# Appendix 2: Overview and Rationale of RoHS restricted substances in Medical Devices as controlled by Directive 2002/95/EC (RoHS)

**Short explanation of each column**

**Modality**
The generic name of the Medical Device.

**Substance**
Usage of any restricted substance(s) listed in the RoHS directive.

**Typical Application and Approximate amount per product**
Function or part of a medical device in which the substance is applied and the amount of each Substance used.

**MDD class**
The Medical directive under which the modality belongs; for the MDD the risk class.

**Total Weight of the substance put on the EU market in kg/Year**
Information in this column is derived from approximate units of Modalities marketed in the EU per year supplied by all manufacturers worldwide and the amount of Substance used by each Modality.

**Benefit**
Benefits, including medical, for using the Substance(s) in a Modality.

**Replace**
Lists any viable alternative to the restricted Substance. When considering this both technical alternatives and their associated financial implications are considered.

**Rationale**
This column gives the rationale for the continued use of a Substance as listed in the RoHS directive by a Modality.

**Colour coding in the table**

| | |
|---|---|
| (orange) | Lead |
| (yellow) | Cadmium |
| (green) | Hexavalent Chromium |
| (grey) | Mercury |
| (black) | PBB, PBDE |
| (yellow-green) | Weight of the RoHS substance put on the European market |

| | Modality | Sub-stance | Typical Application [Approx amount per product] | MDD class | Total Weight of the substance put on the EU market in Kg | Benefit | Repla-ce | Rationale |
|---|---|---|---|---|---|---|---|---|
| **Ionizing Radiation Equipment** | | | | | | | | |
| 1 | Conventional X-Ray | Lead | **Shielding**<br>X-Ray Tube/ Collimator, Primary & secondary beam, Collimator, Raster, Cassettes | all | 348,000 | Reduction in unwanted X-Ray exposure &<br>X-Ray dose reduction for patient/image quality | N | To obey legal requirements all X-rays not intended to be used to generate the diagnostic image are being shielded by a layer of lead.<br>Thin strips of lead are used in x-ray beam path to reduce the amount of x-ray scatter. This enables lower x-ray doses to be given to the patient and also reduces film fogging enhancing image quality. The effectiveness of x-ray shielding is a function of the density of the material. Any very dense material (e.g. Uranium) will shield against x-ray but may have other limitations. Lead offers the only realistic compromise between mass and volume.<br>ECOMASS or some other high density polyurethane/metal matrix. Approx. 92% density of lead<br>ECOMASS would require 8% increase in size and current cost limitation is approximately an order of magnitude over lead. Alternative material is brittle and is typically cast or molded to shape and machined.<br>*See the article on Lead shielding by Hans Sethi*. |
| 2 | Conventional X-Ray | Lead | **Shielding**<br>Flat panel Image Detector &<br>X-Ray Image Intensifier and other detectors & (Well Type) Ionization Chambers | all | 55,000 | Reduction in unwanted X-Ray exposure,<br>Shielding staff from X-rays. | N | Heavy metal such as tungsten alloy is difficult to machine work, difficult to recycle, expensive (approximately 10 times higher cost). In case of iron there is a disadvantage that the size and weight of equipment also becomes large. (This is difficult on X-ray receptors where size is critical to anatomical positioning such as at the breast as well as the moving room for the doctors)<br>Increased volume of alternative has cascading effect on peripheral supports. |
| 3 | Conventional X-Ray | Lead | **Shielding**<br>(Pediatric) X-ray Filters | all | 1000 | Reduction of radiation load especially to children | N | The effectiveness of x-ray shielding is a function of the density of the material. Lead oxide offers the possibility to provide optical transparent radiation filters. |
| 4 | Conventional X-Ray | Lead | Microchannel Plate (MCP)<br>Capillary Plate (CP)<br>Image Intensifier | all | 1 | Reduction in unwanted X-Ray exposure<br>Improvement to image quality<br>Product reliability | N | The PbO, which is essential for product's characteristics, is chemically stable material in the glass and is not replaceable with other material. Disadvantage in health is expected due to the failure in reducing X-ray exposure to patient and manipulator. |
| 5 | Conventional X-Ray | Lead | X-ray test objects that are part of the equipment | IIb | 100 | Improve quality assurance | N<br>cost | Difficult to replace by any other material at appropriate cost |
| 6 | Conventional X-Ray | Lead | X-Ray tube rotating anode bearings | IIb | 1 | Bearing life | N | X-ray tubes use rotating anodes to handle the large amount of heat generated during an x-ray exposure. Anode bearings are therefore subjected to high temperatures beyond the range of normal lubricants; also they are sealed for life within the tube evacuated envelope. Routine lubrication is therefore not possible<br>. |

