RELIABILITY AND FAILURE ANALYSIS

Review of Directive 2002/95/EC (RoHS) Categories 8 and 9
- *Final Report*

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Erratum

The original report referred incorrectly on page 11, line 11 and page 248, line 7 to 90/385/EC (the Implanted Medical Devices Directive) whereas this should have been to 98/79/EC (the In-vitro Medical Devices Directive). This has been corrected in the present version.

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Executive Summary

Article 6 of 2002/95/EC (RoHS) requires the European Commission to carry out a review of this Directive and present proposals for including Category 8 and 9 equipment within the scope of this Directive. This is the final report of the study carried out by ERA Technology for the European Commission to provide the technical basis for this review process.

This report is based on the Interim Report (ERA Report No. 2006-0134) submitted to the European Commission in March 2006. Some sections are largely unchanged while others have been completely rewritten or are new. This final report takes into account comments and suggestions made at, and subsequent to, the "Experts Workshop" organised by the European Commission in April 2006 to obtain the views of Member States and other Stakeholders.

In order to amend the RoHS Directive, it is necessary to take into account the impact this would have on healthcare, safety and the environment as well as technical issues. The Lisbon Strategy of the EU aims to protect the environment as well as EU industry and employment and so these issues are also taken into account. Manufacturers have been extensively consulted as well as many other organisations.

Quantities of equipment and RoHS substances

The quantities of equipment within Categories 8 and 9 sold annually in EU and the quantities of the six RoHS restricted substances have been estimated:

Category 8 equipment	~30,000 tonnes
Category 9 equipment	~30,000 tonnes

The estimate for Category 8 is fairly accurate but it has proven to be very difficult to obtain reliable data for Category 9 because manufacturers are unclear of the scope of this Category. The best estimate for the actual quantity is about 30,000 tonnes and is probably no more than 60,000 tonnes. A total of 60,000 tonnes is approximately 1% of all electrical equipment sold annually in EU. Of the six RoHS substances, lead is used in Category 8 and 9 equipment in the largest quantities at an estimated 1414 tons with only 2.2 tonnes of cadmium, ~30 kg mercury, 800 kg of hexavalent chromium and <10 tonnes total for the two types of flame-retardants PBB and PBDE.

Reliability of substitute materials

One of the main reasons that Categories 8 and 9 were originally excluded from the scope of the RoHS Directive was concern over the reliability of substitute materials, especially lead-free solders. This was reasonable as unexpected early failure of equipment in these Categories could have serious and potentially fatal consequences. It has been prudent to wait until research has been carried out to investigate the substitute materials and develop strategies to ensure that these are not less reliable than the products manufactured using the RoHS-restricted substances. The long-term reliability of lead-free solders has therefore been extensively investigated in this study. There are five main concerns with the use of lead-free solders:

- Manufacturing defects
- Thermal fatigue
- Tin whiskers
- Vibration and effect of g-forces
- Corrosion

The risk of manufacturing defects is increased by the use of lead-free solders but most of these are well understood and should be avoidable provided that sufficient time and resources are available.

Research into thermal fatigue is not yet conclusive. Accelerated tests show that at low stress levels lead-free solders appear to be superior to their tin/lead equivalents, whereas they appear to be less reliable when stress levels are high. It is not yet possible, however, to predict the field life of equipment with sufficient accuracy for products that are used for >10 years and in hostile conditions on the basis of accelerated test data. This is because there is as yet no comparable field data for equipment made with lead-free solders as these are new materials. Estimation of field life from accelerated test data should be possible within the next five years but this is not yet possible with sufficient certainty for the most safety critical applications.

Tin whiskers occur on electroplated tin coatings such as those used on component terminations. Extensive research is beginning to show how these are produced and whisker minimisation strategies are being developed so that the risk of whiskers is very low if these are followed. Whether Categories 8 and 9 are included in the scope of RoHS will not make a significant difference to whisker risk as manufacturers of Category 8 and 9 equipment are already being forced to buy components with tin coated terminations as alternatives are not usually available.

Lead-free solders and tin-lead solders are equally reliable at low g-forces but lead-free solders have been shown to be less reliable at high g-forces in the direction perpendicular to printed circuit boards. This could affect certain types of product.

Recent research has shown that printed circuit boards made using lead-free materials can be more susceptible to corrosion than their tin/lead counterparts. Unexpectedly, it has been found that corrosion occurs to gold-coated boards and components used in the most severe environments. This work is continuing but shows that sufficient time for research should always be allowed as unforeseen behaviour such as this can occur where new materials are used and not adequately understood.

There has also been concern about substitutes for hexavalent chromium passivation coatings and so this has also been reviewed. These account for ~99% of all hexavalent chromium used in Category 8 and 9 products. However, research has been carried out with substitute materials and results to date indicate that these can be used as replacements under all conditions except those found in the most severe environments such as within chemical and petrochemical process plant.

The characteristics of Category 8 and 9 equipment

Category 8 and 9 equipment has several important differences to equipment in the other eight WEEE Categories. In general, the majority of Category 8 and 9 products are made in small numbers, are produced for long periods without modification or changes to the design, and have to be very reliable. Although some products in the other eight Categories also have these characteristics, most are made in large numbers, models are changed more frequently and failure is inconvenient but does not pose a environmental, health or safety risk.

When a manufacturer of Category 8 or 9 equipment modifies a product, they need to carry out similar activities to those manufacturers in other sectors but in addition also have to carry out extensive reliability testing, carry out validation or clinical trials and submit data to Notified Bodies for compliance with a range of Directives and industry standards. The number of trained engineers available to carry out this work is limited and so, where a manufacturer has a very large range of products, the time required to modify these to comply with RoHS can be very long. In reality, it will not be feasible to change all these products and many will be withdrawn from the EU market. It is already being shown by a small number of manufacturers that it is possible to make RoHS compliant Category 8 and 9 products but the time required is in general longer than has been required for products in the other eight Categories. For the most complex products, testing and validation can take 18 months or more and obtaining approvals under ATEX and the Medical Device Directives can take a year or more.

Manufacturers would typically replace Category 8 and 9 product designs with new models after 7 – 10 years. The cost to develop a new non-RoHS compliant product would be a little lower than the cost of development of a new RoHS compliant product, at least initially, but this difference will not be large because testing and obtaining approvals will be required for all new products and so RoHS compliance normally incurs a small cost increase. This has been the experience of manufacturers with the other eight WEEE Categories. However, if manufacturers have to modify their more complex existing products to comply with RoHS, this adds considerable costs to the amount originally spent on design, testing and authorisation as these will have to be carried out for a second time - doubling these costs during the life of the product. Moreover, since this modification will occur part way through the lifecycle of an existing design, the residual number of future sales available to support these additional costs will be less than for a new design. As the sales of many Category 8 and 9 products are fairly small, price increases will be necessary in some cases and, if these were excessive, the products would have to be withdrawn from the market with a knock on effect for users who still wish to purchase the product.

Other legislation and industry self regulation

All electrical equipment sold in the EU is required to comply with legislation based on EU Directives but Category 8 and 9 equipment needs to comply with a larger number of Directives than most of the products in the other eight WEEE Categories. Approval by Notified Bodies is required under some legislation but it may not be possible to obtain this if the reliability of Category 8 and 9 products were to be affected detrimentally, particularly for the most safety critical products. Hence, time for research, additional testing and approval by Notified Bodies will be required for equipment in these two Categories. As long as it can be satisfactorily demonstrated that reliability is not detrimentally affected and sufficient time is permitted for manufacturers to modify, test and obtain authorisation for products, there will be no conflict with other Directives.

Impact on users

The potential effect on users from the inclusion of Categories 8 and 9 in the scope of RoHS has been investigated. The impact on users will depend on how long manufacturers are allowed to comply. For diverse reasons explained in this report, manufacturers would need to increase prices or remove products from the EU market if the time allowed for compliance is too short. This is mainly due to the limitation in resources to carry out the work required and the withdrawal from sale of products where future sales were insufficient to support the required changes. The loss of product diversity would have a negative impact on users within the EU. There could also be a negative impact on healthcare if inclusion of Category 8 in the scope of RoHS were to occur too early and cause product price increases. If prices were to rise on average by 5%, this would cost EU healthcare providers €2.7 billion per annum. However, as all healthcare providers have limited budgets, this would result instead in them being able to buy fewer, or less advanced items of new equipment and this in turn would affect healthcare in EU. If, however, manufacturers have a much longer time period to comply, very few existing products would need to be modified as they could be replaced by new RoHS compliant product designs at the time when they were originally planned to be introduced to replace old models and price increases would be minimal or zero.

Exemptions

Categories 8 and 9 could be included in the scope of RoHS but new exemptions will be required. Over 40 have been reviewed but some similar requests could be combined and nine or ten will not be required beyond 2012. Several are not required as there are suitable substitutes available and others are not required as they would be covered by existing exemptions. A few requests cannot currently be justified as there is insufficient technical evidence to support them.

It appears sensible to combine all exemptions for sensors, detectors and electrodes because almost all are justified and the one that is not (Calomel electrodes) is already being phased out by manufacturers voluntarily because a superior alternative is available. There are 17 new exemptions required for Categories 8 and 9 (including one for sensors, detectors and electrodes) based on the criteria of Article 5.1 (b) of the RoHS Directive. There are an additional three that should be considered for other reasons.

A temporary exemption for lead in solders is also proposed. As sufficient certainty over the reliability of lead-free solders will not be available for another 5 years, Categories 8 and 9 could be included in the scope of RoHS without additional risk from unreliable products by allowing this exemption for as long as it is justified. It is possible that this exemption can be withdrawn before Categories 8 and 9 are brought within the scope of RoHS as this will be reviewed in 2010 (for servers, etc.) - four years after RoHS came into force.

Other issues

Scope: The scope of Category 8 is essentially clear but that of Category 9 is very unclear and will need to be clarified to harmonise interpretation. This will be essential for inclusion of Category 9 in the scope of RoHS to ensure that the single market (Article 95) requirements of the Directive are met.

Spare parts: Article 2.3 has been interpreted by the EC that spare parts for the repair, refurbishing or upgrade of products put onto the EU market prior to the 1st July 2006 are outside the scope of RoHS. This is permitted to extend the life of electrical equipment and should be extended to Categories 8 and 9 but with an appropriate adoption date.

Innovation: One issue of concern is the possibility that the RoHS substance restrictions could prevent the future development of new life saving technology. Researchers do not intentionally use toxic substances but sometimes the physics and chemistry dictates that only one material has the required properties. Under these circumstances, producers would not consider requesting exemptions because the present nine months or longer wait for an official response is too long for most research projects (which last one or two years in total) and so they would be forced to abandon this work that potentially would have been very beneficial to healthcare, the environment or safety. Moreover this protracted process, which gives only a temporary allowance to use a restricted substance, would be a sufficient reason for most to avoid even investigating potentially beneficial uses of these substances at all.

It is impossible to predict future discoveries and so there are few options for mitigating this potential problem;

i) exclude Categories 8 and 9 from RoHS or

ii) change the exemption review procedure so that it can be completed in much less time - for example less than 1 month, or

iii) permanently exclude certain areas where high innovation and high benefit is likely - e.g. sensors, detectors and electrodes.

Note that only option i) will guarantee a solution to this problem.

Conclusions

1. Most manufacturers have assumed that Categories 8 and 9 will be included in the scope of RoHS and are working towards this. It is possible to include them in the scope of RoHS but manufacturers will need sufficient time to comply and some sectors will need more time than others.

2. The date for inclusion of Categories 8 and 9 in the scope of RoHS will need to take into account the specific characteristics and requirements of Category 8 and 9 equipment. One essential characteristic of these types of products is high reliability. This could be affected detrimentally if these Categories were to be included in the scope of RoHS at too early a date. In addition, sufficient time is required for testing, validation, trials and obtaining approvals.

   Manufacturers of products in Categories 1 – 7 and 10 have had about 3½ years in which to modify their products between the date that RoHS was published and the date that it came into force. This has been sufficient time for most products in these Categories although ERA is aware of many examples where manufacturers were not be able to meet this deadline despite their best efforts.

   Products in Categories 8 and 9 require the same amount of time plus additional time for extensive testing, validation and trials, which can be as long as 2 years and then approval which can be as long as another 2 years. Therefore 6 years from the current date (mid 2006) should be sufficient for most producers of Category 8 and 9 products, but with three notable exceptions. Many will be able to comply sooner but the date chosen should be far enough into the future to allow the most complex products to be modified to comply. The three exceptions are:

   - Active implanted medical devices – These are the most safety critical of all medical devices. Early unexpected failure could be fatal. Therefore, as only a relatively small quantity of AIMD equipment is sold in EU annually and it is already excluded from the scope of WEEE, it is recommended that these products should continue to be excluded from the scope of the RoHS Directive.

   - *In-vitro* diagnostics devices – these are very complex instruments which carry out many different tests. When the equipment is modified, all of these tests have to be laboriously validated to ensure that accuracy is not compromised. The time required for IVD manufacturers to modify, validate and gain approval for all of their products is longer than for other medical devices and it will not be possible to include this sector until 2016. This provides an additional four years without significant loss of product diversity.

   - Industrial test and measurement equipment – Manufacturers in this sector typically produce a very large range of technically complex products and each is sold in relatively small numbers. Many of these products are safety critical and so require lengthy testing and approval by Notified Bodies after any modifications are made. Although most products could be converted to comply with RoHS, the additional costs of this and the limitations on availability of engineers means that many would not be modified and would have to be withdrawn from the EU market. This would have a negative impact on users. Given additional time, however, existing models would be phased out and replaced by new RoHS compliant equipment with little or no loss of product diversity. Manufacturers in this sector have requested a date of 2018. The scope of equipment within this sector needs to be clearly defined.

Recommendations

1. Include Categories 8 and 9 in the scope of RoHS from 2012 except for:

    a. *In-vitro* diagnostic (IVD) equipment - include from 2016.

    b. Industrial test and measurement instruments - include from 2016 or possibly 2018. A clear definition of these products is essential, for example:

    "Products that would normally be within the scope of European Standard EN61010-1, section 1.1 (a). This would include equipment that is normally tested to this standard even though customer requirements might result in other standards being utilised".

    c. Active implanted medical devices - exclude permanently or delay inclusion until 2020.

    The date of 2012 provides the same length of time that was made available to manufacturers of products in the other 8 Categories (i.e. from February 2003 to July 2006) plus additional time required for validation and reliability testing and subsequent approval by Notified Bodies for compliance with other EU Directives (allowing for the more complex products) and other regulations and industry requirements. Also, by 2012, up to ten of the requested exemptions will no longer be required.

2. Provide a temporary exemption for lead in solders.

    We suggest the definition:

    7.2 "Lead in solders for servers, storage, storage arrays, telecommunications network infrastructure equipment and equipment in Categories 8 and 9."

    The current exemption will be reviewed in 2010 by the European Commission and could be removed if field data (and by this time over five years of this will be available) indicates that the reliability of lead-free solders is not significantly worse than current predictions based on accelerated tests. It is possible that by 2012, this exemption will not be required and so Category 8 and 9 products could be made using lead-free solders without additional risk. The period of time allowed for this exemption after it is terminated should be considered as changing products to lead-free versions is time consuming and two years would not be unreasonable for more complex equipment.

3. Provide exemptions for the requests listed in Table 71.

   These are justified, as currently no substitutes exist. Note, however, that research is being carried out to find alternatives and so all exemptions specifically for Categories 8 and 9 should be reviewed every four years and terminated when substitutes are commercially available. The Commission will require sufficient funding for independent consideration of the technical issues in a timely manner.

4. Provide exemptions for the requests listed in Table 72 until 2012 if Categories 8 and 9 are included in the scope earlier than this date.

5. Do not provide exemptions for the requests listed in Table 73.

   There is insufficient evidence to support these requests since manufacturers have carried out only very limited research. Note that manufacturers may discover in the future that more exemptions will be required and the European Commission will need to review these when required in a timely manner.

6. Provide a permanent exclusion from scope for "Lead, mercury and cadmium in sensors, detectors and electrodes used in Category 8 and 9 equipment".

   This will provide some limited scope for innovation which is potentially hugely beneficial to health and the environment but with minimal impact in terms of the quantities of restricted substances used.

7. Clarify the scope of Category 9 within the text of the Directive.

   The scope of Category 9 is very unclear and is causing difficulties for manufacturers. WEEE registration bodies have difficulty interpreting the intended scope and different decisions are made by Member States. This inconsistency is unacceptable given the Article 95 basis of RoHS which requires the same interpretation by all EU Member States. The amended Directive should explicitly clarify the intended scope of this Category explaining what is included and, equally important, which types of product are excluded. The definition in Section 4.4 with accompanying notes may be suitable:

   "Equipment whose primary function is monitoring, control, measurement or test;

   AND is placed on the market as a finished product;

   AND is not an integral part of a large-scale stationary industrial tool;

   AND is not part of another type of equipment that is outside the scope of Directive 2002/96/EC"

Whether "laboratory equipment" that is within the scope of European standard EN61010-1:1993 should all be regarded as Category 9 should also be considered. This would have the advantage that decisions on the status of these products would be simplified although some laboratory equipment neither monitors nor controls.

8. Clarify the scope of Category 8 within the text of the Directive.

   The current scope of Category 8 is ***"Medical Devices (with the exception of all implanted and infected equipment)"***.

   This definition is broader than the scope of "electrical equipment within the scope of the three Medical Device Directives" as this also includes accessories and a few other types of equipment. An alternative definition for RoHS could be:

   "Electrical equipment within the scope of the medical device Directives (93/42/EEC and 98/79/EC) and accessories specifically designed to be used with these products"

   This is clearer than the first definition.

9. Amend Article 2(3) to ensure that equipment outside of the scope of the Directive put on the market on and after 1 July 2006 but subsequently brought within scope can be repaired or upgraded with non-RoHS compliant parts. The following wording may be suitable:

   "This Directive does not apply to spare parts for the repair and/or upgrade of electrical and electronic equipment which fall outside the scope of this Directive".

   At present if an exemption is removed, any product put on the market after the 1 July 2006 cannot be repaired using a spare part which made use of this exemption. This is clearly at variance with the intent of the Directive since it will result in equipment reaching end of life prematurely. To avoid this the following wording may be suitable:

   "This Directive does not apply to spare parts containing 'certain restricted substances' for the repair and/or upgrade of electrical and electronic equipment which fall inside the scope of this Directive where these 'certain restricted substances' were permitted to be used by an exemption when the equipment was put on the market".

10. Clarify the meaning of the following issues in the Directive to aid a harmonised interpretation across the EU and EEA. We suggest that the following would be helpful:

    a) Put on the market - make explicit that this has occurred when a product is put on the market anywhere in the EU as per the "Guide to Implementation of Directives based on the New Approach and the Global Approach" and refer explicitly to this.

    b) Provide a definition of spare parts such as that used in the guidance to the EMC Directive[7].

c) Transpose the text of Article 2.1 of the WEEE Directive into the RoHS Directive to make this understanding explicit.

d) Provide a definition of “part of” in the transposed Article 2.1 of the WEEE Directive.

e) Add the text of Article 2(3) of the WEEE Directive as a new clause in the RoHS Directive to make the explicit the exclusion of equipment intended specifically for military and national security purposes.

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List of abbreviations

AAS	Atomic absorption spectroscopy
AIMD	Active Implanted Medical Device Directive (90/385/EEC)
BGA	Ball grid array
CAASS	Copper accelerated acid salt spray testing
CCTV	Close circuit television
CLCC	Ceramic leadless chip carrier
CP	Capillary plate
CSP	Chip scale package
CT	Computed Tomography
DTGS	Deuterated triglycine sulphate
EC	European Commission
EBSD	Electron back scatter diffraction
ECG	Electrocardiogram
EMC	Electromagnetic compatibility Directive
ENIG	Electroless nickel immersion gold
EPMA	Electron probe micro-analysis
ESTCP	Environmental security technology certification program
EU	European Union
FAQ	Frequently asked questions
FOP	Fibre optic plate
FT	Fourier transform
GPSD	General product safety Directive
HASL	Hot air solder levelling (coating)
ICP	Inductively coupled plasma
IVD	*In-vitro* diagnostic (equipment)
IT	Information technology
JGPP	Joint group on pollution prevention
LVD	Low voltage Directive
MCP	Micro-channel plate
MDD	Medical Devices Directive (93/42/EEC)
MRI	Magnetic resonance imaging
PBB	Polybrominated biphenyls
PBDE	Polybrominated diphenyl ethers
PBGA	Plastic ball grid array
PCB	Printed circuit board
PDLP	Plastic dual in line package
PET	Positron emission tomography
PLCC	Plastic leadless chip carrier
PMT	Photomultiplier tube
RFI	Radio frequency interference
rms	Route mean square
RoHS	Restriction of the use of certain hazardous substances Directive
SAC	Tin silver copper (SnAgCu)
SEM	Scanning electron microscopy
SIR	Surface insulation resistance
SQUID	Superconducting quantum interference device
TCE	Thermal coefficient of expansion
WDS	Wavelength dispersive spectroscopy
WEEE	Waste electrical and electronic equipment Directive
XRD	X-ray diffraction
XRF	X-ray fluorescence

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1. Introduction

Directive 2002/95/EC on the restriction of the use of certain hazardous substances (RoHS) and the closely related Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) were published in the Official Journal on the 13th February 2003. The scope of the RoHS Directive is based on the Categories listed in Annex IA of the WEEE Directive but excludes two of these Categories:

- Category 8 Medical devices (with the exception of all implanted and infected products)
- Category 9 Monitoring and control instruments

These Categories were excluded because at the time there were genuine doubts over the reliability of certain substitute materials and products that are used within both of these Categories. Unexpected early failure of some types of Category 8 and 9 equipment could cause injury, loss of life or harm to the environment and so these Categories were originally excluded from the RoHS Directive's scope whereas unexpected failure of most products in the other eight WEEE Categories would be inconvenient but would not pose a risk to health, safety or the environment.

Article 6 of the RoHS Directive states that the Commission shall present proposals for including in the scope of this Directive equipment which falls under Categories 8 and 9 set out in Annex IA of Directive 2002/96/EC (WEEE).

The aim of the RoHS Directive is to reduce the quantity of restricted substances present in electrical waste. It is generally accepted that these six substances are hazardous and this is widely reported elsewhere and so their potential effect on health and the environment will not be discussed in this report. It should be noted that there is no direct evidence that the use of these substances in Category 8 and 9 equipment causes harm to the environment or human health and the RoHS Directive restricts these substances on the basis of the precautionary principle. Category 8 and 9 equipment are not the only uses for these materials and so the quantities used in products in these Categories have been determined in order to allow the relative impact of including these two Categories within the scope of RoHS to be determined.

New EU legislation will need to take into account the Lisbon Strategy which is a commitment to bring about economic, social and environmental renewal in the EU. This policy encourages initiatives that protect the environment but these should not be detrimental to the EU economy or jobs. An amendment to RoHS legislation should aim to protect the environment but should also consider the impact on EU industry and so the views of manufacturers and users have been sought for this review.

