Application for granting new Exemption: Lead in solders and solderable coatings used on non-magnetic components and circuits that are used in magnetic fields or are associated with circuits used inside strong magnetic fields.

1. Name and address of applicant

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2. Summary of the application

Several medical and analysis techniques use very powerful magnets and so must avoid using magnetic materials in their construction where possible. One example is Magnetic Resonance Imaging (MRI) which is a medical diagnostic technology that uses very powerful magnetic fields and sensitive detectors to detect magnetic resonance signals. Magnetic materials cannot be used inside or close to powerful magnetic fields as they will be strongly attracted and could cause damage. Magnetic metals can also cause distortion of the magnetic resonance image so that they cannot usually be used. As a result, electrical circuitry cannot be constructed with standard electronic components as these contain nickel which is magnetic and so special nonmagnetic components are used. It is significantly more difficult to produce good quality and reliable solder bonds to the solderable termination coatings of these components and manufacturers have encountered poor yields and high rates of failures when they use lead-free solders. Poor reliability is unacceptable for health critical medical devices. A lot more research will be needed to identify suitable solder alloys and production processes that can replace tin/lead processes and so an exemption is requested that will allow manufacturers sufficient time to complete this research and obtain the reliability data that will be needed to obtain approval under the Medical Devices Directive.

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

Several medical and analysis techniques utilise very powerful magnets. These are used for example in Magnetic Resonance Imaging (MRI), high-end Nuclear Magnetic Resonance (NMR) analysis and in cyclotrons, all of which utilise very powerful superconducting magnets. This exemption is also needed for special patient monitors that are attached to patients and are used inside the MRI.

MRI is a medical technique used to diagnose conditions associated with soft tissue such as detecting tumours, blockages in blood vessels and damage to internal organs. MRI uses the very powerful magnetic field of a large very powerful magnet in which the patient is placed. Circuits that are located close to and within the magnetic field use non-magnetic components where possible to avoid degradation of the MRI image. This is especially important for the electronic circuits that are within the MRI magnet or are electrically connected to these circuits nearby and so would affect the magnetic field.

When a patient is examined by MRI 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. Coils transmit RF signals which excite magnetised protons in soft tissue of the patient and the protons then emit characteristic signals that are received and measured by these coils. One of the essential characteristics of the coils and the electronic circuitry that is connected to each coil is that these must be non-magnetic because any magnetic materials degrade the weak RF signals resulting in distorted MRI images. Research has shown that metals with even very small magnetic susceptibility degrade the image quality reducing the ability to detect small features such as tumours or blood clots. The types of components used are the same as in other electrical equipment such as capacitors, inductors and resistors but special "non-magnetic" versions need to be used. The most common termination coating used for standard electrical components in most electrical products is tin or tin/lead electroplated over a nickel plated barrier layer. Nickel prevents loss of tin coating during storage as tin and copper react to form an unsolderable intermetallic phase but nickel is however strongly ferromagnetic and so cannot be used within the region of the RF coils.

Other types of medical devices made with non-magnetic circuitry that are used within the MRI magnet are special types of patient monitors that are portable devices connected to patients who are very ill and need to be constantly monitored. As these will be inside the MRI's magnetic field with the patient, they must also be constructed from non-magnetic components.

Components used for MRI within the magnetic field or connected to send and receive coils need to be soldered to create the electronic circuits and so components having nickel-free solderable coatings are used. These non-magnetic components are manufactured specifically for MRI and similar applications. The choice of terminal materials is very limited as the metal used for the outer surface must be wetted by solder easily and quickly.
Several related applications are reviewed here:

- Lead in solders used for making connections to non-magnetic components in MRI radio frequency (RF) send and receive coils
- Lead in the solderable coatings of non-magnetic electronic components used in MRI RF send and receive coils.
- Lead in solders and solderable coatings of other electrical circuits, such as in patient monitors, that are used inside MRI magnets or are sufficiently close to cause distortion of MRI images.
- Lead in solders and solderable coatings of circuits of high-end NMR, cyclotrons and other devices that use superconducting magnets where magnetic materials will degrade performance.

Many different components are used for these applications and some, but not all, are available without lead in the termination coatings.
Most non-magnetic components of MRI are soldered to flexible PCBs by hand with soldering irons, although surface mount technology is beginning to be used by some manufacturers. An example of an assembled PCB is shown in the Figure below. All of these components are non-magnetic.

