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To whom it may concern

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Directive 2002/95/EC RoHS Recast proposals

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1. Background

The negotiations to recast the RoHS directive include several issues that were not originally considered as part of the European Commission's review. These include:

- Scope of equipment that may utilise the exemptions in Annexes V and VI
- Refurbished equipment and their spare parts
- Nanomaterials.

2. Annexes V and VI

ERA carried out a study in 2006 for the European Commission to determine whether medical devices (category 8) and monitoring and control instruments (category 9) could be included in the scope of the RoHS directive. This concluded that equipment in these categories could be included in scope as long as manufacturers had sufficient time to adapt and justified exemptions were granted. Additional exemptions required for these products were reviewed and those that were justified have been included in Annex VI of the Commission's proposals. ERA also considered exemptions in the RoHS directive's Annex and identified those that were needed for these sectors in table 44 of its report. These were not assessed in detail as it was known at the time that this would be subsequently reviewed in a separate study that was carried out by the Öko Institut. ERA assumed when it carried out the study for the Commission that the existing exemptions in the RoHS Annex would be applicable to categories 8 and 9 once these were included in scope.

Exemptions listed in Annex VI are not needed for equipment in WEEE categories 1 – 7 or 10 and so manufacturers of these products would not need to utilise them. However equipment in categories 8 and 9 contains identical electronic components to those used in other types of electrical equipment in addition to many special parts that are used only by these sectors. Therefore they will inevitably need many of the exemptions in Annex V as well as those in Annex VI. It has been suggested that manufacturers of category

8 and 9 equipment should formally request exemptions that they need in Annex V but this is unnecessary as the exemptions in Annex V have recently been reviewed and accepted and the applications in category 8 and 9 products are identical to those in products in other categories. To repeat this assessment would involve manufacturers and the EC in unnecessary duplication of work that has already been carried out whereas there is currently an opportunity to allow category 8 and 9 manufacturers to use the exemptions in Annex V as well as Annex VI.

Many of the exemptions in Annex V that would be required for categories 8 and 9 are for applications in commonly used electronic components. Here are three examples which illustrate this;

- **Exemption 7a: Lead in high melting temperature solders** – used in rectifiers and other power semiconductors. These are common in mains powered electrical products such as televisions, medical CT imaging and a very wide variety of other products.

- **Exemption 7c - Lead in glass of electronic components** – used in glass diodes, chip resistors, etc. These are used in most types of electrical equipment including medical equipment.

- **Exemption 6c: Lead in copper alloys** – these alloys are used in connectors, electric motors, etc. which are used in computers, washing machines, tools as well as many types of medical device.

2.1 Expiry period for categories 8 and 9

Various automatic expiry dates have been proposed for exemptions unless they are renewed. The medical industry is different to most other sectors because its products must be thoroughly tested and then submitted to a notified body for approval before any design changes can be made as required by the Medical Devices Directive. This can take several years in addition to the time required for research into replacements for a RoHS substance. As requests for exemption renewal are required at least 18 months prior to the expiry date (to guarantee a decision in time) and these need to include research data and other information that will take many months to collect, a four year expiry period is clearly far too short for exemptions applicable to medical devices (and also for any other safety critical product). Eight years should be adequate but this time is not only needed for the exemptions listed in Annex VI but would also be needed for exemptions in Annex V that are required for medical equipment. A television manufacturer can replace components almost as soon as an alternative is available whereas a medical device manufacturer is not permitted to do this until reliability and safety testing is complete and approvals have been granted. Grace periods once exemptions renewal requests have been rejected have been widely discussed but also need to be sufficiently long for medical device manufacturers to comply with the medical device directive.

3. Refurbished equipment

It has been accepted that equipment placed on markets outside the EU prior to 1 July 2006 and then refurbished and imported into EU after this date needs to comply with the RoHS directive even though the