This final report is based on the interim report (ERA Report No. 2006-0134 submitted to the European Commission in April 2006. Comments received at the Expert Workshop on the 26th April 2006 organised by the European Commission and subsequently have been taken into account in this final report. Some subsections of the interim report are unchanged in this final report but many sections have been changed significantly.

The options open are to leave the RoHS Directive unchanged or to include Categories 8 and 9 in its scope. It is true that some of the applications for some of the RoHS restricted substances in Category 8 and 9 equipment could be replaced very soon but new legislation needs to consider all six substances, their diverse uses and the many thousands of types of equipment in these two Categories. Manufacturers of equipment within the other eight Categories have had nearly three and a half years since February 2003 to carry out research and make the changes needed to comply with this Directive by 1st July 2006. Equipment within Categories 8 and 9 is significantly different in many respects and these differences are explored in detail as part of this review in order to understand the implications of inclusion in the scope of RoHS but in particular to determine when it would be possible to include these Categories without a negative impact on environment, safety, healthcare or EU industry and jobs.

Important considerations are:

- Technology - will substitute materials pose a risk to equipment reliability and therefore negatively affect safety?
- Timing - how long do manufacturers need to comply, taking into account any reliability testing and authorisations to comply with other EU Directives that will be required for these two Categories of products?
- What would be the economic, environmental, safety and healthcare impacts of including these Categories in the scope of the RoHS Directive? The European Commission will carry out an impact assessment and data for this will be provided by this study. This will include estimates of the quantities of RoHS substances currently used in Category 8 and 9 equipment. Some of this could not be replaced, at least initially, as no substitutes exist and so exemptions would be justified.

Since the RoHS Directive was adopted and published in February 2003, manufacturers of equipment in the other eight WEEE Categories have been working towards compliance. The difficulties encountered and timescales required vary considerably. Simple consumer products that require hand soldering only can be made as RoHS compliant versions in as little as nine months. More complex equipment, especially those needing authorisations, take considerably longer and 3½ years has in a few cases been insufficient.

2. Scope of this review

Indicative examples of Category 8 “Medical devices (with the exception of all implanted and infected products)” and Category 9 “Monitoring and control instruments” are listed in Annex IB of Directive 2002/96/EC (WEEE). These subcategories are all considered in this review and are listed in Table 1 with specific examples of products which appear to be implied by these.

Table 1. Subcategories of equipment specifically listed as falling within Categories 8 and 9

No.	Categories & indicative examples	Products implied by these examples
8. Medical devices		
8.1	Radiotherapy equipment	Radiation cancer treatment using X-ray, gamma rays and electrons
8.2	Cardiology	Cardiac monitor, blood filter, ECG
8.3	Dialysis	Machines for removal of blood toxins
8.4	Pulmonary ventilators	Equipment to monitor and aid breathing
8.5	Nuclear medicine	Two main technologies; Molecular Imaging (MI) and PET scanners which uses radioisotopes. New technology combines PET with CT in one machine
8.6	Laboratory equipment for *in-vitro* analysis	Machines for the analysis of blood and many other materials
8.7	Analysers	Excludes in-vitro laboratory analysers so would include self-test analysers for blood sugar, cholesterol, etc.
8.8	Freezers	Medical freezers that comply with the Medical Devices Directive
8.9	Fertilization tests	In-vitro diagnostic test, usually as self-test units
8.10	Other appliances for detecting, preventing, monitoring, treating, alleviating illness, injury or disability	Includes X-ray imaging, ultrasound imaging, CT, MRI, endoscopes, dental equipment, pumps for controlled drug delivery, hearing aids, anaesthesia equipment, electric tools used for surgery, clinical evaluation devices, etc. (Electric wheel chairs, laboratory equipment for producing dental work, hospital beds and other electrical aids for the disabled may be borderline cases although some will be within scope)
9. Monitoring and Control Instruments		
9.1	Smoke detectors	Carbon monoxide gas detectors, possibly also fire alarm equipment, security equipment, etc.
9.2	Heating regulators	Products to control building temperature (thermostats may be used with these)
9.3	Thermostats	Temperature control, used inside buildings and for industrial process control
9.4	Measuring, weighing or adjusting appliances for household or as laboratory equipment	Laboratory analysis instruments, household and lab scales
9.5	Other monitoring and control instruments used in industrial installations (e.g. in control panels)	Equipment for measurement, testing, monitoring and control of any parameter; e.g. temperature, voltage, current, weight, flow rate, liquid level, etc.

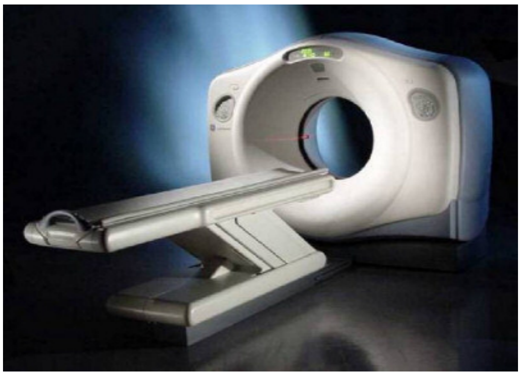
Typical Category 8 and 9 products are illustrated in Figures 1 and 2, respectively.

Endoscopy capsule – swallowed by a patient and transmits images and other data

Clinical system – has a variety of functions and monitors patient health

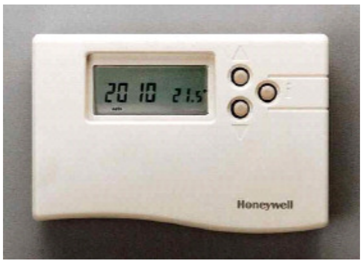
Immunoassay equipment for in-vitro diagnostics analysis

Computed Tomography (CT) Scanner



Blood pressure meter

Figure 1. Some examples of typical Category 8 products



Thermostat – timer for control of heating system

Heating regulator – fitted to heating radiators

Scanning Electron Microscope with X-ray analyser

Carl Zeiss SMT

Laboratory furnace, an example of a product which might be classified as category 9

Electrical measurement (LCR) instrument

Figure 2. Some examples of typical Category 9 products

The main tasks of this review are defined in the technical annex of the Tender Specification and are as follows:

- Provide a clear assessment and evaluation of the type and amount of the substance(s) listed in Article 4(1) of the Directive 2002/95/EC present in Category 8 and 9 products, the evaluation shall be provided for each product under the Categories;
- Provide a clear assessment and evaluation of the functionality of the hazardous substance(s) in the material for each product under the Categories;
- For each application of hazardous substances under the listed Categories, indicate substances currently available or potential substitutes under development and their level of performance. When applicable, provide a clear assessment on the possibility and an indication of the time frame for the elimination of the hazardous substance(s);
- Indicate for which applications the use of hazardous substance(s) in the products under Categories 8 and 9 need to be granted a temporary exemption with the indication of the year until which the exemption should be granted;
- Provide for each exempted application the precise definition.

In addition, other considerations that will affect Category 8 and 9 products are investigated:

- Determining the quantities (weight) of Category 8 and 9 products placed on the EU market including data for the subcategories listed in Annex IB of Directive 2002/96/EC (WEEE);
- Reliability and safety issues where these might arise from inclusion of Categories 8 and 9 within the scope of RoHS;
- The likely impact of inclusion of Categories 8 and 9 in the scope of RoHS on producers and users for example, in terms of cost or EU employment;
- Other issues such as spare parts;
- The clarity of the scope of Categories 8 and 9.

3. Characteristics of the Category 8 and 9 electronics sectors

Equipment within Categories 8 and 9 has many significant differences to products in the other eight WEEE Directive Categories. The main differences are:

a) **Products are often safety critical** – Unexpected defects can cause injury or loss of life or harm to the environment. The only other sectors of the electronics industry that have many products which are safety critical are aerospace, automotive, IT servers and telecom infrastructure, all of which do not currently have restrictions on the use of lead in solder and so do not need to use lead-free solders.

b) **Large SME involvement** – All sectors of the electronics industry have a high proportion of SMEs and Categories 8 and 9 are not an exception. It is estimated that the proportion of small to medium sized enterprises in the medical sector is at least 80% and in the monitoring and control sectors the figure is probably similar or larger. SMEs, particularly those with a large variety of products, would have much greater difficulty complying with the RoHS Directive's requirement because they do not have the necessary available resources or manpower to take on the additional tasks that would be required.

c) **EU market share is significant** - Category 8 and 9 manufacturing is particularly strong in the EU in comparison with other sectors of the electronics industry accounting for significant exports to countries outside of the EU. Eucomed has determined that the EU has 30% of the world's medical market with exports of 50 billion Euros against imports of 30 billion Euros[1]. There are no clear figures for the EU's proportion of the world's monitoring and control instrument market share but this is expected to be very significant with most manufacturers in this sector being based in EU and USA with some also in Japan. Statistics published for the UK electronics industry shows that 30% of UK electronics manufacturers produce Category 9 equipment, 18% medical devices whereas only 11% are in the consumer sector[2]. The Category 8 and 9 sectors are quite distinct from the other Categories which are dominated by Far East producers. Therefore, inclusion of Categories 8 and 9 within the scope of the RoHS Directive would have a more significant impact on EU industry than has been the case for the other eight WEEE Categories.

   If European manufacturers were forced to compete with US or Asian manufacturers in the US and in Asia, they could be at a commercial disadvantage if their non-European competitors decide to avoid the cost of changing their existing products to comply with RoHS. These manufacturers may decide to avoid the cost of designing RoHS compliant versions if their markets in Europe are relatively small, their costs in US and Asia will therefore be smaller than their European counterparts and this could potentially harm EU industry and employment. However legislation based on EU-RoHS is being introduced world-wide.

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[1] Data from Eucomed Industry Profile 2003

[2] Science, Engineering, Manufacturing Technology Alliance (SEMTA) 2003

China, Japan, South Korea, Australia and some North American States are introducing or planning to introduce their own versions of RoHS and so manufacturers who start to change their products earlier will be in a much better position to comply and this could help EU based manufacturers.

d) **Numbers of items produced is relatively small** - Although some products such as thermostats and smoke detectors are produced in fairly large numbers, the majority of Category 8 and 9 products are produced in much smaller numbers than consumer, household, IT and telecom products. In the course of this review, several examples of Category 9 products were found where less that two are sold in Europe annually and one example of a product where only one has been sold in a five-year period. The majority of Category 8 and 9 products are supplied in numbers of less than 500 in the EU annually. One of the largest medical equipment manufacturers currently sells a total of only 80,000 products world-wide annually and this includes a very large variety of different products; this is a relatively small volume compared with consumer electronics and IT where for example several million PCs are sold every year.

e) **Product diversity is great -** Unlike household and consumer products, medical devices and monitoring and control instruments are produced in a much greater variety of designs to suit customers' diverse requirements. It is not uncommon for some medium size producers of Category 9 equipment to make over one thousand different designs of product, most of which would be sold in very small numbers. The Test and Measurement Coalition has estimated that manufacturers in their sector each have on average 1600 different models in production although many are sold in very small numbers annually. This is necessary because of the diverse and specific requirements of their industrial customers. As there will be work required and costs incurred for each product that has to be modified, the impact of the RoHS Directive would be proportional to the number of different product. One large manufacturer has provided data that shows that it if they are able to modify then release for sale six of their analysis products (this includes accessories) every working day, this will take four years[3].

f) **Product lifecycle is long** – Most industrial monitoring and control instruments have much longer development cycle than the other WEEE Categories.

Particular models or designs of products can have lifetimes from 3 years or less for some consumer products and up to 30 years for complex test equipment before they are replaced by new versions.

Individual models of products sold in large numbers and some high technology medical products where innovations are incorporated in new products to maintain competitiveness are often replaced after 3 – 7 years. Test and measurement products have on average product

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[3] Private communication from Test and Measurement Coalition.

lives of 10 years before being replaced (5 to 30 years). Consumer, household, IT and telecom products are typically replaced after less than 3 years.

g) **Product lifetime is long -** Category 8 and 9 products are typically characterised by much longer lifetimes in use than consumer, household, IT and telecom products and may be used for 20 – 30 years. The lifetime for products in other sectors is quite varied. Mobile phones may be discarded by first owners after less than one year, Desktop computers become out of date within 5 years but large professional servers are designed for lives of over 10 years. Most consumer equipment is discarded after less than ten years but some products such as large household appliances typically have lives of 15 years.

h) **Product development time is long** - The development time for new Category 8 and 9 products is usually much longer than is typical for consumer and household products because of the need to ensure high reliability. Typically, consumer product development times from concept to launch are less than two years although some take less than 1 year. Typical mobile phone manufacturers will have introduced 7 new models since 2003 with no pre-2003 models on the market in 2006. The new product development time for many Category 8 and 9 products is over 4 years and can be 7 years or longer. This length of time is required for the more complex products because extensive validation and testing is required for compliance with legislation, licensing and approvals world-wide. The time taken to obtain approval (particularly for medical equipment) can take up to a year in EU and over 3 years in some Far East countries.

i) **Availability of skilled engineers and leadership of high technology markets is limited -** Most Category 8 and 9 products are technically very complex, requiring experienced engineers with highly specialised skills to develop new products or to modify existing products to comply with RoHS. The number of suitably qualified engineers available is finite and currently, within the medical and monitoring and control sectors, most are working on new product development. In some cases these new products will be close to being RoHS compliant as a significant proportion of manufacturers have decided to develop all new products as "RoHS compliant". Many other manufacturers are carrying out research into RoHS compliant processes and materials evaluation but have not yet started production of RoHS compliant products. It is clear that even if these two Categories remain excluded from the scope of RoHS, older models will be phased out over time to be replaced by an increasing number of RoHS compliant products.

   If Categories 8 and 9 are brought within the scope of RoHS, manufacturers will have to decide whether to modify older models or discontinue production. This decision will be based on the cost of changing the product to comply and the predicted future profits from the RoHS compliant versions (which could be from sales in EU only). If the future profit exceeds the cost of modification then the product could be modified, economically, and would continue to be available in the EU. However, the ability of manufacturers to carry out the very large amount of work required is limited by the number of skilled engineers that are available. In some cases there may be insufficient engineers to modify potentially profitable products in the limited time that would be available and so some potentially profitable and useful products could not be modified and so could not be sold legally in the EU, although sales outside the EU would continue. Moreover, while modification work is being carried out it may not be possible also to carry out research on new innovative products with the result that European producers in particular could lose their technological lead over their competitors. This potential problem for manufacturers is resolved by allowing sufficient time for RoHS compliance and this will need to consider those manufacturers which require the most time. Some would be able to change their entire range in less than 3 years but others which have many complex safety critical products will require much longer. This timing issue is considered in more detail later in this report.

This situation does not pertain for most products in the other eight WEEE Categories which needed to be RoHS compliant from 1st July 2006 because:

- Changing relatively simple product designs is less time-consuming;
- Many products have short product life cycles and so have been replaced by new RoHS compliant products rather than being modified. As most are not safety critical, extensive testing is not required;
- Less work is required by design engineers because usually it is possible to avoid re-designing equipment as substitute RoHS compliant versions of components (identical function) are available. This is more often possible with consumer, household, IT and telecom products as current designs of these types of products tend to use newer component types which are usually available as RoHS compliant versions. Many safety critical Category 8 and 9 products use older circuit designs with known high reliability and these inevitably include older types of components which are more often not available as RoHS compliant versions (since they are obsolete as far as the main stream market is concerned and so manufacture has been discontinued) and this therefore necessitates circuit redesign;
- There are some exceptions to the above situation where manufacturers have found that, as of June 2006the amount of work and the time required to produce RoHS compliant equipment had been considerably more than expected and many manufacturers have not met the July 1st deadline despite the best efforts.

j) **Cost of compliance is high relative to turnover** – The cost of compliance for products within the current eight RoHS Categories is not insignificant. Most manufacturers have not calculated the cost but industry estimates vary from ~1 to 4% of turnover. This increased cost arises from the need for labour (additional employees), new equipment, increased materials costs and for testing. The cost for converting a Category 8 or 9 product to a RoHS compliant version will include many fixed costs such as:

- High product complexity with high proportion of custom made parts (estimated to be 20 - 25% in some cases), all of which will have to be modified;
- Circuit redesign - a greater proportion of components used in Category 8 and 9 equipment will not be available as RoHS compliant versions than has been the case with the other 8 WEEE Categories;
- Writing new software (needed if processor chips are changed). Rewriting software is particularly expensive in terms of the effort required and is usually more time consuming than hardware redesign;
- Reliability testing (to avoid early failures and to obtain data for approvals from Notified Bodies);
- Obtaining approvals (Medical Device Directive, ATEX, etc.). For Categories 8 and 9, there is also the cost of compliance with other legal requirements world-wide which can be very significant. Manufacturers would not normally make one version for the EU and another for the rest of the world and so, when a product is changed to comply with RoHS, this would need to be re-tested and re-approved in countries that do not accept the European CE mark and this includes USA, Japan, China, South Korea, etc.

All of these will be required for each product and the cost will need to be borne by profits from future sales. For products sold in very large numbers, the cost per item will be very small and no price increase will usually be necessary. However many Category 8 and 9 products are sold in small numbers and the fixed costs will need to be financed by future sales. Therefore the impact on turnover is much greater and it is more likely that price increases will be necessary. In some cases, products would be withdrawn if costs are too high and this would negatively affect turnover and product availability to users.

The costs that would be incurred by Category 8 and 9 producers are discussed in section 9.4.

k) Product functional characteristics are diverse and technically demanding

Product complexity: The complexity of Category 8 and 9 products is very varied, with relatively simple devices like thermostats to very complex products such as Computed Tomography (CT) scanners and some types of industrial test and measurement equipment. A typical CT scanner will have over 200 PCBs containing 75,000 components and 500,000 individual solder joints.

Signal frequency: Most electrical equipment operates at relatively low frequencies, mainly at mains voltage frequency which in EU is 40 – 60 Hz. Some products however utilise much higher frequencies, in particular industrial test equipment but also telecommunications network infrastructure equipment. In Category 9, for example, instruments used to monitor the performance of high speed telecommunications need to operate at frequencies up to ten times higher than the telecom signals they are used to measure. Telecommunications network infrastructure equipment currently has an exemption for lead in solders and changing high frequency telecom equipment to lead-free technology is much more complicated than standard frequency circuits.

Design of equipment that operates at very high frequency is considerably more difficult than low frequency circuits and many components will be operating at their design limits. Therefore, an apparently small change can involve a great deal of research and may require significant design changes.

Sensitivity requirements: Several medical products rely on extremely sensitive detectors which are used to detect very weak signals. With X-ray imaging, manufacturers aim to reduce X-ray dose to patients but this is possible only with new types of very sensitive X-ray detector. It is possible to detect brain and heart activity by measurement of minute electrical signals using superconducting quantum interference device (SQUID) sensors. Detection of extremely weak signals requires particularly good shielding from external interference.

l) **Use of "life-time-buy" components affects product diversity** - Manufacturers of equipment in Categories 1 - 7 and 10 always try to use freely available components. However components do eventually become obsolete as these are replaced by new technology. It is clear that the introduction of the RoHS Directive has accelerated this trend and is causing difficulties to these manufacturers as can be seen from the large number of requests to the European Commission for a temporary exemption which would allow stocks of obsolete components to be used instead of becoming waste. Producers of Category 8 and 9 equipment are also affected by the recent increase in the number of components being made obsolete and because of the technical difficulty and high cost of re-design more often opt to buy sufficient components to last the life of their products. Category 1 – 7 and 10 manufacturers try to avoid life time buys if at all possible but producers of Categories 8 and 9 equipment are more often forced to buy components before they become obsolete because of the much longer time period that individual models are produced which can be up to 30 years. Continued production is sometimes possible only by use of "life-time-buys" of obsolete components. However these older parts will usually contain lead and so could not legally be used in "RoHS-compliant" products.

Category 8 and 9 products also frequently contain unique components and materials that are not used in products within the other 8 Categories. These are often produced as a short special production run in sufficient numbers for the life of the product. If these contain a RoHS-restricted substance, they could not be used in RoHS-compliant products but no compliant substitute will be available. Industry estimates are that 10 to 25% of components in Category 8 and 9 products are unique to these Categories. Most Category 8 and 9 manufacturers consulted as part of this review were not in favour of an exemption for "life time buys" specifically for these Categories as, with sufficient time to comply, such an exemption would be unnecessary. If the date that Categories 8 and 9 is included in the scope of RoHS is too early then a "life time buy" exemption might be justifiable to avoid having to scrap components that cannot be used.

m) **Conflicting customer requirements -** Some Category 9 products are sold to industrial users in Europe but are also used by military, marine and aerospace customers. Frequently the military and aerospace users will not accept changes to these products and insist that tin/lead solder continues to be used. Products of this type are usually produced in small numbers and so it would be uneconomic to manufacture both a RoHS compliant version and a non-RoHS compliant version. These products would therefore be unavailable to either industry or to military/aerospace and producers will lose sales. This situation is very rare in the other eight WEEE Categories.

n) **Use of military components -** A few manufacturers have reported that they are able to manufacture state-of-the-art equipment by utilising novel components that are manufactured predominantly for military customers. These components are not RoHS compliant and the suppliers will usually not be willing to modify these parts if their military customers do not accept these changes.

o) **Legislative, qualification and approvals requirements are more onerous** – Equipment in Categories 1 - 7 and 10 must comply with EU legislation such as EMC (Electromagnetic Compatibility), LVD (Low Voltage Directive), GPSD (General Product Safety Directive), etc. Category 8 and 9 products also have to comply with these Directives but are also required to comply with additional legislation and in some cases also stringent customer qualification requirements. Medical devices must comply with the EU Medical Device Directives and the corresponding regulations in other countries where these products are sold. As production of different designs for each market is both impractical and uneconomic, manufacturers would have to obtain approval in all countries that they operate if they change their equipment to comply with the RoHS Directive. Obtaining approval in the EU can take up to two years (e.g. for ATEX compliance) and longer for Medical Devices in some Far East countries. Manufacturers need to obtain approval for all new products but this is a significant extra cost where existing models need to be re-designed. Due to the length of time this can take, in some cases this would not be worthwhile resulting in lost sales.

To illustrate the differences between specialist industrial equipment and mass-produced consumer products, data provided by manufacturers of industrial test equipment is used to show the difference between their products and mobile phones as an example of a product made in very large numbers. This is shown in Table 2.

Table 2. Comparison of industrial test equipment with mobile phones

Characteristic	Test equipment	Mobile phone
Typical numbers sold	350	5.5 million
% of pre- 2003 products on market in 2006	>80%	<1%
Number of current distinct models per manufacturer	1600	300
Number of engineers available for each product	1.9	61.6
Time between launch of one product and its replacement	7 years on average	~ 6 months
Custom made parts	~25%	<5%
Time required for reliability testing (average per model)	4.3	0.7
Authorisations	Up to 2 years	< 6 months

Data from the Test and Measurement Coalition.

