



Use of RoHS Substances in Medical Devices

Joint Industry Statement

1. Executive Summary

There are a number of benefits and risks which must be considered in bringing Category 8 Medical Devices within the scope of the RoHS Directive. The amount of medical electrical equipment is extremely small (less than 0.25% of the total 12 million tonnes of EEE sold annually in Europe). The environmental impact arising from the RoHS substances currently used in medical devices is also very small compared to other WEEE product categories. This must be balanced against the health and safety risks of unexpected failure of medical devices, which could cause injury or loss of life.

A small number of medical device manufacturers producing simple, less safety-critical products have succeeded in introducing RoHS compliant versions. For more complex and safety-critical equipment, the key issue concerning the timescale for potential inclusion of medical devices within the scope of the RoHS Directive is the availability of adequate field reliability data for long-term use of lead-free soldering in safety critical applications.

This impacts on gaining regulatory approval from Notified Bodies, which is required before RoHS compliant versions can be sold in the EU. In particular, to avoid conflicts between the RoHS Directive and the medical devices Directives, it is essential to ensure that adequate field data is available to validate the laboratory data from accelerated testing. Adequate field data should be available by 2012 and should be fully evaluated before lead-free solder is used in safety critical applications.

In view of this, and the length of time required for testing and validating RoHS compliant designs and subsequent conformity assessment by Notified Bodies, the medical device industry believes that the earliest date that medical devices could be included within the scope of the RoHS Directive is:

- 2014 for Medical Devices (Directive 93/42/EEC).*
- 2016 for in-vitro Medical Devices (Directive 98/79/EC), due to the complex nature of the design process.*
- Active Implanted Medical Devices (Directive 90/385/EEC) should be excluded from the RoHS Directive. The earliest date that this decision for AIMD devices is exclusion could be reconsidered is 2020.*

Finally, the medical device industry has serious concerns regarding limitations on innovation for new designs of medical devices, if inclusion in RoHS does not provide the flexibility to develop new applications of hazardous substances.

New medical devices are designed to give better and earlier diagnosis, more effective and successful treatment and completely new treatments. In some cases, the physical or chemical properties of lead, cadmium, mercury or other hazardous substances could provide a significant technical advantage that could lead to new products which are beneficial to human healthcare and safety, and where this benefit far outweighs the environmental impacts.

Innovative new designs require considerable investment and time to bring them to market. The medical device industry is concerned that a clear legal basis is needed so that the RoHS Directive does not prevent these long term investments in future potentially life-saving innovations.

A list of proposed specific exemptions is provided in section 10.

2. Introduction

Under Article 6 of the RoHS Directive 2002/95/EC, the European Commission is required to assess the possibility of including Category 8 Medical Devices within the scope of this Directive.

Under Article 5 (1) (b) the Commission is required to establish exemptions from the RoHS Directive for materials and components of electrical and electronic equipment if:

*"... their elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to in Article 4 (1) is **technically or scientifically impracticable**, or where the **negative** environmental, **health and/or consumer safety impacts** caused by substitution **are likely to outweigh the environmental, health and/or consumer safety benefits** thereof."*

This joint statement addresses the issues raised in Article 5 (1) (b) in relation to Medical Devices, and has been prepared jointly by COCIR, Eucomed, EUROM VI and EDMA. These associations represent more than 98% of the European Medical Device Manufacturing market. This document:

- Discusses the benefits and risks that need to be considered in bringing Category 8 Medical Devices within the scope of the RoHS Directive.
- Highlights that the medical device industry strongly supports environmental design and has voluntarily created a new International Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment.
- Emphasizes that the key issue concerning the timescale for potential inclusion of medical devices within the scope of the RoHS Directive is the availability of adequate field reliability data for long-term use of lead-free soldering in safety critical applications.

