



## Joint Statement of the Medical Device Industry on the ROHS Directive (2002/95/EC)

### 1. Introduction

As from 1<sup>st</sup> July 2006 the RoHS directive 2002/95/EC will restrict the use of certain hazardous substances in certain electrical and electronic equipment (EEE). Medical Devices are excluded under Article 2 "Scope", however under Article 6 "Review", the Commission is required to assess the possibility of including Category 8 in the scope of the Directive. This document has been prepared by the COCIR Focus Group Environment in cooperation with corresponding groups in Eucomed, EUROM VI, FIDE and EDMA to support the study sponsored by the European Commission. These federations represent 98% of the European Medical Device Manufacturers' market.

### 2. RoHS - the current situation of Medical Devices

- The Medical Device Industry in Europe represents 60 billion € market with 30% export share and employs 406 000 people.
- Medical Devices are currently not within scope of the RoHS Directive. This is taken to include MDD (93/42/EEC), AIMD (90/385/EEC) and IVDD (98/79/EC).
- Medical Devices frequently incorporate components and assemblies from the non-medical electrical sectors (mainly consumer electronics). By 1st July 2006 these components will either comply with the RoHS Directive or will become unavailable because there are no viable alternatives to the proscribed substances. Medical Device manufacturers must consider the implications of the substitution of the RoHS compliant components/assemblies in their Medical Devices and where this substitution is not possible, design modifications are being considered.
- Manufacturers in the process of developing new generations of devices are attempting to reduce usage of the restricted substances. However, in many cases it is proving impractical to produce a device without RoHS restricted substances *and* meet the obligation under the Medical Device Directives to provide high levels of performance and safety for patient & healthcare professionals.
- There are many Medical Devices where there are no viable alternatives to the restricted substances and these are likely to increase in costs, adding to healthcare budgets.



### 3. Rationale for exemption

Electrical and electronic Medical Devices are manufactured in relatively small numbers, however they provide significant benefits to the health of the people of the European Communities.

The Medical Devices consist of a large number of different products, including products of less than 5 grams (e.g. hearing aids) up to more than 50 tonnes (e.g. Linear Accelerators or some Magnetic Resonance Imagers)!

The Medical Device industry took voluntary initiatives to reduce its environment impact and also created the future IEC 60601-1-9 medical electrical equipment standard "Requirements for Environmentally Conscious Design".

However the vast majority of electrical and electronic Medical Devices will need to use these substances in comparatively small quantities in order to provide the degree of protection and performance required by the Medical Device Directive 93/42/EEC and standard EN ISO 14971 Medical Devices - Application of risk management to medical devices.

These documents require that the benefits outweigh the risks (including risks to the environment). The manufacturers achieve this by applying the risk management methodology across the lifecycle of a Medical Device.

Manufacturers are mindful that innovative new designs require considerable investment and time to bring them to market. Making material substitutions in critical areas of a design usually takes many years.

Future research in areas so far unknown (e.g. molecular therapeutics) will have to create breakthroughs. It is not unusual for this process to take many years. In the research mentioned the use of the RoHS restricted substances should not be forbidden up front.

When Medical Devices reach end of life, the restricted Substances will not compromise the Community objectives of protecting health and the environment as the requirements of the Waste Electrical and Electronics Equipment Directive must be complied with. The majority of these products are not available to households and will not enter the domestic waste stream. Manufacturers have a strong interest to take back as much as possible for reuse (e.g. of the 1000 tonnes lead placed on the market in medical devices, nearly all is reused).

The amount of waste that is generated from this type of equipment is relatively small. The total quantity of 12 million tonnes EEE yearly only contains about 1% Medical Devices.

Full application of RoHS without the right exemptions would cause the Medical Device Industry to significantly increase the costs of some products which would influence healthcare budgets unfavorably.



#### **4. Justifications for exemptions**

The abovementioned federations strongly believe therefore that Medical Devices, Actives Implantable Medical Devices (AIMD) and In-Vitro Diagnostic (IVD) equipment will require continued exemptions to ensure the uninterrupted availability of many current and future innovative products to healthcare in the EU.

Justifications are:

- I. Personal protection to ensure safety of patient and personnel (e.g. protection for unwanted ionizing radiation);
- II. Patient safety e.g. optimization of patient dose and reduction of stray radiation to achieve the necessary image quality;
- III. Quality of care:
  - i. Validated product reliability and stability by use of proven technology;
  - ii. Essential technologies for optimal performance, capability and quality;
- IV. Innovations/breakthroughs in all the above 3 items.

#### **5. Proposal for exemptions when Medical Devices will become part of the scope of the RoHS directive**

The Medical Device Industry always played a forerunner role in protecting the environment and will continue doing so.

In drafting the proposed exemptions it was assumed that the Medical Device Industry will continue its efforts to decrease the amount of RoHS restricted substances. In view of the assumed timetable of the process it is expected that Medical Devices will not be in the scope of the RoHS before 2012. The proposal below is therefore valid for the expected situation in 2012.



**Proposal** for exemptions, based on substance and application (detailed list in appendix 1: Summary of required exemptions)

Restricted Substance	Application
All substances	Existing product designs already on the market before the entry into force of the revised RoHS directive*
Lead	Ionizing radiation shielding
	Image Detectors
	Calibration accessories
	X-ray tube bearings in vacuum
	X-ray tube glass envelope
	Counterweights in CT gantries and options
	Optimal conductivity at extreme low temperature
	Heatsink in Stirling cooler
	Soldering of Ultrasound transducers
	Oxygen sensors
	Soldering for AIMDs In protective glass for thermal expansion reasons
Cadmium	Detectors
Hexavalent chromium	EMC shielding
Mercury	Calomel electrodes
	Detectors & Infrared detectors & breakthrough research

\* Restricted substances are part of the technological design of a product. Changing this is costly and time consuming, see chapter 3, 3<sup>rd</sup> paragraph. Specifically for the smaller manufacturers this might be an exemption with major business impact.

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*Enclosed documents:*

*Appendix 1: Summary of required exemptions*

*Appendix 2: Overview and Rationale of ROHS restricted substances in Medical Devices*

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