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Report Title: # Additional Exemptions from the RoHS Directive needed by the Medical Industry

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Executive Summary

The European Commission contracted ERA to determine if it would be possible to include medical devices and monitoring and control instruments in the scope of the RoHS Directive (2002/95/EC) in 2005/6. ERA concluded that it would be possible but manufacturers would need sufficient time and they would require certain exemptions. ERA also recommended that the inclusion of a temporary exemption for lead in solders should be reconsidered nearer to the time that the RoHS Directive is amended to determine if this is still required as significant research was underway in 2006.

Since 2006, the medical industry has carried out a great deal of research into new products and the substitution of RoHS substances. Significant progress has been made and some lead-free soldered products have been developed and are being sold in EU, and the other RoHS substances are also gradually being replaced. However, in the course of this research, manufacturers have discovered applications where substitution is not possible. This is not surprising because when RoHS was originally adopted in 2003, there were only 9 items in the RoHS Annex and now, six years later, there are 38 items although a few have been deleted or expired. COCIR, a medical equipment trade association, has asked ERA (now trading as Cobham Technical Services) to carry out an independent technical review of additional exemption requests that they are requesting be added to Annex VI of the proposed recast RoHS Directive.

Exemptions have been assessed on the basis of the criteria listed in the new Annex 5.1b of the proposed recast directive. In the course of this review it was found that three of the requests were not justified as suitable alternatives are available and one request was withdrawn by the applicant. There were several requests that relate to shielding for ionising radiation. These types of application were originally intended to be covered by items 5 and 6 but the wording used may not be totally clear and unambiguous and so recommended alternative wording has been provided in this report. A review of these exemptions has confirmed that they are still justified for a variety of reasons. The main potential alternative to lead is tungsten but due to its chemical and physical properties, its use would have a greater negative impact on health and the environment than lead as explained in this report. It is also about ten times more expensive which would increase the price of products, some significantly.

Increased product price may not be a concern for consumer products but could have serious consequences for healthcare equipment. Healthcare providers in EU Member States have limited budgets that would not be raised due to RoHS. Therefore increased prices would result in less new equipment being purchased and so the heath benefits from new technology would be delayed resulting in less effective detection and diagnosis of disease and inferior treatment of patients leading to reduced quality of life and inferior outcomes including possibly earlier death.

Eleven new exemptions are recommended for addition to Annex VI of the proposed recast RoHS Directive. These involve diverse technologies that are essential for certain medical devices. For example, connector terminal coatings and solders that are stable at very low temperatures are used in MRI and other techniques. Standard lead-free solders and pure tin disintegrate as a result of a phase transformation that occurs at very low temperatures and so these metals cannot be used. Magnetic metals such as nickel must not be used in MRI and MEG as they degrade the image quality and so special non-magnetic components are used. Soldering these with lead-free alloys is very difficult and manufacturers have little experience. These are safety critical products and must be extensively

tested before they can be approved under the Medical Device Directives. Therefore industry will need a temporary exemption to allow them more time before they introduce lead-free soldered MRI and MEG.

Although there are a growing number of lead-free soldered medical devices on the EU market, the most complex and advanced products cannot yet be produced with a high degree of confidence over their long term reliability which is essential for medical devices. This situation is the same as for high-end servers which already have an exemption for lead in solders and was recently reviewed by the Öko Institut for the Commission (item 7b of the RoHS Annex). Their recommendation was that this exemption should continue until the next 4-yearly review because of technical production problems that have not yet been resolved and reliability concerns. As an exemption for lead in solders for all medical products is clearly not necessary, certain specific exemptions with limited scope have been recommended. One of these is a variation in item 17 of Annex VI of the proposed recast directive which includes specific types of portable medical device that have a high risk of being dropped and could also experience unusually high levels of vibration. Research has shown that lead-free solders are likely to fail after being dropped fewer times than tin/lead solders and so a temporary exemption for lead in solders is recommended until research into ways of assuring adequate reliability is completed.

A key distinction between medical devices and consumer / household products is that improvements in performance to medical products can save lives. Some of the recent gains in medical device performance have been achieved by utilising state-of-the-art components that were developed for other industry sectors that are all out of scope of RoHS and will remain out of scope when medical devices are included in scope in 2014. Many of these components are not RoHS compliant (mainly as they contain lead solders) and as the medical industry buys only very small quantities, the manufacturers will in most cases be unwilling to invest in developing RoHS compliant versions. In some industries such as aerospace and military, their main customers will not accept any changes. The medical industry does not have the same level of expertise on specialist component design as their suppliers and so they will often be unable to redesign their products with the same level of performance that were achieved with specialist components from other industries. Replacement products will as a result not provide the same high level of healthcare and patient treatment could be inferior. To prevent this situation from arising, an exemption to allow the continued use of these components is recommended in addition to exemptions 18 and 19 of Annex VI of the proposed recast directive which are exemptions for two specific military non-RoHS components with superior performance over all RoHS compliant types.

Of the 25 requests considered here, only 11 additional exemptions are recommended partly because some similar requests could be combined. The scope of one item (17) could be broadened and two items (5 and 6) reworded to aid with their interpretation. Recommendations for revising Annex VI of the proposed recast directive is given in section 5 and a glossary of medical terminology is provided in Appendix A.

One other issue described in this report relates to the proposal that all exemptions expire automatically after four years unless renewed. Although this may be acceptable for consumer, household and office equipment, this introduces difficulties for the medical sector due to the need for

lengthy testing and approvals. A longer period before automatic expiry should be considered for medical device exemptions.

Table 1 of this report lists the requested exemptions, table 6 listed these requests and the resulting recommendations from this investigation. The recommendations for amending Annex VI of the recast proposed RoHS directive are in section 5.

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Abbreviations List

BGA	Ball grid array
CSP	Chip scale package
CT	Computed tomography
CZT	Cadmium zinc telluride
EC	European Commission
IC	Integrated circuit
IVD	In-vitro diagnostics
LSIT	Large-scale stationary industrial tools
MDD	Medical device directive
MEG	Magnetoencephalography
MRI	Magnetic resonance imaging
OJ	Official Journal of the European Union
PCB	Printed circuit board
PET	Positron emission tomography
PMT	Photomultiplier tube
PVC	Polyvinyl chloride
PWD	Patient worn device
QFN	Quad flat no lead (semiconductor package)
RF	Radio frequency
RoHS	Restriction of the use of certain Hazardous Substances Directive (2002/95/EC)
SPECT	Single Photon Emission Computed Tomography
SQUID	Superconducting quantum interference devices
TAC	Technical adaptation committee
TCE	Thermal coefficient of expansion
WLCSP	Wafer level chip scale package

1. Background

The Restriction of use of certain Hazardous Substances (RoHS) Directive (2002/95/EC) was published in the Official Journal in February 2003 and came into force in the EU on 1 July 2006. The original directive included nine items listed in the Annex to the directive which described exemptions that allowed the use of RoHS substances for specific applications where no alternatives were available, or the alternatives were more hazardous to humans or more harmful to the environment. Since the original directive was published, manufacturers of electrical equipment have discovered further applications where no suitable substitutes exist and so have requested additional exemptions. As a result, three years after the directive came into force, the RoHS Annex includes over thirty exemptions. Some of these will be deleted as a result of technological developments that have identified suitable alternatives but many are still justified.

The original directive excluded from its scope medical devices and monitoring and control equipment, mainly due to concerns over the reliability and resultant safety of using products made with lead-free solders. The European Commission has reviewed the RoHS Directive and one aspect has been to determine whether it is possible to include in scope medical devices and monitoring and control equipment, as is required by Article 6. The Commission asked ERA Technology Ltd (ERA) to carry out a review of these categories of equipment to determine whether it would be possible to include these categories in scope. ERA was not asked whether inclusion was justified on the basis of cost benefit as a separate impact assessment was subsequently carried out by the EC to address this. ERA concluded that it would be possible to include these categories but manufacturers needed sufficient time and some additional exemptions which were listed in table 71 of the final report. The Commission accepted most of ERA's recommendations and has included the exemptions listed in table 71 in a new Annex (Annex VI) in the proposed recast RoHS Directive.

Since ERA completed its study in 2006, the medical industry has carried out research on substitutes for RoHS substances. In the past three years, some manufacturers have discovered additional applications where no substitutes exist and some of the applications for which industry expected to be able to find substitutes by 2012 have proved to be technically more challenging than expected. It is not surprising that the medical industry has discovered additional applications requiring exemptions as many were discovered, requested and granted for those products that have been in scope since 1 July 2006.

COCIR, a trade association that represents manufacturers of medical equipment including the most advanced and complex devices, has asked ERA to review additional applications for which their members believe no substitutes exist with the intention of petitioning the EC to add those that are justified to the new RoHS Annex VI. This would give manufacturers reassurance that their existing products can continue to be sold in the EU once they are in scope of RoHS – rather than having to request additional exemptions which will be possible only after RoHS has been amended and with the uncertainties that this creates.

2. Requested exemptions

The applications that have been submitted for investigation are listed in the table below with the sections in this report where these are discussed.

Table 1. Exemptions requested that have been reviewed

Description	Section number
Lead for X-ray grids and X-ray markers	3.1.2
Lead in Anti Scatter in CT X-ray detectors	3.1.1
Lead and lead alloys for collimation of ionising radiation	3.1.3
Lead in positioning systems for multisource radiosurgery and particle therapy equipment	3.1.4
Lead acetate marker for use in stereotactic head frame for use with CT and MRI	3.5.6
Lead for thermal management of cryocooler cold heads in MRI magnets	3.2.1
Lead for thermal management of cryocooler cold heads in MEG systems	3.2.1
Lead in solder for cryogenic MRI applications	3.2.2
Lead in solders in MRI Radio Frequency send and receive coils	3.3
Lead in non-magnetic electronic components used in MRI send and receive coils	3.3
Lead used in pin connector systems requiring non-magnetic connectors	3.2.3
Lead in solder for array connections and interconnections of CT X-ray detectors	3.4.6
Equipment and assemblies that were developed specifically for other industry sectors not in the scope of RoHS (e.g. military, aerospace, robotics, research equipment, large scale industrial tools) and are then used in medical applications.	3.4.1 to 3.4.5
Specific Opto-coupler for IVD instruments	Request withdrawn
Lead in solders for array interconnections to photodiode CT detectors	3.4.8 and 3.4.9
Lead in solders of imaging systems including CT, PET, SPECT, MRI and molecular imaging	3.4.9

Description	Section number
Lead in solders for connections to BGA and CSP area arrays and QFN devices	3.4.8
Lead to enable thermal compression process to make a vacuum tight connection between aluminium and steel for X-ray image intensifiers	3.5.5
Lead as an alloying element for radiotherapy equipment and radio-surgery equipment and for patient and equipment support systems	3.5.1
Lead as PVC stabiliser in medical tubing	3.5.2
Cadmium pigments in ECG patient cables	3.5.3
Flexible copper cadmium wire	3.5.4
Hexavalent chromium for in-situ production of photocathodes	3.5.5
Cadmium in output phosphors of image intensifiers	3.5.5
Re-use of parts of X-ray tubes containing lead and hexavalent chromium in new X-ray tubes	3.6

In addition, several of the existing exemptions in the RoHS Annex are reported to be required by the medical sector and have been briefly considered here because, in the recent review of exemptions, the investigators (Öko Institut) recommended that several be either severely restricted in scope or deleted. These include the exemptions listed in Table 2 below.

Table 2. Exemptions in the existing RoHS Annex that are used in medical devices and that are proposed to be deleted prior to 2014

Item number	Brief description and recommendations from Öko Institut	Medical applications
3	Lead in straight fluorescent lamps for special purposes – recommend deletion December 2012 as alternatives for display backlights are available	LED displays are already being used in laptop PCs and a few televisions but supply is limited. Capacity increase is possible only by building new factories which is currently unlikely in view of the current economic climate. 2012 may be too soon.
9b	Lead in lead-bronze bearing shells and bushes – restrict to specific refrigeration application only	Required for bearing and sliding surfaces exposed to ionising radiation.

Item number	Brief description and recommendations from Öko Institut	Medical applications
11	Lead in compliant pin connector systems – continue until 31 December 2012 except for C-press which are recommended to expire 30 June 2010	Widely used in medical equipment. Tin as an alternative poses risk of tin whiskers, gold is being investigated but implementation is not straightforward.
23	Lead in finishes of fine pitch components – delete as required only for equipment covered by exemption 7b and in medical equipment	Pitch as low as 0.3 and 0.4 mm used and currently available with SnPb coatings. Production process modification required for lead-free and this introduces a risk of tin whisker failures. Although risk can be minimised by following industry guidance, the use of conformal coatings on such fine pitch components is problematic.

The aims of this investigation are:

- to determine if the requested exemptions listed above are required as additional exemptions. Some may not be required because they are already covered by one of the exemptions in proposed RoHS Annex VI or because the product will not be in scope of RoHS after it is amended.
- to determine if the application is justified on the basis of the criteria in Article 5.1b of the RoHS Directive proposals
- to provide clear descriptions of the applications
- to recommend clear unambiguous wording for additional exemptions.

Any of the applications that do not appear to require exemptions are not described in detail in this report. A glossary of the medical terminology used in this report is given in Appendix A.

One of the new criteria for considering exemptions under the proposed recast of the RoHS Directive is socio-economic issues. As far as medical devices are concerned, increased costs have an indirect impact on human health as is explained below.

2.1 Indirect impact of cost on health

RoHS compliance costs (research, board redesign, reliability testing, etc.) will be incurred by all medical equipment manufacturers and these costs will inevitably be largely passed on to customers as higher prices. These increases in healthcare equipment prices may not be matched by increases in resources available to healthcare providers such as the NHS in the UK and its counterparts in other Member States. Without increased funding, even a small overall equipment price increase will restrict

the quantity of new equipment that each healthcare provider can purchase as medical staff always asks for more new equipment than budgets allow. As a result, purchase of some new, state-of-the-art equipment may be delayed for a year or more to compensate for this funding shortfall. It is however difficult to determine the impact of a one year delay in purchase of new equipment to replace old equipment. For example, the National Radiotherapy Advisory Group[i] advised UK Government Ministers in 2007 that radiotherapy equipment should be replaced every 10 years because old equipment suffers from breakdowns due to wear causing longer recovery times, is less accurate and so causes more side-effects and modern equipment gives superior performance so that full recovery is more likely and shorter treatments are needed. Overall, the healthcare costs from older equipment are higher than with new equipment but there is also an impact on patient's health. The extent of the impact on health is however impossible to quantify. Over a ten year period there will have been improvements in diagnosis expertise, drug treatments, etc. as well as advances in medical technology so that the success rates of equipment built 10 years ago cannot be directly compared with success rates with new equipment.