- Explains how this key issue impacts on gaining regulatory approval from Notified Bodies for Medical Devices. In particular, to avoid conflicts between the RoHS Directive and the medical devices Directives, it is essential to ensure that adequate field data is available to validate the laboratory data from accelerated testing. Adequate field data will not be available until 2012.
- Highlights medical device industry and DG Enterprise concerns that inclusion of medical devices within the RoHS Directive must not prevent long term investments in future potentially life-saving innovations. In some cases, the physical or chemical properties of lead, cadmium, mercury or other hazardous substances could provide a significant technical advantage that could lead to new products which are beneficial to human healthcare and safety.
- Proposes timescales for when Medical Devices could be included within the scope of the RoHS Directive, and specific ongoing exemptions that will be required beyond these dates. For example, lead is needed in X-ray and Gamma ray applications to protect personnel from harmful ionizing radiation by providing shielding and collimation of the beam to avoid scattered radiation.

3. Balancing the benefits and the risks of including Medical Devices within the scope of the RoHS Directive

The medical device industry places 30,000 tonnes of electrical and electronic equipment (EEE) on the market in Europe each year. This represents less than 0.25% of the total 12 million tonnes of EEE sold annually in Europe¹.

Benefits

Recital (5) highlights that one of the rationales for establishing the RoHS Directive was that despite the collection and recycling arrangements mandated under the WEEE Directive:

"... significant quantities of WEEE will continue to be found in the current disposal routes. Even if WEEE were collected separately and submitted to recycling processes, its content of mercury, cadmium, lead, chromium VI, PBB and PBDE would be likely to pose risks to health or the environment."

Medical devices put on the EU market each year contain about 1,148 tonnes of lead, of which 760 tonnes is used for shielding and 325 tonnes is used for lead counterweights. The shielding and counterweights are 100% recycled at end-of-life, in part because easily recyclable lead in these quantities is a valuable resource. Most of the remaining 63 tonnes of lead is reused through medical equipment manufacturers' highly efficient WEEE collection and recycling processes. It is estimated that about 9 tonnes of lead is currently used for in-vitro diagnostics (IVD) instruments. However, current design changes, particularly the transition to lead-free solder, will reduce lead consumption by 90% in the future.

Medical EEE put on the market each year also contains about 1.7 tonnes of cadmium, 8 kg of chromium VI and 12 kg of mercury.

¹ Comprises 6.5 million tonnes per year of consumer EEE and estimated 5.5 million tonnes per year of business EEE

Risks

The main reason why Categories 8 and 9 were originally omitted from the scope of the RoHS Directive was due to concerns over the reliability of certain substitute materials, in particular the long-term performance of lead-free solders. Although failure of equipment in Categories 1 to 7 and 10 is inconvenient, it does not pose a health and safety risk. In contrast, unexpected early failure of Category 8 Medical Devices can cause injury or loss of life. For example:

- Heart monitors – Failure could result in problems being overlooked with potentially fatal consequences.
- Radiotherapy equipment (cancer treatment) – The applied dose is critical; too little would be ineffective and too much is harmful. Unexpected breakdown is also harmful to patients if treatment is interrupted or delayed.
- Oxygen sensors are used in anaesthetics, intensive care and premature baby incubators to measure oxygen concentrations. Failure or inaccurate measurement could be fatal.
- Defibrillators - failure could result in death of heart attack patients.
- IVD blood analyser – failure could result in incorrect blood tests, including screening for blood borne pathogens such as HIV Hepatitis B, with resulting health consequences for the individual and the general public.
- IVD bedside diagnostics - test results are used as basis for urgent decisions in emergency cases. Failure or inaccurate diagnosis could be fatal.

Alignment with RoHS legislation in other parts of the world

There is currently no legislative pressure on medical devices to comply with RoHS-type restrictions in other parts of the world.

The Japanese RoHS labelling requirements (J-MOSS) apply to household and IT equipment. There are no plans to extend this to cover medical devices.