| | Modality | Sub-stance | Typical Application [Approx amount per product] | MDD class | Total Weight of the substance put on the EU market in Kg | Benefit | Repla-ce | Rationale |
|---|---|---|---|---|---|---|---|---|
| 6a | Conventional X-Ray | Lead | X-Ray tube glass envelope | IIb | 500 | Glass used as vacuum adhesive | N | Glass containing PbO is used as adhesive between the different glass and the metal ring. PbO serves to make the expansion coefficient of different glass correspond to that of the metal ring, enabling firm adhesion between the two to maintain a high level of vacuum without causing any mechanical strain. No other material to replace PbO in glass exists in an industrial and/or commercial scale at present. |
| 7 | Conventional X-Ray | Lead | Lead Acid Batteries | all | 135,000 | - Mobile equipment moving power.<br>- Power backup in case of power failure.<br>- Examinations can be performed at sites where no power facility is available. | Y, But costly | To provide drive electric power of sufficiently large capacity and to keep safe and steady movement. Replacement is very costly. |
| 8 | Conventional X-Ray | Lead | Counterweights | IIb | 274,000 | Counterbalance to movable heavy components to enable precise equipment positioning without patient involvement. | Y, In the future design | Some parts of an X-Ray system are heavy but have to move in order to take optimum pictures, as it may be impossible/undesirable to move the patient. Conventionally counterbalances consisted of lead to be effective with the lowest volume. Revised design solutions, and alternative approaches means lead counterweights can be eliminated over the coming years. Counterweights for balancing options (e.g. smaller or larger X-ray tube) will require significant design changes |
| 9 | Conventional X-Ray | Cadmium | High Efficiency Phosphors and radiation detectors | IIa | 3 | Used in Image Intensifier input and output screens | N, in future designs it is replaceable | Input screen - Need for high X-ray absorption and high conversion efficiency<br>Output screen – high contrast for small details |
| 43 | Conventional Xray (Bone Mineral Densitometry) | Lead | Pb (in X-ray Shielding): 2350 Kg/yr | IIb | 2350 | Meeting legal requirements | Y, 2012 | As X-rays are involved in this special application shielding of unwanted X-rays must be provided |
| 10 | Conventional Xray (Bone Mineral Densitometry) | Cadmium | Cd (in CdZnTe and CdTe): | IIa | 0.8 Kg/Yr | Image detectors for specific applications are made this way. | N | This material gives high photoelectric gain necessary for detector performance parameters. |

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|---|---|---|---|---|---|---|---|---|
| 11 | Conventional X-Ray Computed Tomography & Convent-ional Nuclear Medicine, SPECT and/or PET | Hexavalent chromium | Alkali dispensers of Photo cathode tubes and X-ray Image Intensifiers. Photocathode of Photomultiplier Tube (PMT) and Phototube (PT) | all | 1.5 kg | Forming alkali metals which are essential materials for these intermetallic photosensitive compounds | N | To take them out of the tube would necessitate a major redesign of the production process and the product, total costs estimated to be about 20M€<br>The introduction of alkali metal from the outside of the tube requires experienced know-how therefore it costs money and faces difficulty, and it becomes common knowledge among the PMT manufacturers that we built the source inside of the tube using the pellet or the sleeve.<br>Forming alkali metals utilizing chromate such as cesium chromate has been a well-established manufacturing process for over forty years. No alternative technology that is industrially and commercially practicable has been developed yet. |
| 12 | Conventional X-Ray Anesth Equipment | Mercury | Position Switches, Passive Safety Circuitry | IIa | 1 | Accurate sensing of position of imaging systems and of drug delivery systems – Known hazard for drug delivery if device is used when in a tilted position. Overdose of these drugs can lead to patient injury and death. | Y 2012 | These devices are small and by user request portable. As a result, they are subject to tilting. Accurate activation of the switch is required to prevent patient over-dose.<br><br>This product design is mature at this time, so replacement of the design will take 3-5 years. |
| 14 | Computed Tomography (CT) | Lead | **Shielding**<br>X-Ray Tube/ Collimator detector | IIb | 98,500 | X-Ray dose reduction for patient and improvement of image quality. Patient and Operator Safety. Reduction in unwanted X-Ray exposure | N | The collimator restricts the x-ray beam to the minimum necessary and thus enables lower x-ray doses to be given to the patient. It also reduces detector 'noise' enhancing image quality<br>The effectiveness of x-ray shielding is a function of the density of the material. Any very dense material (e.g. Uranium) will shield against x-ray but may have other limitations. Lead offers the only realistic compromise between mass and volume. |
| 16 | Computed Tomography (CT) | Lead | Counterweights<br>In the rotating gantry | IIb | 12,000 | Dynamic balancing of heavy, fast moving components. | Y, Future design | Some parts of a CT scanner are heavy but have to move at very high speed (a 1000 kg gantry) in order to take optimum pictures. Conventionally counterbalances have been lead to be effective with the lowest volume. Due to limited space it will be extremely difficult to replace these counterweights. |
| 17 | Computed Tomography (CT) | Cadmium | Collimators | IIb | 0.5 kg | Corrosion protection and conductive coatings, blades | Y, 2012 | Replacement materials must be rigorously tested for reliability in multi-stress high G force environments. |
| 19 | Computed Tomography (CT) | Cadmium | X-Ray detector crystals ($CdWO_4$) | IIb | 630 | Efficient and fast decay detector, reduction of radiation to the patients, improvement to image quality | N | It is impracticable to replace current detector material with the same benefits under the current state of knowledge.<br>In that case the thickness of the scintillator and the shielding must be changed. So, it is an impossible to maintain the same performance. Moreover, the after-glow effect is very important for the CT imaging quality. |

