Application for granting a new RoHS exemption:

Lead in solders for Positron Emission Tomography detectors and data acquisition units installed in Magnetic Resonance Imaging equipment

1. Name and address of applicant

COCIR : European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
Blvd A. Reyers 80
1020 Brussels
Contact: Mr. Riccardo Corridori
Tel: 027068966
corridori@cocir.org

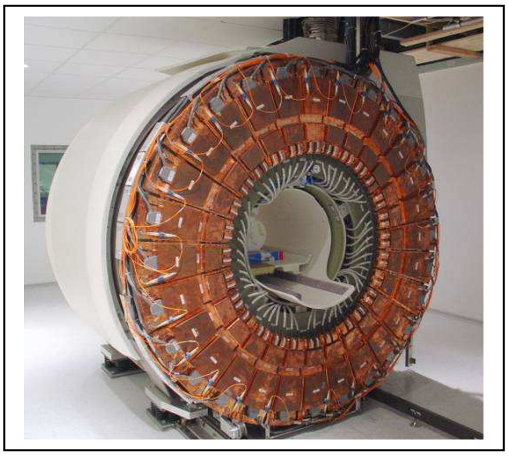
2. Summary of the application

PET/MRI is a relatively new technique which uses an array of complex high component density printed circuit boards that will experience severe vibration for long periods in use. Research has shown that lead-free solders that have been investigated for vibration susceptibility are more susceptible to early failure under severe vibration conditions than bonds made with tin/lead solder and so PET/MRI could fail prematurely if lead-free alloys were used. Therefore this exemption is requested to allow manufacturers sufficient time for research to identify suitable lead-free materials and designs

3. Description of materials and equipment for which the exemption is required

Magnetic resonance imaging (MRI) is a medical technique used to obtain three dimensional images of soft tissue and organs of the human body. Positron Emission Tomography (PET) is also a three dimensional imaging technique which is used for viewing biological activity in the human body such as tumours, for neurology, cardiology, etc. using radioactive markers that are imaged by an array of sensitive radiation detectors. More detailed and precise diagnostic information can be obtained by combining these techniques into one machine.
MRI uses a very powerful circular electromagnet into which the patient is placed and they are exposed to a very powerful magnetic field. "Radio Frequency (RF) send and receive coils" are located around the patient and inside the magnetic field and these transmit RF signals which excite magnetised protons in soft tissue and organs of the patient and the protons then emit characteristic signals that are received and measured by these coils. This process induces very large forces inside and close to the electromagnet which the patient perceives as a very loud noise and they need to have ear protection during imaging. Manufacturers have measured acoustic pressure waves of 145dB which will impose severe mechanical stresses on the electrical circuitry. For comparison, 130dB causes aural pain and a jet engine at 30m is 150dB.

The PET circuitry consists of many multilayer high component density printed circuit boards (PCBs). Inside the magnet and arranged around the patient are an array of detector PCBs and each detector PCB is connected to a data acquisition unit (DAU) and these are arranged in an array around one side of the magnet as shown below.



As the array of detector PCBs and DAUs are arranged symmetrically around the patient and consist of many small size components each of which has a very small nickel content, it is not necessary to use non-magnetic components for the PET circuits although nickel cannot be used for PCB pad coatings (i.e. ENIG cannot be used). For this application, many of the types of component used are not available as non-magnetic versions. As these PCBs are located inside or close to the electromagnet, they will experience very intense vibration and high g-forces and so need to be assembled with materials that will be reliable during the normal life of this equipment which is typically 25 years.

The detector and DAU circuits have high component densities with 2000 components on each detector PCB and 4000 components on each DAU PCBs. If any one of the soldered connections to most of these components were to fail, at least one segment would cease to function giving inferior PET image quality which could prevent diagnosis. Failure of some component connections would cause complete failure. In total, there are 336,000 connections in a typical PET system that is used as part of the PET/MRI. Solder bonds to simpler small components are relatively robust but these PCBs have many large and complex ball grid array (BGA) devices including 112 with 780 ball connections and 28 with 1152 connections. These BGAs are particularly susceptible to bond failure due to large stresses such as from vibration.

Another characteristic of these PCBs that is different to most other types of electrical equipment is the combination of high component density with high voltage with 550V being present at over 700 components on the detector boards as well as many components on the DAU PCBs. This is an issue if a short circuit were to occur as at this voltage, this would cause arcing and severe damage. As explained below, 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.