Substitution of materials or different designs to comply with RoHS may result in very significant price increases and a few examples are given in this report. One manufacturer of radiotherapy equipment has estimated that without an exemption for lead as shielding for ionising radiation, prices would increase by about 5% plus any increases due to compliance costs. It is a general principle that if the price of a product were to increase significantly, there would be a tendency by hospitals to delay purchase for as long as possible.

There is also a third issue that was described in the 2006 ERA report. The percentage of turnover spent on new product development by medical technology companies is relatively high in comparison with other industries but funds are not unlimited. This money should be spent principally on the development of new and better products that give improved diagnosis, more effective and sometimes cheaper treatments and higher success rates. If significant resources are diverted to RoHS substance substitution, then new life-saving technologies will either not be developed or at least delayed. This is an issue of timing where the medical industry has sufficient time to implement RoHS without a negative impact on future healthcare and there are two issues that need to be addressed which are described here.

The two timing issues are: i) the Commission's proposals that all RoHS exemptions will expire after four years unless renewed and applications for renewal must be made at least 18 months before the expiry date and ii) transition periods for exemptions where requests for renewal are not accepted.

2.2 Timescales for exemptions and transition periods

Four year expiry: Table 3 below outlines the timescales required to undertake research and development (R&D), reliability testing, and obtain approvals for new types of typical consumer equipment compared to typical medical devices. Under the current draft of the recast directive an exemption will expire after 4 years unless its renewal is sought. To obtain such a renewal a manufacturer would need to apply at least 18 months before the exemption is to end to ensure sufficient time for a request to be assessed, agreed by the TAC (Technical Adaptation Committee) and published in the OJ.

Table 3: Timescale required for R&D and application for exemptions where no substitutes can be identified

Time required	Typical consumer product	Typical medical device
R & D to identify alternative to exempt material	Can be about 3 months if a design change is possible (otherwise much longer)	Likely to take >2 years to identify alternative material or design (although may be much longer, or no alternatives may exist)
Reliability testing and validation	2 – 3 months or less	1.5 - 2 years typically
Gaining MDD* approvals and equivalents in rest of world	Not required	1 year (EU and rest of world), can be up to 2 years for very significant changes
Deadline of application to renew exemption	18 months (plus time to prepare substitution plan)	18 months (plus time to prepare substitution plan)
Total time period	**~ 2 years**	**>6 years**

*Medical Devices Directive. Directives (Council Directive 93/42/EEC of 14 June 1993, OJ No L 169/1 of 1993-07-12)

As the above table illustrates, the 4 year timescale for a typical consumer product should not be a significant problem, but for a typical medical device 4 years is too short. Research to identify a substitute will usually take a significant period of time, often much more than two years. For Category 8 equipment there is the additional obligation to carry out reliability testing and also clinical trials in order to obtain approvals for new equipment designs. The current proposal for a maximum 4 year exemption (unless renewed) is an unnecessary burden on manufacturers of Category 8 products.

Transition period: Research is often carried in secret by manufacturers so that if one manufacturer develops a new technology that allows a RoHS exempt substance to be replaced, only they will be in a position to utilise this development. Other manufacturers would be able to utilise this technology if the inventor allows their use of the intellectual property rights - but this is not automatic. They then have to carry out redesign work, reliability testing and clinical trials and finally obtain MDD approval. This could take 3 – 5 years depending on the complexity of the redesign. This should to be taken into account when exemptions are reviewed. Clearly exemption requests should not be refused if the substitute is not “available” because the inventor will not grant a licence to competitors to utilise their inventions. Where the new substitute is available, then a suitable transition period should be allowed to provide time for changes to be made. RoHS is intended to gradually phase out hazardous substances but is not intended to give competitive advantage to individual manufacturers that harm the rest of the industry and stifle competition.

When European “EN” standards are ratified, it is normal to allow a transition period of three years to allow manufacturers to modify products. Modification of products as a result of withdrawal of

exemptions would involve a similar effort for medical devices and so the transition period would need to be the same.

2.3 Additional substance restrictions

The ERA study in 2006 did not consider additional restricted substances and the proposed recast directive does not include further restrictions but sets up a procedure (Article 4.7) for restricting additional substances although few details are provided. The timescales for the development, testing and gaining approvals for medical devices is far longer than for consumer or household products and so any new restrictions are likely to require much more time for the medical industry to implement than other industry sectors although this will depend on the substance. For maximum benefit to human health and the environment, but without preventing the availability in EU of life-saving products, the transition period needs to be carefully considered and it may be appropriate to phase in new restrictions on additional substances so that some types of products such as medical devices have a longer transition periods than products with shorter design cycles.

3. Review of applications

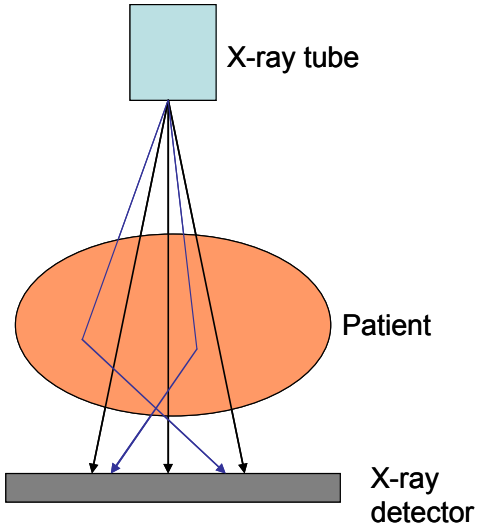
Exemption requests have been grouped, where appropriate, by either applications or technologies. There are several that relate to shielding of ionising radiation, others that are required for use at very low temperatures and many that require lead-based solders. The technical, environmental, health and socio-economic aspects of requested exemptions are described here.

3.1 Requests related to radiation shielding

Three of the requests relate to applications where a material is required to act as a physical barrier to ionizing radiation.

3.1.1 Lead in anti-scatter devices and grids for X-ray detectors

X-radiation that passes linearly through the patient to the detector located at the opposite side from the X-ray tube and is required to produce a clear image. However when a person is exposed to X-radiation, some of the X-rays are scattered and so emerge within a wide range of angles. X-radiation that that does not pass linearly through the body and emerges at angles from the linear degrades the quality of the image as shown below (scattered beams are shown in blue).



This occurs with all X-ray imaging techniques and various devices such as “grids” are used with image intensifiers, semiconductor digital detectors and on X-ray film. It is particularly important with CT as this generates three dimensional views by combining many 2D image slices, all of which must be clear and well resolved. Scattered radiation reduces the clarity of images obtained by the detector and so needs to be removed and a wide range of designs of anti-scatter devices are used. There are many patents and various proprietary designs used. Figure 1 below shows a relatively simple design that allows unscattered X-rays to pass through but scattered radiation is blocked by the sides of the device. Lead is normally used as it is one of the most effective materials for shielding ionizing radiation and is also easily fabricated into complex shapes.

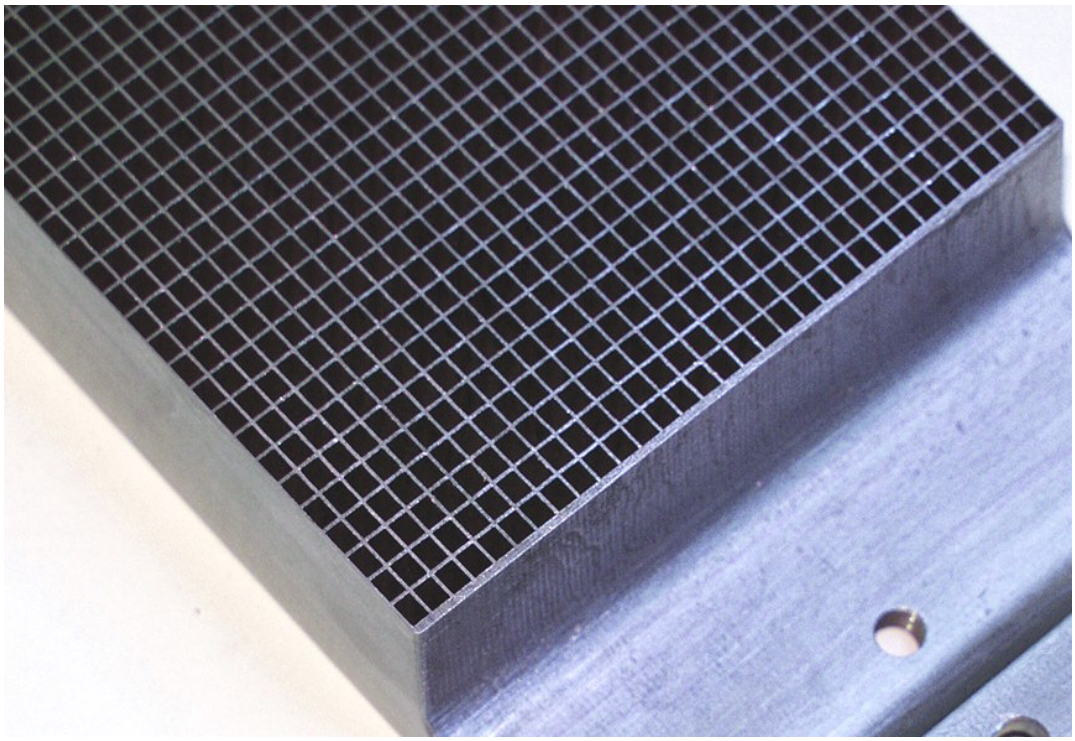


Figure 1. Device for blocking scattered X-rays

X-ray grids were originally developed in 1913 and are still used to improve the image quality of X-ray images for all types of X-ray imaging equipment. Grid designs vary from the relatively simple type shown in Figure 1 to very complex precise patterns of lead supported on X-ray transparent films. The grids consist of various patterns of lead strips which can be supported by materials which are transparent to X-rays such as aluminium foil or fabric and these are placed in front of the image intensifier input phosphor screen, on the X-ray film or on the digital detector. The grids improve image quality by as much as a factor of 5 by blocking scattered radiation and they also reduce X-ray dose[ii]. The grids may be supplied as accessories and have no electrical function. If they are fitted to X-ray films by the hospital technician they would be are out of scope of RoHS but most are supplied with the X-ray equipment and these are in-scope[iii]. Lead is used because thin layers are effective X-ray barriers and can be made into precise and intricate patterns more easily than other high density metals such as tungsten although at least one manufacturer has developed grids made with tungsten (see section 3.1.2 for a comparison of lead and tungsten).

A relatively new treatment technology is proton therapy which uses protons and other high energy particles mainly for cancer treatment. Typically, a proton beam from a cyclotron or synchrotron is generated but is too narrow to affect the whole tumour. Therefore scattering devices made of lead are used to control the width of the beam. As the lead in these applications acts as a barrier to X-rays, this application is very similar to items 5 or 6 of Annex VI of the proposed recast RoHS Directive.

3.1.2 Lead for X-ray markers

X-ray markers are used to impose information onto X-ray images. These include arrows, the letters "L" and "R" to indicate left and right and words[iv]. These are supplied to hospitals as accessories and have no electrical function and so would be excluded from the scope of RoHS. They would however be regarded as being in scope if supplied with the X-ray equipment. Lead is used due to its low price, high opacity to X-radiation and flexibility. Lead is used as a barrier to X-radiation and this application is an example of "shielding for ionising radiation" that is already covered by items 5 or 6 of Annex VI of the proposed recast RoHS Directive.

One of the exemptions reviewed by ERA in 2006 was "lead in X-ray test objects" and this is item 5 of Annex VI of the proposed recast RoHS Directive. Two types of test object were discussed in ERA's report, one which was used for calibration and the other "L" and "R" letters. X-ray test objects, X-ray grids and X-ray markers all have effectively the same function – blocking X-radiation and all use lead produced in precise patterns. The only possible alternative would be tungsten. This is difficult to fabricate, unlike lead, and although tungsten/polymer matrices are available for shielding and could be used to make fairly intricate shapes this is much more difficult to recycle than lead. The life cycle impacts of lead and tungsten have not been compared but it is likely that tungsten would have a greater negative impact because:

- Tungsten is a relatively scarce metal whereas lead is common and occurs in ores at relatively high concentrations. Mining scarce metals requires large quantities of rock to be mined to recover the metals and creates very large quantities of waste.

- Lead is easy to recover from the ore by a one-step thermal process after mineral concentration. Tungsten requires several process steps involving various hazardous chemicals to concentrate, extract and produce tungsten metal.

- Tungsten has a very high melting point, unlike lead and so requires a much larger input of energy to fabricate shapes than lead.

- Tungsten is very hard and so is difficult to fabricate into shapes whereas lead is soft and easily formed into any required shape

- Lead used for shielding is a pure metal that can be re-used after remelting and casting. Tungsten requires many complex chemical process steps to recycle the metal.

- Tungsten/polymer composites are produced for shielding and can be made into shapes more easily than the solid metal but this is not easy to recycle

- When medical devices are recycled in compliance with European legislation, both lead and tungsten can be safely recovered although the tungsten recovery process is more complex and consumes more energy. However, a lot of medical equipment is reused in developing countries where the recycling infrastructure is often less advanced and in some countries, dangerous processes are used which cause harm to the local populations. Recovery of lead from shielding is relatively safe as these are large pieces which can be removed, melted into

ingots for sale with no lead emissions. Suitable safe processes for recovery of tungsten will not be available in many countries and so, as tungsten has a fairly high value, there will be an incentive to attempt recovery using chemical processes that expose workers and local populations to corrosive and toxic substances.

Since the 2006 ERA review, manufacturers have realised that test objects made of lead are not only used for X-ray image quality control and for verification imaging before radiotherapy but are also used for other types of ionising radiation such as gamma radiation, mainly for verification of the position of the patient.

X-ray grids are also very similar to the application described in section 3.1.1. It is recommended therefore that these are combined with either item 5 or 6 of Annex VI of the recast directive; see section 3.1.3.

3.1.3 Lead and lead alloys for collimation of ionising radiation

X-radiation emerges from X-ray tubes at a wide angle and some is also scattered. What is required for imaging and also for radiotherapy is a narrow collimated X-ray beam. Collimators of various designs are used to remove scattered radiation and to obtain a narrow beam with a clear demarcation at the edge. Devices of the type shown in Figure 1 are used to remove scattered radiation whereas thin leaves of high atomic mass metal are used as a physical barrier to obtain a narrow beam. It is often necessary to alter the size of the areas exposed to radiation. For example, there is no need to expose the whole body if only one joint needs to be examined. This is even more important with radiotherapy where high levels of radiation are used to destroy cancer cells and it is important that healthy cells surrounding the tumour are not exposed. Collimation of the radiation beam is achieved by moving the metal leaves to block radiation so that only the tumour is exposed. The ideal material for this has high density and high atomic mass, and so heavy metals such as lead and tungsten are used. It is also important that radiation is blocked by thin leaves as this creates a sharper boundary at the edge of the radiation beam whereas thicker leaves allow some stray radiation to reach healthy cells. Lead has several technical advantages in this regard:

- Lead is a self-lubricating metal so that organic lubricants are not essential. Organic lubricants decompose when exposed to radiation.