The California RoHS restrictions (Section 25214.10 of the Health and Safety Code) apply only to video display devices containing a screen greater than 4 inches, measured diagonally, and not to medical devices. Two recent attempts to extend the California RoHS restrictions to cover the same scope as the EU RoHS Directive were rejected. There are no plans to go beyond the current scope of the EU RoHS Directive and seek to include medical devices.

The China RoHS labelling requirements do apply to medical devices, but the Chinese Ministry of Information Industry has indicated that any subsequent material restrictions for medical devices are likely to be in line with any RoHS restrictions for medical devices introduced in the EU.

The Korea RoHS major requirements were published in April and will come into effect from 1 January 2008. The materials restrictions apply to ten specific product

categories – medical devices are not included in any of these categories. There are no plans to increase the scope of Korea RoHS to include medical devices.

Australia, Taiwan and other parts of the world have not yet introduced RoHS-type restrictions for electrical and electronic equipment.

In summary, the EU is ahead of the rest of the world in its plans for requiring Category 8 Medical Devices to comply with the materials restrictions contained in the RoHS Directive.

4. Medical Device Industry strongly supports environmental design

The medical device industry strongly supports life cycle thinking and the environmental design objectives behind the RoHS, WEEE and EuP Directives. There are many ways that companies are dealing with these environmental issues and indeed the industry sector has voluntarily created the new International Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment.

The IEC 60601-1-9 environmental design standard was published in July 2007 and enables medical device design teams to:

- Identify and prioritize the significant environmental aspects of the product across all of its life cycle phases.
- For significant environmental aspects, establish and document environmental design targets to reduce adverse environmental aspects.
- Use a risk management based approach to evaluate environmental design options.
- During the product conception and design specification phases, consider innovative emerging or alternative design technologies and/or solutions that can significantly reduce adverse environmental aspects.
- Assess the actual environmental performance of the final prototype against the environmental design targets. Any deviations from the targets must be documented for consideration in future designs.
- Identify the types and mass of packaging material(s) and, in the absence of local laws, the appropriate method for returning, recycling or disposal of the packaging materials.
- In the documentation accompanying the product, provide instructions for minimizing the product's environmental aspects during normal use and disposal at the end of life.
- List substances and materials that can be recovered and recycled from the product.

The medical device industry has extensive experience in reducing the life cycle environmental impacts of its products while maintaining safety and performance, minimizing harm and advancing healthcare performance. Examples include:

- Filmless X-ray systems
- Voluntary take-back systems (in advance and in parallel with the WEEE Directive) including refurbishment of used equipment and reuse of components
- Established procedures for risk analysis of use of hazardous substances
- Hazardous substance replacement where possible
- Extensive implementation and use of ISO 14001 and EMAS Environmental Management Systems

5. Reliability data for long-term use of lead-free soldering in safety critical applications

The key issue concerning the timescale for potential inclusion of medical devices within the scope of the RoHS Directive is the availability of adequate field reliability data for long-term use of lead-free soldering in safety critical applications.

Field reliability data

Lead-free solders have been used for many years in certain specialized products, in particular where the equipment is used at constant high ambient temperature. However, these products were used for relatively short time periods and so do not provide an insight into long-term field behavior. benign

The first products made in large numbers using lead-free solders were produced in Japan by consumer electronics manufacturers. However, consumer products tend to be in service for relatively short time periods (typically 3 – 5 years), are used infrequently (a few hours per day) and in relatively tranquil conditions experiencing only small temperature changes. No reliability issues have been published by these consumer electronics manufacturers. But this must be viewed with caution as a small increase in failure rate in these types of products may not be detected. Most consumers do not report faults that occur after warranty and older faulty products are rarely examined to determine the cause.

One Japanese manufacturer of air conditioning equipment has been using lead-free solders for more than 5 years. Some of that equipment has been used continuously during this time, and no unexpected failures due to the characteristics of the lead-free solder have been reported to date. However, this product is designed to maintain a constant temperature and therefore would have experienced only limited thermal cycling.

In summary, although there is no doubt that lead-free solders are suitable for equipment where temperature changes are small and the expected life is less than 10 years, there is up to now no field data available to confirm the reliability of equipment which is expected to operate for 10 or more years and where thermal cycling occurs.