4. The scope of products within Categories 8 and 9

The RoHS Directive is an Article 95 Directive and so it is important that the scope of this Directive is clear and is interpreted in the same way in all 25 EU Member states and EEA members. In the course of this review, it has become clear that the interpretation of the scope of Categories 8 and 9 by WEEE registration bodies in EU Member States is not consistent. Variations in scope of the WEEE Directive in EU States may be acceptable as this is an Article 175 Directive, but this is not acceptable for RoHS. Many manufacturers are unclear as to the status of their products, especially those that are used in industrial installations.

4.1 Scope issues affecting Category 8

Useful and recognised definitions of Medical Devices are given in the Active Implanted Medical Device Directive (90/385/EEC), the Medical Devices Directive (93/42/EEC) and the *in-vitro* Medical Devices Directive (98/79/EC). Manufacturers are familiar with these Directives and no concerns over their scope have been reported. Neither the WEEE nor RoHS Directives refer to any of the three Medical Device Directives as definitions of Category 8, "Medical Devices", and so the scope of Category 8 would be larger than the scope of the electrical products in these three Directives.

Medical Devices as defined by the WEEE Directive could be defined as:

"Equipment that meets Article 3(a) of the RoHS Directive AND is within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC"

or by the different (broader) scope

""medical devices" as defined by the WEEE Directive."

Most medical equipment manufacturers are happy with the current broader definition and rarely have difficulties determining the status of products.

Using a definition for Category 8 as "Medical Devices" could be seen to include ancillary products and accessories that are not within the scope of the medical device Directives although they may be sold with a medical device. It is less clear if this definition would include, for example, tools used to manufacture dental implants and self-contained machines that manufacture drugs, both of which may also be regarded as being in Category 6 of WEEE – electrical and electronic tools. Electrical veterinary equipment are outside the scope of these three medical device Directives but might be regarded as being in Category 8 if the broader definition is used. This issue is simplified by the inclusion of Category 8 and 9 within the scope of RoHS as these products will need to comply irrespective of which Category they are in.

An example of a product which is not within the scope of the Medical Device Directives but is used with a "medical device" as an accessory is equipment that records data from insulin pumps used by pregnant women. The recorded data is periodically downloaded by doctors who use this to optimise the pump settings. The reliability of this device has to be as good as that of the insulin pump and it is supplied as an accessory to the pump. Guidance to the medical device directives[4] states that accessories that are intended to have a "medical purpose" are themselves medical devices. This example of a data recorder does not however have a "medical purpose" and so would not be within the scope of Directive 93/42/EEC. Its status could therefore be interpreted as being within Category 3 of WEEE, not Category 8, but this needs to be clear and the same interpretation used in all EU Member States.

Category 8 of the WEEE Directive excludes "infected products" and "implanted products". The status of these and certain other products within the scope of RoHS will need to be clarified before inclusion of medical devices within the scope of RoHS.

Industrial installations

Despite speculation, there is no exclusion for industrial installations in the WEEE or RoHS Directives. Industrial installations are not referred to in either Directive but are an important issue with the EMC Directive (2004/108/EC) although these installations are included within the scope of this Directive. Most medical devices could never be referred to as "industrial installations" but some may be regarded as fixed installations which are discussed below.

Infected products

Annex IA of the WEEE Directive defines the scope of Category 8 as "Medical devices (with the exception of all implanted and infected products)". This is because infected medical products pose a safety risk to personnel involved with disposal of these products at their end of life. Therefore, if it is not permissible, practicable or desirable for medical staff (the last user) to disinfect these products then they are generally required to be incinerated and so cannot be recycled.

However, it should be realised that new equipment is not infected initially- it only becomes so during use. It is therefore feasible to include products within the scope of the RoHS Directive that are likely to become infected during use since the presence or otherwise of the RoHS restricted substances is a separate issue from that of appropriate disposal. Note that, as the scope of the RoHS Directive is based on the Categories of the WEEE Directive, this could create an anomaly which might lead to confusion.

Implanted products

Active implanted medical devices are defined by the AIMD Directive (90/385/EEC). The definition is clear and could be used to define implanted products that would be outside of the scope of WEEE and therefore also outside the scope of RoHS (if its scope is based on the WEEE Directive Categories). However, as with infected products, these are implanted during use and are not

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[4] "Guidance relating to the Application of: The Council Directive 90/385/EEC on Active Implanted Medical Devices the Council Directive 93/42/EEC on Medical Devices MEDDEV 2. 1/1 April 1994

implanted when new. It is reasonable to exclude implanted products from WEEE as these are usually not recoverable when the patient dies and in any event, if removed, would be an infected product. It would be technically possible, however, to include these products within the scope of the RoHS Directive as long as their reliability is unaffected. The main question is whether this is technically possible or necessary. Implanted medical devices include products which pose the highest risk to life if failure occurs and includes products such as heart pacemakers, defibrillators and insulin pumps. High reliability is essential for all medical devices but the impact of failures is highest with products that are implanted and so it would be advisable not to impose restrictions until there is no possibility that this will affect reliability. One of the widely publicised examples of product failures due to tin whiskers (see section 8.2) was in heart pacemakers[5] although this was many years ago before tin whiskers were understood.

4.2 Scope issues affecting Category 9

The scope of Category 9 is less clear to manufacturers than that of Category 8 and is being interpreted in different ways by WEEE registration bodies and RoHS enforcement authorities across the EU. A large proportion of products that "control" or "monitor" and are installed in industrial installations or in commercial buildings and as such may be outside the scope of Category 9 of the WEEE Directive if these are defined as being "part of the building" and therefore a "fixed installation" although the original intention is unclear. Clearly, products that "measure, monitor or control" and which are designed for use by consumers, use in laboratories, workshops, etc. and as freestanding and self-contained equipment, will be within Category 9. However, many Category 9 products are attached to walls, floors or ceilings. This in itself does not affect their status, for example, WEEE Annex IB includes "smoke detectors" and these will always be used attached to a ceiling or wall.

Annex IB of Directive 2002/96/EC includes a list of indicative examples of Category 9 products. However, these examples are in some respects ambiguous and some contradict other parts of the WEEE and RoHS Directives or the way they are being interpreted. This has led to much confusion within the electronics industry and different interpretations by WEEE registration bodies and Member State governments.

Smoke detectors: These are always attached to a wall or ceiling. Self-contained units which are battery powered and include an audible warning are widely used in households. Also available are smoke detectors which are also self-contained units but are always connected to a fire detection system. These smoke detectors detect smoke and send a signal via cables or wireless connections to a control unit. The detectors do not include an audible warning capability as a typical system includes a klaxon, warning lights, actuator switches and a central control panel. These may also have telecommunications links to the fire service. Also, more than one detector may be included in one system. These "systems" are installed in households and in commercial buildings and they may be installed in a building when it is constructed or into an existing structure.

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[5] Report from US FDA http://www.fda.gov/ora/inspect_ref/itg/itg42.html, 1986.

Some Trade Associations and WEEE registration bodies have decided that these systems, and therefore their component parts, are outside the scope of the WEEE Directive because they are "part of another type of equipment that is not one of the WEEE Categories (Article 2.1 of WEEE)" - the "other type of equipment" being the building. Some WEEE registration bodies also interpret these as part of buildings and so outside the scope of WEEE, whereas most interpret these as being within the scope but the original intended scope of this Directive is not known.

Heating regulators: These range from relatively simple, self contained units that regulate temperature to more complex custom-built units installed in a control panel. Both types are always used with other equipment as part of a system. In buildings, these control the temperature but other types are also used to control industrial process temperatures. According to the EC's FAQ guidance[6], industrial processes are large-scale stationary industrial tools and so regulators used within these are outside the scope of WEEE. If buildings are "another type of equipment" that is outside the scope of WEEE, the building heating regulators may also be outside the scope of these Directives. On this basis, heating regulators would be entirely outside the scope of the WEEE Directive. Clearly this cannot be a correct interpretation since "heating regulators" are listed in Annex IB and so are considered as included in Category 9.

Thermostats: Thermostats regulate temperature and so could also be called heating regulators. Thermostats are usually attached to a wall of a building to control the local temperature by controlling heating or air conditioning equipment. These are self-contained units, attached to a wall and usually powered by and connected to the heating system. These are essentially a part of (a component of) the heating or air conditioning system and some EU WEEE registration bodies have decided that these are outside the scope of WEEE. In Holland, only battery powered thermostats are regarded as being within the scope of WEEE whereas other States have different views. As a component, the RoHS status of the thermostat should depend on that of the equipment in which it is installed. For example, if it were installed in a self-contained air conditioning unit, it will be Category 1. This situation is far from clear and needs clarification as to the intended interpretation. Clearly inclusion in Annex IB of WEEE implies that thermostats are in the scope of Category 9.

Measuring, weighing or adjusting appliances for household or as laboratory equipment: This indicative example includes a broad range of self-contained products that are used either in households or laboratories. The categorisation of "scales" is ambiguous as they are included in Category 2 as well as in Category 9 as weighing appliances but these are the same product. There are also possible misinterpretations within the laboratory equipment industry. Manufacturers and distributors of laboratory equipment frequently assume that all electrical products used in laboratories are within Category 9. However, many of these products do not monitor, control, measure, weigh or adjust as their main function and may be included within other Categories or the scope of Category 9 should be clarified to include them. For example, equipment used to prepare samples of rock by grinding for subsequent analysis is a better fit with Category 6 since it carries out a physical operation similar to the other indicative examples in this Category. Presumably this could be viewed as a laboratory "adjusting" appliance as it alters the size of particles.

The status of some products is even less clear. For example, a laboratory oven fits

- Category 9 - as it controls and monitors temperature, and
- Category 6 - as it heats materials to change their properties,
- and, according to some, Category 1 despite the fact the specification of and market for a laboratory oven is generally quite unlike that of a household appliance - the term “household” being arbitrarily ignored.

Inclusion of all “laboratory equipment” within Category 9 would simplify interpretation as well as including some products that do not fit into any of the WEEE Categories. One suggestion is that all “laboratory equipment” that is within the scope of European standard EN61010-1:1993 should all be regarded as being in Category 9. However, if Categories 8 and 9 were included in the scope of RoHS, this issue would be less important as these products would need to comply with RoHS irrespective of categorisation.

Other monitoring and control instruments used in industrial installations (e.g. in control panels): As with the other nine Categories in Annex IB, this phrase was probably intended to include all other products that are not encompassed by the previous indicative examples. However, most equipment used in industrial installations (including process control panels) is part of large-scale stationary industrial tools that match the definition in the EC’s FAQ guidance. Therefore, this indicative example and the definition of large-scale stationary industrial tools could be viewed as being contradictory. Many manufacturers consulted during this review were unclear whether industrial process control products were in Category 9 or outside the scope of WEEE as part of a large-scale stationary industrial tool. Also, manufacturers are finding that different interpretations are being made by WEEE registration bodies, Member State governments and enforcement authorities for process control instruments that are used in control panels.

Moving beyond the Annex IB examples, there are several types of product (some of which monitor or control) which manufacturers believe are outside the scope of both the WEEE and RoHS Directives. This is based on interpretations and is not always clear and it would be useful to all parties to clearly define these excluded products.

Large-scale stationary industrial tools: The EC has published guidance on the scope of the WEEE and RoHS Directives which defines “Large-scale stationary industrial tools” (LSIT)[6]. This guidance is being interpreted by examples of LSIT such as factory production lines, chemical manufacturing plant, oil refineries, oil drilling platforms, water treatment works, etc. Any equipment that forms an integral part of an LSIT would not be within the scope of the WEEE or RoHS Directives. Portable products that can be used at other locations or have a function not related to the LSIT may however be within the scope of WEEE and RoHS. For example, a handheld portable thermometer is a Category 9

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[6] Frequently Asked Questions Guidance http://europa.eu.int/comm/environment/waste/pdf/faq_weee.pdf , February 2006

product but a temperature sensor permanently installed in a process tank would be a component of an LSIT and so outside the scope.

Whether LSIT should be within the scope of RoHS is not within the remit of this review. However, many manufacturers of products that have monitoring, measurement or control functions are finding that some products are used by their customers in applications where they will be defined as being in Category 9 and other customers use the same products in a way that they are LSIT components. There are also examples where these parts may be used as components within products in other WEEE Categories. Frequently, manufacturers do not know what their customers do with their products and so this causes difficulties for them in estimating quantities placed on the EU market for WEEE registration and also in providing data for this review.

Another ambiguity identified is the status of control panels that are part of LSIT. A production line, for example, will be controlled from a control panel (e.g. controlling conveyer speed, temperature etc.) and this is seen as an integral component part of the LSIT by most WEEE registration bodies but some have decided that these are Category 9 products. This may be because one of the indicative examples in Annex IB of WEEE is "other monitoring and control instruments used in industrial installations (e.g. in control panels)". The latter interpretation appears to be in conflict with the exclusion (from Category 6) of LSIT.

Products that are part of another type of equipment that is outside the scope of the WEEE Directive: Article 2.1 of Directive 2002/96/EC (WEEE) states that any equipment is within its scope provided that it is not part of another type of equipment that is outside the scope of this Directive. Although this phrase is not included in Directive 2002/95/EC (RoHS), the European Commission's legal services have stated that this definition also applies to the RoHS Directive. The European Commission's FAQ guidance[6] document provides additional information to help manufacturers decide on the scope of these products. This has clarified some areas but there is still confusion over others. Equipment that is installed in aircraft, ships, trains, vehicles, are clearly excluded from the scope of these Directives as there are no Categories for aircraft, ships, trains or vehicles. However, the FAQ guidance also states (Section 1.3 item 5) that the equipment that is outside the scope may be a fixed installation and states:

"*If the "other type of equipment" is a fixed installation it will not fall under the scope of the WEEE Directive*". This is the definition of fixed installations given in Directive 89/336/EEC (EMC).

Fixed Installations: Neither of the WEEE or RoHS Directives exclude fixed installations from their scope; in fact these are not referred to in either Directive's preambles or articles. The European Commission's guidance implies that fixed installation may be outside the scope of WEEE and RoHS and uses the definition of fixed installations from the EMC Directive. However, fixed installations are within the scope of the EMC Directive and are defined as a separate Category within this Directive because the legal responsibility for meeting EMC requirements is placed on installers of fixed installations whereas manufacturers are responsible for finished products. This issue is causing difficulties because the status of "fixed installations" is being interpreted differently by EU WEEE registration bodies, governments, enforcement authorities and Trade Associations. Some interpretations must be incorrect although there are no records available that show whether the original intention of the WEEE and RoHS Directives was to include or exclude fixed installations from the scope of the RoHS and WEEE Directives.

The wording used in both the WEEE and RoHS Directives implies that the original intention was apparently to include all fixed installations. For example,

- An exemption in the Annex of the RoHS Directive is for "lead in solders of servers, storage, storage arrays and telecommunications network equipment". These products are all "fixed installations" and are clearly within the scope of WEEE and RoHS.

- In the list of indicative examples in Annex IB of the WEEE Directive under Category 9 the last item is *"other monitoring and control instruments used in industrial installations (e.g. in control panels)"*. If an instrument is within a control panel and used in an industrial installation then it will usually be within a "fixed installation" as defined by Directive 89/336/EEC.

- Thermostats are one of the items listed under Category 9 of Annex IB. These are used in buildings as part of central heating systems and in industrial processes for temperature control. They would not normally be used as a separate item of equipment to control temperature but not fixed to something else. Those used in buildings could be regarded as part of fixed installations whereas those used in industrial processes are part of large-scale stationary industrial tools. Note that others might be used as components such as within a refrigerator to control temperature. Under these circumstances the refrigerator is Category 1 and the thermostat is not "equipment" but a component.

The function of the "other type of equipment" is important. For example, the main function of a mobile phone base station is telecommunications. These are also "fixed installations" but as the function is within Category 3, these are within the scope of WEEE and RoHS. Buildings however are not included in any of the ten WEEE Categories and buildings could be considered to be "products". Some electrical equipment is installed as "part of" buildings and installed within walls, floors and ceilings as integral building functions. Mains sockets, light switches, wiring buried within walls are all part of the fabric of the building and manufacturers have assumed that these are outside the scope. Luminaires may be attached to the surface of ceilings (and therefore Category 5 products) or built within walls or ceilings in which case their status may be different, although this is unclear. This issue is important for Category 9 which includes a wide variety of products which monitor and control and are used in buildings. For example, fire detection systems, intruder alarms, temperature control systems for heating, ventilation and air conditioning (HVAC), etc. All of these consist of a number of items, which are installed within buildings with parts located at different locations and usually connected by wiring. Individual items may be placed on the market in several ways. Each part could be available for sale to users or sub-contractors as separate items. Installers of equipment in buildings could buy the specified numbers of individual items that they require or they buy these as a kit (containing all of the required components). The way these are placed on the market is the same for installations during new building construction, refurbishment of buildings and for both commercial buildings and private households.

Equipment or component?: An issue with industrial products is how they are used. For example, an electronic product used to measure temperature which has a meter to indicate the temperature as well as an electrical connection to provide this information as an electrical signal could be categorised in a number of ways:

- if used in isolation to measure ambient temperature, this is a Category 9 product;
- if attached to a production line to measure temperature within a process, then this is a component of an LSIT under Category 6 and as such outside the scope of WEEE and RoHS;
- if installed in a self-contained machine tool, used in a workshop (not a production line) to measure cooling oil temperature this application would be as a component within a Category 6 product;
- if installed in a refrigerator to control temperature, this is a component of a Category 1 product.

Frequently manufacturers do not know how their customers use their products or whether they are purchased by OEMs or users as these are often supplied through distributors. The simple example of a temperature sensor discussed above is fairly straightforward to deal with as it is the responsibility of the OEM to determine whether a product needs to comply with RoHS and should specify this when purchasing components. However, in some industrial and commercial installations, complex equipment is originally installed as many separate units with associated wiring, components and materials. This is discussed in more details under "spare parts" below. Manufacturers are not clear whether these units are "equipment" or "components". The equipment is frequently installed together in racks for ease of installation and replacement. These systems rely on each module functioning as originally designed. If one module fails, it is normally replaced by an identical module. If, in the time since the original installation was carried out, the new modules have had to be re-designed in order to comply with RoHS, it may not be technically possible to replace the original defective module (if new modules are incompatible) and so the entire system would have to be scrapped. However EC guidance to the EMC Directive[7] provides a definition of "spare parts" which would include modules of this type (see section 4.3).

Examples of "grey area products": For a producer to comply with the WEEE and RoHS Directives, it must first determine whether its products are within the scope of theses Directives and, if so, in which WEEE Category they fall. This is not always straightforward and three examples are used here to illustrate this point:

<u>Closed-circuit television (CCTV)</u>: Most security equipment manufacturers have assumed that CCTV equipment is within Category 9 because the primary function of the equipment is monitoring. However, this monitoring function is achieved by the incidental transmission of information which

implies an apparent Category 3 function. The views of Member States vary but UK RoHS enforcement body's opinion is that where the equipment viewed by an operator it is Category 3 but where the equipment is automatically activated by movement and then records images, it is Category 9.

Fire alarm senders: Fire alarm and security equipment manufacturers all assume that their products are Category 9 as their primary function is monitoring and control (e.g. of fires). This is clearly correct for smoke detectors and control panels but commercial fire alarm systems usually include manual actuators. These devices are essentially switches which are actuated by people when they discover a fire and the actuator sends information to the control panel. The control panel may also automatically contact the fire service. These functions are telecommunications although the primary function of the fire alarm system is monitoring and control. Fire alarm senders are also likely to be within the scope of Directive 86/109/EC the Construction Products Directive.

Circuit breakers: Modern power control systems in buildings use electrical circuit breakers instead of mains fuses. These devices shut off power when a fault is detected. These are used as integral parts of household and business electricity distribution but are placed on the market as finished products with a direct function. These are usually installed in a control panel which is attached to the wall of a building but the wiring that connects to this panel is buried within the walls. It is unclear whether these devices are in Category 9 or are outside the scope of WEEE as they are part of another type of product (the building) which is not in the ten WEEE Categories.

Laboratory equipment: The Categories of the WEEE Directive do not refer to where products are used but to their main function. A significant proportion of laboratory equipment monitors, controls or measures and so is within Category 9 but there are many other laboratory products that do not monitor or control as their primary function.

- A laboratory oven is used to heat materials at a controlled temperature. It is not clear if this is Category 1, 6, 9 or out of scope.
- Instruments used to prepare samples for analysis are in some respects part of the measurement system although are sold and used as self-contained products. A laboratory grinder for example could be regarded as Category 6 or 9. This is an important issue because at present, if it is in Category 6 it needs to comply with RoHS whereas if it is in Category 9, there will be more time to make changes necessary for compliance.
- The status of some equipment such as centrifuges is unclear and these may not fit any WEEE Category.

There are many products that are used in laboratories which alter the properties of materials; grinders reduce particle size, ovens change temperate, various devices alter composition, shakers mix substances, etc. These are not clearly electrical tools as given as indicative examples in Annex IB of WEEE, nor are they monitoring and control instruments and in most cases their status is not clear.

Specialist laboratory freezers and refrigerators are used in laboratories but these would never be used as household appliances and are similar to medical freezers which are in Category 8.

If Category 9 were included in the scope of RoHS, questions as to which WEEE Category is applicable for laboratory instruments would become less important except for those that appear to be in none of the WEEE Categories. Some laboratory equipment manufacturers have said that they would prefer that the status was clear and that all laboratory equipment is in Category 9. Laboratory equipment and equipment for monitoring and control are both within the scope of the EMC and Product Safety Directives are considered to have the same status by the European Standards for these Directives: EN 61010-1:1993 and EN 61326:1997. These standards also include definitions of laboratory equipment.

4.3 Spare parts

The RoHS Directive excludes spare parts for the repair or refurbishment of equipment placed on the EU market for the first time before 1st July 2006 (Article 2.3). The EC has stated in its FAQs 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. This cut off date is not suitable for Categories 8 and 9 and so a new date would be required for products within these Categories.

Unlike products in most other Categories, many Category 9 products are used in complex systems with many individual units or modules combined to perform a particular function. Frequently, these modules are in the form of printed circuit board (PCB) cards but often they are in their own housings with separate power supplies and so could be viewed as individual items of equipment as defined by WEEE and RoHS.

If these modules or units (which are used as integral parts of more complex systems) are viewed as “components” and replacement units are defined as spare parts, then the life of these systems can be maximised. It is worth noting that many of these complex systems are part of LSIT and so outside the scope of WEEE and RoHS but there are likely to be exceptions to this and this will depend on how LSIT are defined and interpreted.