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|---|---|---|---|---|---|---|---|---|
| 21 | Convent-ional Nuclear Medicine. Single Photon Emission Computed Tomography (SPECT) and/or Positron Emission Tomography (PET) | Lead | **Shielding**<br>Raster (collimator) & Gamma Camera, Collimator, NM-Detectors, PET-Detectors<br>X-ray shielding, Scatter Shield, Source Storage | IIb | 110,000 | Improved image quality, decrease of dose to the patient and staff.<br>Detectors side and back shielding<br>Reduction in image noise by natural radiation levels gives better image quality | N | Layers of lead are used to shield all but the patient from ionizing radiation as is legally required.<br>Lead honeycomb or thin strips of lead and sometimes cadmium are used in photon path to reduce the amount of scatter. This enables lower doses to be given to the patient and also enhancing image quality.<br>No practical economical alternate solution for storage shielding of radioactive sources. Lead offers the only realistic compromise between mass and volume.<br>Detectors are sensitive to extraneous naturally occurring signals and need to be shielded from these signals to ensure only information from the region of interest is captured. |
| 22 | Convent-ional Nuclear Medicine and/or Positron Emission Tomography (PET) | Lead | NM-Counterweights | IIb | 28,000 | Counterbalance to movable heavy components to enable precise equipment positioning without patient involvement. | Y | Some parts of gamma cameras are heavy but have to move in order to take optimum pictures, as it may be impossible/undesirable to move the patient. Conventionally counterbalances have been made of lead to be effective with the lowest volume. |
| 25 | Radiotherapy Linear Accelerators | Lead | **Shielding**<br>for ionizing radiation | IIb | 43,000 kg | In addition to ionizing radiation shielding:<br>Attenuation of ionizing radiation to meet legal requirements | N | Linear accelerators must frequently fit into pre-existing hospital radiation shelters, this limitation and the clinical patient volume, determines the equipment's maximum physical envelope. Lead offers the optimal compromise between mass and volume and is present as shielding components that are readily removed and recycled. The lead is enclosed within the machine enclosure and poses no threat to human health. Any activation of the lead by the linacs high energy ionising radiation exhibits a very short isotope half life not exhibited by the potential alternatives thus reducing EOL environmental impact. Tungsten and uranium have greater impact due to more difficult extraction from the ore, the additional energy required to shape it and greater environmental impact at end of life. Lead has a positive value, which encourages recycling; the resulting material has characteristics as good as the first use. Linear accelerators are only available to professional institutions and those responsible for disposal will have a duty of care to the environment. |
| 26 | Radiotherapy Linear Accelerators | Lead | Counterweights | IIb | 9,600 kg | Counterbalance to enable equipment positioning to precisely target treatment point | Y | Linear Accelerators are heavy but have to move in order to provide optimum treatment. It is usually impossible/ undesirable to move the patient. Conventionally counterbalances have been made of lead to be effective with the lowest volume.<br>Counterweights are in principle re-used in next generation products without any effect on the environment |