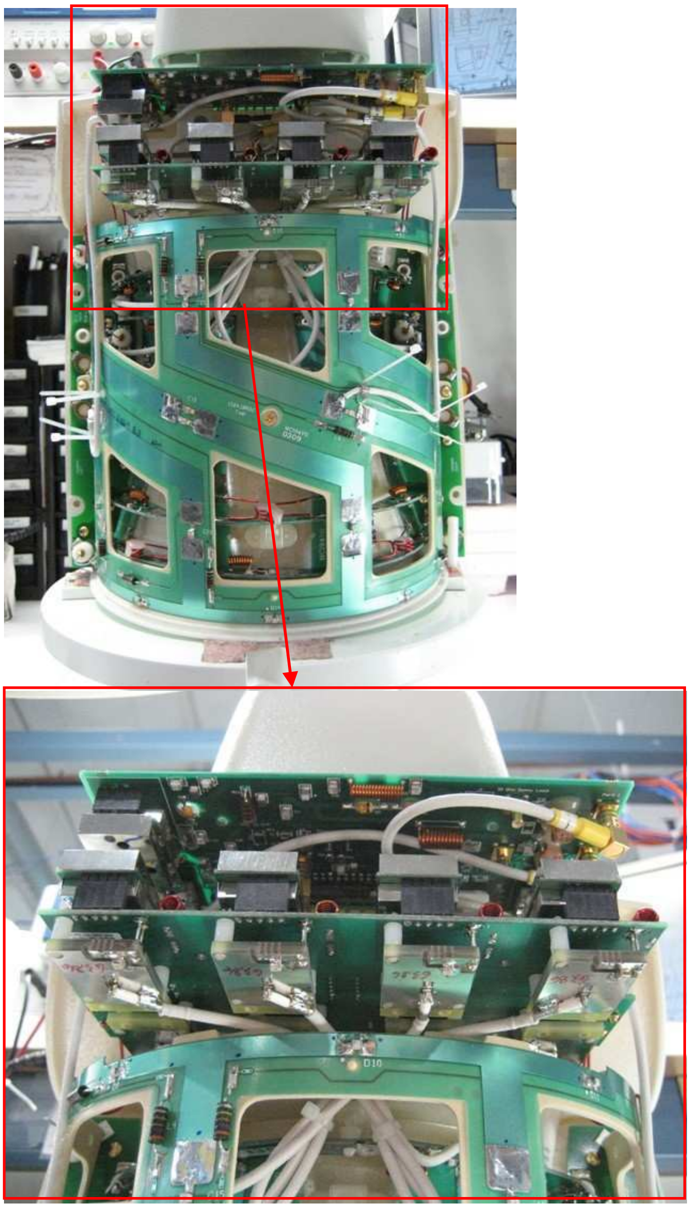

Figure 1. Non-magnetic circuitry of MRI equipment

It is however possible to use magnetic components but only under certain specific circumstances:

- Components containing very small amounts of magnetic metals such as nickel, many MRI components are quite large (see figure 1 above) and so the magnetic versions contain large amounts of nickel
- If many very similar circuits having identical magnetic fields are arranged around the patient cavity, it is possible to design these so that the impact of the magnetic components on the image is minimal. This is not possible with most MRI circuits and so they must use non-magnetic components. For example, there may be only one of a type of module that is located at one side.

For similar reasons to MRI, circuitry in high-end NMR and cyclotrons also uses non-magnetic components. Magnetic materials will be strongly attracted by the powerful magnets and so either be damaged by the strong attraction force or they cause distortion that interferes with their function which limits accuracy.

4. Justification for exemption – Article 5 criteria

The reasons for continued use of lead in this application are technical difficulties with manufacture of lead-free assemblies and uncertainty over long term reliability. The alternative to lead-based solders and termination coatings are lead-free solders with three types of termination coating. As will be explained below, it is not yet technically possible for MRI manufacturers to convert their designs to use lead-free processes. This is because:

- Some of the non-magnetic components are not available as RoHS compliant versions and this is extending the time needed to carry our R&D work
- Trials to construct some circuit designs with lead-free solders have given very poor yields and testing of lead-free MRI circuits has found poor reliability
- There are concerns that lead-free designs may have a negative impact on reliability and a lot more research is needed to ensure that patient healthcare is not affected

5. Analysis of possible alternatives

Lead-free solders and non-magnetic lead-free terminal coatings are the only possible alternative. 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 this application and can be less reliable. The technical issues with substitute materials are described here:

5.1. Alternative Non-magnetic termination coatings

Standard electrical components have terminations that are most often tin electroplated onto nickel, but as nickel cannot be used for MRI applications within or connected to the magnetic field, alternative types of termination coating capable to being used on non-magnetic components have been developed.
Metals that can be wetted by solder include tin; tin alloys with lead, copper, silver; some bismuth alloys; gold, silver and silver palladium However reliability and solderability issues limit the choice of termination coatings offered by manufacturers to the following three options :

- Tin/lead over copper has been used for many years with tin/lead solder and has proven reliability
- Silver/palladium has been used as a lead-free option but the wetting properties of Ag/Pd are different to both lead-free and tin/lead solders and has caused solder leaching and wetting problems
- Tin over copper was developed as an alternative to Ag/Pd as it wets easily but it also experiences reliability problems that will be explained here.