Complex control systems may cost many millions of Euros and contain thousands of individual modules where each module is originally designed as part of the original system. When a module fails, it must be replaced by an identical module for several reasons. If the module has been redesigned to meet the requirements of the RoHS Directive, it is likely that some components were not available in RoHS compliant versions and so the circuit has had to be redesigned. This will often change the function so that it is no longer compatible with the system.

Semiconductor ICs containing embedded software are components which frequently become obsolete and so new versions must be used to comply with RoHS. Changes in function are difficult to compensate for but the changes in software are often much more difficult to deal with. Often the new software will not be compatible with older systems but where this can be modified, re-training operators and changing the system to avoid faults from occurring due to combining new with old software will be very time consuming and expensive and often will be impractical so that the entire system has to be scrapped earlier than planned. Where the design of spare parts is necessary this may be seen as a substantive change in the design which requires re-qualification before use. Therefore, to meet the aims of the WEEE Directive, these replacement modules should be regarded as spare parts and an amended RoHS Directive should clearly define spare parts to avoid different interpretations within EU Member States.

The definition of spare parts is provided in official guidance to the EMC Directive[7]. This is

> *"**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 wording (in bold type only) is suitable for RoHS.

4.4 The definition of Category 9 products

The scope of Categories 8 and 9 should be interpreted by all EU Member States in the same way because RoHS is an Article 95 Directive. Currently there are significant differences especially for equipment that "monitors or controls" and so would be regarded as Category 9. Although it is unclear what was originally intended to be the precise scope, Member States and manufacturers need clear guidance on this issue. It will be particularly important to clarify the status of "fixed installations" and this could be achieved by providing a clear guidance to describe products that are within the scope of Category 9.

Category 9

RoHS enforcement bodies need to use the same interpretation in all EU States and guidance for the intended scope is required. Although it is currently not known where the boundary between "in-scope" and "out of scope" products should lie, the following guidance is suggested:

"*Equipment whose primary function is monitoring, control, measurement or test;*

AND is placed on the market (see Note (a)) as a finished product;

AND is not an integral part of a large-scale stationary industrial tool;

AND is not part of another type of equipment that is outside the scope of Directive 2002/96/EC (see Note (b))

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

where:

- "monitoring" implies a function of a product which measures a variable and then carries out calculations or processes on this data input from sensors, detectors, electrodes or other sources;

- "control" equipment has one or more output quantities to specify values, with each value determined by manual setting, by local or remote programming, or by one or more input variables (see Note (c))

- "measurement and test" equipment is equipment which by electrical means measures, indicates or records one or more electrical or non-electrical quantities, also non-measuring equipment such as signal generators, measurement standards, power supplies and transducers (see Note (d));

- a "finished product" is any device that has a "direct function", its own enclosure and, if applicable, ports and connections intended for end users;

- "direct function" is defined as "one that fulfils the intended use specified by the manufacturer for use by the end user (see Note (e))";

- "part of another type of equipment" implies that the "product" is specifically designed to be installed in this other equipment. Examples of this other equipment include an aircraft, train, or ship but may also be an installation such as a railway network, an airport or road infrastructure (inclusion of indicative examples would be helpful);

  - Comment - "part of another type of equipment" where the "equipment" is a fixed installation such as a building, is difficult to define precisely as the interpretation of EU Member States varies. A suggestion from Orgalime is as follows:

    "In the case of the equipment being incorporated into a building and so be outside the scope of Directive 2002/96/EC, it would mean that

    - *The equipment would form part of the infrastructure so that its removal is possible only by damage to the infrastructure/building or*

    - *It would not normally be practical to remove it and install it at another location and would not normally be removed once fitted"*

- for guidance on whether a product is a part of a large-scale stationary industrial tool, refer to the EC's FAQ guidance (See Note (f)).

Notes:

(a) Guide to Implementation of Directives based on the New Approach and the Global Approach.

(b) Article 2.1 of Directive 2002/96/EC, also applies to Directive 2002/95/EC.

(c) Wording taken verbatim from EN 61010-1:1993 "Safety requirements for electrical equipment for measurement, control and laboratory use".

(d) Wording taken verbatim from EN 61326:1997, "Electrical equipment for measurement, control and laboratory use – EMC Requirements".

(e) The EMC Directive.

(f) This is based on the EC's Frequently Asked Questions Guidance[6]. Additional guidance here would be beneficial, ideally by inclusion of more indicative examples.

This definition of Category 9 is based on the following assumptions:

i) Products that are excluded are part of other equipment that is outside the scope of WEEE and RoHS (from Article 2.1).

ii) There is no exclusion for <u>all</u> fixed installations.

iii) Attachment to the fabric of a building such as walls, floors or ceilings does not necessarily exclude a product.

iv) "Part of" means either that the equipment is installed in, i.e. physically and permanently attached in some way <u>or</u> is designed to be installed in the other type of equipment which relies on this equipment as an accessory to it and the equipment is not designed to be used in any other way. The operation of the other type of equipment relies on these products to function correctly.

v) Where a product can be installed and then removed at a later date and installed elsewhere, it is a finished product with a clearly defined direct function.

Assumptions iv) and v) above are criteria used by at least some EU State enforcement bodies and the European Commission to determine product status.

As discussed in Section 4.2, laboratory equipment (which would normally comply with EN 61010-1:1993) could also be included in the scope of Category 9 if the definition reflects this.

The originally intended scope is unfortunately not clear and conflicting interpretations are confusing producers and could hinder the free flow of goods within the EC. The above guidance is based on views expressed by the European Commission, Member States and Trade Associations but may not represent the original intended scope of this Directive. In any event, it is recommended that the intended scope is made <u>very</u> clear in future amendments to the RoHS Directive.

4.5 Large installations

The status of most medical equipment is clear but this is less so for Category 9 products. Many “control” products are in fact used as part of production processes and so are currently regarded in most EU States as “large-scale stationary industrial tool” components. However, some control, measurement or monitoring products are used as part of installations that are not “tools”. Two specific examples are provided here of installations where manufacturers are unclear as to the status of their products:

Category 8 – Proton beam therapy

Proton beam therapy represents a very new range of treatments for cancer with less than 10 installed world-wide. Installation of the first in the EU will begin in 2006 or 2007. The “product” consists of a new purpose built building to house the equipment which includes:

- Particle accelerator
- CT imaging equipment
- Equipment to focus particle beams onto the exact location in patients
- IT infrastructure
- Wiring and beam guides within building infrastructure, conveyers and equipment within the building infrastructure to move and position patients.

The “product” is all of the above listed items but not all of the component parts are medical devices. The building infrastructure is not electrical and so is outside scope. The particle accelerator is connected to the local mains supply but uses a high voltage (>1000 VAC and > 1500 VDC) to function and so may be considered to be outside the scope of the WEEE and RoHS Directives but this is not clear. The particle accelerator is constructed on site from components and forms part of the building infrastructure. The boundary between building infrastructure and medical devices is unclear in this situation. Moreover, it is not possible for a manufacturer to obtain a legally binding decision that will be followed in all 25 EU Member States and so there is a risk that individual Member States could interpret the status of this equipment differently.

Category 9 – Astronomical telescope

The status of large professional astronomical telescopes is not clear. They typically consist of:

- The building
- The telescope – often supplied as many individual parts
- A variety of measurement instruments such as spectrometers

- Cameras
- IT equipment
- Cryogenic coolers (for detectors)

These could be considered to be in the "monitoring and control instruments" Category as these are used to monitor and measure however they are not what would normally be understood as laboratory instruments or as industrial equipment but are used primarily for research. An alternative interpretation would be that they are not within any of the ten WEEE Categories at all but, again, this is unclear. As with the proton therapy equipment, there is a risk that the status of equipment used within the astronomical telescope could be interpreted differently between EU Member States.

5. Quantity of equipment in Categories 8 and 9 on the EU market

Tan estimate of the quantity of equipment in Categories 8 and 9 is required by the European Commission to carry out an impact assessment. It has proven to be very difficult to obtain accurate data for a variety of reasons and therefore this has had to be estimated from a variety of sources. The reasons that data is limited are as follows:

- Eurostat data includes quantities of electrical equipment sold in the EU. However, data is limited to only a few Category 8 and 9 products and there is no data for most types of Category 8 or 9 equipment;

- The UK Government Office of Statistics publishes useful market data for most types of Category 8 and 9 equipment but this is frequently provided in terms of financial data or the data is for UK production and it is not possible to estimate EU sales from the figures provided;

- Manufacturers should be determining sales data for WEEE registration but most Category 8 and 9 manufacturers have been slow to do this. In Category 9, this is partly because there is confusion over scope as discussed in Section 4. Some useful data has been obtained from manufacturers which is accurate but unfortunately this is not complete. For Category 8, the gaps exist where the Trade Associations collaborating with ERA do not include members who produce products in certain subcategories. Sales of these products in terms of weight however are not thought to be significant in comparison with the total quantity of WEEE in these Categories.

- Data for Category 9 is particularly difficult to obtain because of the lack of clarity of scope and because of the very large variety of products. It is inevitable that products whose status is unclear will be excluded from totals. Also there are no Trade Associations specifically for Category 9 products and none of those who have submitted information to ERA have been able to provide data except for the Test and Measurement Coalition.

- WEEE registration bodies have been consulted. Several have been operating since 2005 but all have found that Producers are late to register and they are not yet able to provide accurate data for this review. The Dutch NVMP compliance scheme has been operating in Netherlands for many years but, until August 2005, was involved with predominantly consumer equipment. Since 13th August 2005, NVMP has collected and recycled Dutch B2B equipment including Category 8 and 9 products. Data for the 8.5 months until June 2006 is now available and included in the table of data below but the figures are clearly low. Many EU States have not yet started registration and so no data will be available from these until 2007 at the earliest.

- Some data for medical equipment has been obtained from Compliance Schemes in Norway and Sweden and from German Government statistics. Using data from Eucomed for national expenditure on medical electronic equipment, these figures have been extrapolated to predict EU sales. The figures extrapolated from the Norwegian and Swedish data is very similar to industry estimates but the German figure gives a somewhat higher total. This may be due to the very large size of the German medical market and the strength of the German medical industry

- A widely reported figure for Category 9 is from the Industry Council for Electrical Recycling (ICER)[9], based in UK. This estimated that in 1998, "monitoring and control instruments" accounted for 0.83% of all WEEE in UK. At this time the scope of the WEEE Directive was unclear and so this estimate probably included all equipment of this type including items used as part of fixed installations and in factories which would be regarded as "large-scale stationary industrial tools". This would explain why the ICER figure is higher than other estimates in Table 3.

The estimated quantities of equipment arising in the EU are given in the table below. More accurate figures will eventually be available from WEEE registration but none of the WEEE registration bodies that have been contacted in the course of this review are yet in a position to provide annual totals.

Table 3. Estimated weights of Category 8 and 9 equipment put onto the EU market

No.	Categories & indicative examples	Estimated weight placed on EU market (tonnes)
8. Medical devices		
8.1	Radiotherapy equipment	1460 (COCIR estimate)
8.2	Cardiology	3240 (COCIR estimate)
8.3	Dialysis	<500 (no data available)
8.4	Pulmonary ventilators	<500 (no data available)
8.5	Nuclear medicine	540 (COCIR estimate)
8.6	Laboratory equipment for *in-vitro* analysis	3500 (estimate from EDMA trade association)
8.7	Analysers	<100 (estimate based on very small size and there are very few electrical self test analysers, no accurate data available)
8.8	Freezers	<500 (no data available)
8.9	Fertilisation tests	<100 (no data available, most are not electrical but some digital models exist and these are fairly small in size)
8.10	Other appliances for detecting, preventing, monitoring, treating, alleviating illness, injury or disability	X-ray 2360 CT 4590 MRI 5610 Ultrasound 1290 Others 4310 Total 18160 (COCIR estimate)
	All Category 8	**21,000** based on estimate from El Kretsen, for Sweden extrapolated for EU based on data from EUCOMED
		29,000 based on estimate from El Retur for Norway extrapolated for EU based on data from EUCOMED
		46,000 based on estimate from German Government estimate for 2000, extrapolated for EU based on data from EUCOMED
		300 only, based on data from NVMP (Netherlands) for collected professional medical devices (clearly too low)
		26,900 - estimate from COCIR and EDMA

No.	Categories & indicative examples	Estimated weight placed on EU market (tonnes)
9. Monitoring and Control Instruments		
9.1	Smoke detectors	4000 (ERA estimates in EU and life of units based on number of homes and offices and expected life is 10 years)
		Carbon monoxide detectors ~ 300 based on estimate (CoGDEM trade Association) of 750,000 sold per annum in UK (0.1kg each) extrapolated for EU sales
9.2	Heating regulators	40 (consumer only, estimated from data from a thermostat manufacturer) Does not include industrial heating regulators
9.3	Thermostats	500 (estimated from data from a thermostat manufacturer but includes those used as part of building heating systems) 3000 (extrapolated from UK Government Statistics, assumes 0.2 kg average weight, probably too high as many will be used as part of equipment in other WEEE Categories) The exact figure will depend on the definition of “part of another type of equipment” and so whether thermostats that are part of household heating systems are in or out of scope
9.4	Measuring, weighing or adjusting appliances for household or as laboratory equipment	Laboratory analysis instruments: 3000 – 6000 (estimated from data from a manufacturer of analytical instruments)
		Weighing equipment: 6000 – 8000 (estimated quantity from extrapolation of UK Government statistics, excludes household scales and medical equipment)
		Gas and electricity meters – ~ 2000 (ERA estimate based on UK Government statistics)
9.5	Other monitoring and control instruments used in industrial installations (e.g. in control panels)	Industrial test and measurement equipment: 3000 (estimated by Test and Measurement Coalition)
	All Category 9	**18,840 – 26,340** total from above estimates plus unaccounted for equipment
		156 only, based on data from NVMP (Netherlands) for collected monitoring and control instruments (clearly too low)
		63,000 based on ICER estimate for UK in 1998, extrapolated for EU[8]

The figures in Table 3 are based on the current interpretation of the scope of Category 9 as described in Guidance published by the European Commission[6]. The figures estimated for Category 8 and 9 WEEE collected in Netherlands are clearly too low. This is likely to be because most B2B Category 8 and 9 WEEE is not collected by NVMP but is either collected and recycled by others or is re-sold outside Holland.

However, this guidance is being interpreted differently by some EU Member States WEEE registration bodies, Trade Associations and individual manufacturers, which affects the estimated

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[8] Based on increase in the quantity of EEE sold since 1998 and on the difference in population between the UK (60 million) and the EU (454 million).

quantity data that has been provided for this review. This inevitably introduces some uncertainty. In general, data on the quantity of equipment installed in “fixed installations” and equipment used as components of large-scale stationary industrial tools have been excluded (except from the ICER[9] data - based estimate). If all equipment that monitors and controls includes products used in fixed installations and in large-scale stationary industrial tools, the total figure would be somewhat higher but the actual quantity is not known as manufacturers have had no reason to determine this data.

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[9] ICER = Industry Council for Electronics Recycling, UK www.icer.org.uk

6. Current uses of RoHS substances and possible substitutes

Substitutes are available for many of the applications of the six RoHS substances but there are some where these are suitable only for certain applications, some are not yet available but are expected to be in the near future and some where there are currently no prospects of substitutes being developed. The following sections list the uses of the six RoHS substances in Category 8 and 9 products and describes the potential for the use of substitute materials.

6.1 Lead

Lead has many different uses in Category 8 and 9 equipment. The main uses are described in the table below and others in Section 10 on exemptions.

Table 4. Current uses of lead in Category 8 and 9 equipment

Application	Reason for use	Availability of Substitutes	Use in Category 8 & 9 subcategories
Solder, usually tin/lead	Permanent and reliable electrical connections between components and printed circuit boards or wiring have been made with tin/lead solders for many decades. Tin/lead solder is used because it melts at a relatively low temperature (~180C) to form strong bonds with good electrical conductivity. Important properties include an ability to readily “wet” metal surfaces at a temperature which is not too high as to damage components and materials which frequently contain heat sensitive plastics.	Lead-free solders based on tin have been developed but these are not drop-in replacements as modifications to processes are required.	All
Solder with high melting point with >85% lead	Solder is also used to make electrical and mechanical bonds at locations which subsequently become hot during use or in subsequent soldering operations. For example, these alloys are used in power semiconductor devices to attach silicon die to leadframes. These components become hot in use and the heat is conducted away from the silicon by the solder. The solder must not melt inside the component.	There are currently no substitutes with both high melting point and good ductility.	All
Coatings on component terminations, usually tin/lead	Component leadframes are made of metals, such as copper, which readily oxidise. The solderability of metal surfaces gradually deteriorates as oxidation occurs making it impossible to form good solder joints without the use of corrosive fluxes. Good solder wetting can be maintained by coatings of tin/lead alloy. These form very thin oxide coatings which prevent further oxidation and so maintain solderability. Originally lead was added to the tin because tin alone is susceptible to tin whiskers and lead inhibits this problem.	Tin/lead coatings are being replaced mainly by tin.	All
PVC stabiliser	PVC is widely used in electrical equipment for wire insulation, encapsulation of components and in connectors. PVC is a thermally unstable polymer which would decompose during the extrusion processes used to fabricate parts. Thermal decomposition is prevented by the addition of stabilisers and one of the most effective materials are fatty acid salts of lead.	Alternative stabilisers are used in PVC where lead is not permitted such as in electrical toys.	All

Application	Reason for use	Availability of Substitutes	Use in Category 8 & 9 subcategories
Optical glass	The chemical composition of glasses can be tailored to obtain the required combination of properties. In many types of electrical products (e.g. consumer cameras), this is possible without the addition of lead but some particular combinations of optical properties cannot be achieved without the addition of lead such as the glass used in projectors. As lead-containing optical glass is more expensive than lead-free glass, manufacturers use this only if there is no lead-free alternative.	Much larger quantities of lead-free optical glass are used than lead based optical glass for applications where lead-free glass is suitable. However lead based glass cannot be replaced in certain applications.	8.10, 9.4, 9.5
MCP, CP and FOP	These three types of device amplify electromagnetic radiation. These are explained in more detail in Section 10.5.	No material substitutes	8.10
Other uses of glass	Glass has physical properties that are like very viscous liquids and non-crystalline solids. This gives them several unique and useful properties: good light transparency and as a binder for other materials. Glasses have been known for thousands of years and their main constituents are silicates, alkali metals and lead although alternative formulations are also used. Lead is useful as it lowers melting point while maintaining the glassy properties. Glass is used in light bulbs, cathode ray tubes and in a variety of electronic components. The use of lead in cathode ray tubes is as shielding against radiation and as a binder. It is also used in electronic components as the glass melting point must be low enough to form a seal or bond without destroying the component's function. Other uses in Category 8 and 9 products include glass for reference electrodes and leaded glass as radiation shielding.	Lead-free glass compositions are widely used for example in light bulbs but certain combinations of properties require the addition of lead.	All
Thick film materials	Electrical connections to some types of components and the conducting pathways in electrical circuits can be obtained using a mixture of noble metals such as silver with a glass binder. Some types of component such as chip resistors and chip capacitors contain layers of materials which require electrical connections at each end of the device. This is conveniently made by a layer of the silver/glass mixture applied to each end. This is then heated to melt the glass. Hybrid or thick film circuits are made where space is limited or special electrical characteristics are required. There are various types that are used in electrical equipment. Typically these are produced by printing various pastes, which have various electrical properties in the product. The pastes are heated in a furnace and this drives off solvents and melts the glass binder to form resilient structures.	Lead-free thick film electrically conducting materials have been developed by material manufacturers but these are not suitable for all applications. Some lead-based materials (as a glass) are used within electronic components and this is permitted by an existing exemption.	All
Ceramics	Ceramics are essentially mixtures of metal oxides. Examples of ceramics containing lead that are used in electronic components are in dielectrics (used in ceramic capacitors), in resistive materials (in chip resistors) and in piezoelectric devices. The electrical properties of the ceramic is controlled by the chemical composition and frequently these cannot be achieved without the inclusion of lead	Lead is used to provide particular properties which currently cannot be met by lead-free ceramic materials.	All, widely used in chip resistors and ceramic capacitors. Also used in piezoelectric transducers used for ultrasound diagnostics (8.10)

Application	**Reason for use**	**Availability of Substitutes**	**Use in Category 8 & 9 subcategories**
PZT crystals	Some types of ultrasonic transducers used for medial diagnostics use piezoelectric (PZT) ceramics which would be within the scope of an existing exemption but PZT single crystals give superior performance but cannot be defined as "ceramics".	None.	8.10
Lead stearate	Component of x-ray diffraction crystal used for chemical analysis	Substitutes already exist (e.g. tungsten/ carbon) but no substitutes are available for applications where the highest resolution of light element spectra is required.	9.4
Paint and ink driers	Paints and inks contain organic materials that produce the hard resilient surface on drying. In the paint (or ink), these are in the form of liquids which are required to polymerise during the "drying" process to form the paint coating. Lead compounds act as catalysts for the drying" process.	Alternative driers based on cobalt, manganese, zinc and zirconium are available.	Could be all
Pigment	Lead compounds have been used in plastics and paints as white pigments. It has also used as lead chromate as a yellow pigment. Lead chromate has the advantage over most organic yellow pigments in that it has a superior heat resistance and is totally light fast and so not affected by sunlight	Titanium oxide is preferred as a white pigment, Yellow pigments based on bismuth vanadate or organic pigments are used.	Could be all
Machining additive	Metals that need to be machined to produce shaped parts contain lead as a lubricant. Steel, aluminium and copper alloys such as brass are the main metals that use lead additions. The lead addition permits intricately shaped parts to be produced.	Covered by an existing exemption. No suitable non-toxic substitutes at the exempted concentrations. Substitutes are available for alloys with higher concentrations of lead	Could be all
Bronze bearings	Self-lubricating bronze bearings and bushes are used in Category 8 and 9 products.	Currently no substitutes available and an existing exemption.	Could be all
Radiation shielding	X-rays and γ-rays are very harmful to humans but are useful for a variety of purposes. Humans are protected from stray radiation by adsorbent materials and lead is one of the main choices. Metals such as lead are popular as they are easy to fabricate and glass containing high lead content can be produced. Metals with high atomic number are preferred as these are more effective at adsorbing these types of radiation.	Other materials will adsorb X-ray and γ-radiation but all have disadvantages over lead. Tungsten is used in some applications – see Section 10.2.1.	8.1, 8.5, 8.10, 9.4, 9.5
Counter-weights	Some medical X-ray equipment has structures which are suspended over patients and need to be easily positioned. This requires radiation shielding which is very heavy and needs to be counterbalanced to maintain stability. Space is frequently limited and so high density metals are used and lead is a common choice. Surgical microscopes also require counterweights	Steel is the main alternative as a counterweight but its density is lower than lead and so occupies a larger volume. It cannot therefore replace lead in many existing product designs but can be used in new products but there may be some exceptions. Tungsten and concrete may be used in certain circumstances	8.1, 8.5, 8.10

Application	Reason for use	Availability of Substitutes	Use in Category 8 & 9 subcategories
Lamps for atomic absorption spectroscopy (also mercury and cadmium)	These lamps must contain the element that is being analysed, i.e. a lead analysis lamp contains lead, the mercury analysis lamp contains mercury, etc. The metal is vaporised within the lamp and light passed through this vapour contains light of wavelengths characteristic of the metal. This light then passes through a flame into which the material being analysed is injected where the metal vapour adsorbs light of these characteristic wavelengths and this is used to determine the concentration in solution.	No substitutes possible.	9.4
Super-conducting connections	Lead is one of the very few superconductors at 4K (-269C) and so is used as lead or a lead alloys to make electrical connections to MRI magnets and SQUID sensors.	None that provide all of material properties. Research into different designs being carried out.	8.10, 9.4
Heat transfer material at very low temperature	At temperatures close to absolute zero (-273.16K), the thermal conductivity of lead is relatively high whereas most other metals are unsuitable.	None currently available but research is being carried out.	8.10, 9.4
X-ray tube bearings	Lead is used as the bearing material in higher power tubes.	No material substitutes where the internal temperature of the anode is maintained by rotating the tube. Lead is the only suitable bearing material which can act as a lubricant in vacuum. May be avoided by alternative tube designs.	8.10, 9.4, 9.5
Lead sulphide and selenide	Infra-red detectors used, for example, in spectrometers used for analysis of organic materials.	Substitutes have different characteristics.	8.10, 9.4
Lead oxide and iodide	X-ray detectors. Lead iodide is a new material so far used only by one manufacturer for mammography and lead oxide is used for X-ray measurement and photon counting.	Substitutes have different characteristics.	8.10, 9.4, 9.5
Lead	Security seals in weighing equipment	Paper seals are already being used as replacements	9.4

6.2 Cadmium

The main uses of cadmium in Category 8 and 9 equipment are described below; other uses which are the subject of exemption requests are discussed in Section 10.

