Assistance to the Commission on technological, socio-economic and cost-benefit assessment related to exemptions from the substance restrictions in electrical and electronic equipment (RoHS Directive)

Final report

Freiburg, 12 December 2012

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12 Exemption request no. 9

"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"

Abbreviation

G_{rms}	unit to specify and compare the energy in repetitive shock vibration systems[24]

12.2 Description of requested exemption

Magnetic Resonance Imaging (MRI), high-end Nuclear Magnetic Resonance (NMR) analysis and cyclotrons for particle therapy utilise very powerful magnets. MRI is a medical technique used to diagnose conditions associated with soft tissue such as detecting tumours,

[24] Doertenbach, Neill, QualMark Corp.: The Calculation of G_{rms}; http://www.dfrsolutions.com/uploads/services/HALT_grms_calculation_ndoertenbach.pdf; last accessed 23 April 2012

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. When patients are 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. (COCIR 2011)

COCIR (2012c) states that in particle therapy, powerful magnets are used in the cyclotron and in the beam transport line. The cyclotron magnets are used to maintain the particles in an accelerated path. This creates a beam of high energy particles, which leaves the cyclotron. Transport magnets direct the beam to the patient who is in a different room, some distance away from the cyclotron. Beam transfer (or beam transport) from the cyclotron to the treatment room happens via a "tunnel" of magnets in which the beam is held inside the magnets. At the end of the beam transport section close to the patient is the "nozzle" which contains a number of powerful scanning magnets that are used to bend and direct the beam accurately in order to focus it onto the patient's tumor. The nozzle controls the beam's final direction.

According to COCIR (2011), 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. Magnetic materials will be strongly attracted by the powerful magnets and so either be damaged by the strong attraction force or they may cause distortion of the magnetic field and thus reduce the image accuracy. The same applies to special patient monitors that are attached to patients and are used inside the MRI for patients who are very ill and need to be constantly monitored during the diagnostic examination.

COCIR (2011) mentions research, which 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 (see Figure 4 and Figure 5). 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. Nickel is, however, strongly ferromagnetic and so cannot be used within the region of the RF coils.

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 (COCIR 2011). Soldering non-magnetic components with lead-free solders creates technical difficulties and concerns about the long-term reliability of the solder joints.

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 printed circuit boards by hand with soldering irons, although surface mount technology is beginning to be used by some manufacturers. Figure 3 shows an example of such a printed circuit board assembled with non-magnetic components.

