strong vibrations in PET? (a) does apply

2. You describe that PCBs used in PET have high component density and are operated with high voltage. You claim that the combination of high component density and the inability to use PCB coatings such as ENIG result in an increased risk of tin whiskers which due to the high voltage could cause catastrophic failure.
    a) If nickel can be used on components in this case due to the symmetric arrangement, why is it impossible to use it on the PCB pads as well? Ni content of assemblies mounted to or within the MR magnet/bore impacts (1) the magnetic field uniformity, which needs to be shimmed mechanically and

electrically to a uniformity of 1ppm and (2) the ability to service the respective assemblies safely with the high-strength (3T) magnetic field present. From an MR perspective the assemblies would have zero Ni content and this was the original requirement. But there are certain small electronic components that do not exist in a Ni free deployment and they needed to be used. Where ever possible Ni was excluded in the deployment, which includes the Printed Circuit Board.

b) In case nickel may not be used on the pads of PCBs applied in PET, whisker mitigation techniques not depending on nickel, such as postbake, can prevent whiskers as well. The postbake generates an annealing copper-tin layer preventing the further diffusion of copper from the pad into the solder joint. Thus, the supply of copper forming interphases with tin is stopped and whiskers do not form. Why should this not be applicable and sufficient to prevent whiskers? Post-bake must be carried out within 24 hours of tin plating to be effective but most electronic components that are available commercially have not been post-baked so it is too late for the PET/MRI manufacturer to do this. Post-baking must be carried out very soon after plating to ensure that a thin coherent SnCu intermetallic layer forms that prevents the formation of thicker irregular SnCu that induces compressive stresses. Post-baking long after component manufacture is ineffective because it causes pre-existing SnCu intermetallic crystals to grow and this induces stress in the tin coating. Post-baking of electroless tin coated PCBs is also not possible for three reasons; i) because PCB laminate polymers slowly decompose at the post-bake temperature of 150°C making them too brittle and causing delamination ii) at 150°C the tin and copper interact to form a SnCu intermertallic. This is an intended effect of postbaking but the electroless tin layer can be completely consumed forming SnCu intermetallic so that no solderable tin remains. Electroless tin deposition is a self-limiting process so the thickest possible electroless tin coatings are ~ 1µm and most or all of this will react with the copper substrate at 150°C during the normal post-bake treatment time. iii) Electroless tin is relatively porous and will oxidise at 150°C making it difficult or impossible to solder. The post-bake process is intended for electroplated tin which is usually >2µm in thickness and is not porous so oxidation is not an issue.

3. COCIR explains in its exemption request that whiskers may form if lead-free ball bonds are soldered to a copper PCB pad with a nickel barrier layer that is not completely non-porous. If a small amount of copper reaches the solder, the intermetallic that forms is SnNiCu which has been found to be very brittle and fractures easily.

COCIR states in the same exemption request that nickel may be used on small components of PET circuits, but not on the pads of printed circuit boards.

Please explain these converse statements! Ni content of assemblies mounted to or within the MR magnet/bore impacts (1) the magnetic field uniformity, which needs to be shimmed mechanically and electrically to a uniformity of 1ppm and (2) the ability to service the respective assemblies safely with the high-strength (3T) magnetic field present. From an MR deployment perspective the assemblies would have zero Ni content and this was the original requirement. But there are certain small electronic components that are simply not available in a Ni free configuration and so they needed to be used with Ni. But where ever possible Ni was excluded in the deployment, which includes the Printed Circuit Board.