Table 5. Current uses of cadmium in Category 8 and 9 equipment

Application	Reason for use	Availability of Substitutes	Use in Category 8 & 9 subcategories
Special solders	Low melting point solders for thermal cut-outs, soldering to aluminium, etc.	Substitutes exist for Category 8 and 9 applications.	All
Coatings	Electroplated cadmium is restricted by the Marketing and Use Directive but is used, where permitted as a coating on steel parts to prevent corrosion in hostile industrial and marine environments.	Zinc and zinc alloys may be suitable but are less effective. Stainless steel causes other corrosion problems.	All
Electrical contacts	Silver / cadmium oxide is used as a switching contact where arcing occurs. The cadmium oxide maintains the structure of the contact while the silver melts in the arc.	Silver / tin oxide, silver / zinc oxide are suitable at lower current and voltage but have shorter life at high voltage / current.	All
Pigments	Bright light-stable yellow, orange and red pigments. Restricted by marketing and use Directive but used for safety labels (e.g. yellow in radioactivity symbol) and for colour coding of ECG patient cables.	Many inorganic and organic pigments are available but few match the light stability and brightness of cadmium pigments; e.g. bismuth vanadate – yellow, cerium sulphide – red Replacement of Cd in ECG cables by 2009	All
PVC stabilisers	Heat stabiliser for PVC which is used as cable insulation, mouldings, labels on components and tubing used in medical equipment.	Effective substitutes exist including Ca/Zn stabilisers.	All
Copper / cadmium alloy wire	Flexible wire for making connections to parts that move frequently in service.	Flexible cadmium-free copper alloys available (Cu, Cr, Zr and Cu, Mg, P, Sn) Cu-Cd should be replaced by 2012.	8.10
Light sensors	Cadmium sulphide and cadmium selenide; their electrical resistance changes when illuminated.	Silicon photodiodes (lower sensitivity and different spectral response).	8.10 and possibly others
Infra-red detectors	To detect and measure infrared radiation, including near infrared (NIR) for infra-red spectrometers for analysis of organic materials and thermal imaging equipment.	Substitutes that operate at the same wavelength exist but sensitivity is 100 times less (see Section 10).	8.10, 9.4

Application	Reason for use	Availability of Substitutes	Use in Category 8 & 9 subcategories
X-ray detectors	Two types of X-ray detector contain cadmium. Semiconductor type detectors based on cadmium telluride or zinc doped cadmium telluride are very sensitive detectors which convert X-rays directly into digital signals. Cadmium tungstate X-ray detectors are of a scintillator type which produce light when exposed to X-rays which is converted into an electrical signal - usually by photodiode arrays.	Alternative scintillators and semiconductor X-ray detectors exist but all have different characteristics (see Section 10.1.1).	8.10, 9.4, 9.5
Thick film materials	Small but complex circuits and some types of components such as resistor arrays are produced from various electrically conducting and insulating materials. These are applied as printed inks, dried and fired. Cadmium is used in glass binders to maintain the structure. Cadmium gives the benefit that parts can be made smaller than with cadmium-free materials.	Cadmium-free glass binders are available for most applications although some contain lead. Various substitute elements are used including bismuth.	Potentially all
Helium – cadmium lasers	Laser used in Raman spectrometer used for semiconductor analysis and analysis of biological materials.	None. This is the only UV laser currently available that gives light of 325 nm.	9.4
Woods alloy (Pb, Cd, Bi, Sn)	Alloy used to make superconducting connections to MRI magnets (which also contain lead) and remains superconducting even in the presence of the very high magnetic fields used.	Research being carried out but none currently available.	8.10
Ion selective electrodes (also lead)	Cadmium is used in special electrodes used to measure very low concentrations of cadmium in water. A similar electrode containing lead is used for lead analysis	No substitute materials.	9.4
X-ray equipment calibration	Used in measurement instruments used to calibrate the energy of X-ray equipment.	Possibly silver or indium but further investigations required.	9.5
Purification columns for chlorine monitors	Used as a consumable and so outside scope of RoHS. Used to remove impurities that would affect the accuracy of the chlorine monitor.	Work underway to determine if zinc can replace cadmium but no date for substitution available.	9.4

6.3 Mercury

Mercury has relatively few uses in electrical equipment and the main applications are listed in Table 6

Table 6. Current uses of mercury in Category 8 and 9 equipment

Application	Reason for use	Availability of Substitutes	Use in Category 8 & 9 subcategories
Switches	Switches that use liquid mercury to form the electrical contact have very long life and there is no “bounce” on closure of the switch. There are no parts that wear or are degraded by arcing unlike with alternative solid contacts. Various designs are used but most utilize glass ampoules containing mercury and with two wire contacts that pass through the glass. In one type, the switch is actuated when it is tilted so that mercury flows over the two wires making an electrical contact.	A variety of alternative materials and designs are available which are being used to replace mercury switches. The choice of material and design depends on the switching characteristics. Gold may be used for low current and voltage whereas silver/cadmium oxide is chosen if arcing is likely and the voltage is high Issue with very high frequency switching.	All except 8.9 and 9.1
Thermostat	Thermostats control temperature by switching power on and off to heaters. Mercury has been used in the switches for the reasons described above.	See above.	9.2, 9.3
Level sensors	These function in a similar way to the mercury switches described above. The switch is “on” when mercury is in contact with the two terminals but when the orientation is changed, mercury flows away from the terminals, breaking the circuit. Several applications which used mercury in the past have already been changed to mercury – free substitutes including consumer electronic laser guided level sensors.	Gold contacts with a gold ball used to make the circuit instead of mercury are the most common alternative although they may not always be as reliable. Alternative liquid metals have been considered but are unsuitable. Liquid gallium alloys contain rare metals and tend to wet all surfaces unlike mercury. This can cause a short circuit when the sensor is supposed to be off. Potassium/sodium is also liquid but is extremely dangerous, exploding in contact with water.	8.1, 8.5, 8.10, 9.4, 9.5
Barometers	Barometers with electrical contacts.	No longer produced and mercury-free barometers are widely available.	9.4
Mercury cadmium telluride	See Table 5 on uses of cadmium.		9.4

Application	Reason for use	Availability of Substitutes	Use in Category 8 & 9 subcategories
Pigments	Phased out many years ago; believed to be no longer used	Many alternatives – organic pigments.	All
Polymerisation catalysts	Used in the past but very uncommon, no evidence for use in Category 8 and 9 products.	Alternative catalysts usually available.	All
Lighting	Mercury is used in a variety of lamps which are covered by exemptions 1 to 4 in the Annex of the RoHS Directive. The main use of mercury in lamps in Category 8 and 9 equipment is as discharge lamps used to back illuminate liquid crystal displays.	None at present although organic LEDs may be suitable in the future. Xenon lamps consume double the power of mercury lamps. Certain lamps used for specific spectral range where there are no substitutes.	All
Reference electrodes	Several types of mercury reference electrodes are produced. These are used for monitoring corrosion and in chemical analysis.	Silver/silver chloride electrodes have replaced mercury chloride electrodes in most applications but cannot replace low chloride, mercury sulphate or mercury oxide.	8.6, 9.4, 9.5
Environmental mercury monitors	Mercury is used to calibrate mercury monitors and some mercury is present in the product when it is placed on the market.	None possible as only mercury can be used to calibrate instrument but this is used as a consumable so is outside scope.	9.5

6.4 Hexavalent chromium

Hexavalent chromium has a few but important uses in electrical equipment which are listed below.

Table 7. Current uses of hexavalent chromium in Category 8 and 9 equipment

Application	Reason for use	Availability of Substitutes	Use in Category 8 & 9 subcategories
Corrosion resistant coatings	Chromate conversion coatings are used on aluminium alloys, zinc coated steel and copper foil used in PCBs as a corrosion resistant coating. These coatings are used either on unpainted metal or as an aid to paint adhesion. Chromate passivation coatings are also used in some applications to maintain low electrical resistance. This is important for meeting the requirements of the EMC Directive as well as for shielding sensitive detectors	Commercial products available but these are not drop-in replacements. Most common substitutes contain trivalent chromium, fluoro-titanium or fluoro-zirconium compounds	All
Corrosion resistant paints and primers	Coatings for metals which contain chromate compounds that provide corrosion resistance for use in hostile environments.	Chromate-free substitutes exist but their performance is inferior although often adequate – some use proprietary organic corrosion inhibitors.	All
Alkali dispensers	Alkali metal chromates (CrVI) are used in photomultiplier tubes, image intensifiers and other products to create in-situ the photocathode.	Substitutes under development and expected by 2010.	8.10, 9.4, 9.5

6.5 Polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE)

PBB and PBDE are used as additives to plastics as flame retardants. Flame retardants are usually added to plastics as a legal requirement and to prevent fires. The requirements vary depending on the equipment. Battery powered toys do not usually contain plastics with flame retardants but the fire regulations in the EU for IT, medical and monitoring and control equipment are more stringent than for consumer electronics products. Many types of plastics that are used in electrical equipment are combustible and electrical equipment is a potential source of heat, especially where defects result in overheating of components or electric arcing occurs. Also, fires can start from external ignition sources and so flame retardants are added to housings. As a result of legal requirements, flame retardants are added to the plastics used to make printed circuit boards, plastic connectors, component encapsulations and coatings and in plastic mouldings. There are several hundred different types of flame retardant but RoHS restricts only two types.

An ideal flame retardant would be used at low concentrations and would not affect the physical or electrical properties of the plastic. However, in reality, all flame retardants have an effect on the plastic's physical characteristics and some also affect electrical properties. The fire resistance achieved also varies. The level of fire resistance that is required is mandated by legislation but can be achieved in some types of plastics with only certain types of flame retardant. Also, the quantity of fire retardant required to achieve the legal fire resistance is very varied. Decabromo-diphenyl ether (deca-BDE, one of the PBDE flame retardants) is very effective with additions of less than 10% whereas alumina trihydrate must be present at a concentration of over 50% to meet legal requirements and this can have a very significant effect on the plastic's physical properties.

PBB is toxic and has not been intentionally used in Europe, Japan or USA for many years. However, it is reported that there is at least one plant in China that is still manufacturing this material and so imported Chinese plastics could potentially contain this flame retardant. There is also a risk where recycled plastics are used. However the extent to which PBB is present in equipment imported into Europe is not known as this information is not provided by suppliers and widespread analysis has not yet been carried out and therefore there is no information available as to where PBB is used. This is already a significant problem for manufacturers of equipment within Categories 1 to 7 and 10 as these need to comply with RoHS from July 2006 whereas manufacturers of Category 8 and 9 products will have the benefit of their experience if and when these Categories are brought within the scope of RoHS.

PBDE are a series of flame retardants (differing in the number of bromine atoms in the molecule) but only three of the series have been produced in recent years. Two, pentabromodiphenyl ether (penta-BDE) and octabromodiphenyl ether (octa-BDE) have already been restricted by Directive 2003/11/EC and so should longer be being used in Category 8 and 9 equipment and they are no longer intentionally used by European, Japanese or US manufacturers.

- Penta- BDE – The main use was in polyurethane foam which is infrequently used in Category 8 and 9 products but penta-BDE was also rarely used in other applications. The production status of this flame retardant in the Far East is not known.

- Octa-BDE – The main use was as a flame retardant in Acrylonitrile-Butadiene-Styrene (ABS) which is a plastic that is widely used in electrical equipment. It was also occasionally used in other plastics but this is uncommon. The production status of this flame retardant in the Far East is not known and it may be present in imported equipment and plastics.

- Deca-BDE – This is widely used in electrical equipment in many different polymers. It is a very effective flame retardant which does not have a detrimental effect on the physical properties of plastics. The performance that can be achieved with this flame retardant in some plastics, such as PBT, is difficult to achieve with alternative flame retardants. An extensive risk assessment has been carried out by the European Commission to determine if this substance poses a risk to human health or the environment. No risk was found and, as the risk from potential substitute flame retardants have not been as extensively investigated, deca-BDE was granted an exemption from RoHS and so can continue to be used as a flame retardant in Category 8 and 9 products.

There are many hundreds of possible substitute flame retardants but all have different characteristics and so only certain materials will be suitable for specific applications. Substitutes include for example:

- Alumina trihydrate

- Zinc borate

- Brominated types such as Tetrabromo-bisphenol A (TBBPA) and Brominated phenyl indan

- Phosphorous based such as red phosphorous and Tris (2-chloroisopropyl) phosphate (TCPP).

The risks from some alternative flame retardants have not been thoroughly investigated and some may pose a risk to health and the environment.

7. Quantities of RoHS restricted substances currently used in Category 8 and 9 equipment

Medical equipment manufacturers have estimated the quantities of RoHS restricted substances that are currently used (as of 2006) but most Category 9 manufacturers (except for the Test and Measurement Coalition) have not been able to provide this data and so ERA has estimated the quantities used from a variety of other sources. The quantities used are constantly changing; new restrictions in the USA have resulted in very significant reductions in the quantity of mercury used in electrical products in the EU during 2004 and 2005 and this is on-going and so data for 2000 – 2003 is already out of date and is much higher than is currently in use.

Many manufacturers are already using lead-free solders in new models although not changing existing designs. This will result in a decrease in the quantity of lead used in solder in Category 8 and 9 products in future years. The Trade Association EDMA estimates that currently 6 tonnes of lead is currently used in solder in *in-vitro* diagnostics equipment and this will decrease to 600 kg within ten years even if Category 8 is not included in the scope of RoHS.

The following three tables provide estimates of weight of the restricted substances used in Category 8 and 9 products.

Table 8. Weight of RoHS restricted substances used in Category 8 equipment including data for subcategories where known

	Subcategory					
Substance/ uses	Radio-therapy	Nuclear (PET)	Lab in-vitro	AIMDs	Others types of equipment	Category 8 totals
Lead shielding	43,000	110,000			605,700	758,700
Lead counterweight	9,600	28,000			286,000	323,600
Lead in MCP & CP					1	
Lead X-ray tube bearings					1	
Lead in X-ray test objects					100	
Lead in superconducting connections (MRI)					6,000	
Lead in superconducting connections SQUID detectors					< 0.1	
Lead in refrigerator cold head					100	
Lead in ceramics (ultrasonic transducers)					80	
Lead in single crystal ultrasonic transducers					100 - 200	
Lead in lead stearate X-ray diffraction crystals for X-ray spectroscopy					< 0.001	
Lead in solder to transducers					6	
Lead anode in oxygen sensors					50	
Lead in solder			6,000	800		66,000
Lead PVC stabilisers					500	
Lead in alloys			3,000			
Lead in electrode glass			70			
Cadmium plating					0.5	
Cadmium in switches and contacts						
Cadmium in phosphors					13 - 103	
Cadmium tungstate					630	
Cadmium semiconductor radiation detectors					300 (of Cd)	
Cadmium in superconducting alloys					600	
Copper - cadmium wire					50	
Cadmium pigments					5	
Cadmium stabilisers in cables						Should be zero
Hex Cr in alkali dispensers					1	
Hex Cr passivation						7
Mercury in position switches					1	
Mercury in backlights & other lamps						0.7
Mercury in electrodes			2 - 10			

Units: kilograms.

Table 9. Weight of RoHS restricted substances used in Category 9 equipment including data for subcategories where known and totals for Categories 8 and 9

	Subcategories			
Substance/ uses	**Household and lab instruments**	**Other monitor / control**	**All Cat 9**	**Total Category 8 + 9**
Lead in shielding			~20,000	779,000
Lead in lead stearate X-ray diffraction crystals for X-ray spectroscopy				<0.001
Lead anode in oxygen sensors				~ 10,000
Lead in solder		26,000		~ 150,000
Lead in optical glass				130,000
Lead PVC stabilisers				13,000
Lead in AAS lamps	~30			
Lead in ion selective electrode membranes	0.02			
Lead in infra-red detectors				<2
Cadmium plating		0.02		
Cadmium electric contacts		<1		
Cadmium semiconductor radiation detectors				260 of Cd in CdTe until 2010
Cadmium stabilisers in cables			Should be zero	Actual figure unknown, use illegal
Cadmium in optical filters				80
Cadmium in AAS lamps	~ 5			
Cadmium in ion selective electrode membranes	0.01			
Cadmium in total residual chlorine monitors		1-2		
Mercury cadmium telluride				5 - 10 (Actual figure may be much less if military applications are excluded)
Hex Cr passivation		11		250 - 810
Mercury in position and other switches		0.025		6,000 (2002 estimate)
Mercury in relays and switches		0.025		
Mercury in backlights & other lamps		0.6		
Mercury cadmium telluride				~ 5
Mercury in electrodes		~ 3		
Mercury for callibration of environmental mercury monitors		0.2		
PBB				not known, not intentionally used
PBDE				<8,000, not intentionally used. Est. based on 1% of 1999 usage of Deca-BDE

Units: kilograms.

Table 10. Summary of data on quantities of RoHS restricted substances used in Category 8 and 9 equipment

Application	Quantity in Category 8	Quantity in Category 9	Totals
Lead as radiation shielding	759,000	~ 20,000	780,000 (i)
Lead as counterweights	324,000		324,000
Lead in MCP & CP	1		1
Lead X-ray tube bearings	1		1
Lead in X-ray test objects	100		100
Lead in superconducting connections (MRI)	6,000		6,000
Lead in superconducting connections SQUID detectors	<0.1		< 0.1
Lead in refrigerator cold head	100		100
Lead in ceramics (e.g. ultrasonic transducers)	80		~ 100 (ii)
Lead in single crystal ultrasonic transducers	100 – 200		<200
Lead in lead stearate X-ray diffraction crystals	< 1		< 1
Lead in solder to transducers	6		~ 10 (iii)
Lead anode in oxygen sensors	50	10,000	10,000
Lead in solders	66,000	~ 90,000	~ 150,000 (iv)
Lead in optical glass			130,000
Lead PVC stabilisers	500 (v)		13,000 (vi)
Lead in alloys	3,000	?	
Lead in electrode glass	500		
Lead in AAS lamps		30	30
Lead in ion selective electrode membranes		0.02	0.02
Lead in infra-red detectors			< 2
Cadmium plating	0.5	< 0.5	< 1
Cadmium in switches and contacts			75 (vii)
Cadmium in phosphors	~ 100		~ 100
Cadmium tungstate scintillators	630		< 1,000 (viii)
Cadmium in semiconductor radiation detectors	300		~ 300 (ix)
Cadmium in superconducting alloys	600		600
Cadmium in copper - cadmium wire	50		50
Cadmium pigments	5	?	5
Cadmium as polymer stabilisers in cables			Not known as its use is illegal but cadmium stabiliser is occasionally found during enforcement
Cadmium in optical filters			80
Cadmium in AAS lamps		5	
Cadmium in ion selective electrode membranes		0.01	0.01
Cadmium in total residual chlorine monitors		1 – 2	1 – 2
Cadmium in mercury cadmium telluride		5 – 10	5 – 10 (x)

Application	Quantity in Category 8	Quantity in Category 9	Totals
Hex. Chromium photocathode, image intensifiers, PMT & PT	1	trace	~ 1
Hex. Chromium passivation coatings	~ 1		~ 300 – 800 (xi)
Mercury in position and other switches	1		~ 6,000 in 2002 ~ 10 in 2006 (xii)
Mercury in backlights & other lamps	0.7		~ 3 (xiii)
Mercury in mercury cadmium telluride		~ 5	~ 5
Mercury in electrodes	2 – 10	~ 3	5 – 13
Mercury for calibration of environmental mercury monitors		0.2	0.2
PBB			Not known, should be zero
PBDE			<8,000 (xiv)

Units: kilograms.

Data supplied by manufacturers unless stated otherwise.

Notes:

i) Quantity of lead in radiation shielding unknown because manufacturers of security scanning equipment are uncertain of what proportion of their products are classified as National Security and so outside scope.

ii) Quantity used in Category 9 not known but thought to be much less than in Category 8 so 100 kg estimated.

iii) High melting point solders used for most Category 9 transducers.

iv) 1% of estimated quantity of electronic solder used in EU gives figure of 42 tonnes which is clearly too low. Figures given for Category 9 and the total are ERA's estimates.

v) Refers to PVC tubing and does not include wire insulation or mouldings.

vi) From "Heavy metals in waste" final report, Feb. 2002 COWI A/S Denmark, Project ENV.E.3/ETU/2000/0058 assuming that Categories 8 and 9 is 1% of all types of equipment.

vii) Based on UK Regulatory Impact Assessment of RoHS Directive, published by Department of Trade and Industry: 750 tonnes Cd used in EU (excludes batteries), 1% in electrical equipment contacts and Categories 8 and 9 assumed to be 1% of all EEE.

viii) Cadmium tungstate scintillator used in security screening but manufacturers unable to supply figure. Quantity used in Category 9 estimated to be less than quantity used in medical X-ray equipment.

ix) Medical industry estimate is 300 kg but semiconductor manufacturer's estimate was 260 kg for current use.

x) Industry estimate but may be much less as large quantities are used for military applications.

xi) Difficult to estimate. These figures estimated from: 9010 tonnes Cr(VI) used in EU, 15% in electrical equipment. 20% of this is in product (rest is discarded). Categories 8 and 9 = 1% of all EU equipment and coatings contain 10 – 30% Cr(VI).

xii) The quantity of mercury currently used in Category 8 and 9 equipment in EU is unclear. ERA's estimate is that the quantity is now very small because most of the uses in 2004 have been phased out (relays, thermostats, switches, level sensors, etc.). Relatively large quantities of mercury are still used in some non-electrical products such as mercury thermometers, barometers and Sphygmomanometers which are outside the scope of WEEE and RoHS and so not considered in this review. The actual quantity is unclear and may be somewhat greater than 10 kg. Although all of the known uses of mercury in Categories 8 and 9 are known and data on all of these has been included in the total. However, the actual figure could be higher although it is much less than was used in 2004.

xiii) Assumes similar quantity in Category 9 equipment as in Category 8.

xiv) 8 tonnes is 1% of quantity of Deca-BDE used in all equipment in Europe in 1999. Since then its use has declined and a more realistic figure would be less than 4 tonnes. Manufacturers were unable to provide data as these materials are not knowingly used.