same products placed on the EU market for the first time prior to 1 July 2006 do not need to comply. A similar situation would exist for category 8 and 9 products once these are included in scope. This was not considered by the ERA study but may have unintended consequences for healthcare in EU. The ERA study did establish that healthcare providers in the EU always have restricted budgets for new equipment and so if RoHS were to prohibit the purchase of lower priced refurbished equipment then healthcare providers would be able to replace fewer old machines each year. If for example a hospital wants to replace one old MRI (magnetic resonance imaging) and one old CT (computed tomography) machine but has funds sufficient only for one new machine, they could buy both as refurbished machines that would be far superior to the old machines they replace. If this option were no longer available, the average age of equipment in hospitals would increase. It is well established that new state-of-the-art medical equipment provides earlier diagnosis and better treatment for patients than very old equipment and so healthcare providers need to regularly update their equipment. At present, a considerable amount of refurbished equipment is purchased in the EU because doctors want a wide range of equipment but resources are always inadequate for all of their requirements. One way to update as many large items as possible is to buy refurbished equipment that is less than 10 years old. This is fairly common, for example in Germany, Spain, France, UK and on average in these countries; about 17% of MRI and CT purchases are refurbished units. EU hospitals also upgrade their MRI and CT systems by replacing parts such as magnets and tables with more sophisticated ones. The returned parts function as new and so can be used within refurbished systems that may be sold to other EU hospitals. Refurbished units are attractive as their price can be less than half that of new equipment so that twice as much old equipment can be replaced than if new equipment had to be bought. About 70% of refurbished medical equipment that is re-sold in the EU was originally placed on markets outside the EU so the majority of this could be affected by changes to the RoHS directive. COCIR has published an industry standard for refurbishment that ensures that it is safe, reliable and complies with the Medical Device Directive. This issue could be resolved by an exemption for refurbished products and their spare parts that were originally placed on the market outside the EU before medical devices are included in scope of RoHS. These same products would be excluded from RoHS if they are placed on the EU market before this date.

4. Nanomaterials

A restriction of nanosilver and carbon nanotubes has been proposed although this was not recommended by the Öko Institut study. Nanomaterials consist of very small particles which often have different properties to the same substances with larger particles. Nanomaterials are used in plastics composites with unusual properties that are used in vehicles and aircraft, food colouring, medicines, surface coatings (in paints and on fabrics), sunscreens and in lubricants. Several types of nanomaterials are also used to make and are present in electrical equipment.

Nanosilver

Nanosilver is a very effective biocide that kills bacteria and viruses and is used in antimicrobial dressings. It has been used in electrical appliances including washing machines and vacuum cleaners. In washing machines very small amounts of nanosilver are released during each wash and act as a biocide. However

the nanosilver is discharged into the waste water supply and there are concerns that if used in significant quantities could affect sewage treatment bacteria and it is toxic to aquatic life. Nanosilver is a relatively new material which is not believed to be harmful to humans with low levels of exposure although there are concerns that it is being sold on-line as a health aid and harmful effects could occur with large doses and this is where restrictions on sales may be beneficial. It is not known whether the limited quantities that are likely to be used in electrical equipment pose a risk as further research is needed. Furthermore, if it were to be restricted, there are many other biocidal substances available and many are hazardous materials, (some may be more toxic than nanosilver) and so before nanosilver is restricted, the risk from alternatives should be considered.

Carbon nanotubes

Although research is not yet conclusive, there are concerns that carbon nanotubes, originally developed in 1952, could be a carcinogen as they are very thin fibres. Some research has shown that it has an effect when inhaled slightly worse than silica which is classified as a carcinogen. Despite extensive research, carbon nanotubes so far have only a few practical uses which include brushes in electric motors and in supercapacitors. There is research into their use in displays, transistors, circuits, photovoltaic cells and as a replacement for transparent electrically-conductive ITO (indium tin oxide) coatings. Health risks from carbon nanotubes arise from inhalation and so there would not appear to be a risk in the types of materials that are used by the electronics industry (no dust). Humans may however already be exposed to carbon nanotubes as these can be produced in small quantities from flames.

Although there are few current uses for carbon nanotubes, these have huge potential including many beneficial uses in electrical equipment which could not be marketed in EU if this restriction were to be adopted. The electronics industry uses many very toxic chemicals to make its products but these are well controlled and so pose a negligible risk. Full risk assessments or impact assessments of carbon nanotubes have not been carried out and so the full impact of this proposed ban is not known. Carbon nanotubes are an expensive material and so industry will use it only if there are no alternatives. As it is classified as hazardous and there may be a small risk at the production phase if dust is created, the REACH regulations would be a better way of controlling this substance.

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ERA Technology Ltd trades as Cobham Technical Services and is an independent technical consultancy specialising in electrical equipment and environmental legislation.