4. COCIR is concerned about tin whiskers due to the high component density on PET PCBs. This results in very small gaps between the edges of adjacent pads so that fairly short whiskers could cause a short circuit in this application.
    a) Please explain the distance between the pads. The PET/MRI equipment has 28 PET Data Acquisition Units (DAU) mounted on the back of a 3T MR Magnet. Each DAU has over 4,000 components with 12,000 connections made on/within a 16 layer large copper content PCB or 112,000 components. There are collectively 119,616 fine pitch BGA balls with **0.44mm distance** between pads; 89,012 0402 chip components with **0.40mm distance** between pads; 46,144 integrated circuit pads with 0.20mm distance between pads. High voltages are used for biasing the photosensors in the detector. These supply voltage to the detectors can be up to 550 VDC. This supply voltage is distributed to the detectors through the Data Acquisition Unit circuit boards, and locally distributed to the photosensors through the detector circuit board. High voltages require more component spacing to protect against arc damage, but the deployment required minimal design volume. Due to the design volume limitations, the voltage gradient for these supply voltages can exceed 270 volts/mm. Whisker growth increases the probability of arcing at these tight voltage gradients.
    b) What is the length of whiskers observed on real PCBs under field conditions of any other lead-free soldered applications? Whiskers can grow to lengths of several millimeters and there are examples at http://nepp.nasa.gov/WHISKER/photos/index.html . One example shown here is of a tin whisker that short-circuits an 8mm gap. Whiskers that form as a result of stresses caused by tin corrosion induced by high humidity have no limit on the maximum length and the longest whiskers are believed to form as

a result of this mechanism. Therefore whiskers are often longer than the 0.4mm gap between pads.

5. The COCIR exemption request no. 9 (lead in solders of circuitry used in strong magnetic fields) from the previous exemption request round would allow the use of lead solders already for a combination of MRI-PET assuming that this device works with strong magnetic fields similar to an MRI. Please explain why and where this exemption is still needed. Exemption 9 from the previous round is for non-magnetic components whereas with PET/MRI, magnetic components with very small amounts of nickel can be used in a way that the magnetic effects are cancelled out by the symmetry of the circuitry.

6. In its exemption request, COCIR reports about JPGG test results from highly accelerated testing of components on PCBs applying g-forces of more than 9.9 for 7 hours. Predominantly lead-free soldered components failed this test (table 1 in the exemption request). You conclude that PET/MRI or any other electrical device, irrespective of which type of solder was used, were to be exposed to g-forces of 9.9 or more, it would not survive 25 years.
    a) You explain in the same exemption request that "The maximum vibration force experienced is equivalent to well over 2 g […]." How does this relate to your above statement that equipment exposed to 9.9 g would not survive 25 years, and what can be concluded for equipment exposed to a maximum g-force of 3 over 25 years? The JGPP tests are for only 7 hours although some bonds failed after only 1 hour at 9.9g. This high g-force is used for a relatively short time to simulate much longer periods at lower g-forces because circuit designers cannot wait many years to assess their designs. The acceleration factor for SnPb solder is well understood because this solder has been in use for many decades but there is insufficient life data with lead-free solders to determine the vibration acceleration factor.
    b) How do you know that the applied high g-force is the correct acceleration factor? Possibly, it is simply above a destruction threshold that destroys the lead-free solders more than the lead solders without relation to the actual life time of the components. Please explain. In reality we do not know if lead-free solder bonds will survive 25 years with no failures. Acceleration factors for lead-free are not yet known because lead-free solders have not been used in this type of environment for sufficiently long. The Medical Device Directive requires that the equipment is safe and reliable and evidence must be provided to prove this. Reliability with lead-free solders under these conditions cannot be proven to be reliable.

7. COCIR mentions National Physical Laboratory (NPL) research in its exemption request showing that "[…] vibration testing of assembled PCBs can not be used for comparison of solder alloys as solder joint shape, vibration amplitude, frequency, etc. all affect the time to failure for a specific type of component. This was clear from the JGPP research which showed that for a few types of components, lead-free solders gave superior performance to SnPb."

    a) If the NPL results show that the comparison of solder alloys in vibration testing is impossible, why do you compare such results nevertheless? NPL state that accurate comparison of solder alloys by vibration testing of real PCBs is impossible and so they use a different approach that compares alloys under identical conditions to obtain a quantitative comparison. Real PCB tests are however useful as they show that vibration does cause failures and that lead-free alloys appear to be inferior which is consistent with the NPL results. Real PCB testing compares alloys qualitatively so is useful. Also, vibration testing is standard for assessing the reliability of medical devices which is needed to gain approval under the Medical Devices Directive. If vibration testing with lead-free were to show inferior reliability, which seems likely from the JGPP results, the equipment may not be approved for use in the EU.