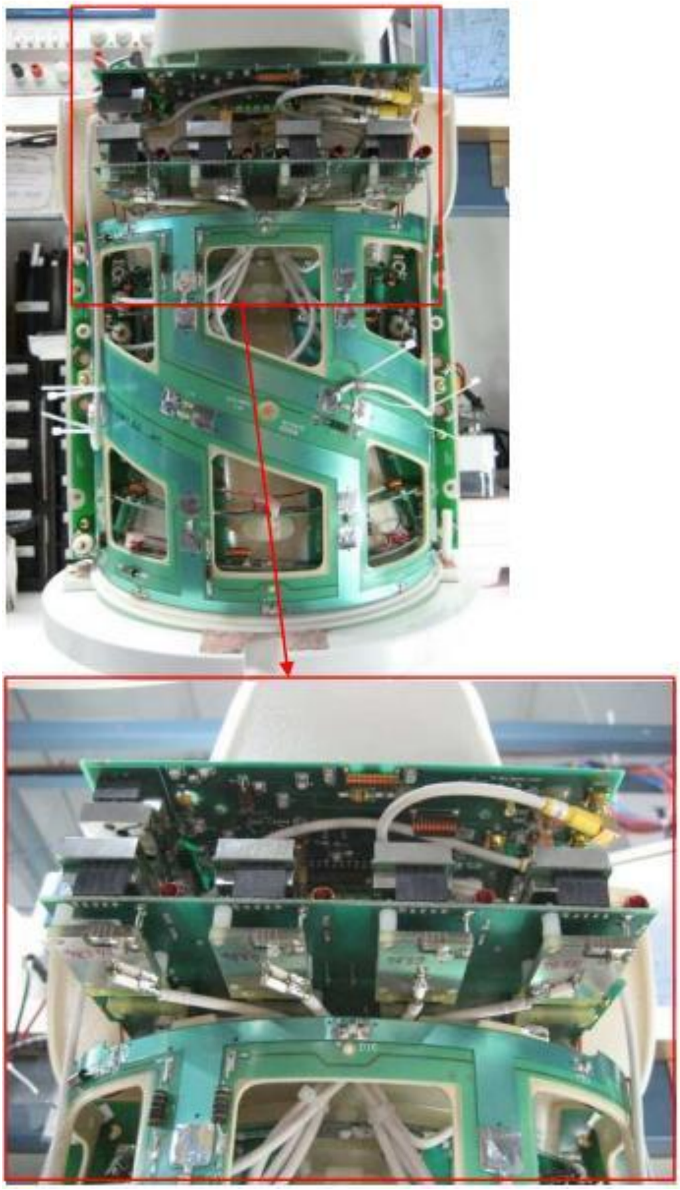

Figure 3: Non-magnetic circuitry of MRI equipment

COCIR (2011) concludes that the use of lead-containing solders and component coatings is therefore still required in MRI, high-end NMR and cyclotrons requiring the use of non-magnetic components. Several applications are thus related to this exemption request:

- 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, which are used inside MRI magnets or are located 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.

COCIR (2012a) calculates the amount of lead used in these applications as follows:

- Predominantly MRI as scanners and as coils will use this exemption, but also NMR. For RF coils, a head coil is representative. A head coil contains around 18 g of lead.
- An MRI scanner typically has 63 printed circuit boards each with roundabout 2.5 g of lead, and one body coil with an average 4.5 g of lead resulting in around 162 g of lead.
- Annually, the world sales of RF coils amount to 20,000, from which 6,000 (30%) are put on the market in the EU. For MRI scanners, the world market is 2,600 scanners per year, from which 780 units (30%) are sold in the EU.

Based on the above data, COCIR (2012a) calculates a total of around 750 kg of lead applied in this exemption worldwide, with approximately 250 kg (30%) of lead put on the EU market.

12.3 Applicant's justification of the exemption

COCIR (2011) claims that the continued use of lead in this application is required, as its substitution is technically not yet practicable. Lead-free assemblies are difficult to manufacture, and the manufacturers are concerned about long term reliability.

COCIR (2012a) puts forward that the main roadblock to lead-free soldering in these application, in comparison with the use of lead-free soldering in other applications, is the requirement to use non-magnetic components, where the electrical and electronic circuitry is exposed to strong magnetic fields. These components are usually coated with lead solder or alternatively are validated to only be used with solders that are in the lead based temperature range and not the non-lead based temperature range. In addition, many of these components have wires that connect to the component body part, where lead is also used for that termination inside the component. Examples of these components include leaded capacitors, variable capacitors, diodes, inductors, RF connectors, etc. The medical devices industry is the only industry that actually asks for no nickel coating, which can easily be replaced by lead-tin finishes on the terminations.

COCIR (2011) explains that the use of magnetic components is possible only under specific conditions:

- Components containing very small amounts of magnetic metals such as nickel, however, many MRI components, are quite large (see Figure 3 above) so that the magnetic versions would 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.

COCIR (2011) claims that in most cases, the use of non-magnetic components is indispensable. Figure 4 shows an image of a breast phantom acquired with a breast coil. The coil employed pre-amplifiers which had a voltage regulator containing nickel. The field distortion resulting from the nickel in the pre-amplifier caused a loss of image in the lower right hand corner.

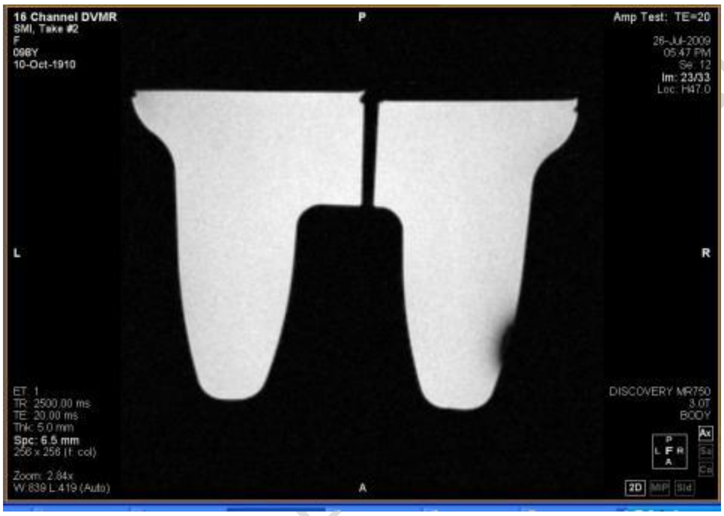

Figure 4: Loss of image in the lower right hand corner due to magnetic field distortion caused by a nickel-containing pre-amplifier (COCIR 2012a)

Figure 5 demonstrates a loss of image on the upper left due to nickel on capacitor terminations.