7.1 Comparison with other uses and environmental sources of the RoHS substances

These quantities of RoHS restricted substances should be considered by comparison with other uses and other environmental sources.

Lead: Lead is produced and used in very large quantities but only a relatively small proportion of this is used in electrical equipment. Electronic solders, for example accounts for only 0.4% of lead produced. The main use of lead is in batteries (75% in 1998)[10].

Cadmium: 19,700 tonnes of cadmium was produced in 2000[11]. The main use of cadmium is in nickel/cadmium batteries (excluded from RoHS) (73% of cadmium consumed in 2000[10]), pigments (12%) and electroplating (8% but exempt from RoHS). Emissions of cadmium to the environment are from a variety of sources including volcanoes (up to 1500 tonnes in 1983) and significant amounts are released from extraction of minerals and non-ferrous metal production. Data for Denmark showed that 50% of total air emissions were from waste incineration and 35% from coal and oil combustion but other countries will have different figures. Data included in reference 11 reports that in 2001, a total of 2522 tonnes of cadmium was released to land, a very significant figure compared to the quantity of cadmium that is currently used in Category 8 and 9 equipment.

Mercury: Much larger quantities of mercury are used in dental amalgams than in Category 8 and 9 equipment. Data for Sweden in 1997 showed that 45% is used in this application whereas at that time, 9% was used in switches, measuring and control (this includes non-electrical products)[10]. There are several sources of mercury to the environment not related to the use of mercury but as emissions of impurities. Data for Denmark in 2001 show that industry emitted 70 – 180 kg of mercury to air whereas waste incineration 280 – 1000 kg and coal and other fuel combustion 210 – 420 kg. Mercury emissions also occur to soil, water and to landfill[12]. In the same study, Danish consumption of mercury was estimated as ~ 1 tonne per year of mercury in dental amalgams, 60 – 170 kg per year in lamps and up to 24 kg in electrical switches and relays. Up to 1 tonne was present in coal consumed in Denmark although a significant proportion of this was not released to atmosphere.

Hexavalent chromium and PBB and PBDE: Data for the quantities of these entering the environment is not available.

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[10] "Heavy Metals in Waste", Final report 2002, European Commission DG ENV. E3 Project ENV.E.3/ETU/2000/0058

[11] "Cadmium Review", Nordic Council of Ministers, Jan 2003 http://www.norden.org/miljoe/uk/NMR_cadmium.pdf

[12] "Substance flow analysis for mercury 2001", Danish Environmental Protection Agency, Environmental project No. 808, 2003.

Summary

The impact of inclusion of Categories 8 and 9 on the quantity of RoHS restricted substances used in these products needs to take account of reductions that are already taking place voluntarily or because of other legislation and justifiable exemptions. The quantities of the six substances listed in Table 10 are summarised in Table 11 to show the likely impact of including Categories 8 and 9 in the scope of RoHS

Table 11. Impact of inclusion of Categories 8 and 9 in the scope of RoHS on the quantities of the six substances used

Substance	Totals	Weight used by apparently justified exemptions*	Voluntary reductions **	Maximum quantity that would be restricted ***
Lead	1413.5 tonnes	926.5 tonnes	Some in solders and some in counterweights	< 487 tonnes
Cadmium	2225 kg	2165 kg	-	60 kg
Mercury	Unclear, may be as low as 30 kg	10 - 15 kg	5 kg	10 kg
Hexavalent chromium	800 kg			800 kg
PBB & PBDE	<10 tonnes	10 tonnes (Deca-BDE)	Penta-BDE and octa-BDE should already be phased out	Minimal impact except due to increased vigilance by producers

* See discussion of exemptions in Section 10.

** Reductions in usage which manufacturers are already carrying out.

*** Taking into account exemptions and voluntary reductions.

The impact of inclusion of Categories 8 and 9 in the scope of RoHS on the quantities of PBB and PBDE is impossible to calculate. There is no data on how much PBB is presently used and the use of penta-BDE and octa-BDE are already restricted by the Marketing and Use Directive. The impact on deca-BDE is unclear while the current exemption exists. However it is possible that small amounts of PBB and penta-BDE and octa-BDE are present in these products although manufacturers are unaware of this. The compliance procedures that all manufacturers will have to follow to ensure RoHS compliance should ensure that the use of these three materials is discontinued in EU.

8. Reliability of substitute materials and safety implications

The main reason why Categories 8 and 9 were originally omitted from the scope of the RoHS Directive is believed to be due to concerns over the reliability of certain substitute materials, in particular the long-term performance of lead-free solders. There is no doubt that high reliability is required from Category 8 and 9 products as many are essential for healthcare consumer safety and protecting the environment. Some examples of such applications include:

Category 8

- 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 anaesthesia, intensive care and premature baby incubators to measure oxygen concentrations, failure or inaccurate measurement could be fatal.
- Failure of defibrillators could result in death of heart attack patients.
- The non-availability of any critical instrument could have fatal consequences if needed in an emergency.

Category 9

- Smoke detectors – failure could result in fires not being detected resulting in loss of life and damage to buildings.
- Carbon monoxide gas detectors – used in households where gas heating equipment is used. Failure to detect poisonous carbon monoxide could result in loss of life.
- Process control equipment – defects that result in incorrect quantities of materials being used in a process could result in unexpected evolution of toxic gas, creation of waste or in extreme cases potentially explosions could result.
- Portable equipment designed for calibration of aircraft instruments must be totally reliable and very accurate. Any errors could have fatal consequences.
- Some process control equipment is used in explosive atmosphere environments. Defects that cause sparks could result in explosions.
- There have been several very serious incidents caused by failures of level sensors.

Clearly there is no doubt that many Category 8 and 9 products are safety critical unlike most products in the other eight Categories where unexpected defects are primarily inconvenient. What is less clear and so has been explored in detail during this review is whether products manufactured using the substitute materials are likely to experience more, less or the same number of defects during normal use than products made with the restricted substances. The material of greatest concern to manufacturers is solder and solderable coatings but equipment manufacturers are also finding that substitutes for hexavalent chromium passivation are difficult to replace.

The UK's regulatory body responsible in this area, the Health and Safety Executive (HSE), has also raised the criticality of safety and reliability issues regarding Categories 8 and 9. Many Category 9 products are required to comply with the ATEX Directive. This Directive states that equipment used in Zone 0 (>1000 hours per year in explosive atmosphere) and in Zone 1 (>10 hours per year) must be reliable and this has to be authorised by a Notified Body. Therefore many Category 8 and 9 products must be reliable and concerns over substitute materials would create a conflict with other Directives such as Safety and ATEX.

8.1 Lead-free solders

Lead is used as a component of solders, typically at 35 – 40% by weight. It is also used as an additive to tin in electroplated component termination coatings with 5 – 30% lead and as a PCB coating to provide readily solderable surfaces. Despite extensive research over the last 20 years, no drop-in replacement for tin/lead has been found. However a variety of substitute alloys are now available and the more commonly used are listed below:

Table 12. Common types of lead-free solder alloys

Lead-free alloy	Comments
Tin – silver – copper types (SAC)	Most widely used substitute. Melts at 34°C higher than tin/lead and wetting performance is inferior but best choice overall
Tin - copper	Lower cost alternative to SAC but has a higher melting point
Tin - silver	Has been used for many years in equipment that is used at higher temperatures
Tin – zinc based alloys	Melting temperature similar to tin/lead and good wetting if correct flux used. However susceptible to corrosion. Suitable for some home/and office uses but unsuitable where corrosion could occur and this is likely in most Category 8 & 9 products
Tin – bismuth alloys	Tin – silver – bismuth used by Japanese manufacturers but melting point higher than tin/lead. Tin-bismuth has a much lower melting point than tin/lead (138°C). The disadvantage of bismuth alloys is that they are brittle so that wire cannot easily be made making repairs very difficult. Also, bismuth interferes with WEEE recycling processes making these less efficient and use more energy
Indium alloys	Indium – silver and indium – tin are soft ductile alloys with low melting point that are too low for many applications. Solder pastes are unstable and so very difficult to use. Indium is a rare metal, only ~200 tonnes per annum produced and most is used for flat screen displays. No reliability data available as not likely to be used

8.1.1 Field experience with lead-free solders

Solders based on alloys of tin and lead have been used for centuries and its use in electrical equipment has been for many decades where it is an ideal choice because of its combination of characteristics. Manufacturers have many decades of experience using tin/lead solders and are able to predict with some accuracy the lifetime in the field for products before failures become a possibility and, even in hostile environments, well designed solder joints usually last several decades without failure. Manufacturers, academics and researchers have been extensively researching the performance of substitute lead-free solders since the late 1990s but relatively few products made using lead-free products have been in the field for more than five years and so there is no long term field data (>5 years) to compare with accelerated test data obtained under laboratory conditions.

Lead free solders have been used for many years in certain specialist products, in particular where the equipment is used at high ambient temperature. However, these products are normally used for relatively short periods and so do not provide an insight into long term field behaviour. The first products made in large numbers using lead-free solders were produced in Japan by mainly consumer electronics manufacturers. Originally solders based on tin/silver/bismuth were used and the products were not totally “lead-free” as many components were not available as lead-free versions. Although this provided valuable knowledge and data on the behaviour of lead-free solders, consumer products tend to be used for relatively short periods, typically 3 – 5 years, are used infrequently (a few hours per day) and are used in relatively benign conditions experiencing only small temperature changes. Not surprisingly, no reliability issues have been published by manufacturers but the use of lead-free solders has continued and increased indicating that there are no very significant reliability problems with these types of products. This evidence has to be viewed with caution as a small increase in the rate of failures in these types of products may not be detected as most consumers do not report faults that occur after warranties have expired and older faulty products are rarely examined to determine the cause. Therefore, there is currently insufficient field data to determine with certainty the long-term behaviour of Category 8 and 9 products. There is no doubt that lead-free solders are suitable for equipment used where temperature changes are small and the expected life is less than 10 years but there is as yet no evidence to guarantee the reliability of equipment used in hostile conditions and expected to operate for 10 or more years,

One Japanese manufacturer of air conditioning equipment has been producing equipment using lead-free solders for more than 5 years and some of these products will have been used continuously for over five years and no unexpected failures due to the characteristics of the lead-free solder have occurred. This product is designed to maintain a constant temperature so only limited thermal cycling occurs This limited field data is an encouraging indication that lead-free solders will not be unexpectedly unreliable but field data for over 10 years and in conditions where thermal cycling occurs is necessary to gain a full understanding of its long term behaviour.

8.1.2 Potential reliability issues

Manufacturers of Category 8 and 9 products will benefit from the experience gained by manufacturers of products that are currently within the scope of the RoHS Directive. Manufacturers and researchers have identified a wide variety of potential failure modes that are more likely to occur with lead-free solders than tin/lead solders although most of these can be avoided if they are fully understood. However, some of the potential failure modes (thermal fatigue and tin whiskers) are not fully understood and research into these is on-going; these will be discussed in more detail in the following sections.

Despite extensive research, no lead-free solder has been found that has the same properties as tin/lead solder. The main differences between the best alternatives and tin lead are; higher melting temperature, inferior wetting properties and differences in microstructure that affect physical properties such as hardness. The lead-free alloy which is now accepted as the best alternative to tin/lead contains tin with small additions of silver and copper. The eutectic alloy which fully melts at a single temperature (not over a range as with non-eutectic alloys) contains 3.5% silver and 0.7% copper and is often termed SAC (from **S**n – tin, **A**g – silver and **C**u – copper). The quantity of silver and copper used in commercial SAC alloys varies, partly for patent reasons and partly to reduce cost (with less silver). Eutectic SAC melts at 217°C which is 34°C higher than eutectic tin/lead solder. This can potentially cause a variety of production problems but can also affect the long term reliability of products. It is a characteristic of lead-free solders that they wet metal surfaces during the soldering process less effectively. This can also lead to early failures. The following table describes some of the more important issues.

Table 13. Modes of failure that can occur or are more likely when using lead-free solders

Potential failure mode	Effect of higher soldering temperature
Heat sensitive components	The maximum temperature that many components can withstand without damage is close to or below the temperature required for manufacture of lead-free soldered PCBs. Some are catastrophically damaged which prevents the equipment from functioning but there are some types where slight damage occurs resulting in defects that grow over time and subsequently cause early failure. Examples of this type of defect include; loss of fluid from electrolytic capacitors, delamination of ICs, distortion of plastics and change in characteristics of some types of capacitor.
Warping and delamination of PCB laminate	All PCBs are susceptible to warping and multilayer PCBs can also be susceptible to delamination between layers. These defects can occur with tin/lead soldering but the risk of damage increases with temperature. Warping can cause poor solder bonding due to misalignment and delamination can cause breaks in internal circuitry. Defects may be produced in manufacture that do not prevent the equipment from functioning but which could cause premature failure in the field, especially if stresses are induced as a result of temperature fluctuations. The risk of cracks in ceramic components such as multi-layer ceramic capacitors (MLCCs) is increased because PCB warping is greater at higher temperature and lead-free solders are less ductile and so transfer stresses into the brittle ceramics.

Potential failure mode	Effect of higher soldering temperature
Cracking of plated through holes and vias	The thermal expansion coefficient (TCE) of copper used to make plated through holes (PTH) and vias is much less than that of the laminate material in the same direction. This results in a strain on PTH and vias during the soldering process as the laminate expands more than copper. Defects in the vias and PTH can result in cracks that cause an open circuit. Sometimes, the cracks do not initially cause an open circuit failure bur the cracks grow as a result of temperature changes eventually causing premature failure of the equipment. This defect occurs occasionally in tin/lead processes but is more likely at the higher lead-free process temperature although high Tg and low z-axis TCE laminates have been developed that reduce this risk.
Conductive anodic filaments (CAF)	CAF also occur in tin/lead processes but is very uncommon. Research has shown however that the risk of CAF increases with process temperature and so will be more likely with lead-free processes. These failures occur as a result of debonding between epoxy resin and glass fibres in glass reinforced laminate. This creates channels within the laminate that can adsorb flux which acts as an ionically conducting pathway between component pads at different voltages. Under the influence of this voltage, copper forms “anodic filaments” which cause an electrical short circuit.
Intermetallic growth	When liquid solder wets a metal surface, an interaction occurs which produces intermetallic phases at the interface. This is normal and occurs with tin/lead and with lead-free solders. Manufacturers have experienced failures under certain circumstances. Wetting tends to be slower with lead-free solders and the time that the solder joint is hot is longer with lead-free solders and so intermetallic phases tend to be initially thicker in lead-free joints although research has shown that subsequent growth rates in service are lower that in tin/lead joints. Circumstances can occur where relatively thick intermetallic layers can form in lead-free systems (e.g. due to long and multiple heating times) This has been found to cause premature failure of the bonds to solder balls of ball grid array packages (BGA), particularly those that are used at higher operating temperatures and where temperature cycling also occurs.
Shrinkage holes and tears	These are uncommon with tin/lead but occurs with lead-free solders. This is because the volume of lead-free solders in the liquid state is greater than as a solid and the difference between these – the shrinkage – is greater than for tin/lead solder. Deep fissures can affect reliability and so are not acceptable. Rapid cooling minimises this problem but is difficult to achieve in wave soldering[13]. Two examples of this examined by ERA indicated that the type and design of components can influence the occurrence of this defect.
Poor wetting of metal surfaces by liquid solder	There is no doubt that good solder joints can be produced with lead-free solders but the inferior wetting properties of most of these alloys can result in solder fillets with less than ideal dimensions. Poor solder joints will fail earlier than good joints but can be detected after production by routine inspection of products. Poor wetting is minimised by correct choice of reflow profiles, clean and oxide-free surfaces and correct choice of flux. Identification of the correct conditions for lead-free solders is time consuming and involves a significant expenditure in time and resources.
Voids within solder	Voids in solder joints are gas bubbles, often resulting from flux volatiles, that have been trapped in the solder. It is known that voids in lead-free solder joints tend to be larger than with tin/lead solders but small voids do not normally cause problems. There is a risk if relatively large voids are formed or there are many at critical locations. Many of the problems that can potentially occur with the higher

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[13] C. Faure, Solectron “Lead-free assembly: process considerations, International conference on lead-free electronics, IPC/Soldertec Global, June 2005.

Potential failure mode	Effect of higher soldering temperature
	temperatures required for lead-free and listed in this table can be minimised by using as low a temperature as possible and using the high temperature for as short a time as possible. Both of these however allow less time for gas bubbles in molten solder to escape and so increase the risk of voids. A recent study published by IPC concluded that voiding in lead-free solders is not likely to cause inferior reliability in comparison with tin/lead solders and recent research in UK by NPL showed that voids in lead-free solders can be minimised and are not a cause for concern.
Kirkendall voiding	This is a different phenomenon to voids that are formed from flux volatiles and is currently being researched to gain a better understanding. This phenomenon is characterised by a large number of very small voids that form at the interface between the intermetallic layer and the solder. This occurs with tin/lead as well as lead-free solders but has been found to be more common with lead-free possibly as higher soldering temperatures are used. The large number of small voids that form after heat aging weakens the solder bond and thermal cycling can cause premature failure. Kirkendall voiding is not yet fully understood but appears to be related to the plating chemistry of solderable coatings but other variables may also contribute.
Fluxes	Good quality solder paste fluxes and cored wire fluxes are now available for lead-free pastes and wire. There has been a trend over recent years to replace wave soldering fluxes based on alcohol solvents with water based fluxes. This will be required by the VOC Solvents Directive (1999/13/EC) which requires manufacturers to reduce emissions of volatile organic carbon compounds (VOC). However, on changing to lead-free solders, the water based fluxes designed for lead-free are not always found to give good results and in some cases manufacturers have been forced to change back to solvent based fluxes.
Rework issues	Although rework can be straightforward, several potential problems have been identified. Removal of components by immersion of the joint in hot liquid solder is effective but due to the high temperature and solubility of copper, can result in erosion through tracks and vias to create open circuits. Replacement of components can be problematic as re-used surfaces are more difficult to wet and so require more aggressive fluxes which can lead to electromigration or surface insulation resistance (SIR) problems. Another problem found with micro-ball grid arrays (BGAs) is that large voids can form which cause poor reliability and this can occur as a result of rework to adjacent components[14].

Most of the potential problems listed in Table 13 are fairly well understood by technical experts who have been involved with lead-free technology for several years but will be unknown to any manufacturer who has not yet investigated this technology. These potential defects can be avoided by the development of robust and well controlled production processes and by carrying out appropriate tests on prototype products. Manufacturers of products that are already within the scope of RoHS have found that this does take a considerable length of time, especially those manufacturers that have a large product portfolio and relatively complex PCB designs. It is common practice that all of the different tin/lead PCB designs made at one factory would be produced using identical soldering process conditions. This may not the case with lead-free PCBs because the process window is much smaller and the manufacturer will need to determine the optimum process conditions for each board

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[14] J. Gleason et al. “Lead-free assembly, rework and reliability analysis of IPC class 2 assemblies, IEEE, 2005.

type. This requires a lot of work and manufacturers of IT and telecom equipment has found that this work has taken typically three or more years to complete.

The quality of PCBs can be determined by assessment of the risk from most of the potential failure modes listed in Table 13 using a variety of tests including accelerated thermal cycling and thermal shock testing. In some cases, these are combined with high humidity and with the equipment under power. These tests are able to determine the risk from these failure modes in a relatively short time, typically 6 months, although this depends on availability of test equipment and safety critical product testing will be more lengthy. The risk of failure by certain other modes however cannot be determined with certainty using accelerated testing because the relationship between the results of accelerated tests and field behaviour is not known. These failure modes include thermal fatigue, corrosion (this is difficult to accelerate realistically) and tin whiskers.

8.1.3 Effect of hostile environments

One important difference between most types of electrical equipment in WEEE Categories 1 to 7 and 10 and many Category 9 and some Category 8 products is that they are used in much more hostile conditions. Although there are exceptions, the printed circuit boards within household and office equipment, consumer products and toys do not experience extremes of temperature, severe vibration, very high humidity or corrosive atmospheres. Category 9 products do experience these conditions and this may for 10 to 20 years. Environmental conditions can affect the reliability of any type of solder joint – lead-free or tin/lead and one of the tasks of this review is to determine whether lead-free solders are more or less reliable. As Category 9 is not currently within the scope of the RoHS Directive, very few products that are used in hostile conditions for long periods have been manufactured with lead-free solders and these few were placed on the market only relatively recently and so there is almost no field experience to provide reliability data. There are a few exceptions but, unfortunately, these do not provide useful data. Sensors with their associated electronics are designed for monitoring conditions within oil wells and needs to operate at 150°C. High lead content solders and tin/silver solder have been used to manufacture these types of products for over six years. However, these sensors are usually used for periods of a few years at most because the high temperature damages the electronic components but these solders give satisfactory performance in this short time. The environmental conditions experienced in vehicles have similarities with those of some Category 9 products. Cars may be parked in the open reaching less than –20°C at night and in warmer climates, exposure to the sun can cause heating within the passenger compartment to over 60°C with some areas reaching 100°C. High humidity, vibration and corrosive conditions are also experienced. However, the End-of-life Vehicles (ELV) Directive (2000/53/EC) provides an exemption for lead solders and so lead-free solders are not frequently used in vehicles. Their use is increasing, but there is no long-term field data although research is being carried out.

8.1.4 Under-fill materials

Thermal cycling and vibration are well known causes of failure to solder joints and are discussed below. The incidence of failure can to some extent be alleviated by the use of under-fill materials; these are semi-flexible resins that are used to fill the gap between components and PCB and bond to both surfaces. Some of the PCBs in CT scanners experience very high G-forces (>20G) as well as vibration and thermal cycling. Larger components would detach if effective under-fill materials were not used.