    b) Why should the impossibility of comparing such vibration test results only justify those results where the lead-free solders performed better than the SnPb solders? Maybe the test results are simply irrelevant for both the lead-free and the lead solders? Tests with real PCBs show where there is a higher risk of failure due to vibration but NPL show that it can give misleading results. NPLs tests indicate that the superior performance found for those components soldered with lead-free solders is not due to the properties of the solder alloys and must be due to other reasons. The NPL results are a real concern for medical device board designers as their results show that under severe vibration conditions, failures are more likely to occur with lead-free solders. The JGPP results show where on a PCB failure is most likely to occur but it is not always practical to design PCBs to avoid high g-forces.

8. COCIR reports in its exemption request that "One MRI manufacturer has evaluated a PCB used close to the PET detector and DAU (data acquisition unit) boards to compare the reliability of SnPb and lead-free solder bonds to RF screen chip capacitors in the conditions experienced in the MRI. Three types of capacitors were tested with two lead-free solders, SAC305 and SnAgBi, and after vibration testing, at worst only 13 % of the PCBs survived and at best 63 % survived. When capacitors were assembled using tin/lead solder, 100 % survival was achieved after testing."

a) Please provide the test documentation including the description of the test conditions. It would be highly appreciated if these results would be non-confidential so that they can be published.

These results are confidential so we are not able to provide the test documentation

b) Please explain whether and how the soldering conditions and the PCB design had been adapted to the specific requirements of lead-free soldering to make sure the lead-free solder joints had optimum quality.

In this example, the design of the PCB is restricted by the need to achieve RF shielding and so component positions and sizes of components cannot be significantly changed. Research into the solder printing and solder reflow profile was carried out but did not achieve 100% survival with lead-free solder. Board design and solder reflow profiles were optimized before testing.

9. COCIR reports in its exemption request about the JPGG vibration test results showing that "[…] the time to failure was strongly dependent on the location [of the components; inserted by the consultants] on the PCB."

a) Please explain why the proper positioning cannot be used to reduce the effects of vibrations in particular to larger or other components, whose solder joints are most prone to breakage. It must be understood that the PET/MRI deployment is constrained with very small design volumes for the high density Data Acquisition Units (28 per scanner each with 4000 components) electronics and PET Detectors (56 per scanner each with 3000 components). Component orientation within the DAU and Detector tri-flex PCBs are constrained by EMI/EMC requirements, thermal requirements, interconnect and routing density to neighbouring components, mechanical packaging stress, manufacturing requirements, printed circuit board layout requirements as well as stress due to vibration and PCB handling. The DAU and Detector PCBs are approximately 37 cm and 56 cm in their longest dimension respectively, giving rise to a significant number of possible resonant frequencies. The frequency content of the MR gradient subsystem is dependent on the gradient sequences programmed by the end user, which is not under the control of the equipment suppler. In general, all component placement requirements were collectively taken together when making the DAU and detector deployments.

b) Please provide evidence that no other measures are available to reduce the stress on components caused by vibration. Examples for such measures might be

- The decoupling of the PCB from the swinging construction Both the DAU and the detector PCBs are decoupled from nearby swinging structures (magnet and gradient coil)
- Use of dampening elements to protect the entire PCBs Both the DAU and detector utilize integrated thermal gaskets that also act as mechanical damping elements.
- Relocation of sensitive PCBs in the device to minimize the impact of vibration Location of the DAU and Detectors are optimized for the best hybrid imaging performance and intended use of the scanner. A fully integrated solution requires that the PET detectors are located in the center of the MR Field of View (FOV, within the MR bore between the gradient coil and MR body coil. The DAUs are located on the back of the magnet, as close as possible to the PET detectors to facilitate interconnect to the 3000 signals coming from the PET detectors, provide conditioned power to the PET detectors and perform the critical time-domain signal processing of the PET detector signals.
- Protection of the PCBs from the noise The DAU is housed in a machined housing for EMI/EMC and vibration protection. The PET detectors are housed in molded plated housing for EMI/EMC and vibration. Both the DAU and PET detector mounting is made in a way to minimize vibration generated by the MR.
- Other measures Everything that we are aware of has been done to decouple vibration.