4. Justification for exemption

The only potential alternative to tin/lead (SnPb) solder for this application would be lead-free solders of which there are many types. The ERA report for the Commission on whether inclusion of categories 8 and 9 in the scope of RoHS concluded that temporary exemptions for lead in solders may be required[1]. This report was published in 2006 and since then research into substitutes has been carried out but results show that lead-free substitutes are not yet technically viable for certain more demanding applications as they may be less reliable than SnPb, in this case due to the very intense vibration experienced by these PCBs. The technical issues with substitute materials are described here:

5. Analysis of possible alternatives

5.1. Research into lead-free solders exposed to high g-forces and intense vibration forces.

Before describing the potential alternatives to SnPb, it is worth first explaining the reasons why failures occur as a result of severe vibration. Failures have been found to occur predominantly at the interface between brittle intermetallic phases[2] and solder although failures as a result of damage to the PCB laminate can also occur. Intense vibration causes PCBs to flex and this imposes strain on solder bonds and the internal structures within the laminate.

5.2. Intermetallic phase formation with solders

SnPb solder interacts with the substrate metals to create a layer of intermetallic phase. This phase is produced as a result of chemical reaction between the tin in the solder and the metal surface of the PCB pad or the component's terminals. With copper circuitry, a SnCu intermetallic is produced whereas if the pads or components have a nickel coating then SnNi intermetallic is formed. SnCu forms more quickly and tends to be thicker than SnNi but both continue to grow after the solder bond has been produced due to "aging". The growth rate depends on temperature and at higher temperatures the intermetallic phase grows more quickly and this effect can be used to simulate accelerated aging. With SnPb solders, the available tin close to the interface is depleted so that this zone becomes lead-rich which retards intermetallic growth as tin is less accessible. Also, the residual lead is relatively flexible unlike the tin/copper and tin/nickel intermetallic phases. Lead-free solders contain mostly tin and so a tin-depleted zone does not form and the structure and behaviour of the bond is different to SnPb bonds. A second effect also occurs with aging. SnPb solder consists of two phases, one tin-rich and the other lead-rich. These are separate grains which gradually grow especially where there is high imposed stress. Grain growth within SnPb does not affect bond reliability unless they become particularly large in stressed regions when thermal fatigue failure can occur after many stress / relaxation cycles.

---

[1] http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf
[2] NPL Report MAT 2, D Di Maio and C Hunt, "High-frequency vibration tests of Sn-Pb and lead-free solder joints", August 2007 http://publications.npl.co.uk/npl_web/pdf/mat2.pdf

Most lead-free solders are mainly pure tin with a dispersion of irregularly shaped SnAg and SnCu intermetallics. When a solder bond is formed on a copper substrate, SnCu forms at the interface and on nickel substrates, SnNi intermetallic is formed. These layers tend to be thicker than those produced with SnPb solder because of the higher soldering temperature and because tin is not depleted close to the interface. Sn_3Ag and SnCu intermetallic crystals form within the solder as soon as the bond is formed and grow in size due to thermal aging. Sn_3Ag crystals are a particular problem as they are needle shaped and can be quite long. In very small solder ball bonds used for micro-BGAs and CSP, large intermetallic crystals can occupy a significant proportion of the ball volume whereas this is not possible with SnPb as lead occupies half of the volume and it does not react with copper or nickel. An additional failure mode that has been found with lead-free ball bonds is where the solder is bonded 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. This is a very uncommon failure mode with SnPb because of the lower soldering temperature but has been frequently found with lead-free products.

5.3. Kirkendall voiding

The use of lead-free solders has introduced other complicating factors. Lead-free processes have been shown to increase the risk of "Kirkendall voiding". This is a process that creates many very small voids at the solder-substrate interface and is believed to be related to the plating process although it is not fully understood. Research has shown that Kirkendall voiding is more likely to occur with lead-free processes than SnPb due to the higher soldering temperature. The latest theory is that electroplating processes trap organic substances within the metal coating and these decompose to give gases during soldering and these gases create the small voids. Due to the higher melting point of lead-free solders, the 20 – 30°C higher temperature increases the risk that the organic substances will decompose to form gases and also increases the volume of the gas as they are hotter. Normally these voids have little effect but they will increase the risk of failure when the equipment is dropped or subjected to stresses such as vibration.