Under-fill development for tin/lead has been underway for over 10 years and effective products are available but manufacturers find that these are often incompatible with lead-free systems. This is because different fluxes are used and process temperatures are higher so that new types of under-fill have had to be developed. This technology is at an early stage and many products appear to be somewhat less effective although this is difficult to demonstrate. One publication[15] showed that under-fills for lead-free flip-chip packages gave inferior thermal fatigue life when compared to tin/lead. However, this work was carried out with large ceramic substrates and in accelerated thermal cycling tests these would be expected to have a shorter time to failure irrespective of the effect of the under-fill.

8.1.5 Thermal fatigue of lead-free solders and accelerated life testing

When the temperature of a circuit increases or decreases, the materials of which it consists expand and contract. The extent to which materials expand or contract, however, varies and depends on their thermal coefficient of expansion (TCE). Where, for example, a large ceramic component is soldered onto a plastic laminate PCB, the TCE of the ceramic component is less than that of the PCB; so when the temperature rises, the PCB will expand more than the component and this applies strain to the solder joints. Repeated rises and falls in temperature occur naturally and also due to internal heating of components and this results in cyclic strain being applied to the solder which eventually leads to failure of the bond by a process called thermal fatigue. This can occur with both tin/lead and with lead-free solders and examples are shown in Figure 3.

Thermal cycling failures with tin/lead are very rare because manufacturers understand the behaviour of tin/lead solder joints under thermal cycling conditions. This is from decades of use and accurate predictive models that have been developed which are based on well-understood field data. Field failures with tin lead occur only if the solder bond is inadequate, there are mechanical design defects that apply large strains or where large low TCE components are used under conditions where large temperature cycles are experienced.

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[15] "Impact of Underfill and Solder Joint Alloy Selection on Flip Chip Solder Joint Reliability", Hillman, D., Wilcoxon, R. The Surface Mount Technology Association (SMTA) conference proceedings, 2004.

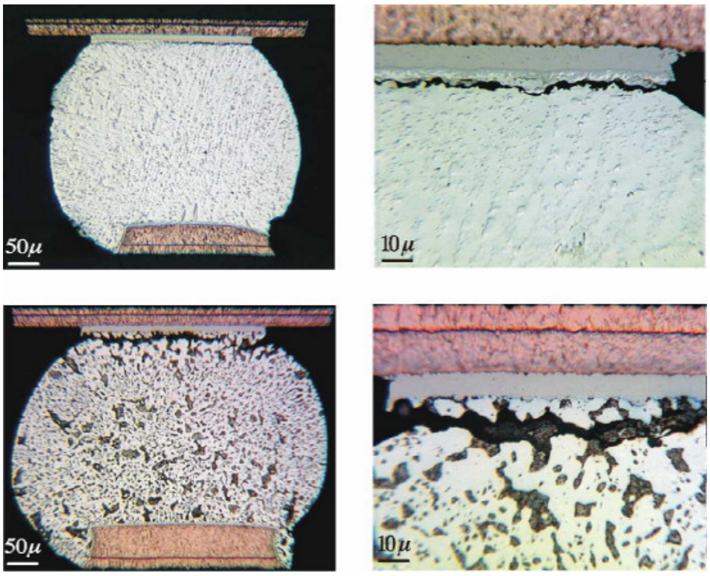

Figure 3. Thermal fatigue failure of SAC (upper images) and tin/lead (lower images) BGAs

To guarantee high reliability for electrical equipment, manufacturers will need to know how lead-free solder joints will behave in the field. Unfortunately, it is not possible to wait for field data as there will be no relevant field data until a significant quantity of Category 8 and 9 equipment has been in use in the field for 5 – 10 years. Manufacturers therefore have to rely on predictions from accelerated tests and authenticated prediction models. There has been a lot of research carried out using accelerated thermal cycling tests over the last 8 to 10 years but new reliability prediction models have been proposed but not yet fully authenticated during the last two years.

Relation between accelerated test results and life predictions - prediction models

Electronics designers can use prediction models to ensure that their tin/lead solder joints will exceed the expected life of the product. Various models are available such as Coffin-Manson and SRS which correlate strain in solder joints against cycles to failure. By carrying out accelerated tests which utilise high strain to determine the number of cycles to first failure, the model can predict the field life from the known strain under field conditions, which will be much less than in the test. These models have been developed over many years and have used field failure data to populate the low strain part of the model.

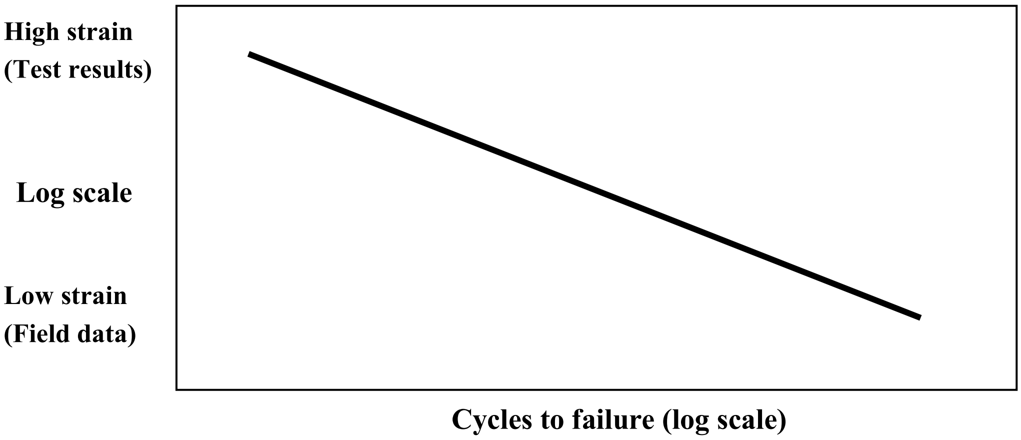

Figure 4. Typical relationship between strain on tin/lead solder joints and number of cycles before failure is predicted

Accelerated test results

There have been numerous studies since the early 1990s into the thermal fatigue behaviour of lead-free solders. The purpose of these studies has been to determine whether the risk of thermal fatigue failure of lead-free solders is greater or less than the risk with tin/lead solders. All of these studies have used accelerated thermal cycling to induce repeated cyclic strain in the solder using parallel test PCBs having a variety of types of components soldered with various lead-free solders and with tin/lead solder for comparison. In all tests, the number of cycles before first failure or 1%, 50% or a different percentage of joints fail was determined. Various thermal cycles (dwell times, ramp rates, maxima and minima) are also used but most take about one hour per cycle in order to carry out sufficient cycles for some failures to occur in a reasonable time period.

There were several studies carried out by various consortia and trade associations, the earliest by National Centre for Manufacturing Sciences (NCMS, USA), IDEALS[16] (EU funded) and by NEMI[17] (USA). There has also been a lot of research by individual manufacturers but much of this has not been published. Results need to be interpreted with caution as the number of cycles before failure can be affected by many variables. In particular, poor wetting or excessive voids will shorten the cycle life significantly and so if these are not considered, an incorrect conclusion could be made.

Research has indicated that lead-free solders based on tin, silver and copper (SnAgCu) give the best results, particularly for surface mount technology (SMT). A selection of test results is listed below to illustrate the types of results that have been obtained.

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[16] IDEALS project, http://www.tintechnology.com/soldertec/soldertec.aspx?page_id=293.

[17] http://thor.inemi.org/webdownload/projects/ese/Pb-free_SMTAI03.pdf.

Table 14. Examples of thermal fatigue failure data from various sources

Component (strain level)	Thermal cycle maxima & minima	Cycles to failure (and % of joints failed)	
		Using SnPb	Using SnAgCu
48 I/O thin small outline package (TSOP) with Alloy 42 leadframe (high strain)	0 – 100°C	2333 (1%)	1092 (1%)
2512 chip resistor (high strain)	0 – 100°C	1183 (1%)	609 (1%)
	-55 – 125°C	333 (1%)	213 (1%)
1206 Chip resistors (high strain)	-55 – 125°C	10,000 (63%)	5100 (63%)
388 I/O PBGA (low strain)	-40 – 125°C	1617 (1%)	2134 and 3122 (1%) two different solder pastes used
169 Chip scale package (low strain)	0 – 100°C	1800 (1%) 3321 (63%)	2700 (1%) 8343 (63%)
	-55 – 125°C	980 (1%) 1944 (63%)	1800 (1%) 3230 (63%)
256 micro-BGA (low strain, reference 14)	0 – 100°C	1500 (50%)	5000 (50%)

Frequently no failures occur during tests carried out with small components such as 0603 resistors, leaded devices or with small IC packages, because the strain within the solder is very low. Some researchers measure bond strength (at the start and end of tests) as an indication of deterioration in solder but frequently no change, or only a small difference in bond strength is found with these types of component[18] or the decrease in strength is similar for tin/lead and lead-free solders[19].

On initial examination, there appear to be contradictory results with some showing that lead-free solders are more reliable and others showing that tin/lead are more reliable. Closer examination however reveals that these results are in fact consistent and where the strain on the solder joint is high, tin/lead gives better results, whereas when the strain is low, lead-free solders perform better. The reasons for this are beginning to be understood but the main concern that researchers have is how to extrapolate these accelerated test results to determine the field life of products when there is no field data to indicate an "acceleration factor" for these tests.

Effect of thermal cycle parameters

Solder properties – Creep

When strain is applied to solder, plastic deformation occurs which acts to relieve the stresses within a solder joint. The rate at which creep occurs depends on the alloy composition and the temperature and is important to understanding the cause of thermal fatigue. As the strain in the solder increases during a thermal cycle, creep occurs and results in a reduction in strain. The creep rate for lead-free

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[18] M. Dusek, "Thermal Cycling Effects on Lead-free Reliability", Lead-free Solder Reliability Conference, 8th December 2005, NPL, UK.

[19] Report from IDEALS project http://www.alphametals.com/leadfree/pdfs/synthesis.pdf

solders is lower than in tin/lead solder so that, overall, lead-free solders experience greater strain than tin/lead solder under identical thermal cycle conditions. Repeated thermal cycles with the corresponding strain relief that occurs as a result of creep causes micro-structural changes within the solder; this eventually create micro-cracks which weaken the solder joint and eventually bond failure occurs.

Until recently, the creep behaviour of lead-free solders was poorly understood but NPL is carrying out research to study creep rates[20]. This work has shown that:

- At low shear stress (10 MPa) and at 21°C, the secondary creep rate for SnAgCu is over one order of magnitude lower than the rate for tin/lead whereas;
- At high shear rate (30 MPa), the secondary creep rate for SnAgCu is about 5 times higher than the rate of tin/lead;
- Creep rates increase with temperature but the rate for tin/lead increases to a greater extent than that for lead-free solders.

Because creep rate and overall strain will be different for tin/lead and lead-free solders, comparison of accelerated thermal cycling tests results to predict field behaviour is uncertain and further research is required to develop better failure rate prediction models for lead-free solders.

Determination of acceleration factors

Without field data, one way to develop a prediction model for thermal fatigue failure of lead-free solders is to carry out two sets of thermal cycling tests under different conditions by varying the test parameters so that one of the test cycles is more severe than the other.

Some of the components listed above in Table 14 were tested under two different sets of thermal cycle conditions; this can give an indication of acceleration factor. Comparison of the results from the 2512 resistor and the chip scale package shows that the number of cycles to failure is less in the more severe tests. However comparison of the results for tin/lead and lead-free solder at the two different test cycles shows that reducing the test severity has a different effect for tin/lead and lead-free and for high strain and low strain situations as show in Table 15:

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[20] M. Dusek and C. Hunt, “The measurement of creep rates and stress relaxation for micro sized lead-free solder joints” NPL Report DEPC MPR 021, April 2005.

Table 15. Effect of severity of test conditions on number of cycles to failure and ratios of results

Test	**Tin/lead**	**Tin/silver/copper**
Chip scale package		
169 Chip scale package (CSP) (low strain 0 – 100°C	1800 cycles	2700 cycles
CSP -55 – 125°C	980 cycles	1800 cycles
CSP ratio of test results	*1.8*	*1.5*
2512 resistor		
2512 chip resistor (high strain) 0 – 100°C	1183 cycles	609 cycles
2512 resistor -55 – 125°C	333 cycles	213 cycles
2512 resistor ratio of test results	*3.55*	*2.86*

Clearly, the acceleration factors based on these ratios for tin/lead and lead-free solders are different as well as depending on strain in solder joints.

Development of a useful prediction model is complex as it needs to take into account the shear stress and shear strain in solder joints under the conditions of the test and the conditions that would be experienced in the field. Thermal fatigue failure prediction models are being investigated by several researchers including J-P Clech [21]. One approach has been to determine the effect of varying each part of the test cycle to determine the effect on results. Tests to investigate short and long dwell times, fast and slow ramp rates and large and small temperature ranges have all been investigated.

Dwell time

Comparison of 10 minute and 1 hour dwells showed that this had only a small effect overall on the stresses in lead-free solder joints and an even smaller effect on tin/lead joints. Calculation of shear stress ranges of joints shows that these are significantly greater for lead-free than for tin/lead solder under identical test conditions but changing the dwell time had a relatively small effect. Increasing dwell time should give slightly more accurate predictions but can make the test far too long to be practical.

Ramp rate

Research carried out using fast and slow temperature ramp rates showed that the ramp rate has a relatively small impact on cyclic stress levels. However, a surprising result was that tin/lead and lead-free solders behaved differently:

- Tin/lead – predicted cycle life decreased as ramp rate (°C/min) increases
- Lead-free - predicted cycle life increased as ramp rate (°C/min) increases.

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[21] Jean-Paul Clech, “Acceleration Factors and Thermal Cycling Test Efficiency for Lead-Free Sn-Ag-Cu Assemblies”, SMTA International Conference, 2005.

This result is new and not easy to explain but may be related to the extent of damage to the solder microstructure caused at different ramp rates with rather more damage to lead-free solder occurring at lower ramp rates than at higher rates.

Temperature range and mean temperature

In the field, temperature changes may be fast or slow but dwell times are usually long. The range of temperature experienced by individual products will vary but in most cases will be much smaller than those used for accelerated tests. A range of 40°C (such as 10 to 50°C) would not be uncommon in the field. The size of the temperature range is proportional to the maximum shear stress within the solder joints but calculations using failure prediction models also show that as the mean temperature increases, the shear strain range (during the thermal cycle) increases significantly.

Acceleration factor

Research to develop models that can be used to calculate acceleration factors is making progress but the lack of field data means that it is difficult to validate these. Many variables will affect stresses and strain and so also cycle life. The thermal coefficient of expansion of components and PCB would be expected to have an influence as well as thermal cycle conditions. Usually, there are no failures when components are tested under mild conditions and so it is not possible to determine if a model's predictions are correct. This is only possible where the combination of component and substrate result in unusually high stress and strain levels so that the time to failure is relatively short and, in a series of tests under these conditions, three thermal cycle profiles were used[22] and the times to failure measured. By using his new prediction model, Clech was able to calculate acceleration factors from the two more severe tests (-40 to +125°C and 0 to 100°C) to the least severe test (30 to 80°C) and these prediction are within 30% of the actual measured result.

This is one of the few studies published where accelerated test results are compared directly with failure rates measured using conditions close to field conditions and it does appear to confirm that the new prediction models could give reasonably reliable results but this should be viewed with caution. This test was possible only because the stresses were unusually high so that even under the least severe test conditions, 63% of joints failed after less than 200 thermal cycles and at the most severe test conditions, 63% failures occurred after only ~ 10 cycles. This extreme test therefore may not be truly representative of most PCBs but this result is encouraging as it suggests that useful prediction models may be available in the fairly near future.

There is a similar relationship between strain and cycles to failure shown in Figure 4 for tin/lead for lead-free solders but the gradient will be different. Under accelerated test conditions, at high strain, lead-free joints fail after less cycles and at low strain lead-free joints will last longer than their tin/lead counterparts. Extrapolation of accelerated test results for tin lead is possible because there is field data and the type of relationship shown in Figure 5 is used to predict field life based on the known

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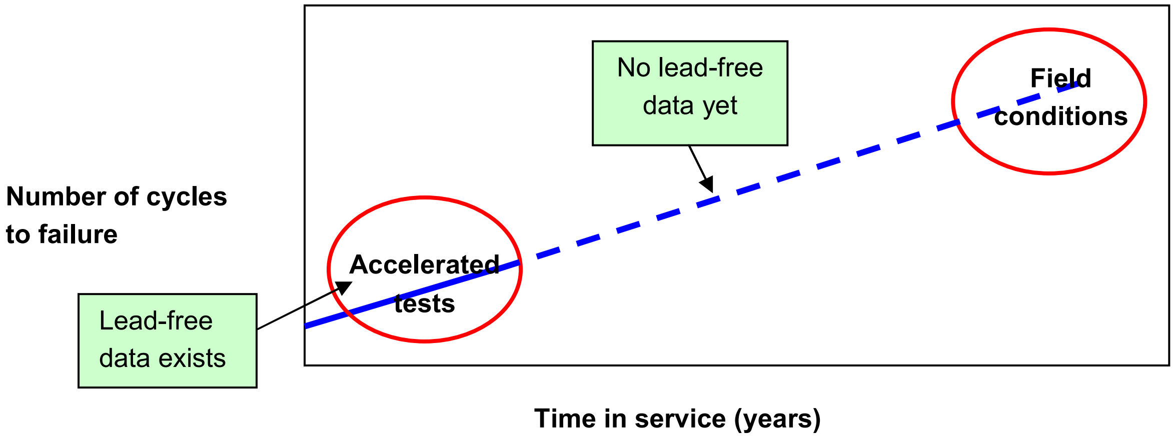
[22] O. Salmela et al., "Reliability analysis of some ceramic lead-free solder attachments", Proceedings of Pan Pacific Microelectronics Symposium, SMTA , Hawaii p. 161, Jan 2005.

strain experienced in the field. This is possible only when the gradient of the number of cycles to failures versus time is known - this is not yet the case for lead-free solders as they are too new. In the future, field data will become available so that the gradient will be known with increasing accuracy and after another five years, it should be possible to estimate field life

Figure 5. Relationship between number of cycles to failure and severity of test conditions ranging from most severe in accelerated tests to least severe in the field



Thermal fatigue conclusions

Whether lead-free solders will perform better or worse than tin/lead solder will depend on many variables such as the types of components used, build quality, extent of any temperature changes that occur and the expected life of the product. Accelerated testing shows that lead-free solders perform better than tin/lead where the strain on joints is low but tin/lead solder gives better test results in high strain situations. This is due to the difference in microstructure of these two types of alloys and makes life predictions for lead-free solder difficult, especially as there is no suitable field data.

In reality, however, as long as lead-free is not substantially less reliable, which seems unlikely, whether tin/lead or lead-free is the superior solder type is less important than having a good understanding of the long term performance of the alloys and to be able to design equipment which will last longer than the expected life. To do this requires accurate predictive models that can account for all of the variables that affect field life.

Research reported in the last two years indicates that our understanding of lead-free solders is improving and that accurate predictive models for lead-free solders could become a reality in the next few years. It is likely that by 2012, accurate models will be available and that these will have been validated by field data from the very large numbers of RoHS compliant electrical equipment that will be placed on the market from the end of 2005 onwards. Knowledge of the relationship between strain and number of thermal cycles to failure for lead-free solders will be required in order to accurately predict field life of products. Early indications are that this relationship will be similar to that for tin/lead as shown in Figure 4 but will not be identical.

8.1.6 Vibration

Review of literature on vibration performance of lead-free solder

Vibration and thermal fatigue are related effects, vibration causes rapid changes in stress and very short strain cycles, usually with no temperature change whereas thermal fatigue is caused by temperature changes that occur over much longer time periods. In general, the number of vibration cycles to failure is much longer than typical thermal cycles to failure but both are types of fatigue. Some researchers call vibration “high cycle” fatigue and thermal fatigue “low cycle” fatigue.

Conventional Sn-37wt%Pb solders have been in use in the electronics industry for over 50 years. During this time an extensive knowledge base about their usage and reliability has been established, including their application in harsh environments where high vibration levels are encountered. Currently this knowledge base does not exist for lead-free solders and even with accelerated testing will take time to establish. This may not be critical for consumer electronics, such as cellular phones, where the product lifetime is short or household appliances, where vibration level may be low, but for products exposed to severe vibration levels or where service lifetimes of years to decades are required the lack of knowledge is a concern.

Fatigue testing has been used extensively to predict the reliability of lead-free solder joints as substitutes for conventional Sn-37wt%Pb solder in electronic components although in reality these rarely experience constant or even uniform continuous fluctuations of stress or strain during their operating lives and such tests may not be appropriate for assessing the in-service reliability of lead-free soldered printed circuit boards (PCBs) as discussed in Section 8.1.5. Fatigue testing can help to model the conditions encountered during thermal expansion and contraction of components on a board but it does not account for the more complex stress states that can be encountered when the board vibrates in services. In addition, most of the information on fatigue behaviour and lifetime performance of lead-free solder joints has been obtained from continuous cycling fatigue experiments where the length of each stress/strain cycle is relatively long - typically 1 hour. Vibration stress/strain cycles are very different and can be as short as milliseconds. Little data is available for more realistic vibration or fatigue experiments combining cycles of stress or strain interspersed with dwell periods during which these parameters are constant, or other isothermal cyclic fatigue experiments.

The use of fatigue data alone to predict vibration performance can be misleading. For example, Kanchanomai[23] performed isothermal strain-controlled fatigue tests and found that Sn-3.5Ag exhibited twice the cycles to failure for a given plastic strain range than Sn-37Pb at room temperature. However, Plumbridge and Gagg[24] investigated the mechanical behaviour of bulk specimens of a conventional Sn-37Pb solder with Sn-3.5Ag and Sn-0.5Cu alloys (two candidate alloys for

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[23] C Kanchanomai, S Yamamoto, Y Miyashita, Y Mutoh and A J McEvily, International Journal of Fatigue, vol. 24, p57–67, 2002.

[24] W J Plumbridge and C R Gagg, Proceedings of the Institution of Mechanical Engineers, Vol 214, Part L, p153-161, 2000.

replacement of leaded solders) and their investigation included both fatigue testing under continuous cycling conditions and testing with a dwell introduced into each fatigue cycle. Under continuous cycling conditions the performance of the three alloys was broadly similar. The introduction of a dwell period in the cycles was deleterious to all the alloys (less cycles to failure as would normally be expected), although for the Sn-0.5Cu alloy brief dwells of approximately 10s increased the number of cycles to failure, whereas extending the dwell period to 100s reversed this trend and the alloy's fatigue life was reduced. The researchers cautioned that the duration of the dwells introduced during their fatigue testing was extremely small compared to the length of hold periods likely to be encountered in service and on the difficulties of comparing bulk solder properties with the properties of solder joints on PCBs. Clearly, the fatigue test results of Kanchanomai or Plumbridge and Gagg are not appropriate for directly predicting the vibration resistance of the alloys tested.