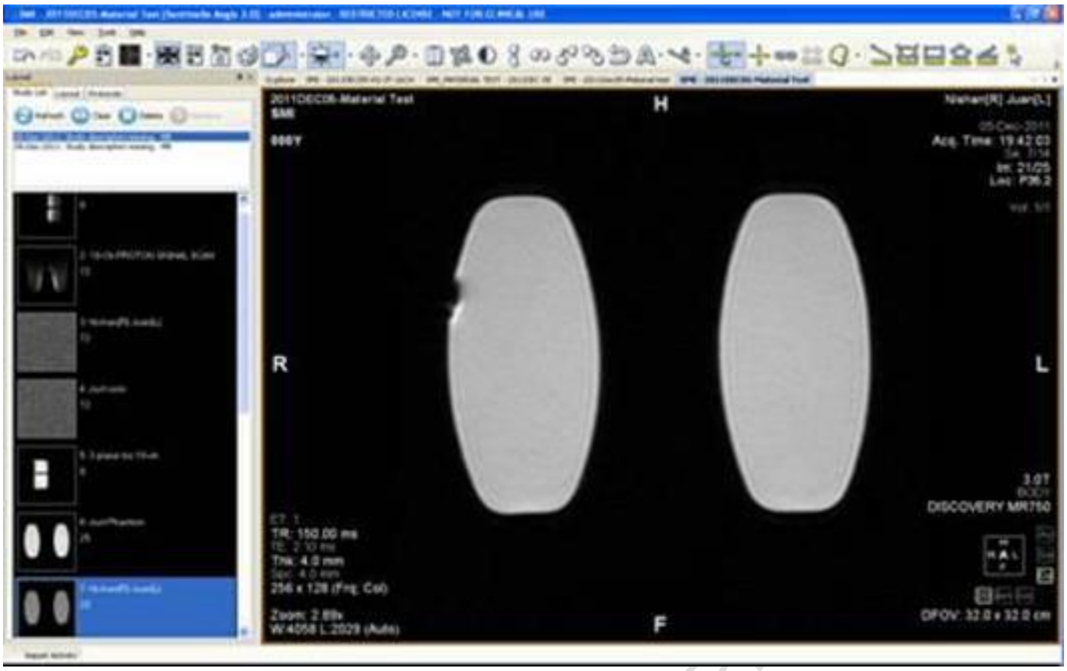

Figure 5: Image loss on the upper left from nickel on capacitor terminations (COCIR 2012a)

Trials to construct non-magnetic (nickel-free) circuit designs with lead-free solders have given very poor yields and testing of lead-free MRI circuits has found poor reliability. This raises 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. Some of the non-magnetic components are not even available as RoHS compliant versions, which extends the time needed to carry our research and development work for the change to lead-free solders and finishes.

12.3.1 Alternative non-magnetic termination coatings

Goodman (2006) concluded in the ERA report for the EU Commission that temporary exemptions for lead in solders may be required should category 8 and 9 equipment be included into the scope of the RoHS Directive. The report was published in 2006 and since then, research into substitutes has been on-going. The results show that lead-free substitutes are not yet technically viable for this application and can be less reliable.

According to COCIR (2011), 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 have been developed to achieve non-magnetic components. Metals that can be wetted by solder include tin; tin alloys with lead, copper, silver, some bismuth alloys, gold, silver and silver palladium. COCIR (2011) argues that reliability and solderability issues limit the choice of termination coatings to the following three options:

Tin-lead alloy over copper

This alloy over copper has been used for many years with tin-lead solder and has proven reliability.

Silver-palladium (Ag-Pd)

This metal 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. The alloy has caused solder leaching and wetting problems.

Tin over copper

This was developed as an alternative to Ag-Pd as it wets easily but it also experiences reliability problems that will be explained here.