5.4. Vibration research

Solder bond reliability is of concern with this application because the circuits are exposed to very severe vibration for a very long period. There are several research publications which compare the vibration performance of SnPb solder with lead-free solder although some of the results appear contradictory. The reasons for contradictory results were demonstrated by research carried out by JGPP[3] which showed that susceptibility depends on:

- The solder alloy composition
- Type of component
- Position on circuit board
- g-force

[3] T. Woodrow, JCAA/JG-PP Lead-free solder project: Vibration and Thermal Shock Tests", April 2006. http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/040406WoodrowVibThShock.pdf

Later research described below also showed that vibration frequency is an important variable.
The JGPP research used test boards having several types of components each attached at several positions. Three lead-free solders and SnPb solder were compared. At lower g-forces, no failures occurred during the 7 hour period of the test but at moderate to high g-forces, there were many failures. The most susceptible type of component to fail was the ball grid array (BGA). The test board had several of these and most of BGAs had bond failures before other types of component although the time to failure was strongly dependent on the location on the PCB. Results with BGAs showed that during the tests, failures were significant at g-forces above 9g and that the lead-free solders tested failed before SnPb. In these tests, g-forces were increased once every hour. Results for two of the BGAs are shown below (BGAs U4 and U6 were of the same type).

Table 1. Proportion (%) of BGAs with failed bonds during vibration testing comparing SnPb with SAC and SACB solders

g-force	**BGA U4**			**BGA U6**		
	SnPb	**SAC**	**SACB**	**SnPb**	**SAC**	**SACB**
9.9	40	80	100	0	20	0
12	80	100	100	20	60	40
14	100	100	100	40	100	60
16				60	100	100
18				60	100	100
20				80	100	100

SAC = Tin, silver and copper
SACB = Tin, silver, copper and bismuth

As component location affects vibration failure it is difficult to compare different types of component but most of the other types of components at locations adjacent to U4 and U6 and so experiencing similar vibration force and amplitude, failed after longer periods than these BGAs. This is a concern to manufacturers of PET/MRI medical device because BGAs are commonly used.

The test results reported from the JGPP research are from highly accelerated testing using very high g-forces. The test duration was only 7 hours whereas PET/MRI scanners have lifetimes of over 25 years and will be in use many hours per day. Clearly if the PET/MRI or any other electrical device, irrespective of which type of solder was used, were to be exposed to 9.9g or more, it would not survive 25 years. Accelerated testing is useful to identify potential failures during the normal lifetime of the equipment based on known characteristics of the equipment such as the level of vibration. The figure below shows the typical level and frequency of vibration experienced by a PET/MRI DAU PCB.