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[1] http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf

Of the other metals that are wetted by solder:

- Gold forms an intermetallic phase with tin which is brittle so that bonds fail when exposed to relatively small forces
- Copper and bismuth oxidise in air becoming unsolderable after a few days in storage
- Silver tarnishes in the presence of minute amounts of hydrogen sulphide which is a very common atmospheric contaminant gas. Tarnished silver cannot easily be soldered

The type of component coating that is used is dependent on the type of electronic component.

- Semiconductor devices such as ICs use lead-frames made of copper or other alloys that are usually electroplated with nickel then tin or tin/lead or with nickel then a thin gold coating. Nickel barriers increase storage life by retarding SnCu intermetallic formation and reduce the risk of tin whiskers (see below). Thin gold coatings cannot be deposited onto copper as these interdiffuse to leave copper that oxidises and becoming unsolderable at the surface.
- Chip components such as resistors, capacitor and inductors use "thick-film" pastes consisting of a metal and glass that are heated to melt the glass to bind the metal conductor. Most thick-film pastes are based on silver, silver/palladium alloy or copper. As these metals all dissolve rapidly in molten solder forming thick and brittle intermetallics, they are usually encapsulated by a nickel layer. As nickel is not solderable, this has to be coated with tin or tin/lead.
- Components with wire connections which include transformers and coils usually have copper wires that are tin plated. The copper wire is usually relatively thick so that the higher copper dissolution rate that occurs with lead-free solders is not an issue and so nickel barriers are not needed. Some however have very fine wires where dissolution in lead-free solders is an issue and exemption 33 of Annex III of the recast allows tin/lead solders to be used for soldering very thin wires (<100 micron diameter) of power transformers

Alternative component termination coatings are compared below:

Coating material	**Advantages and disadvantages**
Tin (Sn)	Good solder wetting properties but susceptible to tin whiskers if deposited onto copper without a nickel barrier layer. Not recommended by iNEMI[2]. Very low magnetic susceptibility.
Tin/lead (Sn/Pb)	Good solder wetting, resistant to tin whiskers without nickel barrier layer. Lead also has a very low magnetic susceptibility.
Tin alloys: Tin/copper, tin/silver and tin/bismuth alloys	Susceptible to tin whiskers especially tin/copper. iNEMI recommends tin/silver and tin/bismuth should be used only with nickel barrier layers. SnAg coatings are not thoroughly researched and SnBi has diamagnetic properties that may affect sensitivity.

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[2] iNEMI has published guidance on mitigation measures against tin whiskers based on many years research, http://thor.inemi.org/webdownload/projects/ese/tin_whiskers/Pb-Free_Finishes_v4.pdf

Coating material	Advantages and disadvantages
Gold (Au)	Cannot be deposited as thin coatings on copper as interdiffusion occurs resulting in copper at the surface which oxidises and then cannot be easily soldered. Thick gold coatings cannot be used as gold forms a very brittle intermetallic compound with tin (with all types of tin based solders) which causes rapid bond failure.
Silver (Ag)	Low magnetic susceptibility but tarnishes during storage becoming unsolderable. Also suffers from fairly rapid interdiffusion with copper (see gold above).
Silver/palladium (Ag/Pd)	Applied as thick film material instead of copper and avoids need for an outer coating. Solder wetting is however inferior and there is a risk of weak solder bonds. Palladium also has a relatively high magnetic susceptibility and tests have shown that components with Ag/Pd terminations give inferior sensitivity of the MRI image. The magnetic susceptibility of components with AgPd is about three times that of tin plated copper.
Copper	Very low magnetic susceptibility but cannot be used without a coating of an oxidation resistant solderable material such as tin or tin/lead because it rapidly oxidises and becomes unsolderable. Copper readily diffuses into tin, gold and silver and so nickel barriers are used when magnetic properties are not important. Electroplated tin deposited onto copper is more susceptible to tin whiskers than where a nickel barrier layer is used.

During soldering, the substrate metal dissolves in molten solder at a rate that is proportional to the temperature and the rate increases as the temperature is raised. Research by two organisations is shown below to illustrate this effect.

Solder alloy	Rate of dissolution of copper immersed in solder bath*	Copper dissolution rate (wave soldering) at specified temperature**
SnPb	1.8µm/sec at 275°C	~1.38µm/sec at 255°C (72°C above m.pt.)
SnCu	2.7µm/sec at 275°C	3.28µm/sec at 275°C (~48°C above m.pt.)
SnAg	4.4 µm/sec at 275°C	3.28µm/sec at 275°C (~54°C above m.pt.)
Sn3.7Ag0.7Cu	-	2.3µm/sec at 275°C (~58°C above solidus.) or 3.3µm/sec at 300°C (~80°C above solidus.)