Laboratory data from accelerated testing

Industry's experience regarding lead-free solders is improving through accelerated testing of lead-free solders. This laboratory data must be validated against real-life

field data. In 2012 sufficient field data will be available (from the large number of RoHS compliant electrical and electronic equipment placed on the market after the end of 2005) to validate the laboratory data.

The need to allow manufacturers sufficient time to carry out research before using new materials in safety critical products is illustrated by recent unexpected results on corrosion of nickel/gold PCB coatings. Nickel/gold was previously regarded as a very highly corrosion-resistant type of PCB coating and the discovery that it suffers severe corrosion in some chemical factory environments was a surprise. Corrosion of this type of coatings was not predictable and highlights that new materials can behave in unexpected ways.

6. Regulatory requirements for placing products on the EU market

There are three Medical Device Directives; the Medical Device Directive (93/42/EEC), the Active Implantable Medical Device Directive (90/385/EEC) and the In Vitro Diagnostic Medical Device Directive (98/79/EC). Before medical devices can be placed on the EU market they must comply with the 'essential requirements' of the relevant Directive. The essential requirements focus particular attention on ensuring that medical devices meet safety and performance levels, and that any risks associated with using the device are acceptable when weighed against the healthcare benefits to the patient.

Depending on the requirements of the relevant Directive and the type of EC Declaration of Conformity chosen by the manufacturer an accredited Notified Body must also examine the design of the products. For manufacturers who maintain a "full quality assurance system" to meet the international standard ISO 13485:2003, the Notified Body performs the examination by assessing the "design dossier". This technical product documentation includes details of all specifications and standards that the manufacturer has applied to design the product and the verification and validation results. The manufacturer can only apply the CE mark to the product, so that it can be sold in the EU, if the Notified Body affirms that the product conforms to the requirements of the relevant Directive.

Conformity assessment for products using lead-free solder

Where an existing product is changed in order to comply with RoHS, the manufacturer must inform the Notified Body that carried out the conformity assessment for the product. In the case of lead-free solders, the Notified Body will require evidence that the lead-free solders are equally reliable as tin/lead solders, for the proposed use and lifetime of the product. Manufacturers of the most safety critical products must provide evidence that reliability has not been negatively affected by using lead-free solders. Where any doubts remain, this could result in failure to gain approval by the Notified Body. This is particularly important for the most safety critical products such as implanted devices.

Article 2 (2) of the RoHS Directive notes that

"This Directive shall apply without prejudice to Community legislation on safety and health requirements and specific Community waste management legislation".

To avoid conflicts between the RoHS Directive and the medical devices Directives, it is essential to ensure that adequate field data is available to validate the laboratory data from accelerated testing. Adequate field data should be available by 2012 and should be fully evaluated by Notified Bodies before lead-free solder is used in safety critical applications. Accordingly, section 10 highlights that a specific ongoing exemption is required for use of lead and cadmium in specific electrical inter-connections.

Article 5 of the RoHS Directive requires the European Commission to review exemptions such as this at least every four years. When carrying out this review, the European Commission must take advice from Notified Bodies on whether the field data available in 2012 is sufficient to ensure that use of lead-free solder will enable medical devices to meet the essential safety and performance requirements in the relevant medical device Directive. In particular, if the Notified Bodies' opinion is that the field data available in 2012 is not sufficient to confirm reliability of long-term use of lead-free soldering in safety critical applications, then the European Commission must maintain this exemption until such time as adequate field data does become available.

The length of time to gain approval from a Notified Body depends on the complexity of the change and if adequate test data is available. The approval process can take a few weeks but six months is not uncommon for more complex products. Many Notified Bodies are already very busy. The increase in workload to re-approve RoHS compliant versions of all existing products would cause further delays so that, in some cases, approval could take up to one year. In the mean time, the RoHS compliant version can not be sold in the EU.