COCIR (2011) states that solders can wet further metals as well, but these exhibit other problems:

Gold

Gold forms a brittle intermetallic phase with tin so that bonds fail when exposed to relatively small mechanical forces such as vibration

Copper and bismuth

These metals oxidise in air becoming unsolderable after a few days in storage

Silver

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.

According to COCIR (2011), the type of component coating depends 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 and then tin or tin-lead, or with nickel and then a thin gold coating. Nickel barriers increase storage life by retarding SnCu intermetallic formation and reduce the risk of tin whiskers. Thin gold coatings cannot be deposited onto copper directly, as these interdiffuse to leave copper that oxidises and thus becomes 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, it 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 normally relatively thick to compensate the higher copper dissolution rate that occurs with lead-free solders with a high tin content. Nickel barriers are not needed therefore. Some of these components, however, have very fine wires where copper dissolution in lead-free solders is an issue, and exemption 33 of RoHS Annex III allows tin-lead solders to be used for soldering very thin wires (<100 micron diameter) of power transformers

Alternative component termination coatings are compared in Table 14:

Table 14: Comparison of different coating materials (COCIR 2011)

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.
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.

Coating material	Advantages and disadvantages
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 coating metal dissolves in molten solder at a rate that is proportional to the temperature. The dissolution rate increases with the temperature. Table 15 illustrates the dissolution rates of various alloys.

Table 15: Copper dissolution rates in solders (COCIR 2011[25] [26])

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.)

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 slower but cannot be used in non-magnetic components, and silver and gold dissolve in liquid solder as rapidly as copper.

Table 15 demonstrates the risk to components that have thin termination coatings, as long periods of contact with liquid solder can cause complete dissolution thus leaving an open circuit. This is exacerbated by the higher melting temperature of all types of lead-free solders

25 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; referenced in COCIR (2011)

26 C. Hunt and D. Di Maio, “A Test Methodology for Copper Dissolution in Lead-Free Alloys”, National Physical Laboratory, UK; referenced in COCIR (2011)

(see Table 16) that are used commercially, as the dissolution rate increases with temperature.

Table 16: Melting points of solders (COCIR 2011)

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

Lead-free solders are now widely used by the electronics industry, but these have significant disadvantages when soldering to non-magnetic components which do not have nickel barrier coatings. (COCIR 2011)

12.3.2 Influence of the 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 components commonly used in MRI that are not yet available in RoHS compliant versions. (COCIR 2011)

COCIR (2011) says that MRI circuits used, either inside the magnetic field or attached to circuits that are in the field, may be either hand 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 to achieve a reliable solder bond without damaging the components. Whether this time and peak temperature are achievable in practice depends on many variables. These variables include:

- The size of other components on the printed circuit board. Larger ones need more time for wetting 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 solder bond between the liquid solder and the termination material. In practice, the liquid metal dissolves the termination metal, and 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 solder (known as SAC) is higher than that of tin-lead due to its higher melting point (217°C 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°C – 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. (COCIR 2011)

COCIR (2011) reports that 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. Table 17 shows a selection of maximum times at reflow temperatures.

Table 17: Published maximum temperatures and peak temperatures for soldering non-magnetic components (COCIR 2011)

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 printed circuit board 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 printed circuit board is soldered, it is necessary to wait until the last bond has formed. This will usually be to the component with the highest thermal mass, which 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 solders are shorter than most types of lead-free solder. Asahi, a solder manufacturer, published tests comparing a variety of alloys by wave soldering a standard printed wiring board at a soldering temperature of 245°C.

Table 18: Wetting Times of Solders at 245 C (COCIR 2011[27])

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

COCIR (2011) admits that 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

COCIR (2011) references Asahi stating 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.

COCIR (2011) presents further results provided by Renasas[28]. The tests illustrate that the effect of the plating layer composition on component terminations when soldered with a SAC lead-free solder is also dependent on termination coating alloy composition:

Table 19: Wetting times of different component packages (COCIR 2011[28])

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.