- Lead is easy to fabricate and recycle and the production and recycling processes are far less energy intensive than those required for tungsten. One of the reasons for this is because tungsten has the highest melting point of any metal at 3422°C and is fairly reactive whereas lead melts at 327.5°C and does not readily oxidise. Tungsten is also extremely hard and so is difficult to fabricate into intricate shapes unlike lead which is soft and malleable. Tungsten composites are available and are used for shielding but this material cannot easily be made into intricate shapes and recycling is more difficult than lead which is simply melted and recast for reuse.

- Shielding thickness depends on the materials atomic mass, its density and the energy of the radiation. Bismuth has a high atomic mass but relatively low density and so is inferior to lead.

The relative thickness of lead and tungsten required depends on the energy of the radiation beam. At kV (kilovolt) energies used for X-ray imaging, research has shown that with monochromatic and perfectly collimated beams, 0.4 mm of lead reduces the energy to one tenth whereas 0.3 mm of tungsten has the same effect[1]. However tungsten has a much higher density than lead so when used to fabricate a system with shielding around the source, etc., the mass of tungsten required is significantly greater than lead. One publication gives figures for shielding required for an 80kV X-ray tube in a CT system[v]

13 kg of tungsten is required or;

Only 8 kg of lead would be required

The difference in thickness required between tungsten and lead is greater at higher energy levels so that less tungsten can be used, but at these energy levels tungsten becomes radioactive unlike lead.

- Tungsten becomes radioactive when exposed to high energy radiation and this radioactivity can last up to 6 years (usually for >1 year) before the materials can be safely recycled.

- No other heavy metals are suitable; bismuth would need to be considerably thicker and is too brittle, gold and platinum are too expensive, mining and extraction consume huge amounts of energy and there is a high risk of theft. Thallium is more toxic than lead.

- Lighter metals such as iron must be considerably thicker for the same blocking power. For example, if 100mm of lead is sufficient, then 330 mm of steel would be needed for equivalent performance and often there will not be sufficient space to accommodate this amount of material. Overall machine size would be far larger (and not fit into hospital rooms) and access to the patient would be difficult or impossible.

Tungsten is a relatively rare metal whereas lead is available in very large quantities. No comparative life cycle assessments for these two metals has been carried out but, based on availability and properties, tungsten is likely to have a much greater impact than lead, see section 3.1.2. Another issue would be the socio-economic impact from the large price increase that would occur with some products if they had to use tungsten instead of lead. This large price increase would indirectly affects human health as explained in section 2.1

Lead is used in grids, markers, anti-scatter devices and for collimation as a physical barrier to ionising radiation. These applications should therefore be covered by exemption 5 or 6 in Annex VI of the proposed recast RoHS directive. If there is any doubt this does cover these applications, then the wording could be modified to:

[1] 0.4 mm lead and 0.3 mm tungsten are the tenth-value layers calculated in specific conditions (monochromatic 60 keV beam in "perfectly collimated geometry"). This is an example of the behaviour of the shielding properties for these two materials, but the values should not be applied as general figures for X-ray imaging energies, where the beam conditions are different (polychromatic spectra and broad geometry conditions, with scatter etc.). A tenth-value-layer reduces the beam intensity (not the energy) to one tenth of its original value.

5. "***Lead in shielding, collimators and scattering control devices and grids for ionising radiation***".

and:

6. "***Lead in ionising radiation test objects and X-ray markers***".

3.1.4 Lead in positioning system for positioning systems for multisource radiosurgery and particle therapy equipment

Lead is used as shielding for ionising radiation for example:

- as glass with a high lead content that allows the operators to see the patient to ensure they remain in the correct position and do not move without themselves being exposed to radiation
- shaping of beam cross-section, for source shielding and beam collimation
- to act as a barrier to protect healthy organs from stray radiation

Lead is chosen for the reasons described in section 3.1.3 and because the only heavy metal that can be made into a clear and stable glass at a high concentration is lead. Most other heavy metals do not form glasses as they crystallise (tungsten) or the glass is strongly coloured (bismuth) or it is moisture sensitive and so unstable (barium).

No additional exemption is needed however as this application is covered by exemption 5 of Annex VI of the proposed recast RoHS Directive.

3.2 Cryogenic applications

MRI and MEG both operate at very low temperatures using superconductors. The behaviour of materials at very low temperature is very different to that at room temperature.

3.2.1 Lead for thermal management of cryocooler cold heads

Cryocoolers are used in superconducting MRI magnets and in MEG systems. The superconducting magnets of MRI and the superconducting quantum interference devices (SQUID) are held at the temperature of liquid helium which 4K (-269°C) to maintain the superconducting properties that are essential for providing very powerful MRI magnets and ultrasensitive SQUID magnetic field detectors. Helium is a rare and expensive element with very limited natural supply and so it is essential to minimize losses as there is no alternative to helium. The MRI and MEG equipment are filled with liquid helium when they are manufactured and should not lose this helium during the life of the equipment unless there is a fault. Helium is maintained at 4K by specially designed compact and efficient refrigeration devices developed by Gifford and McMahon. These are relatively simple devices that alternately compress and expand helium. When helium is compressed its temperature

increases (as do all gases). The generated heat is adsorbed by a material referred to as the regenerator. The cooled and compressed helium is then allowed to expand whereupon it cools so that overall during the compression/expansion cycle, there is a decrease in temperature. With helium it is possible to reach 4K which prevents evaporation of liquid helium. The regenerator material must have high thermal conductivity and high specific heat capacity at liquid helium temperatures. The thermal properties of materials at ambient are very different to those at 4K and so the commonly used metals used in domestic refrigerators are not suitable at 4K. The specific heat of most metals decreases with temperature and the values are very low at 4K.

Research has shown that lead is a particularly good material in this application as it has high thermal conductivity and thermal capacity, much better than metals such as aluminium and copper. Lead is also a superconductor at 4K and so has a very high thermal conductivity, far higher than non-superconducting materials. The specific heat however decreases with temperature as do most other materials. Many metals however undergo a transition at very low temperature and the specific heat values of some rises at temperatures close to 4K when they undergo a phase transition and so some of these metals have higher specific heat values than lead. The most promising research candidates are rare earth metals such as erbium:

Metal	Volumetric specific heat (J/cm3.K)
Lead at 10K	0.13
ErNi at transition temperature	0.61

Rare earth alloys including ErNi, Er3Ni, ErNi2, DyNi2, Nd, HoNi2 and GdRh all have reasonably high volumetric specific heat values and so are possible candidates as regenerator materials for cryocoolers. They do however suffer from several disadvantages:

- Both MRI and MEG are extremely sensitive to magnetic materials which cannot be used within the detection zones of the instruments. All rare earth metals are strongly paramagnetic and so would be highly detrimental to the sensitivity of these machines.

- Rare earths, despite their name are not especially rare. Some are fairly abundant such as neodymium whereas others including erbium (the most promising candidate) are rare and expensive elements. One research publication estimates that ErPr spheres will be $1/g whereas lead/antimony alloy spheres are $0.15/g[vi] however the market price of erbium is much higher than lead. Lead is ~$1 /kg whereas erbium sells for $650 /kg[vii].

- Rare earth compounds with nickel such as ErNi are very brittle and so are very difficult to produce in useful shapes unlike lead. Erbium itself however is fairly ductile.

- Experiments comparing erbium with lead showed that they have similar performance whereas the heat capacity of erbium is significantly higher.

The higher cost of rare earth regenerators would increase the price of MRI and MEG but as cryocoolers are not made by medical device manufacturers, they do not yet know how large this

increase will be. As healthcare providers in the EU have limited budgets that would not be increased to allow for the impact of RoHS, higher equipment prices would inevitably force hospitals to delay purchasing these new products in many cases and this will have a direct impact on healthcare in terms of the ability to diagnose conditions and to provide suitable treatment (see section 2.1).

Manufacturers of MEG and MRI do not make the liquid helium cooling systems such as the cold head – these are manufactured by their suppliers who produce these products for a wide variety of industries. At least one cold head manufacturer is currently carrying out research with erbium as a replacement for lead and plans to have prototypes available by the end of 2009 for evaluation by medical device manufacturers. There is no certainty that these will be suitable but in any event, these will not be available commercially until they have been validated in clinical trials and approved under the Medical Device Directive and this not be before 2014 and would appear unlikely before 2016.

Item 15 of proposed Annex VI of the recast RoHS directive is intended to cover lead in cryocoolers for MRI as lead is used for its thermal conductivity properties (as PbSb alloy). As the same cryocoolers are also used for MEG, this should be added to item 15 as follows:

15. Lead in alloys as a superconductor and thermal conductor in MRI and MEG

3.2.2 Lead in solder for cryogenic MRI applications

Exemption 12 in Annex VI of the proposed RoHS Directive, “lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors”, covers electrically conducting bonds to the MRI superconducting magnet coil and to the SQUID detectors of MEG. Within both of these products are associated electrical circuitry that are very cold but are not at superconducting temperature, for example connections to instrumentation and heaters. The solders used must be stable at very low temperatures and tin/lead has traditionally been used as it is ductile and does not suffer from “tin pest”. The most widely used lead-free solders are tin with silver and copper but it is well known that these alloys cannot be used at very low temperatures as the tin undergoes a phase transformation with an associated large change in volume. This causes the metal to disintegrate into a fine powder so that the electrical connection is lost; this phenomenon is known as tin-pest. One recent example was to a laptop PC made with tin/silver/copper alloys that was used in the mountains of Afghanistan by the US military. This failed after only a few years because the solder joints disintegrated as a result of the very low temperatures experienced in the field.

Tin pest occurs readily with pure tin and can, in theory, occur at temperatures below +13°C although it is not normally a serious problem with commercial lead-free solders at temperatures above -30°C. Some metal additives prevent tin pest and metals that dissolve in tin such as lead are very effective. Silver and copper however do not dissolve and so are not very effective at preventing tin pest. One suggestion is tin antimony because antimony also is known to hinder tin pest, but tin antimony alloys are not ductile, have a much higher melting point so that they are difficult to use and may be too brittle at low temperatures. Bismuth also dissolves in tin and is known to be effective at preventing tin pest. Bismuth is used in some less common lead-free alloys but no research on its low temperature properties have been published and ERA is not aware of any research being carried out. Due to the

need to prove reliability to gain approvals under the Medical Device Directive, it will not be possible to replace tin/lead by an alternative solder before the 2014 RoHS deadline.

3.2.3 Lead used in pin connector systems requiring non-magnetic connectors

Magneto-encephalography (MEG) is a relatively new technique that is used to generate 3D maps of the brain by detecting and mapping the minute brain signals. These signals are extremely small (of the order of femtoteslas – 1/1,000,000,000,000th the strength of a typical domestic magnet) and one manufacturer's product has 300 special superconducting quantum interference devices (SQUIDs) used as detectors. The SQUID detectors are cooled to 4K with liquid helium and connected electrically with special non-magnetic connectors. These connectors will be very cold although not superconducting and must be non-magnetic to avoid interfering with the detection of very small brain signals. An example is shown below:

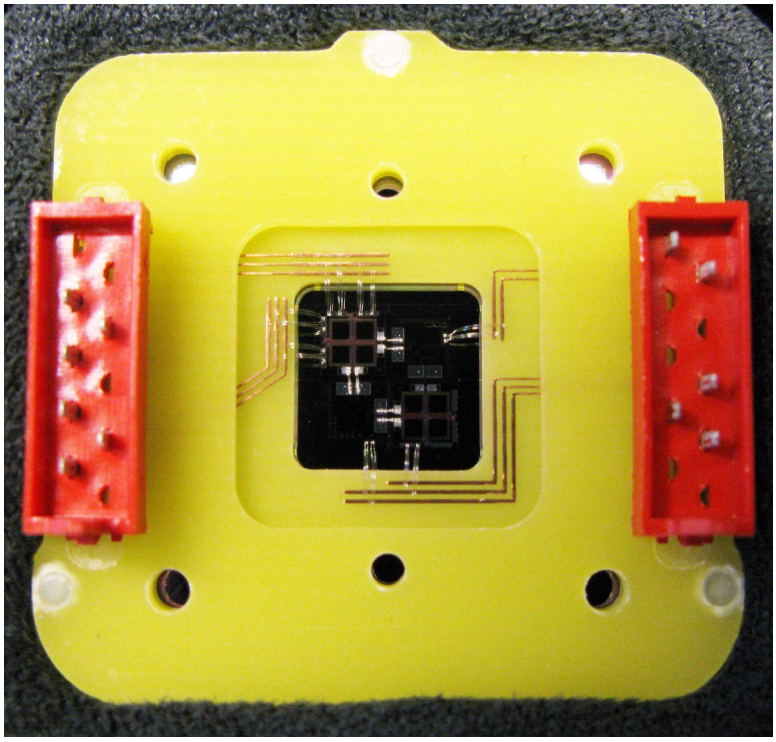


Figure 2. Example of connector used in cryogenic MEG applications

Nickel is a common barrier coating in connectors of this type which is used between the copper or copper alloy terminals and the external coating of tin/lead, tin or gold, but cannot be used in this application as it is strongly magnetic. Table 4 lists the alternative materials that are used for connectors with comments on their suitability in this application.

Table 4. Alternative connector coating materials

Connector terminal coating	Comments
Tin lead alloys	Non-magnetic and stable at liquid helium temperatures
Tin, tin silver and tin copper	Will undergo phase change and disintegrate – “tin pest”
Tin bismuth	Bismuth should prevent tin pest but this material is susceptible to tin whiskers, especially as a nickel barrier layer cannot be used. Also not readily available as a coating
Rhodium	Contact material used in reed relays. Unsuitable as moderately paramagnetic
Silver	Tarnishes to give electrically insulating surfaces
Nickel	Strongly ferromagnetic so not suitable
Gold	Unsuitable without nickel barrier because copper from terminal will diffuse into gold and then oxidize at surface to give electrically insulating surface layers
Silver palladium alloy	Alloys with high silver content tarnish. Palladium increases magnetic susceptibility and increases electric contact resistance. Cannot be electroplated, usually applied as thick film material which is not practical for connectors

Although only small numbers of MEG are placed on the EU market annually, each contains ~ 1000 connectors of this type and one manufacturer estimates that the total quantity of lead used in this application is 100g per year for worldwide sales for this manufacturer (there are less than 5 MEG manufacturers in total worldwide).

3.3 Non-magnetic components

Two related applications are reviewed here:

- Lead in solders in MRI radio frequency send and receive coils
- Lead in non-magnetic electronic components used in MRI send and receive coils.

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 the coils transmit RF signals which excite magnetised protons in soft tissue of the patient. 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. Research has shown that metals with 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 include capacitors, inductors and resistors. The most common termination coating used for standard components that are used in most electrical products is tin or tin/lead plated over a nickel plated barrier layer. Nickel is strongly ferromagnetic, however, and so cannot be used within the region of the RF coils.