Availability of trained engineers

In addition to the time required to test and validate any required engineering design modifications the manufacturer has to compile the reliability testing data into a revised technical file, when submitting a RoHS compliant version for approval. For the most complex products, testing and validation can take 18 months or more. The number of trained engineers available to carry out this work is limited. For a manufacturer with a very large range of products, the time required to test and to validate all of the design modifications and re-submit the technical files can be very long.

7. Limitations on innovation

Limitations on innovation for new designs of medical devices are a serious concern both to the medical device industry and also for DG Enterprise, which has responsibility for Medical Devices within the European Commission.

Innovations are continually introduced into all products in all of the WEEE categories. RoHS substances are unlikely to be used in new innovations for new products in Categories 1 to 7 and 10. However, this will not have a negative effect on human health or safety – the only impact would be the potential loss of some new features on these products.

Healthcare benefits from innovative use of lead and cadmium

New innovations for new medical devices are designed to give better and earlier diagnosis, more effective and successful treatment and completely new treatments. In some cases, the physical or chemical properties of lead, cadmium, mercury or other hazardous substances could provide a significant technical advantage that could lead to new products which are beneficial to human healthcare and safety.

For example, new semiconductor X-ray detector arrays based on cadmium telluride have been introduced in the last few years. These allow a ten-fold reduction in X-ray dose – clearly a benefit to the patient and a reduction in risk to healthcare professionals. Also, the images obtained from these detectors are clearer so that earlier diagnosis is possible which improves survival and recovery rates.

Another example of a beneficial innovation is MRI and MEG scanners, which rely on superconducting connections made from lead/cadmium alloys. This enables detection of brain and heart activity by measurement of minute electrical signals using superconducting quantum interference device (SQUID) sensors. Detection of extremely weak signals also requires particularly good shielding from external interference.

These innovations, and their associated healthcare benefits, would not have been developed if the use of lead and cadmium had been excluded from research.

Clear legal basis so that RoHS Directive does not prevent innovation

Innovative new designs require considerable investment and time to bring them to market. The medical device industry is concerned that a clear legal basis is needed so that the RoHS Directive does not prevent these long term investments in future potentially life-saving innovations.

Unfortunately there are few options available within the limitations of the RoHS Directive to allow unrestricted innovation. One area where future innovations are likely to rely on lead, mercury or cadmium is in sensors, detectors and electrodes. Certainly, inclusion of Category 8 within the RoHS Directive should allow for a permanent exemption for use of lead, mercury or cadmium in this area. It is impossible to predict which other areas may also be the subject of future innovations.

8. Spare parts

Article 2.3 of the RoHS Directive excludes spare parts for the repair or refurbishment of equipment placed on the market before 1 July 2006. The EC has stated in its FAQ that this extends to spare parts for upgrading equipment because one of the aims of the WEEE and RoHS Directives is to extend the life of products for as long as possible and to avoid waste.

Amendments to Article 2.3

If Medical Devices are included in the scope of the RoHS Directive then Article 2.3 will need to be amended to reflect that the date from which Category 8 products will

be required to comply is different to the date of 1 July 2006 for Categories 1 to 7 and 10.

The wording of Article also needs to be changed to take account of temporary exemptions.

This is illustrated by the temporary exemption for lead in solders. Under this exemption, a server put onto the market in 2008 may use lead solders. Common industry practice is to manufacture spare parts (e.g. circuit boards) at the same time as the original equipment and using the same materials, particularly as some components may not be available several years later. However, if this exemption were to end in 2011, for example, and the server subsequently develops a fault, it could not legally be repaired with the (leaded) spare part made in 2008 because the current Article 2.3 only allows the use of spare parts for the repair of equipment put onto the market before 1 July 2006.