* D. Di Maio, C. P. Hunt and B. Willis, "Good Practice Guide to Reduce Copper Dissolution in Lead-Free Assembly", Good Practice Guide No. 110, 2008, National Physical Laboratory, UK.

** C. Hunt and D. Di Maio, "A Test Methodology for Copper Dissolution in Lead-Free Alloys", National Physical Laboratory, UK.

These results show that the risk of complete loss of copper substrate is higher with lead-free solders than with tin/lead solder. Nickel barrier coatings react with liquid solder much more slowly but cannot be used and silver and gold dissolve in liquid solder as rapidly as copper.

5.2. Lead-free solder alloy properties

The results in the above table demonstrate the risk to components that have thin termination coatings as long periods in contact with liquid solder can cause complete dissolution to leave an open circuit. This is exacerbated by the higher melting temperature of all of types of lead-free solders that are used commercially (see table below) to construct electronic and electrical equipment as the dissolution rate increases with temperature. Lead-free solders are now widely used by the electronics industry but these have different characteristics to tin/lead solder that have a significant disadvantage when soldering to non-magnetic components that are unable to have nickel barrier coatings.

Solder alloy	Melting temperature
SnPb	183 °C
SnCu	227°C (
SnAg	221°C (3.5%Ag)
Sn3.5Ag0.5Cu	217 °C

Soldering process conditions

In the last few years, manufacturers of electronic components have introduced a wider range of components that are "RoHS compliant". These manufacturers give advice on soldering their components and claim that soldering with lead-free solder is possible but there are limitations which are described here. Furthermore, there are still some types of component commonly used in MRI that are not yet available as RoHS compliant versions.

MRI circuits that are either inside the magnetic field or attached to circuits that are in the field may be either hand soldered or reflow soldered. Reflow soldering can be well controlled so that components terminations are exposed to a limited maximum peak soldering temperature for a maximum period of time although whether this time and peak temperature are achievable in practice depends on many variables. These variables include:

- The size of other components on the PCB. Larger ones need more time for wetting to occur so that the smallest components are in contact with liquid solder for much longer.
- Type of flux used (more corrosive fluxes can be faster but can also cause corrosion problems)
- Age of circuit board and components (solder wetting times tends to increase as components age due to increased oxidation of coatings)

In the reflow process using solder pastes, the circuit boards are held at high temperature for sufficient time to melt the solder and to form the bond between the liquid solder and the termination material. In practice, the liquid metal dissolves the termination metal so if left for too long, can remove the termination coating completely. The peak temperature required for lead-free solders such as with eutectic tin/silver/copper (known as SAC) is higher than that of tin/lead due to its higher melting point (217 and 183°C respectively). The actual temperature required depends on the circuit design, component size and the performance of the reflow oven but it is not uncommon for manufacturers to require 250 - 260°C and for the solder to be above its melting point for more than 60 seconds. The problem is that liquid tin-based solders dissolve termination coatings at a rate that increases with temperature. This is rapid with tin and copper but much slower with nickel. Some manufacturers recommend maximum peak temperatures and time at above melting point with lead-free solders such as SAC and some publish recommended limits for the time exposed to molten solder. The limits published by different manufacturers cannot usually be compared directly as they are measured in different ways but they are indicative. A selection of maximum times at reflow temperature are as follows:

Published maximum temperatures and peak temperatures for soldering non-magnetic components

Component manufacturer, component and termination coating	Maximum specified reflow temperature	Maximum specified time at peak temperature
Syfer MLCC with Ag/Pd (from Syfer Technical Summary)	240°C	<20 seconds
	260°C	<~7 seconds
Vishay MLCC with Ag/Pd (Tech note TN-0029)	260°C	<40 seconds
Vishay MLCC with Sn/Cu	260°C	As specified in J-STD-020
Temex MLCC Ag/Pd	260°C	< 10 seconds (120 seconds is OK for Sn on nickel barrier)
Temex MLCC Sn/Cu	260°C	10 – 30 seconds
Temex Chip Trim ceramic capacitor (tin terminations)	265°C	Maximum 3 seconds

MLCC = multilayer ceramic capacitors

The maximum times vary considerably between 3 and 40 seconds. Lead-free reflow soldering usually requires at least 30 seconds above the solder melting temperature (and often more than 1 minute) to achieve good wetting of all components on the PCB whereas times above melting point with tin/lead solder tend to be shorter.