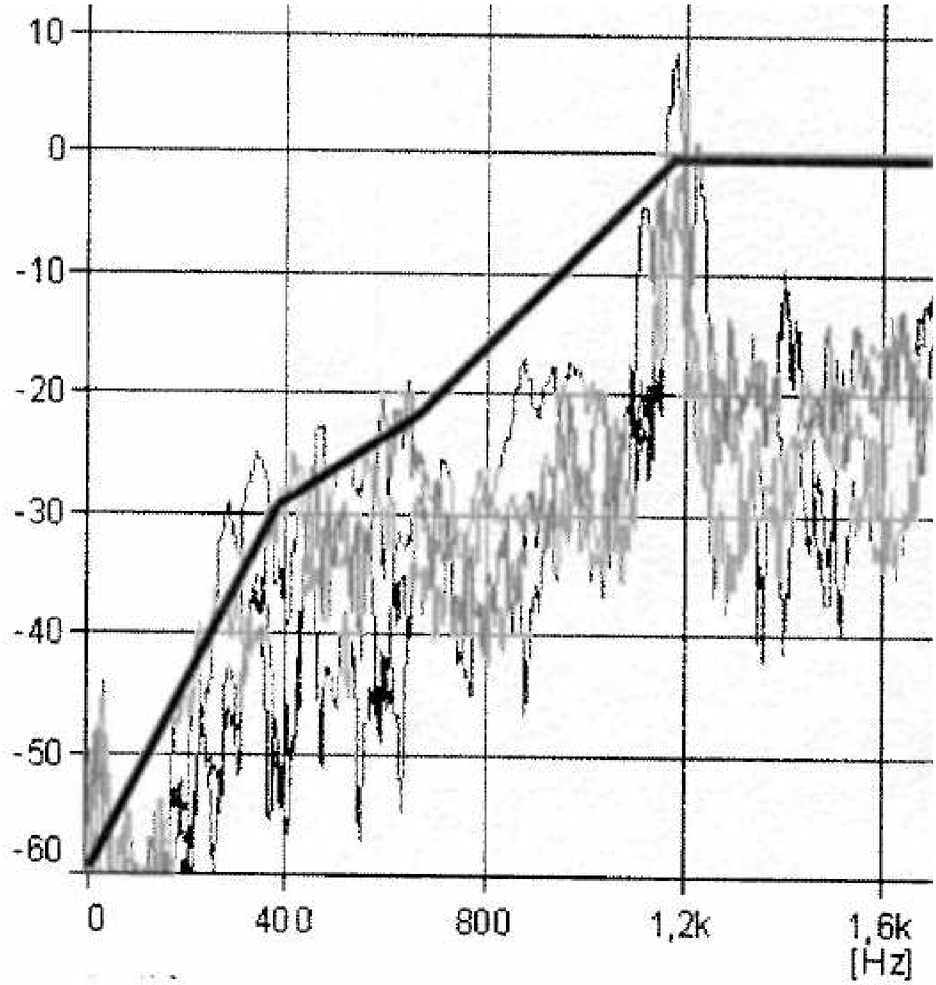


Figure 1. Vibration spectrum of PCBs in PET/MRI (vertical scale = dB/1.0g)

The maximum vibration force experienced is equivalent to well over 2 g which is relatively large for electrical equipment although much less than the value of 9.9g that was used in the JGPP tests. Figure 1 shows that the largest amplitude vibration occurs at about 1.1kHz although vibrations occur at all frequencies from <200 Hz to over 3kHz. Some electrical component bonds failed after less than 2 hours in the JGPP tests whereas PET/MRI PCBs must survive >2g for 25 years. MRI manufacturers have many years of field experience with SnPb solders at high levels of vibration and so can expect that PCBs made with SnPb solder will survive 25 years. As the JGPP tests show that bonds made with lead-free solders will have shorter lifetimes, there can be no certainty that the same PCBs when made with SAC lead-free solders will survive the 25 years. Unexpected early failure of an MRI/PET scanner could be harmful to patients due to the equipment not being available when needed and early failure would also create more waste electrical equipment.

Research published by the National Physical Laboratory (NPL)[2] showed that vibration testing of assembled PCBs cannot 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. NPL's research compared SnPb with four SAC alloys including SAC0305 having only 0.3%Ag which has better drop shock resistance than SAC305. This investigation used piezoelectric actuators to impose controlled vibration forces and vibration amplitude and frequency were controlled in these tests. The main result was that at all frequencies, SnPb had a lower probability of failure than any of the four SAC alloys. This was especially the case at higher frequencies as 400 and 800Hz were compared. The numbers of vibration cycles to 20% probability of failure from Wiebull plots were:

Table 2. NPL vibration results – cycles to failure

Solder alloy	20% probability at 400Hz	20% probability at 800Hz
SnPb	200,000	20,000
SAC305	100,000	2,000
SAC387	60,000	8,000
SAC 0305	40,000	4,000
Annealed SAC305	9,000	-

Figure 1 shows that maximum vibration occurs at ~1,100 Hz which indicates that the difference between SnPb and SAC solders would be even larger than at 800Hz.

5.5. Comparison with SnCuNi solder

The JGPP research also compared Sn0.7Cu0.05Ni (often referred to as SN100C) wave soldering with the two SAC lead-free solders and with SnPb. This could be used only for some types of components and appeared to give superior performance to SnPb with one type of DIP component. The detector and DAU PCBs used for PET/MRI are all surface mount types with BGAs and so SN100C cannot be used. This is because BGAs are made using SAC balls and the solder used to attach these should have a similar melting temperature to avoid reliability problems. Standard SAC that is used for BGA balls melts at 217°C whereas SN100C melts at 227°C. This would result in the BGA ball melting before the SN100C and this would allow flux volatiles to form large voids inside the BGA balls before the SN100C melts. It has been shown that large voids inside BGA balls affects bond reliability[4]. For this reason, manufacturers always use solder pastes with similar alloys to the BGA ball alloy. Another issue is that BGAs are temperature sensitive devices and so are more likely to be damaged by the higher reflow temperature needed for SN100C solder. Too high a reflow temperature can cause delamination or cracking of the circuits of the BGA package.