Components need to be soldered and so nickel-free solderable coatings are used as the terminations of non-magnetic components. The choice of materials is very limited, however, as the metal used for the outer surface must be wetted by solder easily and quickly. The most common choices of coatings of component terminations are tin or tin/lead plated onto copper for non-magnetic components. Copper is used instead of nickel because it can be applied as a thick film coating over the end terminations of chip components and it is also the most common material for the component terminals of through-hole components, ICs, etc. The materials used for these components must have as low a magnetic susceptibility as possible and it must also be possible to consistently deposit the coating materials. Metals that can be wetted by solder include tin, tin alloys with lead, copper, silver, bismuth, copper, gold, silver and silver palladium. These are compared below:

Coating material	Advantages and disadvantages
Tin	Good solder wetting properties but susceptible to tin whiskers if deposited onto copper without a nickel barrier layer. Not recommended by iNEMI[viii]. 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/copper, tin/silver and tin/bismuth	Susceptible to tin whiskers especially tin/copper. iNEMI recommends tin/silver and tin/bismuth should be used only with nickel barrier layers. SnAg is not thoroughly researched and SnBi has diamagnetic properties that may affect sensitivity.
Gold	Cannot be deposited as thin coating 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 which causes rapid bond failure.
Silver	Low magnetic susceptibility but tarnishes during storage becoming unsolderable. Also suffers from interdiffusion with copper.
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. The magnetic susceptibility of components with AgPg 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. Readily diffuses into tin, gold and silver and so nickel barrier are used when magnetic properties are not important.

The choice of termination coatings is therefore very limited and manufacturers offer only three:

- Tin over copper
- Tin/lead over copper
- Silver/palladium.

Many different components are used for these applications and some, but not all, are available without lead. Manufacturers of these components give differing advice on soldering lead-free components.

> **Voltronics** do not recommend lead-free solders for use with their lead-free components as they say that the higher temperatures that are required can damage these devices. This may appear odd but is due to the reliability guarantee that all manufacturers give for their products. Voltronics cannot yet guarantee their components if they are soldered with lead-free processes because they have not yet carried out sufficient research to determine whether they will be reliable but they supply these components for sale to enable their customers to carry out their own research.
>
> **Temex Ceramics** publish more detailed guidance on lead-free soldering. This clearly shows the limitations of not having a nickel barrier layer. They publish a chart showing the maximum time that components can be immersed in solder at 260°C. Tin/nickel coated components can typically withstand 120 seconds whereas tin over copper components are limited to 10 – 30 seconds and silver-palladium only 5 – 10 seconds.

Some coil circuits are soldered by a 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. The peak temperature required for lead-free solders such as tin/silver/copper (known as SAC) will be 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 30 seconds. Temex recommend a peak temperature with SAC of 245°C which may not always be high enough and it will be difficult to keep within the maximum time limit.

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 Figure 3. All of these components are non-magnetic.

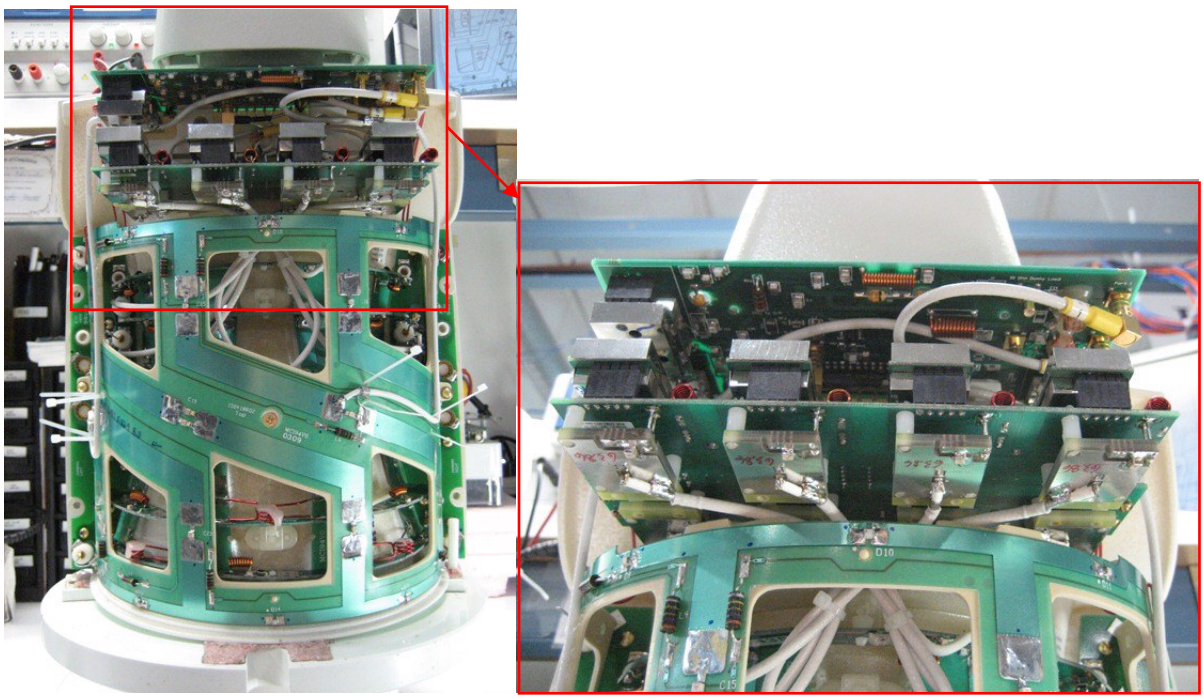


Figure 3. Non-magnetic circuitry of MRI equipment

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 which can damage the components and the flexible PCB. 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 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. Excessive soldering times could at worst cause the end termination material to completely dissolve in the solder. 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 and so the tin/copper intermetallic will continue to grow. Tin/copper intermetallic growth rates are temperature dependent and so could be thicker with lead-free processes than with tin/lead potentially resulting in lower reliability but long-term research would be needed to determine if this is significant for MRI reliability. 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 terminations is increased.

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 lead-free

assemblies within a few years although they will not have completed testing and gained approvals. Furthermore, there are many different RF coil designs and identifying suitable processes for all of these will take many months and possibly 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 our 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 proposed to be included in the scope of RoHS. The time required could be as much as eight years:

Research	1 – 2 years, estimated
Modification of all RF coils	1 – 2 years, possibly longer for all models
Reliability testing and trials	~2 years
Approvals in EU and other jurisdictions worldwide	1 – 2 years
Total	**5 – 8 years**

This indicates that an exemption is needed probably until 2017 (8 years from now) to allow all MRI manufacturers to substitute lead in these applications.

3.4 Solder reliability issues

When ERA reviewed whether it would be possible to include categories 8 and 9 within the scope of RoHS in 2006, many manufacturers of medical devices stated that they were developing new models with lead-free solders. However manufacturers of the more complex and safety critical products expressed concerns over the long-term reliability of lead-free solders. Some also were concerned about the manufacturability of the most complex equipment. There are many parallels between medical equipment and equipment covered by RoHS exemption 7b which allows the use of lead in servers, storage, storage arrays and network infrastructure equipment. Many of these products are also technically complex, are currently difficult or impossible to manufacture with lead-free solders and they are also used in safety or reliability critical applications. ERA concluded in its 2006 report that if exemption 7b were still required when medical equipment were to be included in the scope of RoHS (based on the review that has recently been completed), then an exemption should be considered for categories 8 and 9.

Since 2006, the medical, IT and telecom industries have continued research on lead-free soldering. In the last few years, the less complex telecom products and many low and mid-range servers have moved to manufacturing with lead-free solders. The more complex products however, cannot currently be produced in lead-free due either to technical issues or concerns over the long-term reliability. RoHS exemption 7b was recently reviewed for the Commission by the Öko Institut who recommended that this exemption should continue until 31 July 2014 which should be after the next 4-

yearly review. In its 2006 report, ERA recommended that Categories 8 and 9 should also have a temporary exemption for lead in solders if these reliability concerns had not been resolved by the time that this exemptions review was carried out. A general exemption for lead in solders for all medical devices does not however appear to be necessary as many products are already available with lead-free solders and so only exemptions limited to those applications that need to use lead solders are considered in this report.

There are several specific applications that the medical industry believes require exemptions that should allow the continued use of lead based solders but they accept that a broader exemption for all medical devices is clearly not required or justified. Specific applications for exemptions that have been requested are:

- Lead in solder for array connections and interconnections of CT X-ray detectors
- Lead in plating finishes on lead-less devices e.g. BGAs, CSP, WLCSP, QFN
- Equipment and assemblies that were developed specifically for other industry sectors not in the scope of RoHS (e.g. military, aerospace, robotics, research equipment, large scale industrial tools) and are then used in medical applications.
- Lead in solders for array interconnections to photodiode CT detectors
- Lead in solders for connections to micro-BGA area arrays.

The reasons why these applications require more time to replace lead-based solders with lead-free substitutes include:

- Many involve very advanced technologies that involve relatively new types of electronic devices. Solder bonding devices that use solder spheres to create electrical connections such as BGAs, micro-BGAs and CSPs is technically challenging even with tin/lead solders. Lead-free solders have different physical properties and are not drop-in replacements. They melt at higher temperature, interact with substrates differently, require different flux compositions and are less ductile materials. Manufacturers often experience low yields and poor reliability with these types of components because soldering can be very difficult. These issues are further exacerbated where multilayer PCBs with unusually large numbers of layers and unusually high densities of through holes and microvias are required due to the challenging demands of the equipment (usually many complex functions and compact size). ERA has carried out failure investigations on electrical assemblies for many years and has seen many examples where defects have occurred with these types of components mounted on complex PCBs. Many of these defects were found to be manufacturing faults with either defective solder bonds or damage to multiplayer laminates but others occurred after fairly short periods in service. These types of defects have occurred in the past with SnPb assemblies but more recently with lead-free solders. There is one well-publicised example of the Microsoft X-Box in 2007 that was caused by soldering problems to a lead-free BGA. At the time there were also unconfirmed reports that other manufacturers had experienced similar problems.

- Components manufactured primarily for industry sectors currently excluded from the scope of the RoHS Directive usually contain lead-based solders and sometimes also other RoHS restricted substances. Some types of advanced components are produced primarily for the military, manufacturing or aerospace sectors and so do not need to comply with RoHS. The medical (and monitoring and control instrument) sectors utilise these components but use only very small numbers. The manufacturers of these components often are prevented from changing these parts to comply with RoHS because their principal customers refuse to accept changes, especially to replace lead solders for lead-free (due to reliability concerns). It is not economically viable for them to produce a very small proportion of their products as RoHS compliant versions and so their customers in the medical sector are unable to obtain a RoHS compliant version. Sometimes, substitution by redesign is possible but there are several instances when the performance of the non-RoHS compliant component is unique and cannot be attained by an alternative design. There are two examples included in Annex VI of the proposed recast RoHS directive, items 18 and 19. Further examples will inevitably be identified and several are described here.

Specific examples where an exemption for continued use of lead-free solders is requested are described in the following sections.

3.4.1 Components used by other industry sectors not within the scope of RoHS

One difference between medical devices and consumer and household products is that improvements in performance to medical products can save lives. Improvements to consumer and household products will in general increase sales but usually have no health benefits. Some of the recent gains in medical device performance have been achieved by utilising state-of-the-art components that were developed for other industry sectors. These include robotics used in production lines, aircraft radar components and even particle physics components developed for advanced research. These applications are all out of scope of RoHS and will remain out of scope when medical devices are included in scope in 2014. Many of these components are not RoHS compliant (mainly as they contain lead solders) and as the medical industry buys only very small quantities, the manufacturers will in most cases be unwilling to invest in developing RoHS compliant versions. In some industries such as aerospace and military, their main customers will not accept any changes. When RoHS was originally adopted, manufacturers also experienced this issue with many components not being available as RoHS compliant versions and it was necessary therefore to redesign their products. Medical equipment manufacturers will not have the same level of expertise in component design as their suppliers of the more advanced types of components and so they will often be unable to redesign alternative products having the same performance as those that used specialist components developed by the other industry sectors. Replacement products will as a result not provide the same high level of healthcare and patient treatment could be inferior. To prevent this situation from arising, an exemption to allow the continued use of these components is recommended in addition to items 18 and 19 of Annex VI of the proposed recast directive which are exemptions for two specific military non-RoHS components with superior performance over all RoHS compliant types. A selection of examples of these types of components is described in the following sections.

3.4.2 Components used by other industry sectors not within the scope of RoHS - Absolute position sensor

An example of a unique type of component designed specifically for the industrial manufacturing sector (excluded from RoHS) that is used by the medical sector is an absolute position sensor used in "Multisource Radiosurgery". This technology uses radiation from typically 200 separate radiation sources (cobalt 60 isotope) to destroy cancerous tumours. Patients are usually treated in a single session unlike in standard radiotherapy which requires many sessions and they can leave the hospital after treatment. The 200 sources produce narrow low intensity beams of radiation that each pass through healthy cells without harm but all 200 are focussed on the tumour to produce a zone of very high radiation intensity. It is crucial that the position of the tumour is precisely known so that the beams are focussed at the correct position. One product on the EU market has an accuracy of 0.5 mm so that diseased cells can be killed with minimal harm to nearby healthy cells[ix]. This is achieved by moving collimators that focus the radiation beams and also by moving the patient in three dimensions. The positions are determined using linear encoders. The focusing position is accurately controlled using servo motors and monitored with one position sensor. This is checked for safety reasons by a separate linear encoder and the patient's position is controlled with three more encoders. Two separate encoders monitor the focussing location so that if any deviations occur, the treatment is stopped to prevent harm to the patient. For this approach to function, the position sensors (encoders) must be "absolute" position sensors and so know exactly the position irrespective of what had occurred previously. Most position sensors on the market monitor position against a fixed point (relative position) and this is not suitable. The sensors also need to operate reliably when exposed to radiation. One manufacturer has evaluated many types of linear encoder but found that only one type produced globally by only one manufacturer has the required accuracy and reliability.

The sensors produced are manufactured primarily for use in machine tools used in manufacturing production lines (e.g. to control manufacturing robots). Production lines are currently excluded from the scope of RoHS as these are "Large-scale Stationary Industrial Tools" and so may use lead-solders, etc. The position sensors contain small PCBs fabricated with SnPb solders because most of these sensors are sold to an industry sector that does not require the use of lead-free solders. However, the cost of development of lead-free versions would be significant and so Heidenhaim will not supply RoHS compliant versions to the medical sector as they would purchase only relatively small numbers of these sensors. An EU manufacturer of Multisource Radiosurgery estimates that this application would place less than 1 kg of lead (from all suppliers) on the EU market annually.

