



### **Appendix 3: Remarks and additions to the required exemptions for Medical Devices**

In drafting the detailed exemption list it was assumed that including Medical Devices into the scope of the RoHS would not become effective before 2012.

The following comments apply to various situations, including those not covered in the request for exemptions.

1. High temperature lead solder (exempted)  
Request is assumed to fall under the current exemption in the RoHS directive.
2. Lead in PCBs and interconnects  
Nearly all Medical EEE contain PCBs and/or interconnects. The reliability of lead free soldering hasn't been shown in 2006 to equal that of lead solder. It is expected that for new designed products:
  - In 2012 this situation is expected to be cleared;
  - All suppliers will have changed to lead-free soldering and lead solder is unlikely to be available anymore;
  - All Medical Device manufacturers that do the soldering themselves will have adapted to lead free;
  - The Medical Device industry will have redesigned its interconnects to lead free, meeting the reliability requirements.
3. Lead in counterweights  
Lead counterweights are being used in various applications. The Medical Device industry is dedicated to design these counterweights out before 2012 for all categories of Medical EEE. Some replacements cannot be made in time, like the balancing of fast moving massive gantries like in CT scanners, option balancing and possibly some other devices .
4. Lead and Cadmium in optical glass (exempted)  
The Medical Device industry applies optical glass and filter glass with Pb and Cd. However an exemption is not considered to be required as the RoHS already has an exemption for optical and filter glass.
5. Electrical connections in supercooled (superconductive) parts explained.  
In various Medical EEE the principle of supercooling to enable superconductivity is employed. Examples are Magnetic Resonance Imaging (MRI) and MagnetoEncephaloGraphy, (MEG) and MagnetoCardioGraphy (MCG). Low resistance, high current density connections have to be realized that will function reliably at those temperatures. The conductivity of lead at extreme low temperature cannot be equaled by other low melting metals.



6. Mercury in fluorescent lamps (exempted)  
Medical Devices may employ special light sources, but it was assumed that the current exemptions for light sources with mercury include all applications in Medical EEE.
7. Lead acid batteries  
Lead acid batteries fall under the battery directive and are therefore not restricted. However, this should be safeguarded until the Medical Device Industry is able to replace the lead acid batteries without extreme cost consequences.
8. Flame retardants.  
No use of flame retardants was mentioned by the members. However, the industry should be aware of the risk of the re-use of plastics in this respect.  
Every effort is being made to only use plastics that do not contain the banned flame retardants. However we are also encouraged more and more to use recycled materials in our equipment and it will be difficult to confirm there are no banned flame retardants present in any recycled plastic components.
9. The date of July 1, 2006 in the RoHS Directive must be revised for Medical Devices if those are brought into the scope of the Directive.
10. The date put on the market for refurbished EEE is the date on which that equipment was put on the EU market for the first time. This could cause a problem with the worldwide trade in refurbished (reused) equipment.
11. The impact analysis of the European Commission should show that the Medical Device Industry will not be able to eliminate more than about 40% by weight of the restricted substances.
12. The impact analysis of the European Commission should show that the Cadmium for CT detection crystals is harmless because it is built in non-soluble crystals.
13. The impact analysis for the European Commission should show that in some cases restricted substances are intentionally used by Medical Devices, but in extremely small amounts.