SnCuNi was also assessed by Barry (as well as SAC305) who tested solders in a more consistent way as was also performed by NPL (described above)and this

[4] M. Yunus, et. Al., "Effect of voids on the reliability of BGA/CSP solder joints", Microelectronics Reliability, 43 (2003), 2077, http://www.atv-tech.com/en/pdf/Effects%20of%20voids%20on%20the%20reliability%20of%20BGA%20and%20CSP%20solder%20joints.pdf

research showed that SnPb has superior vibration performance to both the SAC305 alloy and SnCuNi with SnCuNi being inferior to SAC305[5].

5.6. MRI PCB vibration comparative test results

One MRI manufacturer has evaluated a PCB that is used at a location close to the PET detector and DAU boards to compare the reliability of SnPb and lead-free solder bonds to RF screen chip capacitors in the conditions experienced in the MRI. These PCBs were tested using conditions appropriate to the MRI although as an accelerated test. Three types of capacitor 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.

5.7. Risk from tin whiskers

Tin whiskers are thin rods of tin that grow from electroplated tin coatings. These are now very common on component terminations but as often no alternatives are available, manufacturers have no choice but to use these. Tin whiskers have however been found to form[6] on thicker electroless tin coatings that are used as protective coatings on PCB pads. Thin electroless tin may not form whiskers but as tin combines rapidly with copper to form an intermetallic phase which does not wet to solder, thin coatings have too short a shelf-life. As a result, electroless tin pad coatings are rarely used but due to the specific characteristics of PET/MRI PCBs, this is the only option.

ENIG	Cannot be used due to magnetic nickel
HASL[7]	Unsuitable as coatings are not perfectly flat which is required for the 780 and 1152 BGA devices.
OSP	Can impair solder wetting, used predominantly for mass produced consumer products
Immersion silver	Short storage life so unsuitable for detector PCBs. This is used for DAU boards as these are made and populated so shelf life of silver is not an issue. A long shelf live is needed for detector PCBs though, because these are made and part-populated at one location and then additional components are added later at another.

Electroless tin is non-magnetic, thicker coatings have a longer shelf-life than silver and it is perfectly flat and so is suitable except for the risk of tin whiskers. Tin whiskers will only form on areas of pads that are not wetted by molten solder during the soldering process. With tin/lead, this is not a concern as wetting is good so that none of the pad areas should remain without a solder coating. Lead-free solders however are well known to wet surface less well than SnPb and there is a tendency for the corners of pads to remain unwetted and these are locations where whiskers can form. Various methods are used to improve pad coverage

---

[5] N. Barry, University of Birmingham, UK, Ph.D thesis October 2008.
[6] http://www.p-m-services.co.uk/electroless_tin.htm
[7] HASL = Hot Air Solder Level which is a process where molten solder is applied to the PCB and coats pads, OSP = organic solderability preservative (thin organic coatings)

such as decreasing pad size and the use of more unusual solders that have better wetting properties but each of these options will require additional time for research to ensure that very high reliability is achieved which is essential for medical devices.

Tin whiskers are a particular concern due to the high component density which results in very small gaps between the edges of adjacent pads so that fairly short whiskers could cause a short circuit in this application. High voltage is also an issue because high voltage short circuits would cause arcing and catastrophic failure.

One method used to reduce the risk from whiskers is to use conformal coatings but these cannot be used underneath BGA devices.

5.8. Thermal fatigue risk

Thermal fatigue failure can occur after many stress cycles caused by temperature fluctuations such as those caused by components being powered. Research has shown that lead-free solders have a greater risk of thermal fatigue failure than SnPb only if stress levels are high. It is not yet known if this would be a significant risk for lead-free soldered PET/MRI and more research is planned to investigate. However, the following is known:

- PET/MRI can experience one thermal cycle daily and be used for at least 25 years. This would impose 9000 stress cycles which is a significant number
- DAU PCB temperature rises by up to 35°C when powered. Although not very large, this would result in large stresses if the thermal expansion coefficient (TCE) of a component were very different to the PCB laminate.
- The TCE of components is not usually measured or published but the TCE of complex BGAs can be relatively small in comparison with FR4 laminate. This is because FR4 is mostly glass reinforced epoxy which has a fairly large TCE (typically ~15 x 10^{-6}/°C) whereas complex BGAs with large silicon die have much smaller TCE due to the very low TCE of silicon (2.6 x 10^{-6}/°C)

Therefore PET/MRI scanners could experience a significant number of stress cycles and there are indications that stress levels may not be small so thermal fatigue could be an issue so more research will be needed which will require several years of testing to complete.