3.4.3 Components used by other industry sectors not within the scope of RoHS - robotic equipment components

Industrial robots used to manufacture cars and other complex products are highly manoeuvrable and can place items at very precise locations. This is ideal for imaging equipment and equipment that moves patients to specific locations such as for angiography (examination of blood vessels) and radiation therapy (cancer treatment). Increased precision allows shorter treatment times and can lower X-ray doses. One example is produced by Siemens[x] :

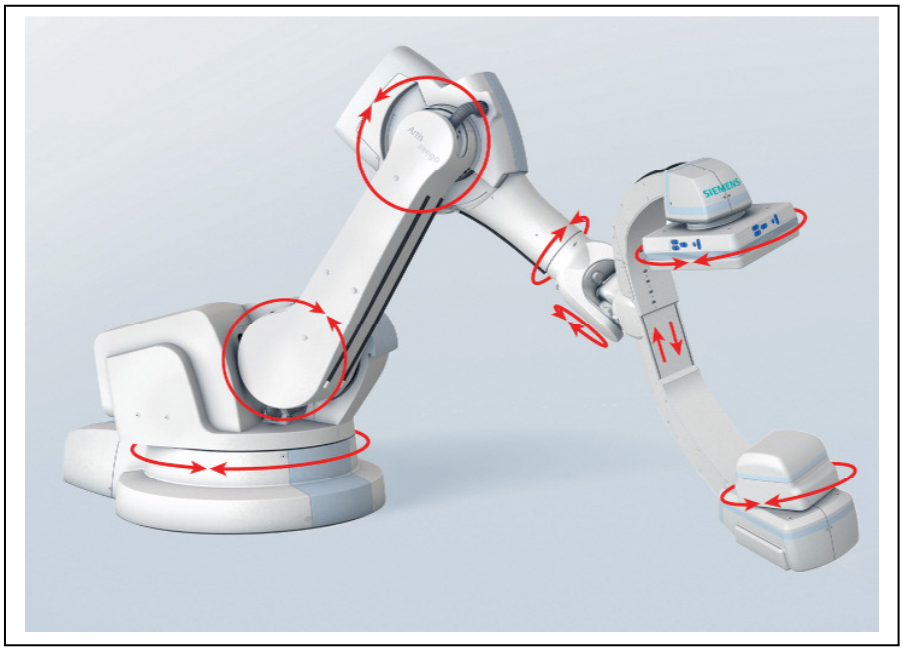


Figure 4. Angiography equipment which utilises industrial robotics components

The medical industry uses much less than 1% (and probably as little as 0.1%) of the total production of these types of components, which are mainly used by the industrial manufacturing sector. As industrial manufacturing is classified as large-scale stationary industrial tools, these products do not need to avoid the RoHS restricted substances. The performance of medical equipment designed with robotics components that are made with lead based solders is superior to designs that use the conventional electronics that could be produced without the RoHS-restricted substances.

3.4.4 Components used by other industry sectors not within the scope of RoHS – Particle accelerator components

Some high power medical devices use components designed for research by other industry sectors. These are very complex devices and redesign for the small numbers of devices used by the medical industry is not practical.

One example is particle accelerators. Most of these are used for particle physics research at establishments such as CERN in Europe and FERMI Lab in USA as well as by many universities. Cyclotrons and synchrotrons are the two main types of particle accelerators but these vary in size and use considerably.

- There are about 200 accelerators worldwide used for research only and would not be covered by any of the 10 categories in Annex I of the WEEE directive. These therefore are out of scope of RoHS

- About 15 of the research accelerators are used for medical treatment (e.g. proton therapy) as well as research or other non-medical uses. The accelerators are not classified as medical devices but are used to generate the particle beam that is guided to the patient by equipment which is classified as medical devices by directive 93/42/EEC.

- There are 10 accelerators worldwide used only for medical applications.

- There are also between 200 and 300 small accelerators used for manufacture of radiopharmaceuticals. These would be classified as large-scale stationary industrial tools as they are used for industrial manufacturing and so outside the scope of RoHS.

Components used by all accelerators include ion sources are used to create high energy particles to create a beam of ion and electromagnets which are used as parts of synchrotrons or a “beamline” to control and accelerate particles such as protons or electrons close to the speed of light. The magnets and other components used in the small radiopharmaceutical accelerators are not suitable for accelerators used for medical applications as they will have incorrect dimensions. Parts for accelerators used for medical applications will be the same as those used for research. Therefore, medical-use accelerators account for about 12% of all large accelerators (only ~5% of all accelerators). However, the proportion of electromagnets used in medical-use accelerators are far less as some of the research accelerators are far larger than typical medical devices. For example, the accelerator at CERN has 8000 electromagnets whereas a typical medical accelerator will use only 80. It is clear therefore that the medical sector will use a very small proportion of accelerator electromagnets and other parts.

These types of components are used by the medical in very small numbers and typically contain very small quantities of RoHS substances.

3.4.5 Components used by other industry sectors not within the scope of RoHS – other examples

A variety of other components such as gas controls and measurement and distribution systems are used in conventional manufacturing industry applications (LSIT) to support equipment for application of specific colours, supply pressured air, supply machines in the food industry to control the process temperatures etc. are used in very small numbers for medical applications such as in anaesthesia support for very specialized applications.

Industrial manufacturing products are also used for particle beam equipment for the high power supply and to measure and control the beam.

High radio frequency (RF) devices that have been developed for military and civil radar and broadcasting applications are used in some types of radiotherapy equipment. Radar in aircraft and military vehicles do not need to comply with RoHS and so use tin/lead solders and hexavalent chromium passivation coatings. Military and aerospace products require approvals and so manufacturers are very reluctant to make changes as this can be a very lengthy and expensive process. The very small numbers sold to the medical sector do not warrant these costs and so

medical equipment manufacturers will not be able to obtain RoHS-compliant versions of these advanced components. Examples of these parts include:

- Klystrons are vacuum tubes used for radar (e.g. air traffic control), telecommunications (covered by exemption 7b of the current RoHS Annex) and industrial microwave heating (LSIT) as well as for medical applications
- Magnetrons are vacuum tubes that generate microwaves for radar
- Thyratrons are used for pulse radar and UHF TV transmission (broadcasting is covered by exemption 7b of the current RoHS Annex).

All three of these examples use very small amounts of lead as solderable coatings and solders.

Some industrial power supplies (LSIT) are also used and contain lead solders. Many of the parts described here also have silver cadmium oxide electric contacts which are currently covered by exemption 8 of the RoHS Annex.

Summary

To summarise the situation for components used by the medical industry but sourced from other industry sectors that are not within the scope of RoHS: The medical industry does not have expertise in robotics, RF engineering and several other areas but, by utilising components from these industries, they can develop medical equipment with superior performance that deliver better healthcare to patients. Not all medical manufacturers use these components as some simpler medical products can be designed with RoHS-compliant parts but this can limit the performance that can be achieved. These non-RoHS compliant components are developed for industry sectors that are outside the scope of RoHS and so lead and hexavalent chromium are used. Many of the component manufacturers will not modify these parts for their medical customers because these account for relatively small proportions of their sales and their main customers will not allow changes to be made as their products would need to undergo extensive testing to be re-approved for use.

Industry sectors from which parts are sourced include: manufacturing (LSIT), military, aerospace, broadcasting and telecommunications and particle physics research. The RoHS substances affected are lead and hexavalent chromium although cadmium is also used but in a RoHS-exempt application (as electric contacts, exemption 8 of the RoHS Annex). Suggested wording for an exemption is:

Lead and hexavalent chromium in components specifically designed for industry sectors that are out of scope of the RoHS Directive and utilised as components in medical devices.

3.4.6 Lead in solders to PCBs for mounting cadmium zinc telluride digital array detectors

Cadmium zinc telluride (CZT) is a relatively new semiconductor used to produce high resolution digital images. It is used in nuclear medicine as the detector in positron emission tomography (PET) and also as the X-ray detector in CT. Single crystal wafers of CZT are fabricated into detectors and these

are mounted onto printed circuit boards (PCBs) that make the many hundreds of electrical connections. One connection is needed for each pixel of the image. CZT is a very fragile and brittle material which is easily damaged, particularly by stresses imposed by the assembly process. CZT detectors are bonded to PCBs using a special electrically conducting adhesive.

To avoid imposing stresses onto the CZT which could cause bond failure or damage to the detector, the PCB must be perfectly flat. Unfortunately the PCBs used for CZT assembly are complex multilayer boards with a high density of internal vias. Laminates tend to distort and warp when they are fabricated, especially complex boards of this type. Distortion occurs during reflow soldering when the electrical components are mounted onto the PCB. It is a general rule for any type of laminate, that the amount of distortion increases with temperature and so laminates will be less flat on average after lead-free reflow than after tin/lead reflow due to the 20 - 40°C increase in temperature. Figure 5 shows two of the PCB pads bonded with conducting adhesive to the CZT detector showing the large difference in thickness of adhesive that is caused by PCB distortion. This large difference in bond thickness has been found to increase the risk of either bond failure or cracks in the CZT semiconductor.

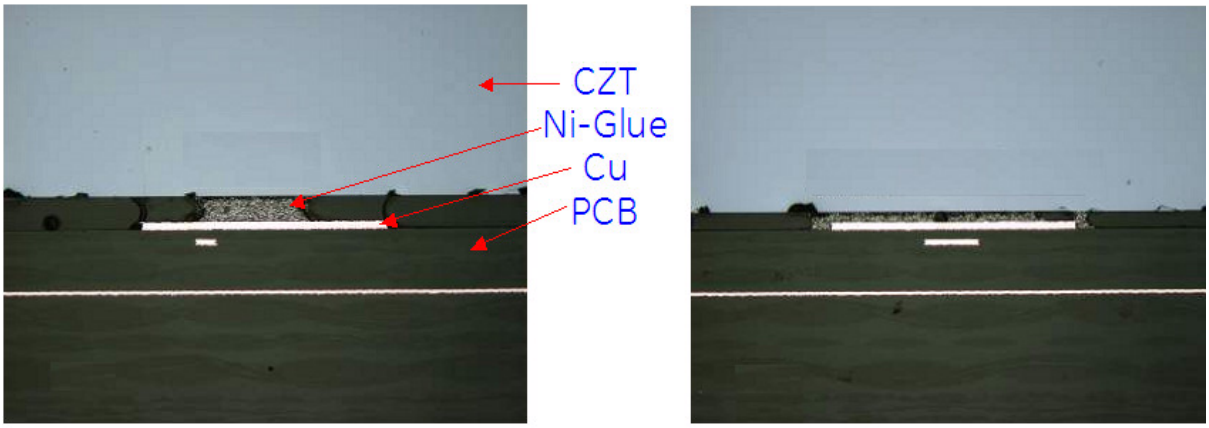


Figure 5. Cross-section through bonds to CZT detector. Left image thick layer of adhesive, right image thin layer

Development work by one manufacturer found that after fabrication with a SnPb soldering process, the yield of good detectors was better than 98%. However on PCBs produced with lead-free processes, there were 5 – 10% failures. This level of failure is high and creates unnecessary waste, but is also of concern because the internal stresses induced by uneven pad dimensions could also cause more failures to occur after several years in service. The long term field behaviour is not known as these are very new devices. This would be a serious problem as the medical equipment could not be used and patients would suffer. For example, failure could result in the only CT or PET machine that was available to a hospital being out of action for several weeks.

This situation clearly would impose an increased risk to patients and so further research by manufacturers is required. The use of alternative laminates is one possibility and although several types have already been evaluated, other types are available that could be assessed. Lower melting point solders are available such as tin/zinc and tin/bismuth but these are not suitable; tin/zinc corrodes

and is suitable only for consumer products and the melting point of tin/bismuth is too low so that bonds could melt if the equipment or individual components (such as power semiconductors) were to operate at elevated temperature. Bismuth alloys are also not good choices as wire is difficult to make so that repairs and rework are often impossible and bismuth also increases the complexity of waste electrical equipment recycling processes as it combines with gold and other elements. The quantity of lead in the solder required for each CZT detector circuit is 1 g whereas 200 – 240 kg of lead is required for shielding ionising radiation.

3.4.7 Lead in solders for portable, safety critical medical equipment

The long-term field reliability of lead-free solders is less certain and the potential risk of failure is greatest in portable equipment because there are two additional failure modes – vibration as a result of transportation and impact from being dropped onto the floor. These are in fact related because when equipment is dropped onto a hard surface, it experiences a brief very high g-force whereas vibration imposes many repeated but smaller g-forces. Vibration induced forces may be small, moderate or quite large. ERA reviewed published research on the effect of vibration on equipment produced with lead-free solders for the 2006 study and concluded that lead-free solders were more susceptible to vibration at relatively high g-forces, especially in the axis perpendicular to the surface of the PCB (the z-axis). Research showed that this effect was most obvious at >9g.

A review of recent drop-test research shows that the risk of bond failure of very small solder ball bonds that would be used in micro-BGAs and in chip-scale-packages (CSP) is higher with lead-free solders than tin/lead. Research results appear contradictory to some extent (mainly as tests are carried out in different ways) with some early research indicating that lead-free was considerably more susceptible to failure if the equipment were dropped whereas other research showed that initially there was little difference between SnPb and Pb-free solder although microstructural changes occur over time due to aging. Research has shown that after aging has occurred, the lead-free CSP bonds failed after less drops than the SnPb CSP bonds[xi] and so there is an increased risk to equipment that is dropped. These results are not surprising as the aging properties of these two types of solder alloy are different.

- SnPb solder interacts with the substrates to create intermetallic layers. These are produced as a result of chemical reaction between the tin in the solder and the metal surface of the PCB pad or the component's terminals. If copper is used, a SnCu intermetallic is produced and if there is a nickel layer then SnNi is formed. SnCu forms more quickly than SnNi but both continue to grow after the solder bond has been produced due to "aging". The rate depends on temperature and at higher temperatures the intermetallic phase grows more quickly and this effect is used to simulate accelerated aging. With SnPb solders, the available tin close to the interface is depleted so that this zone becomes lead-rich which retards intermetallic growth as tin is less accessible. Lead-free solders are mostly tin and so a tin-depleted zone does not form. A second effect also occurs with aging. SnPb solder consists of two phases, one tin-rich and the other lead-rich. These are separate grains which gradually grow especially where there is high imposed stress. Grain growth does not affect bond reliability unless they become particularly large in stressed regions.

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

Recent research has shown that improved resistance to failure when dropped is achieved with under-fill materials. These are materials that are types of adhesives that are injected between the device and PCB laminate. Under-fills compatible with SnPb have been available for several years but lead-free compatible under-fills are relatively new and so their long-term performance is not so well understood although the drop-test performance of lead-free BGA and CSP is greatly improved by the use of suitable under-fill materials. Research has shown that under-fill performance varies considerably with many providing little or no benefit. Thermal coefficient of expansion (TCE) of the under-fill is important with low TCE materials appearing from research to give improved drop-test performance.