Once Article 2.3 has been amended to include any new dates for inclusion of medical devices in the RoHS Directive, it is also particularly important that Article 2.3 continues to allow non-RoHS compliant spare parts to be used to repair or refurbish equipment put on the market before the new deadline dates. Many medical devices have an average product life of at least 15 years. Any spare parts used to repair and refurbish these products must also have passed design verification and validation processes. Hence non-RoHS compliant spare parts will be required to repair and refurbish these products during their working life so that the devices maintain the required safety and clinical performance levels.

Definition of a spare part

The RoHS Directive and EC FAQ do not provide a definition of a spare part. However, official guidance to the EMC Directive² provides the following useful definition of a spare part

"any item intended to replace a defective or worn out item of apparatus, equipment or system previously placed and put into service on the EEA market"

This definition from the EMC Directive can form the basis of a definition of a spare part for the purposes of the RoHS Directive, but further discussions may necessary when 'systems' are involved.

Finally, medical devices represents about 0.25% of the total amount of EEE put on the market in the EU and the amount of medical electrical equipment which is discarded as WEEE is estimated at 0.1% of this total³. Many high value items of equipment and components are taken back by the original manufacturer (even after 15 years of service) to be refurbished and create a new medical device for a new customer. We are concerned that inclusion of medical devices within the scope of the ROHS Directive will hinder refurbishment of this high value equipment.

² Guidance to the EMC Directive, http://ec.europa.eu/enterprise/electr_equipment/emc/guides/chapsev.htm#7.4

³ Commission Contract No: 07010401/2006/442493/ETU/G4 .ENV.G.4/ETU/2006/0032 05 August 2007 title: 2008 Review of Directive 2002/96 on Waste Electrical and Electronic Equipment

9. Proposed timescales for when Medical Devices could be included within the scope of the RoHS Directive

The proposed timescales are different depending on whether the devices fall under the Medical Devices Directive (93/42/EEC), the *in-vitro* Medical Devices Directive (98/79/EC) and the Active Implanted Medical Device Directive (90/385/EEC).

Medical Devices (Directive 93/42/EEC)

This sector includes a very wide range of products mainly aimed at hospitals but also used by general practitioners and in some cases consumers themselves. Some are relatively simple products but others are some of the most complex and safety critical electronic products available, including CT scanners, PET and MRI. Medical devices often have extremely complex designs because of the number of parts which must withstand extreme operating conditions. Indeed, the operating conditions for some medical devices are often compared to the operating conditions for aerospace products in terms of the g-forces, mechanical shocks, vibrations, ionizing radiation and chemical stresses that the products undergo.

A small number of medical device manufacturers producing simple, less safety critical products have already introduced RoHS compliant versions. In many cases, these products have a relatively short life time (less than 5 years) and so concerns over adequate field reliability data for long-term use of lead-free soldering is not an issue. In other cases, the products are used in non-safety critical applications. Even in these cases, however, there are examples where there are no alternative technical solutions, like replacing lead for shielding.

Large complex products may take up to 7 years to design (usually by refining and modifying equipment from previous models) and can contain over 100,000 component parts and cost several millions of Euros. These products are safety critical and have an anticipated service life considerably in excess of 10 years.

As discussed in section 5, there is as yet no field data to confirm the reliability of lead-free equipment which is expected to operate for 10 or more years and where thermal cycling occurs. Section 6 highlights that to avoid conflicts between the RoHS Directive and the medical devices Directives it is essential to ensure that adequate field data is available to validate the laboratory data from accelerated testing. Adequate field data should be available by 2012 and should be fully evaluated before lead-free solder is used in safety critical applications.

It can take up to 18 months to test and validate complex products in order to prepare the technical file for review by the Notified Body. The length of time to gain approval from a Notified Body can take up to one year. In the mean time, the RoHS compliant version can not be sold in the EU.

In view of this, the medical device industry believes that the earliest date that Medical Devices (Directive 93/42/EEC) could be included in the RoHS Directive is 2014.