6. Life cycle comparison of alternative options

The two alternatives are SnPb solder and several lead-free solders and the life cycle impacts have been analysed by the US Environmental Protection Agency (EPA)[8]. This concluded that for the majority of environmental impacts, lead-free solders had greater negative impacts than the tin/lead solder they replace.

6.1. Extraction, refining and production

The US EPA study showed that SAC solder paste reflow consumes slightly more energy than all of the other solders and the main reason is energy for extraction and refining of silver and the higher melting temperature than SnPb. The US EPA study gave environmental impact scores for energy use for the paste solders:

---

[8] http://www.epa.gov/dfe/pubs/solder/lca/index.htm

Alloy	10^4 MJ energy / 1000 cc solder
SnPb	1.25
SAC (Sn3.9Ag0.6Cu)	1.36
SABC (Sn2.5Ag1Bi0.5Cu)	1.31

EPA's results for the low melting point bismuth tin silver alloy are excluded here as this solder cannot be used for PET/MRI PCBs due to its too low melting temperature as it cannot be used with BGAs having SAC or SnPb balls.

Extraction and refining of silver creates significantly more waste than lead and so SAC and SABC have significantly larger environmental impacts

Alloy	dm^3 waste created / 1000 cc solder
SnPb	2.75
SAC	16.2
SABC	11.3

SnPb solder had a greater impact sore than SAC and SABC for occupational health and public health –non cancer but SAC had the largest public health-cancer impact score. Overall SnPb had the largest impact scores for six categories whereas SAC had the largest impact scores for 10 categories.

6.2. Use phase

The choice of solder alloy has no impact on the use phase as long as it does not affect reliability. If an alloys were to be less reliable causing unexpected early failures, this would potentially have a serious impact on patient health and would create additional waste.

6.3. Re-use and recycling of materials from waste EEE

PET/MRI equipment is large, complex and contains valuable metals that can be recovered for re-use. This type of medical device will nearly always be recycled by professional recyclers who recover metals with high yields and comply with national emission legislation. Due to its very large size, (eight tonnes each) and high value it is not likely to exported to developing countries for unsafe and uncontrolled recycling.
The procedure used for MRI/PET is the same whether SnPb or lead-free solders are used. First, these would be dismantled and all PCBs removed. The PCBs are shipped to smelters of which there are several in the EU for thermal processing which recovers the copper, tin, lead, nickel and precious metals with high yields, usually >95%. It is also possible to refurbish removed PCBs for reuse as spare parts for repair of other equipment.

7. Other information

It is estimated that 15 kg of lead will be placed on the EU market annually by this application.

8. Proposed plan to develop substitutes and timetable

Research into a lead-free soldered version of the detector and DAU PCBs of the PET/MRI will be needed to ensure that reliability is not inferior to SnPb soldered versions. This will involve the following activities:
Develop production process suitable for lead-free PCBs. Carry out accelerated vibration testing to compare with SnPb. When a design has been developed with a lead-free solder that has similar performance to SnPb, longer term vibration testing can begin using more realistic conditions to simulate the PET/MRI vibration. If results are satisfactory, then a lead-free PET/MRI can be assembled and tested to ensure that the long-term test results are not different to results with the PET/MRI.

Timescale:

Manufacture lead-free PCBs	Up to 1 year
Accelerated testing and redesign to optimise vibration performance	Up to 1 year
Long term PCB testing	Up to 3 years
PET/MRI testing	Up to 2 years
Reliability testing to collect data for Medical Device Directive approval	1 year
Apply for approval under the Medical Device Directive	Up to 1 year

The total timescale assuming that this is successful will be up to 9 years or until 2020.

9. Proposed wording for exemption

Lead in solders used on detector and data acquisition unit printed circuit boards of PET/MRI scanners.