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

Most of the safety critical medical equipment used in hospitals is not designed to be carried although many items are moved from one location in a hospital to another but have wheels and so vibration is minimal and there is little risk of being dropped. There are however a few safety-critical products that are regularly carried and are likely to be dropped:

- **Portable defibrillators** – many are carried in ambulances and often intentionally dropped when paramedics arrive at the patient. Others are located at workplaces, airports etc. in case of emergency and may be used very infrequently. Very high g-forces have been measured in these products and, as lead-free solders are more at risk from failure at high g-force. These

devices are defined as class III “life-sustaining” by directive 93/42/EEC as a patient would die if these do not function. ERA recommended that lead solders should be exempt in these products and this has been included in Annex VI, item 17 of the proposed recast RoHS Directive

- **Devices carried by patients** – Patient-Worn Devices (PWD) are RF devices carried by patients who have very recently completed surgery. In the past, these devices were large and not portable so patients could not move about. Modern portable devices allow recuperating patients to move around the hospital and be continuously monitored. They need to be continuously monitored while they are walking or being moved and in locations where wired connections are not possible. The vital signs data such as heart condition, blood pressure and temperature are wirelessly transmitted in a short range radio frequency from the PWD to the nearby network router which will then download the data to the nurse stations via an Ethernet network. If a PWD is dropped onto the floor by a patient, which is likely in view of their condition, the PWD could be damaged and fail to transmit a warning alarm. PWD must also be unaffected if they are worn by a patient taking a shower or if dropped into water (bath, toilet, etc.).

- **Portable ultrasound** – Until recently, ultrasound equipment was relatively large and not portable but smaller portable equipment has been developed that can be carried in ambulances and by general practitioners. Small hospitals and doctors practices may have only one ultrasound monitor and increasingly these will be portable types. These are susceptible to damage from vibration during transportation and if dropped in the same way as portable defibrillators. If they could fail to function, as there will be no alternative equipment nearby, patients would be at risk in an emergency.

- **Portable patient monitors** – Equipment for monitoring body functions of patients are widely used in hospitals, ambulances, emergency helicopters and elsewhere. These monitor a variety of functions such as pulse, blood pressure, temperature, etc. Most are designed to be used in a variety of locations and many are fitted with batteries to allow transportation. Some are mounted on a stand by a patients bed and so do not need to be readily portable but others are hand carried or attached to other portable equipment such as a patient transportation trolleys or stretchers. More examples of how these products are used include:

    - monitors mounted on tiltable/ swivel arms, where users tend to pull on the device rather than on the handle provided

    - patient monitors permanently mounted on wheeled anaesthesia machines or ventilator carts, and these carts being wheeled to the ventilator maintenance department (may happen twice a week for critical care ventilators!)

    - patient monitors mounted permanently to patient stretchers in emergency departments or patient receiving areas, where they travel everywhere the stretcher goes

- small patient monitors that are used inside a baby incubator in neonatal intensive care units, where the caregiver constantly has to make sure the device is out of reach of the patient

- flexible/ replacement/ spare monitors that are wheeled or hand-carried to the location inside a hospital where they are immediately needed

- patient monitors mounted permanently to patient stretchers in CT or NMR set-ups or radiology C-bows, where they constantly travel with the stretcher or C-bow.

Patient monitoring equipment is safety critical because if it were to malfunction, any life-critical changes to a patient could be missed. Portable products will suffer from vibration stresses which can be significant in ambulances and especially in emergency helicopters. Clearly there is also a risk of being dropped although this is somewhat less than portable emergency defibrillators and patient worn devices. Due to the high levels of vibration and increased risk of being dropped, there are concerns amongst manufacturers that there would be an increased risk of unexpected early failure if lead-free solders were used for these products and so more extensive research will be required.

Patient worn devices (PWD), portable ultrasound and portable monitors are less safety critical than portable defibrillators and so are classified as class II (A or B) by directive 93/42/EEC "non-life sustaining and diagnostic tool devices". In some circumstances another device will be available if one fails and failure will not always be life threatening unlike portable defibrillators. However there will be circumstances where defects or complete failure would be life threatening. For example if a patient with a PWD suffers heart failure while out of site, no alarm would be sent. If the monitor being used for a patient in an ambulance fails, any changes to the patient would be missed.

Item 21 of Annex VI of the proposed recast RoHS directive already exempts lead in solders in portable defibrillators. It is suggested that this is amended to include other portable medical equipment which is safety critical and has an increased risk of failure with lead-free solders to allow additional time for research into techniques that ensure high reliability:

"Lead in solders in portable medical devices:

- ***Class III Portable defibrillators,***

- ***Class II Patient-worn devices and portable ultrasound equipment and portable patient monitoring equipment".***

3.4.8 Lead in solders for connections to BGA and CSP area arrays, QFN and similar device

All medical equipment has size constraints to enable it to be used in standard size hospital rooms or to make if easily transportable and this forces the equipment designer to utilise very advanced circuit technologies for the most complex types of medical device. This creates reliability issues and some of the more advanced products utilise electronic components that have small sphere solder bonds

such as BGAs, micro-BGAs and CSP. Some increasingly use QFN devices which are also difficult to use. These types of equipment include:

- Portable defibrillators and patient monitoring devices.
- All portable ultrasound devices
- Hearing aid products
- Imaging systems including CT, PET, SPECT, MRI and molecular imaging
- X-ray and MEG
- Urine based automated screening tests.

BGAs are relatively large devices with complex multilayer PCBs as substrates that support complex silicon die. As the thermal coefficient of expansion (TCE) of the device is much less than the PCB laminate, temperature changes impose stress on the ball joints which can cause failures by thermal fatigue cracking. Micro-BGAs are smaller versions of BGAs but the stresses are the same. Although the device size is less, the balls are much smaller so that the stand-off height is less. Solder is fairly ductile so a large standoff helps to relieve stresses by distortion of the solder. Smaller stand-off allows less stress relief. Micro-BGAs have similar size solder balls to CSP and the difference is that in CSP have silicon die that are almost as large as the package whereas micro-BGAs have smaller die. Another type of device used where space is limited is the QFN integrated circuit package. These have an array of solder pads along each side attached directly to the package without flexible terminals as do QFP (quad-flat-pack) devices. As the terminals of QFN and not flexible, they suffer from the same stresses as CSP and BGA devices. In practice, they suffer from higher stresses as ball bonds can distort to some extent relieving stress whereas QFN bonds have only thin solder layers and so stress relief is less significant. Complex medical devices that include BGAs, micro-BGAs, CSP or QFN are therefore the most difficult to fabricate and manufacturers are not yet fully confident of the long-term field reliability. Many of the products that include these devices experience high levels of vibration and some may also be dropped (see section 3.4.7). As there is an increased risk of failure, this necessitate further research into suitable designs and comprehensive reliability testing over several years before it is possible to apply for approvals under the Medical Devices Directive (re-approvals are required if significant changes are made to medical products and any design change is regarded as significant).

Apart from vibration and being dropped, there are two other potential failure mechanisms that are of concern to manufacturers of high reliability products including medical devices but also IT, telecom, military and aerospace.

Thermal fatigue – this failure mode causes solder bonds to crack when exposed to cyclic stresses and occurs with both tin/lead and lead-free solders and a lot of research has been carried out to compare these materials using accelerated testing. The difficulty, however, is knowing how to extrapolate accelerated test results to predict field behaviour over 10 – 20 years. This is possible for tin/lead as data from well over 20 years field behaviour exists, but lead-free solders are too new and so this field data does not yet exist to be compared with test data. Equipment designers have to rely

on predictive models which are as yet not proven to be totally reliable. Research has shown that the behaviour of tin/lead and lead-free solders is different and the early indications are that lead-free will be as reliable as tin/lead, possibly except for high stress situations – but without field data this cannot be known with certainty.

Tin whiskers – these are very fine rods of tin that form on electroplated tin coatings that are under compressive stress. This mainly affects components and a lot of work has been carried out to adopt measures that minimise the risk. Although these have been found to be effective for consumer and office equipment, there are concerns by manufacturers of high reliability equipment (e.g. aircraft, military and medical) that are required to be reliable for at least 10 years that the long term performance in all environments is uncertain. Research on this issue is continuing.

Manufacturing defects can be resolved by the manufacturer with sufficient resources and time although this can be a lengthy and costly process for the most advanced technologies. Design of products that are resistant to vibration, being dropped, thermal fatigue and tin whiskers also requires considerable research effort but also requires lengthy testing that can take several years to produce data and will be sufficiently convincing to Notified Bodies for them to approve the medical devices.

3.4.9 Lead in solders of imaging systems including CT, PET, SPECT, MRI and molecular imaging and radiation therapy

Most imaging equipment is large and very complex and is required to function reliably daily for at least 10 years. Many of these products, including CT, PET, SPECT and MRI, have rapidly rotating parts that induce high g-forces due to the rotational speed and there is also intense vibration. High g-forces and vibration place additional stresses on solder joints and have to be carefully accounted for in new designs. These types of equipment also include complex and fragile components such as micro-BGAs, CSP, QFN and digital detectors made of CZT and other types of semiconductor (see sections 3.4.6 and 3.4.8). Many imaging products including CT and standard X-ray equipment have electronics that is exposed to ionising radiation but circuits in radiotherapy and particle therapy equipment can be exposed to unusually high levels of ionising radiation that does cause damage to silicon chip circuits. Products that are currently in scope of the RoHS directive are not normally exposed to ionising radiation and so the long term effect of intense ionising radiation on lead-free soldered PCBs and lead-free substitute components is not known and research will be needed to ensure that reliability is not compromised. Radiation resistant integrated circuits (ICs) tend to be older products and many are not available as lead-free versions as they were originally developed for military and aerospace markets. Most of the newer lead-free ICs have not been thoroughly tested for reliability in high intensity radiation.

Medical equipment manufacturers are carrying out research into lead-free soldering of these types of products but this will require considerably more time than would normally be required for consumer and household equipment. Several manufacturers have said that they will not be able to design all of these types of imaging equipment with lead-free solders, have completed testing and trials and gained the required approvals before the 2014 RoHS deadline. The timescales expected are similar to those predicted for assembly of non-magnetic components described in section 3.3.

Photodiode CT array detectors are particularly difficult to solder as they are large and very fragile. The ductility of tin/lead solders helps to prevent damage during production and in service and more research is needed to enable lead-free solders to be used reliably.

3.4.10 Lead in solders of high voltage circuits for X-ray generators

High-voltage generators for driving X-ray tubes consist of two main parts. One is the circuit that rectifies mains AC input power, converts it to high frequency power through an inverter, up-converts to high voltage by a transformer and supplies high-voltage power to the X-ray tube. The other circuit controls the rotor and filament of the X-ray tube. The printed circuit boards are not highly complex, but are composed of a number of unusually large components including capacitors, thyristors, IGBT (insulated gate bipolar transistor) and choke coils. These circuits control a high voltage of more than 100kV. These circuits include several components that are heat sensitive and so may be damaged by the higher lead-free soldering temperature including large electrolytic capacitors and IGBTs both of which can be damaged by excessive soldering temperatures. However further research will be required before sufficient data is available to determine if an exemption is required and to generate data to support an exemption application.

3.5 Other applications

Several other exemptions for other applications have been requested and are described here:

3.5.1 Lead as an alloying element for radiotherapy equipment and radiosurgery equipment and for patient and equipment support systems

Lead has been widely used for well over 100 years as a dry lubricant in various alloys, particularly bronzes. This application is currently exempt from RoHS (exemption 9b of the RoHS Annex) but a recent review carried out for the Commission recommended that the scope be limited to a narrow range of applications that do not include medical devices (as these are currently outside the scope of RoHS and so not considered). This recommendation is based on the availability of alternative types of bearings which contain oil or grease as a lubricant.

Lead addition to alloys is used by the medical industry as a dry lubricant particularly at locations exposed to ionising radiation. Ionising radiation causes all organic materials including oils and grease to decompose and these materials would have to be regularly replaced if they were used. Lead is not affected by ionising radiation, however, so that no maintenance is required. Lead-based bearings are often used with some grease added because lead alone is not always adequate as the sole lubricant but the combination of lead with some grease is suitable without maintenance over very long periods so that use of the medical equipment is not interrupted.

One example of this application is bearings used for the doors of multisource radiosurgery equipment. The radiation source used in these products is the radioactive isotope cobalt 60 and the bearings are continuously irradiated. It is essential that the patient entry doors open and close easily to prevent

radiation leakage. Lubrication of these bearings with fresh grease or oil would be a very dangerous operation because of the continuous radiation exposure (the radiation source cannot be “turned off”).

Lead is also used as a dry lubricant as an alloying addition to aluminium where 5% aluminium is added. This material is used for the bearings of linear slider that are used for support systems that allow the patient or parts of the equipment to be moved to precise locations in angiography, radiotherapy and CT equipment. These bearings need to support very high loads but as they are exposed to ionising radiation, oil and grease lubricants will decompose and be unreliable.

3.5.2 Lead as PVC stabiliser in medical tubing

Lead stabilisers are used to prevent PVC decomposition during its fabrication. Suitable alternatives include Zn/Ca formulations which give adequate stabilisation and do not affect performance. Barium based stabilisers are often used where transparent PVC is required and which is usually used for medical tubing. Barium compounds are hazardous materials if they are soluble in water but are less toxic than lead. The European PVC industry plans to have completely phased out the use of lead in all 27 EU States for all applications including medical tubing by 2015 and this plan is on schedule. A manufacturer of lead-free medical tubing has been identified[xiii].

Lead stabilised PVC cable insulation is also being phased out worldwide with substitutes widely available. It is possible that medical device manufacturers are already using these without being informed of the change by their suppliers but the properties of Zn/Ca stabilised PVC insulation should be essentially the same as lead-stabilised types under most conditions.

3.5.3 Cadmium pigments in ECG patient tubing

Electrocardiography (ECG) is a very sensitive technique that measures the electrical signals within the body including those of the heart. Various electrodes are placed at specific locations on the body for measuring specific characteristics. Each electrode is connected to the measurement instrument by a flexible cable and is colour coded. In Europe, an IEC standard specifies which cable is identified by each colour but the cables themselves do not need to be coloured and often coloured tags or clips are used attached to uncoloured white cables. A different standard is applicable in USA which specifies different colours to indicate sensor locations

A significant amount of research has been carried out with cables to develop materials that are bio-compatible, non-allergic to patients and can be sterilised. The cables must also be able to detect very small voltages and currents without introducing artefacts that could result in incorrect diagnoses. There are relatively few materials that are suitable and polyurethane is now the most widely used. Polyurethane cable insulation is very unusual being used primarily for ECG cables and so very few suitable pigments are available. One cable manufacture claims that only cadmium-based pigments give clear bright colours that comply with the ECG cable colour standards but an alternative that has been adopted by several manufacturers is to use unpigmented cables (white) but indicate the cables function by coloured plastic clips or markers which can be made of cadmium-free pigmented plastics.