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|---|---|---|---|---|---|---|---|---|
| 27 | Radiotherapy Linear Accelerators | Hexavalent chromium | Used extensively as conductive passivation coating | IIb | 1 | Optimal EMC shielding between high-energy power circuits and small control signals.<br>Optimization for the patient by a reliable delivery of treatment | Y, 2012 | Optimal EMC shielding between high-energy power circuits and small control signals.<br>Optimization for the patient by a reliable delivery of treatment<br>Conductivity of the passivation coating (EMC and low signal applications), alternatives are not nearly as good.<br>By 2012 the problem will probably be solved. |
| 28 | Multi-Source Stereotactic Radiosurgery | Lead | **Radiation Shielding** | IIb | 3,200 kg | In addition to Ionizing radiation shielding: Attenuation of ionizing radiation to meet legal requirements | N | Lead offers an optimal compromise between mass and volume and is present in shielding components that are readily disassembled and recycled. The lead is enclosed for life within the machine enclosure and poses no threat to health Lead has a positive value, which encourages recycling; the resulting material has characteristics as good as the first use. These medical devices are only available to professional institutions and those responsible for disposal will have a duty of care to the environment. |
| 29 | Brachytherapy Afterloader and Seedloader | Lead | Lead acid batteries | IIb | 2000 | power backup to preserve treatment history when mains power fails | Y 2012 | Other technology is feasible, but requires mechanical and electronic design changes |
| 30 | Radiotherapy Simulators | Lead | Lead acid batteries | IIb | 2000 | portability of system components (patient couch) | Y 2012 | Other technology is feasible, but requires mechanical and electronic design changes |

**Current Detector Developments for future ionizing radiation equipment**

| | Modality | Sub-stance | Typical Application [Approx amount per product] | MDD class | Total Weight of the substance put on the EU market in Kg | Benefit | Repla-ce | Rationale |
|---|---|---|---|---|---|---|---|---|
| 31 | Conventional X-Ray, Computed Tomography (CT)<br>&<br>Convent-ional Nuclear Medicine, SPECT and/or PET | Lead+Cadmium | Radiation detectors of different kinds (PbO, PbI2, CdTe, CdZnTe)<br><br>NM/SPECT<br>Atomic ingredient of CdTe or CdZnTe semiconductor radiation detector<br>0.6 kg per 20cm x 20cm detector | IIb | 300 kg Pb + 300 kg Cd | Improved image quality with reduced dose to patients | N | FPI(Flat Panel Imager) is regarded as the device taking over existing X-ray Image Intensifier electron tube used for medical imaging, because of its characteristic having less distortion of output image. One of the types of commercially available FPI is called indirect conversion type FPI, in which crystal film of cesium iodide with thallium additives or gadolinium oxide with terbium additives converts incident X-ray into visible light, and then photo diode array optically connected to the crystal film convert the visible light into electric charge to be read out by external electronic circuit. Because of the intrinsic property of visible light, it is inevitable that the light is scattered in the crystal film and that may result in blurred image of view.<br>On the other hand Lead+ Cadmium type of FPI is called direct conversion type FPI, in which X-ray is directly converted into electric charge by photoconductive material film.<br>Compared with existing scintillators, CdTe has such features as higher X-ray absorption rate because of its higher atomic number and higher conversion efficiency (because it is a semiconductor that can convert X-ray directly into electric signals) This indicates the superiority of CdTe as a radiation detector for high spatial resolution and high contrast imaging. These characteristics of CdTe are necessary for advanced applications.<br>Free cadmium is not used. It is bound in a stable (melting point = 1000º C) crystal CdZnTe. Similar to the Mercury in tooth fillings.<br>Recommend recovery and return of discard.<br>Small amounts of CdZnTe are required for advanced applications.<br>As described, CdTe is effective and possibly only device for low dose, short response time, improved spatial resolution and quantitative measurements as well as making compact, light weight instrumentation possible for medical radiation detection and diagnostics |
| 33 | Convent-ional Nuclear Medicine, SPECT and/or PET | Cadmium | Measurement of radiation This concerns the detection of gamma rays using a detector employing CdZnTe or CdTe. Note, however, that this is not a product at this time. | IIb | 300 kg | Possible radiation dose reduction for patient/image quality | N | A semiconductor detector that is being developed will show higher performance than the conventional detector consisting of a NaI scintillator and a photomultiplier tube. Therefore, it is possible that the dose can be reduced by reducing the amount of radioactivity administered to the patient. |
| 33 a | Proton therapy systems | Lead | Used as pure metal or in alloys such as AlCuMgPb and CuZn39Pb3 fro collimators, scatterers and modulators<br><br>~1 kg per treatment room | IIb | 100 kg | Treatment field range, neutron flux reductions, ease of machining | N | Material displays good stopping power for protons and reduces beam attenuation. This leads to a more efficient treatment |