Soldering to components with thin termination coatings or to thin wires clearly needs as short a time in contact with liquid solder as possible. Wetting times can also affect the time that terminations are exposed to liquid solder because, when a PCB is soldered, it is necessary to wait until the last bond has formed and this will usually be to the component with the highest thermal mass and so takes longest to reach soldering temperature. Any additional time for wetting to occur extends the time that already wetted bonds are exposed to liquid solder. Wetting time is strongly dependent on the flux composition but in general, as long as suitable fluxes are used, wetting times for tin/lead solder are shorter than most types of lead-free solder. Comparative tests have been published by Asahi (a solder manufacturer)[3] in which a variety of alloys were compared by wave soldering a standard PCB using a soldering temperature of 245°C.

Alloy composition	Wetting time (seconds)
Tin / lead	0.6
Sn0.7Cu	1.0
Sn3.5Ag	1.4
Sn3.5Ag3.0Bi	1.7
Sn4Ag0.5Cu	1.9

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[3] http://www.asahisolder.com/Publication/Comparative.pdf

Temperature also affects wetting times by a solder alloy. It is unrealistic to compare tests at 245°C because SnPb is typically soldered at ~235°C whereas lead-free alloys may be at ~255°C. However at these temperatures, Asahi's test results show that SnPb has the shortest wetting time.

SnPb at 235°C	~0.77 seconds
SnAgCu at 255°C	~1.28 seconds

Asahi state that the Sn3.5Ag and SnAgCu alloys they tested had wetting times that are too slow for wave soldering. These alloys are used for hand soldering and as solder pastes.

Examples provided by Renasas on their website[4] show that the effect of the composition of the plating layer on component terminations when soldered with a SAC lead-free solder is also dependent on termination coating alloy composition:

Component type and termination coating	Average wetting time (secs)	Range of wetting times (secs)
TO package with SnCu	1.33	0.86 – 1.65
TO package with SnPb	0.49	0.43 – 0.60
QFP with SnBi	0.42	0.28 – 0.64
QFP with SnPb	0.24	0.23 – 0.25

Hand soldering of lead-free components with lead-free solders is more challenging than with SnPb solder. Chip-components, especially chip capacitors, are fairly fragile devices and can crack as a result of thermal shock if the soldering iron is placed directly onto the component. Standard practice is to place the soldering iron tip onto the PCB near to the component and allow molten solder to make contact with the component's termination. Wetting times are considerably longer with lead-free solders than SnPb unless the operator uses a much higher temperature than is recommended but this can damage the components and the flexible PCB so should not be used.

Non-magnetic components can withstand only a short time in contact with lead-free solders (as little as 5 seconds) and so there is a high risk that one of the bonds to a component will be defective. With chip capacitors, for example, the assembler would apply solder and heat to each end of the component sequentially. Unless excessive temperature is used, it typically takes about 5 seconds in contact with molten lead-free solder to produce the first bond. The solder from the first bond will however remain molten on very small components while the operator heats the other end to form the other solder bond. The solder at the first end could therefore be molten for about 10 seconds or longer and this may be too long for some types of non-magnetic components. The time to form bonds on larger components will be longer although the first bond is less likely to remain molten while second and subsequent bonds are produced but they will be hot for longer and so the tin/copper intermetallic phase will continue to grow and become more susceptible to failure by cracking of this brittle layer.

Excessive soldering times could at worst cause the end termination material to completely dissolve in the solder so that the bond fails and at best this increases the risk of bond failure due to stresses in service.

In surface mount processes, the time that solders are molten is usually longer than by hand soldering and so the risk of damage to the components' copper/tin

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[4] www.renasas.eu/prod/lead/rt/plating.html

terminations is increased due to the thicker tin/copper intermetallic phase that forms when nickel barriers cannot be used..
Another issue is the large size of the coil flexible circuits as shown in the figure above as these have large areas of copper that are a good heat conductor. When bonds are created with a soldering iron, the copper conducts heat away from the bond area so that it can take a significant amount of time before good solder wetting of the copper tracks is achieved. During this time, molten solder is in contact with the non-magnetic component and this can be too long for some types of non-magnetic components.
Low temperature solders are not necessarily 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. Moreover, SnBi solder is significantly more susceptible to thermal fatigue than SnPb[5].

5.3. Reliability – intermetallic phase formation

Tin from solder and copper terminations react to form SnCu intermetallic phases at the interface between the two layers. These compounds grow fairly rapidly while the bonds are being heated by the soldering process and so the thickness depends on the soldering time as well as the soldering temperature. SnCu intermetallics are relatively brittle and so if they become moderately thick and there is imposed strain from vibration or thermal cycling, both of which occur with MRI, there is an increased risk of failure. Severe vibration occurs as a result of the forces created between the field coil and gradient coils (these are used to produce 3D images) and manufacturers have measured acoustic pressure waves of 145dB which will impose severe mechanical stresses. For comparison, 130dB causes aural pain and a jet engine at 30m is 150dB. Formation of brittle thick layers of SnCu are normally avoided by using nickel barrier layers as nickel reacts with tin much more slowly than tin with copper so that only very thin and so more flexible SnNi intermetallic layers form. Nickel cannot however be used in these high magnetic field applications.