3.5.4 Flexible copper cadmium wire

Flexible wire is needed for applications where frequent movements are required and this is used in any applications where wires connect to parts that frequently move. The wire must be both flexible and not fracture from the repeated movements that would occur with pure copper. Fisk Alloys Inc., a US manufacturer has developed and patented a range of cadmium-free alloys that have similar physical and electrical properties to the most commonly used copper cadmium alloys[xiv]. Many medical equipment manufacturers have already phased out the use of these alloys.

3.5.5 Image intensifiers

There are three applications relating to image intensifiers although alkali dispensers are also used in other products:

Cadmium in output phosphors of image intensifiers

Image intensifiers are used to amplify the images generated by X-ray imaging equipment by up to 5000 times. These consist of an input phosphor with a photoemissive layer that converts the weak X-ray image into a light image which is focused onto the photocathode. The photocathode converts the light into electrons that are projected onto the output phosphor which converts the electron image into a visible light image. The input phosphor is sodium doped caesium iodide which is a very sensitive phosphor material but the most common output phosphor is silver doped cadmium zinc sulphide

Originally all manufacturers used silver doped cadmium zinc sulphide as the output phosphor but a few manufacturers have developed alternative designs that avoid using this material. Image intensifiers are usually specifically designed as components of X-ray imaging equipment. There is a growing trend away from traditional photographic films to either image intensifiers with digital cameras or with digital semiconductor detectors that convert the light image into a digital image. These innovations do not need the cadmium-based phosphors and some X-ray equipment manufacturers plan to have phased out the older designs by 2014. However the newer digital X-ray equipment is more expensive and there are hospitals in EU that will continue to purchase the lower cost versions that require visible light images. If these are not available due to the RoHS Directive, purchase of the more expensive alternatives would be delayed and this would negatively affect healthcare as discussed in section 2.1. Research into cadmium-free phosphors has been carried out during the past few decades. This was successful for colour televisions which originally used cadmium-phosphors but most medical device manufacturers have not found an alternative phosphor with equivalent or superior light output. One of the best cadmium-free phosphors with similar characteristics to silver doped cadmium zinc sulphide is P43 but this gives 10% less light output and so to achieve the same image quality, the patient has to be exposed to a 10% higher X-ray dose which increases the risk from the ionising radiation (e.g. cancer).

One manufacturer has developed an alternative output phosphor but this is patented[xv] and so not available to other image intensifier manufacturers.

Lead to enable thermal compression process to make a vacuum tight connection between aluminium and steel for X-ray image intensifiers

Image intensifiers are used to amplify the weak images produced by X-ray imaging equipment and are often supplied as integral parts of these products. They must have a permanent high vacuum to function reliably and they are assembled from a variety of materials that need to be attached with vacuum-tight bonds. Polymer seals and adhesives are unsuitable as these are all porous to gases so that the vacuum is lost. Soldering, brazing and welding of ceramics or glass to a metal such as steel or aluminium is extremely difficult with a risk that the bond will leak. Therefore one way of producing vacuum tight bonds in image intensifiers and also in other types of vacuum equipment is with gaskets made of soft metals. Gold is used in some types of high vacuum analysis equipment as it is very inert and is a soft material but it is expensive. Lead is also fairly soft and so is suitable for certain applications including image intensifiers.

The design of image intensifiers varies considerably and the designs used by several manufacturers utilise lead to maintain a vacuum tight seal. The entrance shield of these X-ray image intensifiers are made of a low density material, such as aluminium, to be able to minimise the X-ray dose for the patient. Next to this there is the need for glass-metal (steel) joints for electrical insulation reasons. Steel and aluminium must be joined in a way that does not damage the glass-to-metal seal and so thermal processes such as brazing are not suitable. Glass to metal seals can be made with several metals but not aluminium because glass will not easily form a vacuum tight bond to aluminium and the thermal coefficient of expansion (TCE) of glasses and aluminium are not the same. The TCE of aluminium and steel are also not identical and so the seal material must be flexible enough to allow for movements due to temperature changes but not distort permanently and leak. Several soft metals have been considered as possible substitutes:

Table 5. Possible alternative metals for image intensifier seals

Metal	Characteristics
Lead	Ductile but not too soft so that sufficient contact force is maintained
Tin	Slightly harder than lead and tends to form micro-cracks which can cause leaks
Gold	Softer than lead so leaks can occur, also much more expensive. For a 31 cm image intensifier, the price for one lead seal is €0.35 whereas one gold seal of the same size is close to €10,000[2] which would increase the price of the image intensifier by much more than double.
Indium	Very soft and cold welds to all materials so that movements caused by temperature changes would destroy the seal.

[2] Based on 340 mm diameter gold ring of 2.2 mm diameter, gold density of 19.3g/cm^3 and a gold price of €22/g.

Metal	Characteristics
Copper	Used to create vacuum seals between stainless steel but not suitable where differential movement occurs due to the differences in TCE of steel and aluminium. Copper work-hardens and will not distort to accommodate differential movements and so is likely to leak

Clearly, gold may technically be the best substitute but as the high price of gold would cause the price of image intensifiers to much more than double, manufacturers have not carried out reliability tests with this material. There is a strong possibility however that gold would not be suitable. IBM evaluated gold and other materials for a similar application in supercomputer modules to form an air-tight seal between copper and a glass-ceramic. Lead was suitable but tests showed that gold was unsuitable as leaks occurred[xvi].

Hexavalent chromium in alkali dispensers for in-situ production of photocathodes

Several types of vacuum devices including image intensifiers (used with X-ray imaging equipment) and photomultiplier tubes (used for measurement of electromagnetic radiation) are fabricated by a process that uses alkali dispensers. Image intensifiers, photomultipliers and other similar devices include a photocathode which has a vacuum deposited layer of an intermetallic consisting of antimony and an alkali metal such as potassium or caesium. Alkali metals are very reactive and react very rapidly with minute traces of oxygen and moisture and so the antimony/alkali metal coating has to be fabricated and kept within a vacuum. The procedure used is to first assemble the device with a coating of antimony metal on the photocathode support. The alkali dispenser is inserted inside the device with electrical connections and then the device is evacuated to remove all traces of air. The alkali dispenser is a sealed tube containing a mixture of an alkali metal dichromate with a reducing agent, usually zirconium/aluminium (Zr/Al) alloy powder. This mixture is heated electrically (via the electrical connections) and reacts to evolve the alkali metal vapour and in some types, it also opens the dispenser. The alkali metal vapour reacts with the antimony coating to produce the photocathode. This exemption was requested because the chemical reaction with the dichromate salt is usually incomplete and some hexavalent chromium remains in the product.

Research has been carried into alternatives for many years, partly to avoid using hazardous hexavalent compounds but also because the alkali dispenser mixture releases detrimental impurities as well as the alkali metal. These include hydrogen gas released from the Zr/Al alloy which must be removed from the vacuum by a separate “getter”. There are several patents describing possible alternatives including one belonging to SAES Getters which is an Italian manufacturer of alkali dispensers although the only type of alkali dispensers currently sold by SAES Getters are the type that contain dichromate salts. However an Austrian manufacturer, Alvatec, produces and supplies alkali dispensers that do not contain hexavalent chromium[xvii]. These contain intermetallic compounds of bismuth with the alkali metal such as Bi3Cs. A review of patents identified gold, aluminium and silicon as possible alloying elements with alkali metals that release the alkali metals on heating. However, none of these are available commercially.

Research by manufacturers since the 2006 ERA study has not however resolved all technical issues to enable any of the CrVI-free substitutes to be used. Investigations by one manufacturer have shown that many of the possible alternatives that they have evaluated are unstable and so either cannot be

used or they give unreliable results so that the performance of the photocathode was poor. Reduced photocathode performance is unacceptable as this reduces the quality of the X-ray image.

One manufacturer of photomultiplier tubes (PMT) has evaluated Alvatec's alkali dispensers and found two problems. Most PMT designs are fairly small and are made of glass that is sealed by melting the glass after the parts including the alkali dispenser are assembled. The dispenser is hermetically sealed with a low melting point metal and indium is chosen as it melts at a low temperature, forms a good gas-tight seal and is non-toxic. No other metals would have all of these properties. However the glass melting temperature is much higher than the melting point of indium so that the indium melts when the PMT is sealed and some of the alkali metal escapes before it can be used. This leaves insufficient to form the photocathode. The second problem is that a high current is needed to activate the alkali dispenser mixture. This current is passed from outside of the device into the PMT via wires that bond to the glass. The high current however causes the wire temperature to rise and this causes the wire to expand and can crack the glass which would then leak destroying the vacuum. This problem can also occur with larger image intensifiers that are made of metal, usually aluminium. The heater wires must be insulated from the metal with a glass hermetic seal to maintain the vacuum. Resistance heating of the alkali dispenser wires could cause the glass seal to crack compromising the vacuum.

One image intensifier manufacturer has also evaluated the Alvatec dispensers. Because of the design of the Alvatec dispensers, they found that the alkali metal is produced at a very different rate to CrVI-type dispensers so that the image quality was very poor. Many loose particles are formed which remain in the image intensifier and are unacceptable as they appear randomly in images and could give misleading or incorrect diagnoses. No other alternatives are available.

Research has shown therefore that the chromate-based alkali dispensers give the best performance in terms of photocathode quality and least defects from cracks in the glass seals. The early research with possible substitutes in 2006 has not yet resulted in a reliable alternative and clearly further research will be needed. Some manufacturers have found that they are able to complete the chemical reaction between chromate and Zr-Al so that no CrVI remains but this is not always possible. With certain designs of image intensifier, it is possible to produce the photocathode externally and then move it into the device. With some other designs, the alkali dispenser can be connected externally and removed after photocathode fabrication. Both of these result in CrVI not being present in the product although CrVI is still used to make the equipment. However these techniques are not suitable for most types of PMT or for current designs of image intensifiers that form photocathodes in-situ. Image intensifiers are used with X-ray imaging equipment and the space available is very limited so design options are very limited. One manufacturer of image intensifiers estimates that research into alternative designs would cost at least €2 million with a high risk that this would not be successful. This size of investment would very significantly increase image intensifier prices but would not reduce the amount of hexavalent chromium used in the production process. There would be no environmental benefit as this approach moves the hexavalent chromium from one waste stream to another.

This exemption is also needed for photomultipliers that are used in both medical devices and in monitoring and control instruments because external alkali dispensers are technically impractical and the alternative types available from Alvatec give unacceptably poor result.

3.5.6 Lead acetate marker for use in stereotactic head-frames for use with CT and MRI

Stereotactic head-frames enable the co-ordinates of a target to be localised during diagnostic examination and treatment. Lead acetate is used as a marker for both CT and MRI to locate features within the head during surgery. The marker must contain a high atomic mass element such as lead as well as a substance that is easily visible with the MRI but not be adversely affected by the MRI. MRI sensitive materials include water and organic substances with hydroxyl groups. The marker solution contains both water and 1,2-propane diol (propylene glycol) which has two hydroxyl groups. No alternative has been identified that is suitable. Metals for example are suitable as CT markers but cannot be used in MRI as either they are invisible, they become very hot or are magnetic. Water and glycols are good markers for MRI but are not visible by CT. Clearly a solution of a heavy metal compound is ideal but few heavy metal compounds are sufficiently soluble and stable in solvents with high hydroxyl ion content and do not decompose in the MRI. For example, bismuth, precious metals such as gold, platinum and tungsten salts are either soluble only in strongly acidic solution (therefore very low hydroxyl ion content) or do not dissolve without decomposition. Mercury and thallium are more toxic than lead and so are unsuitable. There are no other non-radioactive heavy metals.

This application is justified on the basis of the exemption criteria but is not required for those products with no electrical function as these are outside the scope of RoHS. However products with electrical functions are in scope and so an exemption would be required and is justified on the basis of there being no practical alternative technology.

3.6 Reuse of parts of used X-ray tubes in new equipment

It is common for manufacturers of X-ray tubes to re-use component parts several times. X-ray tubes have a finite life due to the erosion of the electrodes but many of the constituent parts can be re-used. This practice is encouraged by the WEEE Directive, is beneficial to the environment and also reduces the price of X-ray tubes and so lowers healthcare costs.

If the following two scenarios are compared:

- re-use parts 5 times
- do not re-use parts

consider the environmental impact for 5 X-ray tubes:

No Parts re-used	Parts re-used
First tube uses all new parts	First tube uses all new parts
Second tube uses all new parts and parts from first tube become waste	Second tube uses parts recycled from first tube

No Parts re-used	Parts re-used
Third tube uses all new parts and parts from second tube become waste	Third tube uses parts from second tube
Fourth tube uses all new parts and parts from third tube become waste	Fourth tube uses parts from third tube
Fifth tube uses all new parts and parts from fourth tube become waste	Fifth tube use parts from fourth tube
Fifth tube become waste	Parts from fifth tube become waste
Result:	
Five tubes produced **- using five sets of new parts all five of which become waste**	**Five tubes produced** **- using only one set of reusable parts and producing one set of waste parts**

It is clear that the re-use of parts consumes less raw materials, less energy to fabricate parts and produces less waste all of which will be beneficial to the environment. X-ray tubes at end of life are exchanged for new tubes and returned to the tube manufacturer. They are therefore able to re-use any constituent parts after dismantling tubes and recycle the remaining materials. The materials are metals and glass and so are readily recyclable. However, without an exemption to allow parts to be re-used, parts from tubes on the market prior to 2014 which do not comply with RoHS will become waste prematurely which is not beneficial to the environment or healthcare. An exemption would be limited to:

> **Lead and hexavalent chromium in component parts from used X-ray tubes that were put onto the EU market prior to 1 January 2014 and re-used in new X-ray tubes from 1 January 2014 until 31 December 2019.**

Manufacturers of X-ray tubes believe that pre-2014 parts will too old to be re-used with new tubes from 2020. Enforcement of this exemption should not be an issue as the parts that are reused can only be used in X-ray tubes and so there is no risk of them being used in other products. X-ray tubes are used for medical imaging as well as some types of X-ray imaging equipment within the scope of Category 9 of the WEEE directive (monitoring and control instruments).

4. Conclusions

Since ERA investigated whether it would be possible to include Categories 8 and 9 in the scope of RoHS in 2006, manufacturers of medical equipment have been carrying out research into substitution of the RoHS restricted substances. Most mercury switches have been replaced by mercury-free alternatives. Many manufacturers now use trivalent chromium passivation coatings instead of hexavalent types and many have designed new products with lead-free solders and these are being sold in the EU. Inevitably, they have found some applications where it has not yet been possible to identify substitutes for a variety of reasons. In many cases, the apparent substitutes cannot be used because their use is technically impractical, in some the alternative materials would, overall have a more negative impact on the environment and in several applications, and probably unique to the medical sector, the impact of using substitutes would result in price increases that would delay or prevent the purchase by hospitals, etc of new equipment that would have improved the quality of healthcare in the EU. ERA also recommended in 2006 that exemptions for lead-free solders be reassessed before amending RoHS and several soldering applications have been examined as part of this study.