27 See http://www.asahisolder.com/Publication/Comparative.pdf, referenced in COCIR (2011)

28 See www.renasas.eu/prod/lead/rt/plating.html, referenced in COCIR (2011)

Standard practice is to place the soldering iron tip onto the printed circuit board 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, which can, however, damage the components and the flexible printed circuit board and thus often is not practicable. (COCIR 2011)

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. The tin-copper intermetallic phase will continue to grow and become more susceptible to failure by cracking of this brittle layer. (COCIR 2011)

Excessive soldering times could at worst cause the end termination material to completely dissolve in the solder so that the bond fails or at least has an increased 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 so that the risk of damage to the components' copper-tin terminations is increased due to the thicker tin-copper intermetallic phase that forms when nickel barriers cannot be used. (COCIR 2011)

Another issue is the large size of the coil flexible circuits as shown in Figure 3. They 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. (COCIR 2011)

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 for example SnPb with 5% of lead used in component finishes[29]. (COCIR 2011)

12.3.3 Intermetallic phase formation affecting reliability

Tin from solder and copper terminations reacts 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. The thickness depends on the soldering time as well as the soldering temperature. SnCu intermetallics are relatively brittle. 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, which are used to produce 3D images. Manufacturers have measured acoustic pressure waves of 145 dB, which will impose severe mechanical stresses. In comparison, 130 dB 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, however, cannot be used in components exposed to high magnetic field applications. (COCIR 2011)

As tin-copper intermetallic growth rates are temperature dependent, the intermetallic phases are usually thicker after lead-free soldering processes than with tin-lead solder, potentially resulting in lower reliability. Research by JGPP[30] in 2006 showed that lead-free solders are more susceptible to failure as a result of intense vibration than SnPb solders, although this depends on the location of components on a printed circuit board and the type of component. Research has also shown that shock and 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, show that SnPb has a superior shock resistance with bonds made with Sn3.8Ag0.7Cu failing after fewer drops[31]. This research was 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 of around 1.0% have been developed

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[29] Cf. “Low-Temperature Solders”, Z. Mei, H. Holder and H A. Vander Plas. H. P Journal, August 1996; referenced in COCIR (2011)

[30] See 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; both sources referenced in COCIR (2011)

[31] Greg Heaslip, Claire Ryan, Bryan Rodgers, and Jeff Punch, “Board Level Drop Test Failure Analysis of Ball Grid Array Packages”, Stokes Research Institute, 2005; referenced in COCIR (2011)

(mainly to reduce the cost of silver) and are found to have better drop resistance than eutectic SnAgCu with 3.8% of Ag. However, the melting temperature is higher (~226°C with 1% Ag), which is nearly 10°C hotter than with 3.8% of Ag. 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. (COCIR 2011)

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[32] that show that AgPd thick film coatings are more prone to cracking when soldered with lead-free solders than with tin-lead solder due to the thicker SnPd layer formed with lead-free solders at a higher temperature than when SnPb is used. (COCIR 2011)

12.3.4 Tin whiskers affecting reliability

Increased risk of whiskers related to use of non-magnetic components

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. (COCIR 2011)

One reason is the stress 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

[32] See for example http://www.europeanleadfree.net/SITE/UPLOAD/Document/Meetings/San%20Sebastian/Belavic_GreenRoSE.pdf, slide 36, and http://extra.ivf.se/eqs/dokument/7%20pet6005.pdf, page 43; both sources referenced in COCIR (2011)

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 to apply this whisker mitigation technique. (COCIR 2011)

Conformal coating options to reduce risks of whiskers

COCIR (2011) reports about research carried out to determine whether conformal coatings can reduce the risk of tin whiskers. There are several types of conformal coatings available and all have been evaluated. This research has shown, however, that they do not stop the formation of tin whiskers, but delay their formation, some types for longer than others.[33] Whiskers will eventually grow through many types of conformal coatings, but as they are flexible, once they emerge they cannot penetrate the coating over an adjacent termination. COCIR (2011) lists three ways how short circuits can occur despite of conformal coatings:

- Most types of conformal coatings give fairly thick coatings. 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. To date, no examples of failures due to this mechanism have been reported, although they would be very difficult to detect.
- Whiskers can grow beneath coatings across the surface of printed circuit boards or components to the adjacent electrical conductor. It 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, which is fairly common.

COCIR (2011) concludes that short circuits caused by tin whiskers are much less likely when a conformal coating is used, but clearly the long term risk is not completely eliminated.