Tin/copper intermetallic growth rates are temperature dependent and so are usually thicker with lead-free processes than with tin/lead solder and potentially resulting in lower reliability. Research by JGPP in 2006 showed that lead-free solders are more susceptible to failure as a result of intense vibration than SnPb solder[6] although this depends on the location of components on a PCB and the type of component. Research has shown that shock / drop resistance of solder joints is affected by solder alloy composition. Resistance to shock (i.e. being dropped) is relevant to vibration reliability because with severe vibration, the solder bonds are subjected to many high g-force shocks. Drop tests comparing SnPb with eutectic SnAgCu shows that SnPb has a superior shock resistance[7] with bonds made with Sn3.8Ag0.7Cu failing after fewer drops. This research was

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[5] HP tested 58%BiSn with 63%SnPb for cyclic thermal fatigue resistance and found that SnBi bonds failed much sooner than SnPb with all of the package types tested. "Low-Temperature Solders", Z. Mei, H. Holder and H A. Vander Plas. H. P Journal, August 1996.

[6] http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/JTR%20Reliability%20Conclusions%20March%2028%202006.pdf and http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/040406WoodrowVibThShock.pdf

[7] Greg Heaslip, Claire Ryan, Bryan Rodgers, and Jeff Punch, "Board Level Drop Test Failure Analysis of Ball Grid Array Packages", Stokes Research Institute, 2005

carried out with magnetic components but as the SnCu intermetallic will be thicker on non-magnetic components, shock or vibration induced failures would be more likely to occur. SnAgCu alloys with lower silver content (~1.0%) have been developed (mainly to reduce the cost of silver) and are found to have better drop resistance than eutectic SnAgCu with 3.8%Ag. However, the melting temperature is higher at ~226°C with 1% Ag, which is nearly 10°C hotter than with 3.8%Ag and this higher temperature will increase the SnCu intermetallic thickness and thicker brittle SnCu intermetallic will make joints more susceptible to thermal fatigue failure. The higher melting temperature will also increase the termination coating dissolution rate in liquid solder which makes manufacture even more difficult or impossible, especially with large thermal mass components.

Intermetallic phases are also formed with tin from solders and AgPd termination coatings consisting of a mixture of SnAg and SnPd phases. Their thickness is proportional to the soldering temperature and time at soldering temperature. With the higher temperature of lead-free solders, these can be sufficiently thick to become relatively brittle so that quite small forces cause them to fracture and the bond fails. There are several publications that show that AgPd thick film coatings are more prone to cracking when soldered with lead-free solders than with tin/ lead solder[8] due to the thicker SnPd layer formed with lead-free solders at a higher temperature than when SnPb is used.

5.4. Reliability - Tin whiskers issue

Tin whiskers are thin rods of tin that grow spontaneously from electroplated tin coatings. These have been known for many decades and have caused the failure of a wide variety of electrical equipment as a result of short circuits. Only since the introduction of the RoHS directive has intensive research been carried out to determine its causes and identify measures to minimise the risk. This research has shown that whiskers form where the tin has compressive stress which can have many different causes. The US organisation International Electronics Manufacturing Initiative (iNEMI) has co-ordinated a lot of research and published guidance on methods to minimise whisker formation, however these recommendations cannot all be adopted with non-magnetic circuitry. One source of stress is due to the formation of tin/copper intermetallic phases that grow between copper substrates and tin plated coatings. The risk of whisker formation from this source of stress can be significantly reduced by the use of nickel barriers between copper and tin but this is not possible with MRI circuits. A possible alternative is to heat the components to 150°C but this must be carried out within 24 hours of electroplating to be effective. This treatment creates a thin SnCu intermetallic barrier that has been shown in some research to hinder or even prevent tin whisker formation although research disputes these results. This option relies on the component manufacturer but very few use this process, so many of the components needed are not available with this heat treatment. By the time the medical equipment manufacturer receives the components, it is too late.