The main conclusions from this investigation that has been carried out at the request of COCIR on behalf of its members are:

1. Twenty five exemption applications were requested and are listed in section 2.

2. The COCIR exemption request for lead in an IVD opto-coupler was withdrawn after further research was carried out.

3. The COCIR exemption request for stereotactic head frame markers is clearly justified for technical reasons. Some versions of this MRI / CT marker product will have integral electrical functions and so an exemption would be needed.

4. It was not possible to recommend granting exemptions for three of the COCIR requests (lead in PVC, copper cadmium cables and cadmium pigments in ECG cables) as insufficient data was available to demonstrate that they are justified.

5. Proposed exemption 5 from Annex VI of the proposed recast RoHS Directive should be amended to include collimators and anti-scatter grids. This change does not alter the scope of this exemption as it was originally intended to be a broad scope exemption for all applications where lead is used as a barrier to ionising radiation. However, the original wording of this exemption does not unambiguously include collimators or anti-scatter grids and so new wording has been suggested. Lead is technically justified as the best material for collimators and anti-scatter grids and there are also environmental advantages over the main potential substitute for the reasons explained in section 3.1.

6. Proposed exemption 6 from Annex VI should be amended to include X-ray markers because these have close similarities to X-ray test objects and are justified for the same reasons. Both need to act as physical barriers to ionising radiation; both are made of lead with precise dimensions.

7. Proposed exemption 17 of Annex VI of the recast directive should be amended to include three additional types of safety critical portable medical equipment that have a high risk of being repeatedly dropped and subject to vibration.

8. Eleven additional exemptions are being proposed to be added to Annex VI which are justified on the basis of the criteria of Article 5.1b of the recast directive and these are listed in section 5. Several are to allow the temporary continued use of lead in solders until technical problems and concerns over long term reliability of safety critical products have been resolved.

9. Three of the additional COCIR exemption requests are for applications that relate to image intensifiers. Image intensifiers are relatively mature low margin products and each manufacturer uses a different design with different materials.

    - Most use in-situ alkali dispensers containing hexavalent chromium but a few use external dispensers so that the hexavalent chromium is not present in the product although external dispensers are not an option with photomultiplier tubes.

    - Some image intensifier designs use lead vacuum seals but others use different sealing techniques.

    - Some manufacturers use cadmium-based output phosphors which they are unable to replace. One potential alternative to the output phosphor is digital detectors but these would result in very large price increases and also not be practical for some customers (hospitals) who do not have access to the ancillary digital viewing equipment. Another apparent alternative is a patented alternative phosphor that is not available to the competitors of the patent's owners.

    As a result of these issues, most manufacturers of image intensifiers need at least one of these three exemptions. Re-design at this time would be extremely costly so that the price of new designs would be uncompetitive with those few manufacturers who do not need to redesign. Image intensifier design requires know-how that competitors do not have and so there is no guarantee that it will be possible to re-design these products successfully. There is clearly no incentive to spend large sums re-designing image intensifiers in order to avoid using fairly small quantities of RoHS substances. In the example of the alkali dispenser, re-design does not reduce the amount of hexavalent chromium used; it only moves it to a different waste stream so there would be no environmental benefit. Manufacturers will continue to carry out research and it is likely that these exemptions can be deleted at some time in the future but the exemptions are required to avoid a situation where the majority of manufacturers are forced to stop selling image intensifiers in EU from 2014 except as replacement spare parts.

10. Four of the existing RoHS exemptions listed in the Annex are applications used in medical devices. These are items 3, 9b, 11 and 23 of the current RoHS Annex. The recent review by the Öko Institut has recommended that these are deleted or restricted in scope and the new scope excludes medical devices, not because they are not required but because medical devices are currently not in the scope of RoHS. The medical industry expects to require at

least some of these exemptions and two are covered by some of the new exemptions that are recommended for addition to Annex VI of the proposed recast directive (see section 5.1)

Medical equipment manufacturers are continuing to carry out research into substitutes for RoHS substances and some are at a more advanced stage than others. It is clear that alternatives for some of the exempt applications proposed in this report will be found and can be utilised within the next ten years and probably sooner but for others no alternatives are currently foreseen that will not cause either large price increases or use materials that have a more negative impact on health and the environment than those they potentially would replace.

Most of the applications for which additional exemptions are recommended will use very small quantities of RoHS substances and some are much less than 1kg per year in EU. None of the additional applications use very large quantities of RoHS substances although accurate quantitative data is not available for many of these.

The recast RoHS Directive proposes to change the procedure for review of exemptions from a review at least every four years to expiry after four years unless renewed. Four years until expiry may be suitable for consumer and household products which have short design times and do not need to gain approvals but this is too short for products that are within the scope of the Medical Device Directives as explained in section 2.2. A suggested alternative is given in section 5.2.

5. Recommendations

5.1 Exemptions

Some of the new applications considered in this investigation are justified on the basis of new Article 5.1b of the proposed recast RoHS Directive. Some of these can be included by small changes to the wording of the items in Annex VI of the proposed recast RoHS Directive whereas others will require additional exemptions to be added. The recommendations from this investigation can be incorporated into Annex VI with the following changes. Annex VI should be renumbered and the unnecessary section headings should be removed. All changes are shown in ***bold italics***.

1. Lead, cadmium and mercury in detectors for ionising radiation
2. Lead bearings in X-ray tubes
3. Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate
4. Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons
5. Lead in shielding, ***collimators and scattering control devices and grids*** for ionising radiation
6. Lead in ***ionising radiation*** test objects ***and X-ray markers***
7. Lead stearate X-ray diffraction crystals
8. Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers
9. Lead and cadmium in ion selective electrodes including glass of pH electrodes
10. Lead anodes in electrochemical oxygen sensors
11. Lead, cadmium and mercury in infrared light detectors
12. Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide
13. Cadmium in helium-cadmium lasers
14. Lead and cadmium in atomic adsorption spectroscopy lamps
15. Lead in alloys as a superconductor and thermal conductor in MRI ***and MEG***

16. Lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors

17. Lead in counterweights

18. Lead in single crystal piezoelectric materials for ultrasonic transducers

19. Lead in solders for bonding to ultrasonic transducers

20. Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay

21. Lead in solders in

    - ***Class III*** portable defibrillators,

    - ***Class II patient-worn devices and portable ultrasound equipment and portable patient monitoring equipment***

22. Lead in solders of high performance infrared imaging modules to detect in the range 8-14 µm

23. Lead in Liquid Crystal on Silicon (LCoS) displays

24. Cadmium in X-ray measurement filters

25. Lead in solders and in component terminations and connector terminals of Magnetic Resonance Imaging and Magnetoencephalography that operate at temperatures lower than -50℃

26. Lead in termination coatings of non-magnetic components used in Magnetic Resonance Imaging and Magnetoencephalography and solders used to bond these non-magnetic components

27. Lead in solders and in component termination coatings used for assembly of printed circuit boards of medical devices that include BGA, CSP, QFN, and similar devices and medical devices used for imaging including CT, PET, SPECT, MEG, MRI and molecular imaging and for medical devices used for radiation and particle therapy

28. Lead in solder used for assembly of printed circuit boards used for mounting semiconductor digital array detectors, e.g. cadmium zinc telluride and pin-grid array digital X-ray detectors

29. Lead and hexavalent chromium in components specifically designed for industry sectors that are out of scope of the RoHS directive and utilised as components in medical devices

30. ***Lead as a dry lubricant in copper and aluminium alloys for locations exposed to ionising radiation***

31. ***Lead for vacuum-tight seals of image intensifiers***

32. ***Hexavalent chromium in in-situ alkali dispensers***

33. ***Cadmium in output phosphors of image intensifiers***

34. ***Lead acetate marker for use in stereotactic head-frames for use with CT and MRI***

35. ***Lead and hexavalent chromium in component parts from used X-ray tubes that were put onto the EU market prior to 1 January 2014 and re-used in new X-ray tubes from 1 January 2014 until 31 December 2019.***

Table 1 from section 2 is reproduced here to show the recommendations from the investigation of the list of requests for exemptions. Where amendments to items in proposed Annex VI or additional items are recommended, these have been included in the suggested wording for Annex given above.

Table 6. Recommendations for each of the requested exemptions from this investigation

Description	Recommendations
Lead for X-ray grids and X-ray markers	Amend item 6
Lead in Anti Scatter in CT X-ray detectors	Amend item 5
Lead and lead alloys for collimation of ionising radiation	Reword item 5
Lead in positioning systems for multisource radiosurgery and particle therapy equipment	Already covered by item 5
Lead acetate marker for use in stereotactic head frame for use with CT and MRI	New item 34
Lead for thermal management of cryocooler cold heads in MRI magnets	Covered by item 15
Lead for thermal management of cryocooler cold heads in MEG systems	Covered by amending item 15
Lead in solder for cryogenic MRI applications	New item 25
Lead in solders in MRI Radio Frequency send and receive coils	New item 26

Description	Recommendations
Lead in non-magnetic electronic components used in MRI send and receive coils	New item 26
Lead used in pin connector systems requiring non-magnetic connectors	New item 25
Lead in solder for array connections and interconnections of CT X-ray detectors	New item 28
Equipment and assemblies that were developed specifically for other industry sectors not in the scope of RoHS (e.g. military, aerospace, robotics, research equipment, large scale industrial tools) and are then used in medical applications.	New item 29
Specific Opto-coupler for IVD instruments	Request withdrawn
Lead in solders for array interconnections to photodiode CT detectors	New item 27 / 28
Lead in solders of imaging systems including CT, PET, SPECT, MRI and molecular imaging	New item 27
Lead in solders for connections to BGA and CSP area arrays and QFN devices	New item 27
Lead to enable thermal compression process to make a vacuum tight connection between aluminium and steel for X-ray image intensifiers	New item 31
Lead as an alloying element for radiotherapy equipment and radio-surgery equipment and for patient and equipment support systems	New item 30
Lead as PVC stabiliser in medical tubing	Insufficient evidence
Cadmium pigments in ECG patient cables	Insufficient evidence
Flexible copper cadmium wire	Insufficient evidence
Hexavalent chromium for in-situ production of photocathodes	New item 32
Cadmium in output phosphors of image intensifiers	New item 33
Re-use of parts of X-ray tubes containing lead and hexavalent	New item 35

Description	Recommendations
chromium in new X-ray tubes	

Four of the existing RoHS exemptions listed in the Annex that are currently applicable to medical devices have been recommended for early deletion by the Commission's consultants. These are listed in Table 2.

- Current exemption 3 is an issue if suppliers of displays are unable to provide sufficient devices or suitable image quality
- Current exemption 9b can be replaced by new exemption 30 recommended for addition to Annex VI of the proposed recast directive
- Current exemption 11 needs to be reviewed by medical equipment manufacturers and their suppliers to determine whether alternatives will be reliable.
- Current exemption 23 is utilised by the medical industry and would be covered by new exemptions 26, 27 and 28 recommended to be added to Annex VI of the proposed recast directive

5.2 Exemption review process

It is also recommended that Article 5.2 be amended to include:

"***….maximum validity period of four years and may be renewed except for products in Category 8 which should have a maximum validity period of six years and may be renewed. If a request to renew an exemption is not granted then the Commission shall allow a reasonable transition period to allow all manufacturers to modify their products before the exemption expires…..***"

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Appendix A
Glossary

Angiography	X-ray technique used to examine blood vessels.
Computed Tomography (CT)	X-ray imaging in three dimensions – the X-ray tube is located at one side of a large ring, the detector is located at the opposite side and the patient lies at the centre. The X-ray tube and detector spin round rapidly (once every 2 seconds) and move along the patient to generate many images that are combined by the computer into one three dimensional image, CT is mainly used to examine denser materials such as bones but some information on internal organs can be obtained.
Electrocardiograph (ECG)	Technique that measures electrical activity within the body particularly the functioning of the heart. ECG is used to examine the heart for defects and it is also used for patient monitoring.
Magnetic resonance imaging (MRI)	MRI also generates three dimensional images in a similar way to CT but uses a powerful superconducting magnet and an array of radio frequency coils that emit RF radiation that excites certain molecules, especially hydroxyl groups which emit characteristic radiation when they relax. The RF coils measure the emitted radiation to generate a three dimensional image. This is used to examine soft tissues such as the internal organs.
Magnetoencephalography (MEG)	This is a relatively new technique used to examine the functions of the brain. It contains a large array of extremely sensitive magnetic detectors that can detect brain activity and produce a three dimensional map showing brain function.
Multisource Radiosurgery	Used for cancer treatment, particularly for tumours that are impossible to reach by surgery including brain tumours that are not accessible via holes in the skull. The machine contains an array of radio-isotope sources that emit gamma radiation that are focussed onto the tumour. The gamma-radiation from one source does not cause harm to healthy cells that it passes but the intense radiation where they are all focussed is sufficient to destroy the cancerous cells.
Positron Emission Tomography (PET)	Nuclear medicine – the patient is injected or drinks radioactive markers that concentrate at specific parts of the body. The PET detectors scan the body to generate a three dimensional image showing the locations of the radioactive markers. PET is used to examine internal organs, blood supply, bones, etc. Its main use is for oncology to detect tumours and it is also used for cardiology and neurology.

Radiotherapy	Radiotherapy is a more traditional technique for cancer treatment. An intense beam of high energy electrons or particles like protons or carbon ions is generated and directed at the tumour. The standard procedure is to treat the tumour of each patient with a predetermined precise dose of radiation daily over a period of several weeks. The radiation dose and the direction of exposure are calculated to destroy the cancer with minimal damage to surrounding healthy cells. Modern machines can more precisely target the cancer without damage to surrounding healthy cells and this is one reason why medical experts recommend that conventional radiotherapy machines (photons, electrons) are replaced every ten years. The other main reason is that wear causes imprecision and faults occur more often as the equipment ages. Delays in treatment can be very serious to the patient as this result in less effective treatment and longer treatments. Both of these can also have financial implications for healthcare providers. Particle therapy machines use research accelerators like a synchrotron to accelerate the light ions to the energy necessary to destroy the tumour cells in the patients body. Due to the extremely expensive machinery these machines are designed to last for an extremely long lifetime (>>20 years). They usually will not be replaced but upgraded.
Single Photon Emission Computed Tomography (SPECT)	SPECT is also used in nuclear medicine with radioactive markers for similar applications to PET. However, SPECT detects gamma-ray emissions directly whereas in PET, positrons are emitted which annihilate within a few millimetres to two gamma-rays that travel in opposite directions. PET gives higher resolution than SPECT but is a more expensive technique.

Appendix B
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