| | Modality | Sub-stance | Typical Application [Approx amount per product] | MDD class | Total Weight of the substance put on the EU market in Kg | Benefit | Repla-ce | Rationale |
|---|---|---|---|---|---|---|---|---|
| **Non-Ionizing Radiation Equipment** | | | | | | | | |
| 34 | Magnetic Resonance Imaging (MRI) | Lead | Supercooled magnet electrical contacts Application specific materials | IIb | 6000 | To ensure the contact and improve magnet reliability | Y, To be reviewed in 2012 | Once the magnetic field is established, the magnet is effectively 'shorted' out and the established current flows in a supercooled environment (-196°C). The shorting contacts must therefore operate with lowest resistance at this temperature. The material (Wood's Material) uses lead as one of its components. |
| 35 | Magnetic Resonance Imaging (MRI) | Lead | Magnetic cooling materials Application specific materials | IIb | 100 kg | Cooling for maintaining superconductivity Components employing lead have been used in the past, and lead exhibits higher reliability as a heat sink | N (The cooling capacity and durability of materials other than lead are uncertain, and the reliability has not yet been evaluated.) | Lead is used in the refrigerator as a heat sink. Details of the process are described below.<br>Lead has excellent specific heat characteristics in the superconductive range and is easy to process (it can be shaped as required). Currently, we know of no alternative substances with similar properties<br>In the unit called the refrigerator cold head, lead is used as a heat sink in the component called the displacer.<br>(1) Helium gas supplied by the helium compressor becomes cold due to adiabatic expansion.<br>The chilled gas cools the cooling stage and the heat sink and is then returned to the compressor.<br>(2) In the next cycle, the helium gas supplied by the compressor passes through the heat sink and enters the adiabatic expansion process in precooled status, thus becoming colder than in the previous cycle. It cools the cooling stage and the heat sink and is then returned to the compressor.<br>In the cold head, the above process, in which a lower temperature is obtained by adiabatic expansion of the helium gas, is repeated to cool the cooling stage to the specified temperature. |
| 36 | Magnetic Resonance Imaging (MRI) | Lead | Lead Acid Batteries | IIb | 100 kg | Power backup in case of power failure. Examinations can be performed at sites where no power facility is available. | Y, but costly | To provide drive electric power of sufficiently large capacity and to keep safe and steady movement. Replacement is very costly. |
| 37 | Magnetic Resonance Imaging (MRI) | Cadmium | Supercooled magnet electrical contacts Application specific materials | IIb | 600 | To ensure the contact and improve magnet reliability | Y, To be reviewed in 2012 | Once the magnetic field is established, the magnet is effectively 'shorted' out and the established current flows in a super cooled environment (-196°C). The shorting contacts must therefore operate with lowest resistance at this temperature. The material (Wood's Material) uses cadmium as one of its components.<br>Woods metal will be phased out until 2012 |
| 39 | Ultrasound | Lead | General Ultrasonic transducer materials | IIa | 105 kg | Product reliability Improvement to image quality | N | No substitute substances due to the characteristics of ultrasound transmission/reception |

| | **Modality** | **Sub-stance** | **Typical Application [Approx amount per product]** | **MDD class** | **Total Weight of the substance put on the EU market in Kg** | **Benefit** | **Repla-ce** | **Rationale** |
|---|---|---|---|---|---|---|---|---|
| 40 | Ultrasound | Lead | Ultrasonic transducer crystal soldering | IIa | 6 kg | Product reliability and low cost | N | The lead-free solders require higher reflow temperatures which cause problems for performance of crystal<br>**GE**: The lead-free solders require higher reflow temperatures which cause problems for performance of crystal. *See literature.*<br>**Philips:** Most (if not all) Andover designed products use gold to gold. Most Bothell/Reedsville designs use SnPb. There are a few solderless designs and few that use Indium. |
| 41 | Ultrasound | Lead | Probe/Console Electrical connectors (e.g. PCB to cable). | IIb | 0.65 | Product reliability | Y To be reviewed | **GE**: Lead solder is a well understood technology and consequently process reliability issues are to a large extent solved. Lead free solder is a relatively unknown process and so process reliability is still being developed.<br>**Philips** Cable interconnect, if soldering is required, use SnPb. Copper shielding also relies heavily on SnPb solder and is the largest source for SnPb use in a transducer, other than PCB's |
| 44 | Incubators (life support equipment) | Lead | Oxygen sensors in the incubators | IIb | 50 | Reliability | Y, 2012 | Unreliablity can cause overheat or underheat premature babies that cannot thermoregulate themselves. Accurate oxygen measurement is critical to VLBW (very low birth weight) and ELVB (extremely low birth weight ) babies (weight less than 1500 g). |
| 45 | Patient Monitoring | Cadmium | Medical patient cables | IIa | 5 | Stabilizer for colour coded patient cables | Y, 2012 | Colour coding provides clarity and facilitates speed in hooking up patient monitoring cables to monitoring equipment. Currently no alternative exists to provide the standardized colours across all equipment use. Colour coding assures patient safety in placement of cables between equipment and patient, and proper equipment function. Colour codes are essential in emergency life support/saving situations.<br>Situation to be clarified by direct contact between expert and Mr Goodman |