12.3.5 Manufacturability

COCIR (2011) mentions one manufacturer's research that has demonstrated the difficulty of soldering using lead-free processes with non-magnetic components. A circuit was designed for assembly with lead-free solders using non-magnetic RoHS compliant components

33 http://nepp.nasa.gov/whisker/reference/tech_papers/2006-Woodrow-Conformal-Coating-PartII.pdf, referenced in COCIR (2011)

including small 0402 devices. Reflow soldering trials with this printed circuit board resulted in low yields with poor wetting of the chip components. Assembly of one printed circuit board 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%, which is unacceptably high. Failures were found to be due to poor solder wetting of component terminations, especially to AgPd terminated components. Solder bonds not sufficing the requirements of industry standard IPC – A 100, which greatly increases the risks of failure in service, and solder joints with “cracks” were observed (cf. Figure 6 below).

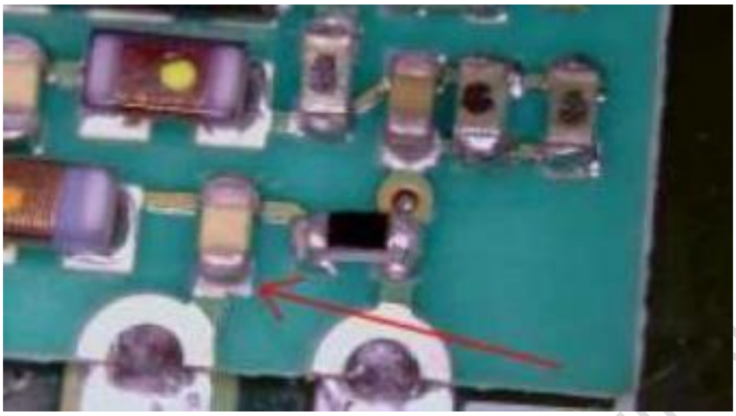

Figure 6: Lead-free soldered printed circuit board of an MRI with poor wetting at arrowed chip capacitor and other components (COCIR 2011)

These defective printed circuit boards could not be reworked as the termination coatings of non-magnetic components have very short maximum times for which they can be exposed 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, which gave yields of 100%. (COCIR 2011)

12.3.6 Reliability test results

COCIR (2011) reports about a manufacturer who achieved better yields in lead-free soldering to RF screen capacitors of a magnet coil, but many of the bonds failed during testing simulating service conditions. Each screen has many capacitors, but one bond failure already causes the failure of the circuit.

COCIR (2012a) argues that MR scanners are expected to be in service with clients for at least 10 years. To simulate actual vibration levels and thermo-mechanical effects for at least 10 years of service, the typical test conditions used for MR environment reliability tests are:

Vibration levels of up to 70 G_{rms} for 180 hours, corresponding to 19,000 hours MRI scan time, which, according to COCIR (2012a), is far worse than automotive.

Number of temperature Cycles (=number of exams on patients) is 6300/year covering 90% of MRI used in the EU. This is, according to COCIR (2012a), far worse than automotive, and comparable with space.

Circuits therefore have to be tested using realistic conditions to simulate the vibration that occurs to MRI circuits. Three types of commercial non-magnetic capacitors 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, 100% survival was achieved in the test.

COCIR (2011) concludes that there is therefore an unquantifiable risk that lead-free solders, which are brittle at low temperatures, have a greater risk of failure at very low temperatures due to vibration, than more ductile tin-lead solders.

12.3.7 Environmental aspects

Even though no technically viable substitute has been identified at present, COCIR (2011) have submitted further information concerning life cycle assessment aspects of potential substitutes (tin, copper, silver, palladium, conformal coatings), to further enhance their argumentation. Information includes reference to the availability of other metals, the energy consumption required for their extraction and refining, information concerning production and use and information concerning the re-use and recycling of waste. In general, the information submitted concerning these aspects also supports lead to be the most suitable candidate for this application.

12.3.8 Roadmap for the substitution or elimination of lead

Manufacturers carry out research to identify substitutes. The main approach is to use lead-free solders with non-magnetic components ideally with tin plated copper terminations. Currently this is not yet possible for the reasons described above. Most MRI manufacturers are carrying out research with lead-free solders using the lead-free non-magnetic components that are currently available. 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 no lead-free components are available for the current designs, manufacturers will either have to wait until they are or redesign their circuitry, which will take additional time, typically another 6 months to 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 into the scope of the RoHS Directive in 2014.