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[8] For example http://www.europeanleadfree.net/SITE/UPLOAD/Document/Meetings/San%20Sebastian/Belavic_GreenRoSE.pdf see slide 36 and http://extra.ivf.se/eqs/dokument/7%20pet6005.pdf page 43

5.5. Conformal coating option

Research has been carried out to determine whether conformal coatings can reduce the risk of tin whiskers causing short-circuits. There are several types of conformal coating available and all have been evaluated. Research has shown however that they do not stop the formation of tin whiskers, they merely delay their formation, some types for longer than others[9]. Whiskers will eventually grow through many types of conformal coating but as they are flexible, once they emerge they cannot penetrate the coating over an adjacent termination. There are however three ways that short circuits can occur with conformal coatings:

- Most types of conformal coating give fairly thick coatings and these tend to be more effective than thin coatings which can leave gaps. However, when used on fine pitch components, the coating bridges between terminals. If a whisker grows from one terminal, it is supported by the coating and will eventually reach the adjacent terminal (as there is no air gap) and cause a short circuit. This will however take a longer time than without conformal coatings and to date no examples of failures due to this have been reported (although they would be very difficult to detect).
- Whiskers can grow beneath coatings across the surface of PCBs or components to the adjacent electrical conductor (these depends on the adhesion strength and is likely only with poor adhesion)
- If two whiskers grow through the coatings of two adjacent terminals into the air, they may touch each other causing a short circuit. This is likely to occur only if there are many whiskers formed although this is fairly common.

The likelihood of a short circuit caused by tin whiskers when a conformal coating is used is much less than without the conformal coating but clearly the long term risk is not completely eliminated.

5.6. Manufacturability

Research by one manufacturer has demonstrated the difficulty of soldering using lead-free processes with non-magnetic components. A circuit was designed to be assembled with lead-free solders using non-magnetic RoHS compliant components including very small 0402 devices. Reflow soldering trials with this PCB resulted in low yields with poor wetting of the chip components. Assembly of one PCB which includes many non-magnetic chip components and preamplifier ICs was initially carried out using lead-free solder processing but due to poor wetting, this achieved a yield of only 80% and the remaining 20% were defective which is unacceptably high. Failures were found to be due to poor solder wetting of component terminations, especially to AgPd terminated components, insufficient solder bonding (not acceptable by industry standard IPC – A 100 as this greatly increases risk of failure in service) and solder joints with “cracks” (so open-circuit). An example is shown below:

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[9] http://nepp.nasa.gov/whisker/reference/tech_papers/2006-Woodrow-Conformal-Coating-PartII.pdf

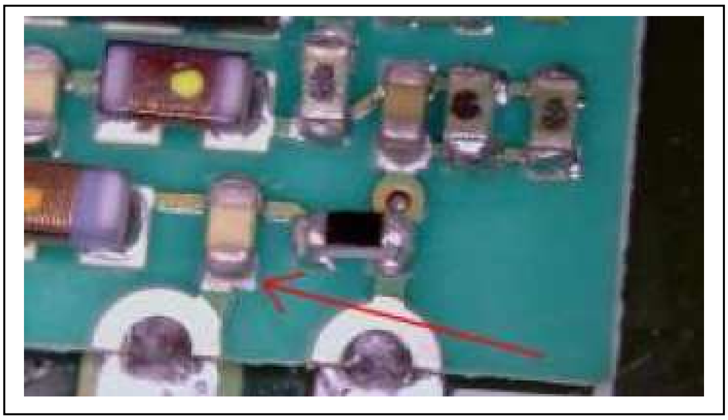

Figure 2. MRI PCB soldered with lead-free solder. Note poor wetting to arrowed chip capacitor and to several other components.

These defective PCBs could not be reworked as they are non-magnetic types and so the termination coatings have very short maximum times they can be exposure to liquid solder as explained above. As it was not possible to achieve a high yield with lead-free solders, soldering with SnPb solder was carried out and this gave yields of 100%.

5.7. Reliability test results

Lead-free soldering gave better yields to RF screen capacitors of a magnet coil that was evaluated by a MRI manufacturer but many of the bonds failed during testing to simulate service conditions. Each screen has many capacitors but only one bond failure is needed for the circuit to fail. MRI coils experience severe vibration in service and solder bonds must survive over 20 years under these conditions. Circuits therefore have to be tested using realistic conditions to simulate the vibration that occurs to MRI circuits. Three types of commercial non-magnetic capacitor were tested and after vibration testing, at worst only 13% survived and at best 63% survived. When capacitors from a different supplier were assembled using tin/lead solder was tested, 100% survival was achieved.

6. Life cycle assessment

Substitute solders alloys and terminal coatings have been considered

Materials that would be used if this exemption were granted:

- Solder containing tin and lead, tin and tin/lead solderable component coatings

Materials that would be used without exemption (although with uncertain reliability):

- Lead/free solders (tin, silver, copper, etc.), tin plated copper and silver/palladium termination coatings, conformal coatings to hinder tin whiskers.