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|---|---|---|---|---|---|---|---|---|
| 46 | Patient Monitoring - Includes Patient Monitoring Equipment, Life Support Systems and Diagnostic Electrocardiograph Equipment | Cadmium | Very flexible patient cables | I, IIa or IIb (accessory, depending on cable) | 50 | Reliability | Y To be reviewed in 2012 | Patient cables shall be very flexible and as thin as possible. They shall have good resistance to mechanical stresses.<br>Cadmium is used in the copper wires of the patient cables to increase flexibility and durability of the cables.<br>Current patient cables containing cadmium have been validated for their current usage. It is expected that the reliability and the lifetime of the patient cables will decrease, if cadmium is removed from the copper wires of the cables. Replacing cadmium with other substance(s) requires thorough and lengthy validation and may require redesign of the cable structures and their flex relief parts. There are several hundred different types of patient cables in use in Europe at this time.<br>In the worst case cadmium free patient cables may not immediately provide as good technical performance as current patient cables. Decreased durability of the patient cables means shorter lifetime and earlier product disposal. That will increase the amount of waste.<br>**GE Response:** "Tethered apparatus and other high flex applications utilize this alloy in certain circumstances. Current test data of substitutes is inconclusive and further testing using multiple stress factors would be required. The number of conductive wires, shielding and outer jacket materials will vary depending the application. All cable vendors have not yet introduced RoHS compatible cables and sourcing of new cable materials will take time. If successful, 2012 replacement would be reasonable |
| 47 | Patient Monitoring | Mercury | Display screens backlight | IIa | 0.1 kg | Superior customer/user interface and clarity of diagnostic information | Possible, dependant on suppliers | Used in backlights. There is no industry alternative that can provide the same performance. Currently the mercury levels are low. |
| 48 | MCG (magnetoencephalography)/MEG (magnetocardiography) | Lead | Superconducting connections in SQUID detectors | IIa | 0.1 kg | Reliability and maximum availability for clinical use. | N | A very high reliability is required for multi channel instruments where hundreds of SQUIDs have to work reliably together; repairs are difficult and very costly.<br>Lead is only possibility for the flip-chip connections. Alternative niobium wire suffers from easy oxidization and unfavourable mechanical properties, moreover it requires heat treatment. Alternatives lead to reduced reliability and reduced availability for clinical use.<br>The essential properties of lead, tin/lead and lead/indium alloys used in this application are:<br>• Superconductivity at liquid helium temperature<br>• Good ductility at liquid helium temperature<br>• Flexibility so that bonds are not damaged during cooling<br>• Easily bonded to lead/indium/gold pads, low melting point.<br>• Resistant to air oxidation.<br>Note: Aluminium is not superconducting at liquid Helium temperature of 4 K, gold is not a superconductor at any temperature. |

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| 49 | MEG (magnetocardiography) | Hexavalent chromium | Used extensively as conductive passivation coating (thicker layers, contains $Cr6^{+}$I) | IIa | 1 | Thorough EMC shielding of very small signal circuits from an electrically noisy hospital environment. Optimization for the patient by providing reliable functioning and diagnosis. | N<br><br>Y | EMC screening for the SQUID detector electronics and other outer enclosures utilise the thicker passivation coating containing hexavalent chromium because it offers reliable high surface conductivity throughout a long service life. Thorough screening is essential to protect the very small signals originating from the patients heart or brain without the use of invasive probes. It is possible that an alternative will become commercially available but it will need to be formally validated. $Cr3^{+}$ may be a candidate.<br><br>Thin passivation films are extensively used elsewhere which could theoretically contain traces of $Cr6^{+}$ but tests conducted within the industry have failed to detect any trace." The thin passivation compliance should be resolved by 2012 anyway. |
| 50 | Therapeutic apheresis | Mercury | 180mg/UV light generator set | | 0.2 kg | Activation of light sensitive drug 8-mop | N | Mercury is used in the lamp set. Specific wavelength of light required for complete and accurate treatment for severe immune mediated disease as well as cancer therapies.<br>General Comment: The rationales given can only take into account technology known to exist at the moment. Future technological developments may render some of the arguments obsolete, and this will need to be addressed at future reviews. For instance for some of the substance applications the industry proposes a review in 2012. |