10. COCIR states in its exemption request that thin electroless tin and immersion silver may not form whiskers but have a too short shelflife.

a) How long is the shelf life compared to tin-lead or to ENIG finishes on PCB pads? Shelf life claims for both tin-lead HASL and ENIG finishes in industry range from > 1 year to > 2 years. Claims for immersion tin and immersion silver range from > 3 months to 12 months. The shelf life of immersion tin is dependent on tin thickness while the shelf life of immersion silver is dependent on storage conditions. The request dossier explains that thin electroless tin has too short a shelf life whereas thicker tin has a risk of whisker formation but is the only option available. As Tin/lead solder wetting is good, no unsoldered tin should remain and so there is no whisker risk but lead-free solder has

poorer wetting that will leave some unwetted tin from where there is a tin whisker risk.

b) Other branches whose products have been covered by the RoHS Directive experienced the same problems and solved them. Why should the shorter shelf life thus be a justification for a multi-year exemption? The shelf-life aspect is unique due to the construction method utilized for the detector. Conventional electronic assemblies had to overcome the difficulties of shelf life for that time between fabrication of the raw PCB card and subsequent soldering of electronics components to create the final product. Due to the nature of the photosensors, this construction technique is not possible. The detector assemblies must face the same shelf life issue as conventional electronic assemblies, but have an additional burden for shelf life for that time between PCB assembly and installation of the photosensors. These photosensors are not capable of surviving conventional reflow processing and are not installed by EMS. The assembly requires additional treatments and methods not generally available at EMS facilities, so the photosensors are installed later at a separate facility. The surface finish utilized on the detector PCB needs to maintain solderability long after its conventional processing at EMS. The shelf life of tin coatings is related to the diffusion rate of the tin coating into the copper base layer, and is therefore primarily related to tin thickness and time. The shelf life of silver coating is related instead to oxidation or tarnishing of the silver itself, therefore its shelf life is related to time, airborne contaminants, chlorine, sulfur, and other contaminates related to handling or surface contact. The contaminants from handling, processing, re-packaging, airborne exposure, and other contact exposure are inherent in the processing of circuit boards. Due to these contaminants, immersion tin is used because its shelf life is only due to storage time whereas immersion silver shelf life is impacted by storage time and exposure contaminants and so is unpredictable (and can be very short).

11. COCIR provides the following roadmap towards RoHS compliance in its exemption request:

1. Manufacture lead-free PCBs	From 0.75 up to 1 year
2. Accelerated testing and redesign to optimise vibration performance	From 0.75 up to 1 year
3. Long term PCB testing	From 2.5 up to 3 years
4. PET/MRI testing	From 1.5 up to 2 years
5. Reliability testing to collect data for Medical Device Directive approval	From 0.75 up to 1 year
6. Apply for approval under the Medical Device Directive	From 0.75 up to 1 year

a) Please explain why some of the tests cannot be (partially) parallelized, e.g. those under point with 5. Steps 1 and 2 are required sequentially first to enable step 3 to begin. Steps 1, 2 and 3 are at the component level. It is critical that parametric performance is established at the component level prior to integration into the hybrid system in step 4. Steps 5 and 6 are regulatory in nature with 5 required before 6 and cannot start until 4 is completed satisfactorily.

b) Please provide a minimum time as well, besides the maximum times provided in the above list. The timescales in the above table assume that an alternative design / solder is available but at present none are known. Trials are currently being carried out with lead-free solders but the most recent results of soldering detector PCBs with lead-free alloys were a failure as severe board delamination occurred. These boards are an uncommon flex-rigid construction. If a suitable substitute were available for evaluation then the minimum timescales are indicated in the above table