Life cycle phases:

- Materials extraction and refining
- Components and equipment production
- Use phase
- End of life

Summary of life cycle impacts of materials under consideration

Material	**Materials extraction and refining**	**Components and equipment production**	**Use phase**	**End of life**
With exemption granted				
Lead	Occurs at fairly high concentrations in ores so less energy consumed and less waste rock than from mining other metals such as silver	Soldering temperature lower so lower energy consumption	Comprehensive field experience so high reliability known. Very low magnetic susceptibility	Lead recycling is very efficient and safe using well regulated modern processes but can cause health problems where unsafe recycling processes are used as lead is toxic
Either with or without exemption				
Tin	Not considered as used for all options			
Copper				
Without exemption				
Silver	Creates a larger amount of waste and emissions of hazardous substances than lead[10]. Cyanide is used for mining and refining	Tin/silver solders have higher melting temperature than tin/lead so that more energy is consumed. AgPd thick-film causes production issues with risk of lower yields and so more waste	Ag/Pd thick films – see palladium below.	Silver is relatively easy to recycle and some is usually present in electronic waste. However cyanide and other hazardous chemicals may be used where unsafe recycling processes are used
Palladium	Rare metal obtained as a by-product from extraction of other	PdAg with high Ag content can tarnish during storage and	Ag/Pd thick films have higher magnetic susceptibility than tin,	Can be recovered in high yields by modern large-scale recycling processes,

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

	metals. Very complex energy intensive process.	become unsolderable	copper or lead which impairs quality of MRI image potentially preventing diagnosis	otherwise lost to landfill
Conformal coatings	Organic substances made by multistage chemical processes	Additional coating process needed. Rework can be more difficult or impossible (depends on type) so possibly more waste	Repairs more difficult or impossible	Cannot be re-used. Destroyed by recycling. Can emit toxic fumes (especially polyurethane types which, when burned on open fires emits cyanide)

7. Other information

Less than 100 kg of lead will be used in the EU annually for this application.

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

At end of life, MRI and other types of medical equipment will be recycled due to its high value metals content. Printed circuit boards are separated for separate recycling as required by Annex II of Directive 2002/96/EC before being recycled. In the EU and in many facilities elsewhere, PCB scrap is recycled using smelter furnaces which are large furnaces that melt some metals such as copper and convert others including lead from solder into oxides which are collected then refined into metals for re-use. Lead is recovered with a very high efficiency and extremely low emissions that are well within EU environmental limits. Uncontrolled and potentially unsafe recycling of WEEE is carried out in some developing countries but this is mostly with IT, telecom and consumer equipment. MRI equipment is very large and heavy (several tonnes) so at end of life is very unlikely to be recycled except by professional recyclers using well-controlled, safe and environmentally friendly processes.

9. Proposed plan to develop substitutes and timetable

Research to identify substitutes is being carried out by manufacturers whose main approach is to use lead-free solders with non-magnetic components ideally with tin plated copper terminations. Currently this is not possible as this is far more difficult than the development of lead-free processes using components having nickel barrier layers as the process window is far smaller as the maximum time that liquid solder can be in contact with components is much less.

Most MRI manufacturers are carrying out research with lead-free solders using the lead-free non-magnetic components that are currently available and a few should be able to produce some lead-free assemblies soon but it will take much longer to convert all of their designs to lead-free versions. The time this will take depends on two variables:

- The number of designs that need to be converted and
- Whether lead-free components are available for current designs. If not manufacturers will either have to wait until they are or redesign their circuitry which will take additional time, typically another 6 months – 1 year longer.

Most manufacturers will not complete this work and will not have completed testing and gained approvals before the date when MRI are included in scope of the RoHS directive.

Some manufacturers have many different RF coil designs and identifying suitable processes for all of these will take many years. Once satisfactory soldered assemblies have been constructed, manufacturers must prove that they will be reliable for the expected 10 – 20 years life of the equipment. This is essential to obtain approval for use in the EU under the Medical Devices Directive. This will require gaining re-approval by a Notified Body for all "significant" changes and requires proof of reliability. It will take up to two years to carry out reliability tests and clinical trials to obtain suitable data and it can then take more than a year to obtain approvals before the new products can be put onto the EU market. Therefore the total timescale for research, modification of all models, testing, trials and approvals will not be complete by 2014 when medical devices are included in the scope of RoHS. The time required could be as much as nine years:

Research and redesign	3 years, estimated
Modification of all RF coils	2 years, possibly longer for all models
Reliability testing and trials	~2 years
Approvals in EU and other jurisdictions worldwide	1 – 2 years
Total	**8 – 9 years**

This indicates that an exemption is needed probably until at least 2020 (9 years from 2011) to allow all MRI manufacturers sufficient time to substitute lead in all of these applications.

10. Proposed wording for exemption

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

This exemption can be included in Annex IV of Directive 2011/65/EC as it will be utilised only by category 8 and 9 equipment.