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|---|---|---|---|---|---|---|---|---|
| 51 | Anesthesia Machines, Anesthesia Systems, Anesthesia Ventilators, Patient Monitoring Equipment | Cd, Hexav. Cr, Lead, PBB, PBDE | Proposal apply to the parts of the medical devices, where lead is likely to be in contact with anesthesia agent or breathing gas that can include medicinal substances.<br>The parts itself are not EEE as defined in the RoHS and WEEE directives. Note: Patient safety of the equipment in question has been tested relating to breathing gases.<br>I see that Annex G (draft IEC 60601-1-3rd) named as "Protection against HAZARDS of ignition of flammable anaesthetic mixtures" is not relevant for this RoHS issue<br>In the IEC 60601-1-3rd it is mentioned as a special category in annex G | The parts in question are as parts for Class IIb devices based on MDD | 340 kg of lead, amount of other RoHS substances is much smaller | Reliability | Y<br>To be reviewed in 2012 | Anesthesia agents are very corrosive and solvent substances.<br>Anesthesia agents and breathing gases that include medicinal substance(s) can cause very harmful chemical attacks to the materials in contact with them.<br><br>At this time Cadmium, Hexavalent Chromium, Lead, Mercury, PBB or PBDE can be in use in parts of the medical devices which are likely to be in contact with anesthesia agent or breathing gas that can include medicinal substance(s).<br>E.g. lead solder connections in gas sensors of the patient monitoring equipment are very likely to be in contact with anesthesia agent and breathing gas that can include medicinal substances. Current materials with current substances have been validated for their current usage.<br>It is not known what will happen to the materials of the parts in question, and to the reliability of the medical devices, if those substances are replaced by other substances. New materials with new substances require thorough and long validation, which takes time.In the worst case RoHS compliant materials and substances may not immediately provide as good technical performance as the older RoHS non-compliant materials and substances currently in use.<br><br>The list of chemicals is available |
| **Active Implantable Medical Devices (AIMDs)** | | | | | | | | |
| 52 | Pacemakers and brady HF devices | Lead | Electrical connections (e.g. PCB) | **AIMD** | 20 kg | Product reliability absolutely paramount | T.b.d. | Active Implantable Medical Devices (AIMDs) are highly critical devices where reliability is absolutely paramount. It is essential that the technology is well settled before changing AIMDS to RoHS compliant.<br>*See a very good article by Dr Bob Youngman of Medtronic* |
| 53 | Implantable Cardiac Ds (Rythm Management) and Tachy HF devices | Lead | Electrical connections (e.g. PCB) | **AIMD** | 760 kg | Product reliability absolutely paramount | T.b.d. | Active Implantable Medical Devices (AIMDs) are highly critical devices where reliability is absolutely paramount. It is essential that the technology is well settled before changing AIMDS to RoHS compliant |
| 54 | Pacemakers | Lead | Electrical connections between SMT components and the substrate | **AIMD** | 25 kg | Product reliability<br><br>(Patient safety) | N | Lead solder is a well understood technology and consequently process reliability issues are to a large extent solved. Lead free solder is a relatively unknown process and so process reliability is still being developed |
| **General modules and components (for many Medical Devices)** | | | | | | | | |

| | Modality | Sub-stance | Typical Application [Approx amount per product] | MDD class | Total Weight of the substance put on the EU market in Kg | Benefit | Repla-ce | Rationale |
|---|---|---|---|---|---|---|---|---|
| 55 | All Medical Equipment | Lead | Electrical connections (e.g. PCB, Flip Chip Area Arrays, connectors, wiring looms)<br>Temperature sensitive components | | 66,000 kg estimated total for all Medical equipment today. | Product reliability (Patient safety, esp. where the device controls the administration of energy and/or drugs to a patient) | Y, To be reviewed in 2012 | Lead solder is a well understood technology and consequently process reliability issues are to a large extent solved. Lead free solder is a relatively unknown process and so process reliability is still being developed. **Risks are inherently greater with immature processes and reliability is key in reducing these risks.**<br>**Other product related possible risks will also need to be evaluated to ensure that such a change does not have a negative impact on patient safety.**<br>Other electrical industries are converting to lead free and when the technology has stabilized, medical devices can make the change. Long term reliability of lead free solders in area array inside of CT rotating environment is not well understood. Conventional HAST qualification acceleration factors are not yet well understood in the area array configuration<br>**Process and product requalification (maybe even with clinical trials or at least validation) after adoption of lead-free solder will be burdensome to industry, likely requiring revised product submissions and approvals, and should not be required without a a complete understanding of the amount of time and money necessary to make this change. The costs associated with this change will result in increased product costs that will be passed onto the consumer.** (**Therefore this, should not be required before 2012**)<br>Lead-free solder processes predominantly use no-clean flux processes. This will reduce the availability of aqueous wash processes. No-clean fluxes are not compatible for high impedance analog circuit designs required by medical monitoring equipment. The no-clean flux residues generate leakage currents which will cause sensitive analog circuits to malfunction. Historical tests have shown that no-clean fluxes have caused equipment malfunctions as well as caused our products to fail our safety tests.<br>Necessary specific integrated circuits and components which are difficult to be replaced by other types not available as lead-free solder versions, conversion by semiconductor industry to lead-free processes may be slow for special low-volume components **and may require longer time-frames**."<br>As suppliers increasingly change over to lead free soldering processes, the amounts put on the market will automatically decrease strongly, possibly by 90% |
| 57 | Various equipment | Lead | optical glasses for lenses and filters | **all** | | refraction index, optical Quality Color Rendition<br>X-ray reduction to safeguard image sensor | N | Lead in glass is essential for top optical performance, this is especially important for devices that use very small lenses like endoscopes.<br>Suppliers will have to deliver RoHS compliant components |
| 57 a | Various IVD equipment | Lead | Lead in glass used to protect electrodes | **IVD** | 70 kg | Thermal expansion coefficient should match the electrode to prevent cracking of the glass | N | Only material fit for protecting this type of electrodes withstanding the sterilizing processes. |