In-vitro Medical Devices Directive (98/79/EC)

In-vitro diagnostics (IVD) equipment has fundamental differences compared to equipment covered by the Medical Devices Directive (Directive 93/42/EEC). IVD

equipment has an additional level of complexity compared to other medical devices which arises from several factors that are all crucial for the analytical result:

- Interaction of the equipment with a large number of chemical and biochemical reagents, run on the instruments for detecting all different clinical parameters
- The requirement for strict temperature control of the reagents throughout the analytical processes
- Dosing and handling of patient samples and reagents
- Validation of the whole analytical process for all reagents - this can include hundreds of different reagents just on one large IVD medical devices system, as a single instrument may test multiple parameters for example infectious diseases, oncology and therapeutic drugs analysis or integrated serum (blood) analysis.

New products (which are typically developed every 10 years or so) may be quite different in their external appearance but internally changes are relatively small. The lifetime of an existing design can be from 10 to 20 years, and in some case extends beyond 20 years. Because these complex products must be very accurate and reliable, only fully tested components and circuit designs are utilised. As a result, new products commonly contain circuit designs with associated software that was developed 20 or 30 years previously.

To continue production of IVD equipment, manufacturers are forced to make life-time-buys of obsolete (non-RoHS compliant) components. It is even possible that an obsolete component will be included in the design of a new product – this would never occur in most other parts of the electronics industry.

For new products the design, test and validation can take between 3 and 8 years; 3 years for 'small simple' instruments and up to 8 years for automated large IVD analysers, and in some cases even longer is required. The validation process alone typically takes about 1.5 years because each IVD instrument is used to carry out a large number of different tests and each one must be validated after any modifications are made, and before the data is available to demonstrate safety and performance. This adds to the complexity and time taken for validation.

There simply are not enough trained engineers in the IVD sector to convert all existing product designs to RoHS compliant versions at the same time, and to prepare the technical files for review and approval. The length of time to gain approval from a Notified Body can be up to one year. In the mean time, the RoHS compliant version cannot be sold in the EU.

The IVD industry has already started a conversion process to RoHS compliant products, including reviewing current designs and implementing RoHS compliance as a design input criteria for new product designs. The impetus for this change comes from the industry's desire to meet its environmental obligations and to adapt to changes in the electronic component supply industry due to the current RoHS Directive. It has been estimated⁴ that 90% of the components used in IVD instruments will be RoHS compliant by 2012, notably in small simple instruments. It is also estimated that some of the small and less complex instruments will achieve 100% RoHS compliance by this date. However, it needs to be stressed that the

⁴ Information from EDMA inquiry to members October 2007

conversion process is so complex that not all of the IVD instruments will be RoHS compliant until 2016. In view of this, the medical device industry believes that the earliest date that *in-vitro* Medical Devices (Directive 98/79/EC) could be included in the RoHS Directive is 2016.

Active Implanted Medical Device (Directive 90/385/EEC)

Active implanted medical devices (AIMD) include heart pacemakers, defibrillators and insulin pumps. These are the most safety critical medical devices and unexpected failure can lead to death or serious injury. Hence the design cycle for new products is very long and most design modifications in new products are incremental changes to existing designs which are known to be very reliable. Typically, the time from concept to clinical trials is 6 to 8 years.

The reliability requirements for AIMD devices are very high. Field reliability data is required in order to obtain approval by a Notified Body so that these products can be sold in Europe. For AIMD products, field reliability data are normally based on field data from existing but very similar products. However, there will be no field data from lead-free versions of similar products for many years.

Until AIMD manufacturers can guarantee the reliability of lead-free solders from field reliability data such as this, it will be very difficult, if not impossible to obtain approval from a Notified Body so that these products can be sold in the EU.

In view of this, the medical device industry believes that Active Implanted Medical Devices (Directive 90/385/EEC) should be excluded for the foreseeable future from the RoHS Directive. The earliest date that this decision for AIMD devices could be reviewed is 2020.