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.

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 worldwide — 1–2 years
- Total — 8–9 years

COCIR (2012a) 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.

12.4 Critical review

12.4.1 Relation to the REACH regulation

Chapter 5 of this report lists entry 30 restricting the use of lead and its compounds in Annex XVII and the related authorization and restriction processes in the REACH Regulation. Lead and its compounds are thus listed in Annex XVII, and their use might weaken the environmental and health protection afforded by the REACH Regulation.

In the consultants’ understanding, entry 30 of Annex XVII does not apply to the uses of lead in the requested exemption. Lead and the tin-lead alloy used may be considered as substance, as constituent of another substance or a mixture. Putting, however, lead in solders and finishes on the market in the consultants’ point of view is not a supply of lead and its compounds to the general public. Lead and the lead alloy is part of an article and as such should not be covered by entry 30 of Annex XVII.

The consultants conclude that the use of lead in this requested exemption does not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

12.4.2 Environmental arguments

The applicant presents environmental data and statements comparing the life cycles of lead with potential substitutes. As none of these can be considered a viable substitute at this time, these arguments were not reviewed. The consultants would like to point out, however, that this neither indicates agreement nor disagreement with the applicant's environmental arguments.

12.4.3 Technical arguments

The applicant justifies its exemption request with typical technical problems that have to be solved when shifting from soldering with lead to lead-free solders. However, manufacturers of other categories of electrical and electronic equipment have or are about to solve these constraints successfully.

In the applicant's case, the following facts have to be taken into consideration as well:

- Shifting from lead to lead-free soldering requires adapting the printed circuit board design, the soldering process profiles, selecting appropriate material combinations of lead-free solders on the one hand, and component and PCB finishes on the other hand, and possibly components and PCB finishes that can withstand the higher soldering temperatures. These adaptations need time.
- The need to use non-magnetic components to maintain the homogeneity of the magnetic field restricts the options for lead-free solutions.
- The combination of long life time of MRIs, the harsh environment due to strong vibrations, and the high reliability requirements not to endanger patients' health and safety aggravate the situation.

The combination of the above specific requirements makes it plausible that additional time is required allowing manufacturers to find reliable and safe lead-free solutions. It was only clear in July 2011 – the date of publication of the new RoHS Directive – that the devices of category 8 (medical equipment) of RoHS Annex I will come into the scope of the RoHS Directive. Thus, granting additional time for researching, testing and qualifying lead-free solutions is justified.

The applicant explains that nine years will be needed. The consultants have no information justifying an earlier expiry date.

The wording COCIR (2011) had originally proposed was changed. The terms “circuitry” and “strong magnetic fields” were found to be not sufficiently clear. Strong magnetic fields require the use of non-magnetic components. The distance to the magnetic field was therefore selected for specification, and the various parts requiring the use of lead were specified in the exemption in order to clarify the exemption's scope:

"Lead in

- solders,

- termination coatings of electrical and electronic components and printed circuit boards,

- connections of electrical wires, shields and enclosed connectors

which are used

a) in magnetic fields within the sphere of 1 m radius around the isocenter of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere.

b) in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy

The proposed expiration date for this exemption is 30 June 2020."

COCIR (2012c) agreed to the above wording.

12.5 Recommendation

Based on the submitted information, the consultants recommend granting the exemption and adopting it to Annex IV of the RoHS Directive. The applicant's arguments are plausible, and an exemption could be justified in line with the requirements of Art. 5(1)(a).

The consultants recommend the following wording:

"Lead in

- *solders,*
- *termination coatings of electrical and electronic components and printed circuit boards,*
- *connections of electrical wires, shields and enclosed connectors*

which are used

a) in magnetic fields within the sphere of 1 m radius around the isocenter of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere.

b) *in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy*

The exemption expires on 30 June 2020"

12.6 Specific references

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COCIR 2012a — Stakeholder document "9_COCIR_-_Exemption_request_-_Lead_solder_magnetic_field.pdf" submitted by COCIR on exemption request no. 9 in March 2012 within the consultation; http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_9/Questionnaire-1_Exe-9_answers.pdf

COCIR 2012b — Stakeholder document "Questionnaire-1_Exe-9_answers.docx" submitted by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) on exemption request no. 9 on 21 December 2011

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RoHS Directive 2011 — Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast); http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT

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