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|---|---|---|---|---|---|---|---|---|
| 58 | Various equipment | Lead | Stabilizer in polymer (e.g. PVC) tubes (2%) | Not even specific for medical devices | 500 kg | Reliability (chemical resistance) | Y 2012 or later | Replacement is currently under review, however it is unclear whether it can be replaced in all applications in time<br>Suppliers have to do the job, not specific for Medical Device Industry. |
| 59 | Various equipment | Lead | Radiation shield for other devices, (e.g. calibration equipment with radioactive source)<br>including device protection | Not a specific medical device | 1000 kg | Reduction in unwanted radiation exposure | N | Difficult to machine work, difficult to recycle, expensive (approximately 10 times higher cost), In case of iron, there is a demerit that the size and weight of equipment also become large. In general, the X-ray shielding can be achieved by adding the heavy metal in the glass component, but it must be achieved along with the optical performance so that the use of Pb becomes essential. |
| 60 | Various equipment | Lead (PbS,PbSe) | Infrared detector crystals | Not a specific medical device | 100 kg | Improvement to image quality<br>Product reliability | N | The each band gap of PbS and PbSe is an unique for its compound at the room temperature that is an equivalent to the infrared wavelength up to 3μm and 5μm. There is no other material can be found in the market. |
| 60 a | Various sensors and electrodes | Mercury | Calomel electrodes and ion specific electrodes | IVD | 2 kg | Reference electrode, required by standard bodies | N | The only known available electrodes |
| 61 | Various equipment | Cadmium ＋Mercury (HgCdTe) | Infrared Detector crystals | Not a specific medical device | 100 kg | Improvement to image quality<br>Product reliability | N | There is no materials which could detect optical wavelength up to 25μm except HgCdTe, and it's measurement temperature limit, which means that temperature of the object to be measured, is lower than other infrared detectors. |
| 62 | Various equipment | Mercury | CRT displays,<br>LCD display backlight,<br>touch screens | Not a specific medical device | 0.4 kg | Superior customer/user interface and clarity of diagnostic information | Possible, dependa nt on suppliers | Used in backlights. There is no industry alternative that can provide the same performance. Currently the mercury levels are low.<br>Suppliers will deliver RoHS compliant screens with equal or better performance, possibly by 2012.<br>*See patient monitoring* |
| 63 | Various equipment | Hexavalent Chromium | inorganic surfaces | | 7 kg | image quality and reliability | Y, 2012 | Used to improve properties of surfaces e.g. media resistance in a clinical environment, sliding properties (friction reduction), corrosion, electromagnetic properties.<br>More time would be needed to assess and deliver a more exact estimation. |
| 65 | Various equipment | Alloy material lead | | Not specific for Medical Devices | 5000 kg | Improve material properties | N | E.g. in aluminum, steel and bronze bearing alloys. Used to improve machinability (more than 0.4%).<br>Specifically in aluminum about 5% is used for machinability |

**Research for future developments in Medical equipment**

| | Modality | Sub-stance | Typical Application [Approx amount per product] | MDD class | Total Weight of the substance put on the EU market in Kg | Benefit | Repla-ce | Rationale |
|---|---|---|---|---|---|---|---|---|
| 66 | Computed Tomography (CT) | Mercury | X-Ray detector Crystals incl. HgI | | | High photoelectric gain detectors yielding potentially high detective quantum efficiencies | | Current research for future products<br>Flexibility for innovations!<br>Wide bandgap direct conversion materials as possible high resolution direct conversion technologies. Potentially lower patient and operator radiation doses as well as lower cost detectors and energy discrimination |
| 67 | Other new technologies (e.g. molecular imaging & therapy) | Unknown | Tracers, new technologies for detectors, decrease of patient radiation at the same image quality etc | Cover letter | unknown | Enabling the new technology for improved healthcare | | An exemption should be demanded if necessary. Flexibility for innovation for better healthcare should be maintained. |