10. Need for specific ongoing exemptions

In addition, there are a number of specific exemptions which will be essential for continued manufacturing of medical devices, after any potential inclusion of Category 8, Medical Devices within the scope of the RoHS. The substances and applications where exemptions are essential are summarised below:

- a. Lead and cadmium for specific⁵ electrical inter-connections.
- b. Lead for radiation shielding.
- c. Lead for high mass applications (e.g. phantoms and counterweights).
- d. Lead for thermal management.
- e. Lead, cadmium, hexavalent chromium and mercury for sensing and detection.
- f. Lead in piezoelectric crystals for diagnostic ultrasound transducers.
- g. Plating finishes on lead-less devices e.g. BGAs, CSPs, WLCSP, QFN.

⁵ Refer to the Final Report, ERA Technology, September 2006, Table 71, no 12 and Table 72, no 8-10

- h. Lead oxide containing glass used in X-Ray tubes (as vacuum adhesive).
- i. Lead in solders in portable emergency defibrillators, Active Implantable Medical Devices (if included into the scope), MRI Radio Frequency Coils and IVD opto-couplers.
- j. Lead in alloys to improve material properties in specific applications.

Exemptions for item (a) above are necessary until adequate field data to validate the laboratory data from accelerated testing becomes available. This will enable accurate prediction of long-term field reliability for long-term use of lead-free soldering in safety critical applications.

These exemptions are discussed in detail in the report prepared by ERA Technology⁶.

11. Cost issues

Recital (6) of the RoHS Directive does take into account economic feasibility in addition to technical feasibility as part of the rationale for ensuring that the RoHS Directive results in a significant reduction of risks to health and the environment.

RoHS conversion cost estimates from manufacturers of products in Category 1 to 7 and 10 vary from 1 to 4% of turnover. This is in line with the Regulatory Impact Assessment carried out by the DTI⁷ which estimated the RoHS conversion costs for UK companies for these Categories as:

- 180 million Euros per year annualised over 10 years for capital costs and research and development costs to comply with RoHS.
- 82 - 144 million Euros per year increased operating costs from using alternative substances to comply with RoHS after 2006.

The DTI Regulatory Impact Assessment confirmed that this represents a cost of about 2% of turnover for products in Category 1 to 7 and 10.

The EU medical device industry has a large number of SMEs (>80%) that produce small volume specialized products which can entail long development, testing and approval cycles. Depending on the particular product in question, the costs of additional product testing as well as delayed product introduction can be substantial and will reduce the benefit that new devices provide to society.

12. Conclusions

The medical device industry takes its environmental responsibilities seriously and it is in our best interests and in those of society to do so. However, this must also be done in conjunction with the development of new products and new technology that will result in improved and better healthcare for all.

⁶ Final Report, ERA Technology, September 2006

⁷ Regulatory Impact Assessment for the UK RoHS Regulations, UK Department of Trade and Industry, March 2003

The medical device industry will move towards RoHS compliance and in many instances already uses RoHS compliant components. For instance, by 2012 we could expect the majority of products in some categories such as Reusable Instruments, Single Use Devices and Technical Aids for Disabled Persons to be RoHS compliant.

The timeline that medical devices come under scope of the RoHS Directive must allow for data to show that medical products will not fail in safety critical situations.

The medical device industry requires exemptions that allow innovation that saves lives.

Like any other technology driven market, market share drives profits and market share is driven by innovation, improved patient outcomes, reduced cost of ownership, etc. To spend time retrofitting an old product is not in society's best interest when those same resources could be applied to the development of new products that offer improved capabilities and patient outcomes as a result of new technologies.

A product that is designed to be tolerant of the mechanical differences between tin-lead and lead-free from the ground up is, by definition, going to be more reliable than one which has replaced tin-lead circuitry with lead-free and still uses the same mechanical support that was designed for the tin-lead technology.

In closing, we would like to highlight that the medical device industry strongly supports life cycle thinking and the environmental design objectives behind the RoHS, WEEE and EuP Directives. For this reason the sector has voluntarily created the new International Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment. This standard drives environmental improvements in new products based on what is technically feasible and using a risk management approach to evaluate environmental design options.