One of the difficulties associated with assessing the resistance to vibration of lead free solders is that the test data available has been acquired by different users and researchers testing different solder alloys under significantly different test regimes. It is essential that these differences be considered, as contradictory claims about reliability may arise from inappropriate or selective use of the data. Table 16 presents a summary of known test data on the reliability of lead free solders exposed to vibration. It includes details of the solder composition, the components tested, the vibration levels and time of testing as well as a brief summary of the outcome. This table highlights the difficulty of drawing any overall conclusions. However this data does suggest that at low vibration force ($<10\ g_{rms}$), the performance of lead-free solders is comparable or better than tin/lead solder.

Table 16. Results of vibration testing lead-free solder from different researchers

Research group	Lead-free Solder Composition	Components Tested	Vibration Frequency Range	Maximum Vibration Level (g_{rms})	Axes Tested	Time period	Conclusions
Song et. al	Sn-0.7wt%Cu Sn-3.5wt%Ag Sn-37wt%Pb Sn-58wt%Bi Sn-8.8wt%Zn Sn-8.8wt%Zn-1.5Ag	Cantilever beam assembly	Resonant frequency of cantilever beam assembly (not quoted)	3.5	Z axes only	Unknown	Sn-0.7wt%Cu = Sn-3.5wt%Ag = Sn-37wt%Pb Sn-58wt%Bi & Sn-8.8wt%Zn failed at <1/3 the number of cycles to failure of Sn-37wt%Pb Sn-8.8wt%Zn-1.5Ag performed 1/3 better than Sn-37wt%Pb
IMECAT	Sn-4wt%Ag-0.5Cu	Demonstration electronic control unit including BGAs	Unknown	3.15 to 17	Unknown	Unknown	No failures at <3.15g High level of failure at 17g
Lau et al.	Sn-57wt%Bi-1Ag	Printed circuit boards (PCBs)	5-500Hz	0.75 to 11	Unknown	20 mins at 0.75g 5 mins at 11g	No failures. Adequate for consumer products
Geiger et al.	Sn-37wt%Pb Sn-3.9wt%Ag-0.6Cu	0201 scale components	5-500Hz	1.5	X, Y and Z	1 hour each axes	No failures
Shan-Pu et al.	Sn-37wt%Pb Sn-3wt%Ag-0.5Cu	Quad Flat Pack (QFP)	50-2000Hz	9.0 to 11.6	X, Y and Z	15 minutes	No failures
Shi-Wei et al.	Sn-37wt%Pb Sn-3.9wt%Ag-0.6Cu	Plastic Ball Grid Arrays (PBGAs)	20-2000Hz	6.0	Unknown	6 hours	No failures
JGPP	Sn-0.7wt%Cu-0.05Ni Sn-3.9wt%Ag-0.6Cu Sn-3.4wt%Ag-1Cu-3.3Bi	Test vehicle including Ceramic Leadless Chip Carrier (CLCC), Plastic Dual In-Line Package (PDLP) with Sn finish, PDLP with NiPdAu finish, BGAs, Plastic Leadless Chip Carrier (PLCC)	20-2000Hz	9.9 to 28	X, Y and Z	1 hour in X and Y. 1 hour in Z then increasing vibration force by 2g per hour	Varying for components. No failures after X and Y axes vibration.

The condition of the solder joints is also important. For example a recent article by Hillman[25] referred to studies showing that lead-free SAC (SnAgCu)[26] solder alloys can fail at loads up to 50% lower than SnPb when subjected to shock, drop, or static board bending. This loss in performance was thought to be the result of a combination of brittle intermetallics, board degradation due to higher reflow temperatures, and a greater transfer of stress because SAC is a stiffer material than SnPb.

However, Hillman indicated that manufacturers of portable electronics, which have been Pb-free for several years, have reported no increase in field returns due to products being dropped. Other manufacturers are primarily focusing on maintaining better control over the manufacturing environment, specifically by reducing the maximum allowable strain values from 1 µm of in-plane movement for every millimetre of board length to 0.75 or 0.5 µm of in-plane movement for every millimetre of board length.

Matsushita Electric (Suetsugu[27]) has performed mass production trials using a Sn-Ag-3wt%Bi lead-free solder alloy to manufacture circuit boards for a portable mini disc player. The standard product tests were performed on boards (dropping, thermal shock and vibration testing) and all met the reliability standards.

Motorola (Melton[28]) has completed thermal cycling and vibration studies on Sn-Ag based lead free solders in comparison with conventional Sn-Pb solders and has also concluded that the Sn-Ag alloys provide adequate results.

Further information on the data presented in Table 16 is given below.

Solder joint failure due to vibration becomes more significant as the frequency of vibration approaches the resonant frequency of the component or structure. Studies by Chuang et al.[29] and Song et al.[30] have sought to identify microstructural features that influence the performance of conventional Sn-Pb solders and candidate replacement lead-free solders. The typical microstructure of conventional Sn-Pb solders containing coarse pro-eutectic grains reduces the ability of these materials to absorb energy during crack formation and hence reduces the vibration resistance of joints made using these solders. In contrast, one candidate lead-free solder from the Sn-Zn system forms a fine eutectic structure in which cracks form and coalesce to limit crack growth. This solder exhibits enhanced resistance to vibration failure that can be further improved by the addition of 1 to 2.5wt% silver, the silver forming large Ag-Zn particles that enhance the crack deflection properties of this solder's microstructure.

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[25] C Hillman (of DfR Solutions (http://www.dfrsolutions.com/), Electronic Products (http://www.electronicproducts.com), September 2005.

[26] According to a 2003 survey by Soldertec 65% of lead free solder use is SAC based.

[27] K Suetsugu, Matsushita Electric Industries Company, http://www.smtinfocus.com/PDF/Leadfree_Matsushita.pdf, 2000.

[28] C Melton, Proceedings from Nepcon West, p1003-1011, 1995.

[29] C M Chuang, T S Lui and L H Chen, Journal of Electronic Materials, Vol. 30, No. 9, p1232, 2001.

[30] J M Song, T S Lui, LH Chen and D Y Tsai, Journal of Electronic Materials, Vol 32, No.12, p1501-1508, 2003.

Song et al. investigated the resonant vibration-fatigue characteristics of some potential lead-free solders, including Sn-Zn, Sn-Ag Sn-Cu, and Sn-Bi alloys. Their results showed that, under a fixed vibration force of 3.5g, the damping capacity and vibration-fracture resistance of Sn-Cu and Sn-Ag eutectic alloys with an off-eutectic structure were similar to that of conventional Sn-Pb solder at approximately 21×10^3 cycles to failure, and higher than experimental Sn-Bi and Sn-Zn based solders (7 and 5×10^3 cycles to failure respectively). This finding was related to the vibration-deformed structure and crack-propagation morphology associated with the microstructural features of the materials. In the Sn-Cu and Sn-Ag eutectic alloys, Song et al. suggested that the striated deformation in the Sn-rich phase was an effective mechanism for absorbing vibration energy. Although initially the vibration-fracture resistance of the Sn-Zn eutectic alloy had been poor, microstructural modification could be achieved through silver additions to significantly improve the damping capacity and vibration-fracture resistance of this alloy. When the silver content of the alloy exceeds 1.5wt% the vibration life exceeded 30×10^3 cycles to failure.

Between 2002 and 2005 the European Community supported a pan-European project FP5-CSG-IMECAT, on the development of lead-free interconnection materials and the uses of these materials for electronic assembly in a wide variety of industrial applications. As part of this project a lead free solder paste was developed by Heraeus/TU Berlin, with composition Sn4wt%Ag0.5Cu and this was used to develop lead-free assemblies for automotive applications (Mango[31]). Although the automotive industry is exempted from the RoHS Directive, development of lead-free solders for this application provides valuable information on the reliability of these solders when used in products included in the Directive. Lead-free soldering in the automotive environment is more difficult to implement than any other electronic consumer product since high reliability and high safety levels must be proven. Required lifetimes for electronic components in automotive applications range from typically 5,000 hours for passenger cars to 20,000 hours for commercial vehicles.

Typical vibration levels encountered in automotive applications are given in Table 17.

Table 17. Typical vibration extremes encountered in automotive applications

Location on vehicle	Vibration level g_{rms} (Root mean square of acceleration)
On engine, on transmission system	17
Under vehicle hood, near engine	17
Inside passenger compartment	3.15

As part of the IMECAT project a number of demonstration ECU units were designed, assembled and submitted to combined temperature/vibration tests to determine the suitability of lead-free solder implementation in automotive applications. One of the components tested on the ECUs was a large BGA of 1mm pitch (PBGA 388), which is the most critical component in every recent ECU application. After vibration testing those BGAs exposed to vibration levels comparable to those

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[31] M Mango, Proceedings of the 15th European Microelectronics and Packaging Conference, X1.07, p451-456, 2005.

encountered within a passenger compartment showed no failures. However those BGAs exposed to vibration levels encountered in under hood applications showed many problems, especially on the balls at the corners of the BGAs. Analysis of the failures showed they were caused by brittle fracture through a 4-5µm intermetallic layer of $(Au,Ni)Sn_4$ that is well known for its brittle behaviour. Flip chip components on the ECUs also failed by the same mechanism when exposed to the higher vibration levels.

This study concluded that although lead-free solders are suitable for applications where low random vibration levels are encountered ($<3.15g_{rms}$) further development is required for their successful use in environments where higher vibration levels are encountered ($\sim17g_{rms}$).

Interrante et al.[32] of IBM investigated the reliability of lead-free package interconnects for ceramic grid arrays using a SAC type solder of composition Sn3.8wt%Ag0.7Cu. In their study BGAs of 1mm pitch were vibration tested according to US Military Standard 810E, with random vibrations in the frequency range 0-500Hz at strengths of 1.04 g_{rms} for one hour in x, y and z axes. Lead-free SAC soldered BGA packages with 1mm pitch exhibited higher reliability than existing tin-lead BGA packages of the same form, due to the superior fatigue properties of the SAC alloy.

Lau et al.[33] of the High Density Packaging Users Group Consortium (which includes Hewlett Packard and Agilent Technologies) conducted a study of process development and solder joint reliability of high-density packages on printed circuit boards (PCBs) using a low melting temperature lead free solder of composition Sn57wt%Bi1Ag. The testing included vibration measurements to a specified Hewlett Packard standard for portable electronic devices (HP Standard Class B1-II) that exposed the PCBs to vibrations between 5 and 500Hz, of strength $0.75g_{rms}$ for differing time periods. Firstly the PCBs were clamped flat onto the vibration table and the random vibration test was run for ten minutes. Next the boards were supported 9.52mm above the vibration table and the test was repeated for a further 10 minutes, before finally determining the dominant resonant frequency of the board and vibrating the boards at this frequency for a further 5 minutes. At the frequency the boards experienced vibrations of strength $11g_{rms}$. Upon completion of the vibration cycles continuity tests were performed and no open circuits were detected. From this test and others performed on the PCB the authors concluded that the lead free solder of this composition was more than adequate for most consumer products under normal operating conditions.

Geiger et al.[34] investigated the reliability of solder joints for 0201 components (dimensions of the order of 0.02 x 0.01inches) that are used in laptop computers, wireless internet devices, personal digital assistants (PDAs) and cellular telephones. Vibration tests were performed on boards that used conventional Sn-37wt%Pb solder and a lead free SAC type solder (Sn3.9wt%Ag0.6Cu). Test

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[32] M Interrante, J Coffin, M Cole, I De Sousa, M Farooq, L Goldmann, C Goldsmith, J Jozwiak, T Lopez, G Martin, VT Truong and D Welsh, EEE/CPMT/SEMI 28th International Electronics Manufacturing Technology Symposium, San Jose, CA, July 16-18, p85-92, 2003.

[33] J Lau, W Dauksher, J Gleason, V Schroeder, G Hesell and B Sullivan, OnBoard Technology, June, p26-29, 2005.

[34] D Geiger, M Wang, D Shangguan, T Castello and F Mattsson, http://www.smta.org/files/SMTAI03-Geiger.pdf , 2005.

frequencies were 5-500Hz at 1.5g_{rms} with the boards tested for 1 hour in each of the three major axes (x, y and z). No failures were found demonstrating that the lead-free solders were as reliable as the conventional leaded solders under these test conditions.

Shan-Pu et al.[35] examined the reliability of lead free quad flat pack (QFP) assemblies by comparing a QFP component mounted with SAC lead-free solder (Sn3wt%Ag0.5Cu) with a component mounted using conventional Sn-37wt%Pb solder. Both components were exposed to random vibrations as defined in US Military Standard MIL-STD-883E method 2025. Test frequencies were 50-2000Hz at between 9.0 and 11.6g_{rms} for 15 minutes in x, y and z axes. The tests were repeated to double the exposure time. All samples passed.

Shi-Wei et al.[36] assessed the board level solder joint reliability of plastic ball grid array (PBGA) assemblies with lead-free solders. The lead free solder investigated was Sn3.9wt%Ag0.6Cu. Two sizes of PBGA were used as the test vehicles, 27x27mm and 35x35mm. Samples produced using conventional Pb-37wt%Sn solders were also tested in parallel. The samples were subjected to random vibrations in the out-of-plane direction. The failure criteria were defined as a change in resistance of 100Ω in the circuit. The vibration frequencies tested were 20-2000Hz with the maximum dynamic loading not exceeding 6g_{rms}. After 6 hours of testing no failures had occurred and it was concluded that this random vibration testing condition was not critical to the reliability of the PBGA-PCB type assemblies.

To date, the most comprehensive study of the reliability of lead free solders when exposed to vibration has been undertaken by the United States Department of Defence Joint Group on Pollution Prevention (JGPP[37]) and Joint Council on Aging Aircraft (JCAA) in partnership with the National Aeronautics and Space Administration (NASA) and Original Equipment Manufacturers (OEMs). Although this project was primarily aimed at military aerospace applications, which are not specifically related to the European RoHS Directive, the severity of the testing regimes implemented provide a useful benchmark for lead-free solder applications in more traditional commercial electronic applications. Any lead-free solder composition that achieved comparable results to conventional Sn-Pb solder in this test regime is likely to be suitable for use in a wide range of commercial applications where the operational conditions are less severe.

The vibration testing was undertaken as part of a wider project to characterise, demonstrate and validate the performance of lead-free solders as potential replacements for use on circuit card assemblies. The following lead free solders were selected for evaluation:

- Sn-0.7wt%Cu-0.05Ni for wave soldering

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[35] Shan-Pu Yu, Yukon Chou, Pei-ying Shie, Chiou-Chu Lai and I-Hsuan Peng, Advanced Packaging Technology Center, ITRI Taiwan. Paper presented at SMTA meeting in Boston, 2001.

[36] RL Shi-Wei, BH Wai Lui, YH Kong, B Baylon, T Leung, P Umali and H Agtarap, Soldering and Surface Mount Technology, 14/3, p46-50, 2002.

[37] Joint Group on Pollution Prevention, http://www.jgpp.com/projects/lead_free_soldering/lead_free_soldering.html, 2006.

- Sn-3.9wt%Ag-0.6Cu (SAC) for wave, reflow and manual soldering
- Sn-3.4wt%Ag-1Cu-3.3Bi for wave, reflow and manual soldering

Test vehicles were built based on a printed wiring assembly (PWA) specifically designed to evaluate the solder joint reliability. This assembly included a variety of plated through hole (PTH) and surface mount technology (SMT) components. All the components were daisy-chained with the soldered joints on each component forming a continuous electrical pathway. This allowed each individual solder joint to be monitored during the vibration testing, with any joint failure being recorded as a break in the electrical pathway.

Vibration testing was performed according to US Military standard MIL-STD-810F Method 514.5, Procedure I. These tests assumed that most failures occur with the vibration in the axis perpendicular to the plane of the circuit board (z axis) as a result of the board bending. During the tests the boards were tested in the x, y and z axes for 1 hour at a vibration strength of $9.9g_{rms}$. The boards were then tested in the z axis, increasing the vibration level by $2g_{rms}$ until all components had failed or total vibration strength of $28g_{rms}$ had been reached. For both lead-free and leaded soldered boards the percentage of components that failed at each vibration level is shown in Table 18.

Table 18. Component (leaded and lead-free) failures under increasing vibration levels

Vibrational Axis	Vibration Level (g_{rms})	% failed
Y	9.9	0
X	9.9	0
Z	9.9	7.6
Z	12.0	18.0
Z	14.0	29.3
Z	16.0	39.3
Z	18.0	47.0
Z	20.0	55.6
Z	28.0	68.8

Data: (JGPP study 2001-2006)

The final conclusions of this study have not yet been published. However the preliminary findings indicate that SnAgCuBi and SnCuNi lead-free solders performed well in comparison to conventional Sn-Pb solders whilst the SAC type lead free solders did not. There was a variation in the performance of the solders for different components on the circuit boards. These are summarised in Table 19.

Table 19. Performance of lead-free solder on different components in comparison to leaded solder

Component	Performance
Ceramic Leadless Chip Carrier (CLCC)	SnAgCuBi solder = SnPb solder> SAC performance
Plastic Dual In-Line Package (PDLP) with Sn finish	SnCuNi perform > SnPb solder >SAC
PDLP with NiPdAu finish	SnCuNi perform > SAC > SnPb
BGAs	SnPb solder with SnPb BGA balls outperform lead-free solder with SAC BGA balls
BGAs	SnPb solder with SnPb BGA balls outperform SnPb solder with SAC balls and lead-free solder with Sn Pb balls
Plastic Leadless Chip Carrier (PLCC)	SnPb perform > SACB > SAC

Data: (JGPP study 2001-2006)

Clearly, designing equipment for long term reliability under conditions where high g forces may be experienced will be important for certain Category 8 and 9 products and equipment designers will need to take into account the sometimes contradictory conclusions from the published research on vibration resistance of lead-free solders. The main conclusions are:

- At low g-force, in any direction, tin/lead and lead-free solders perform equally well;
- At high g-force (>11 grms) in the x- and y- directions, performance of tin/lead and lead-free solders are similar;
- At high g-force (> 9 g_{rms}), lead-free solders appear to be less reliable than tin/lead solder. Some work indicates than SnAgCu is inferior to SnAgBiCu.

Few Category 8 or 9 products would experience g-forces >10 g_{rms} for long periods but there will be exceptions. For example, PCBs used in CT scanners are rotated at 3 times per second and experience up to 30 g_{rms} although this is in one direction, x- or y- and underfill materials are used to prevent failures. As a result of the differences in behaviour of lead-free and lead solders, manufacturers of these products will have to carry out lengthy and comprehensive testing in order to avoid premature failures. There is one type of product where it may be impossible to use lead-free solders. Portable emergency defibrillation equipment that is transported in ambulances and other emergency vehicles receives particularly high g-forces. Manufacturers have measured forces of up 40 g_{rms} and up to 150 g_{rms} when these are dropped onto hard surfaces which is common under emergency situations. As this force could be in the z-axis, the JGPP study results indicate that this will cause premature failure. Emergency defibrillators are transported to the patient and failure could occur as a result of vibration during this journey. If this were to occur when the equipment is needed in an emergency, it is likely that the patient would not survive as no alternative defibrillator would be available.

8.1.7 Corrosive environments

Category 9 equipment may be used in environments where the equipment is exposed to extremes of temperature as well as high humidity, seawater spray and corrosive materials from industrial processes such as hydrogen sulphide, chlorine, acids, etc.

Category 8 equipment is not likely to be used in hostile environments but will be in contact with moisture, body fluids, disinfectants and aggressive cleaning chemicals and some will be exposed to anaesthesia gases.

Resistance to corrosion is therefore important and will be more critical for products in these Categories than products in other Categories, as long-term reliability is important for safety critical products. Lead-free solders are in general equal in corrosion resistance to tin/lead. However manufacturers are finding that some substitute PCB coatings are less reliable than tin/lead coatings when exposed to corrosive environments. Traditionally, PCB coatings were tin/lead solder which protects the copper circuitry very well as it is resistant to corrosion. Substitutes such as silver and organic coatings are much less protective, especially in contact with hydrogen sulphide and ERA has seen several examples of PCBs made with these coatings that have failed as a result of corrosion that has destroyed metallic conductors to give open circuits. Lead-free hot air solder levelling (HASL) should not suffer from this problem but are not a common choice of board coating.

Nickel/gold PCB coatings are commonly used and do not appear to be susceptible to hydrogen sulphide alone but recent research[38] has (rather surprisingly) shown that nickel/gold PCB coatings and precious metal component termination coatings suffer from severe corrosion in tests to simulate polluted industrial environments. This test uses a mixture of hydrogen sulphide, nitrogen dioxide, chlorine and moisture and is a very severe test but does simulate chemical factory environments. This result is new and corrosion of these types of coatings was not predicted. This illustrates the need to allow manufacturers sufficient time to carry out research before changing safety critical products as new materials can behave in unexpected ways.

Another concern is whether the substitutes for hexavalent chromium will give adequate corrosion protection in corrosive environments. Corrosion protection is required to maintain electrical contact between metal parts (for earthing) and to enable equipment to be dismantled for repair (so screws are coated). Substitutes are all relatively new and have not been fully evaluated under field conditions in all industrial environments. Another example of where unexpected corrosion has occurred is discussed in Section 10.9 and recent research has also indicated that the risk of tin whiskers is increased by exposure to corrosive atmospheres[39].

Research into substitutes uses standard salt fog testing for various lengths of time. Substitutes perform well in the shorter tests that simulate less severe environmental conditions but in 1000 hour

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[38] Unpublished research, private communication from M. Plagens, Honeywell Inc.

[39] C. Hillman, DfR Solutions, www.dfrsolutions.com

tests to simulate polluted factory environments they perform poorly in comparison with hexavalent chromium. However if equipment used in production processes is regarded as part of "large-scale stationary industrial tools", these are outside the scope of WEEE and RoHS and can continue to use hexavalent chromium.

8.2 Tin whisker risk from tin based coatings

Many metals are susceptible to spontaneous growth of thin metallic rods known as whiskers. This can occur with metallic elements as well as alloys. Metals which are susceptible to whiskers and are well known to cause failures in electrical equipment are tin, alloys of tin and zinc but many other metals such as platinum, can also form whiskers. Failures of electrical equipment from tin whiskers were known many decades ago and this problem was resolved by the addition of lead to the tin coatings. With the adoption of the RoHS Directive in Europe, the addition of lead to prevent whiskers will not be permitted in equipment that is within the scope of this Directive. Manufacturers will therefore have to find alternative ways of minimising the risk of whiskers.

Tin whiskers are currently being intensively researched to understand why they form, how to determine whether they are likely to form, and how to prevent failures due to whiskers. Whiskers grow on tin and tin alloy surfaces including tin/lead alloys although this is relatively rare (see Figure 6). The formation of whiskers in itself is not a problem but failures occur as a result of electrical short circuits. Some whiskers are very short and resemble "nodules" rather than whiskers. Whiskers are a problem therefore only if they are of sufficient length to cause a short circuit of fine pitch electronic circuits or components (see Figure 7).

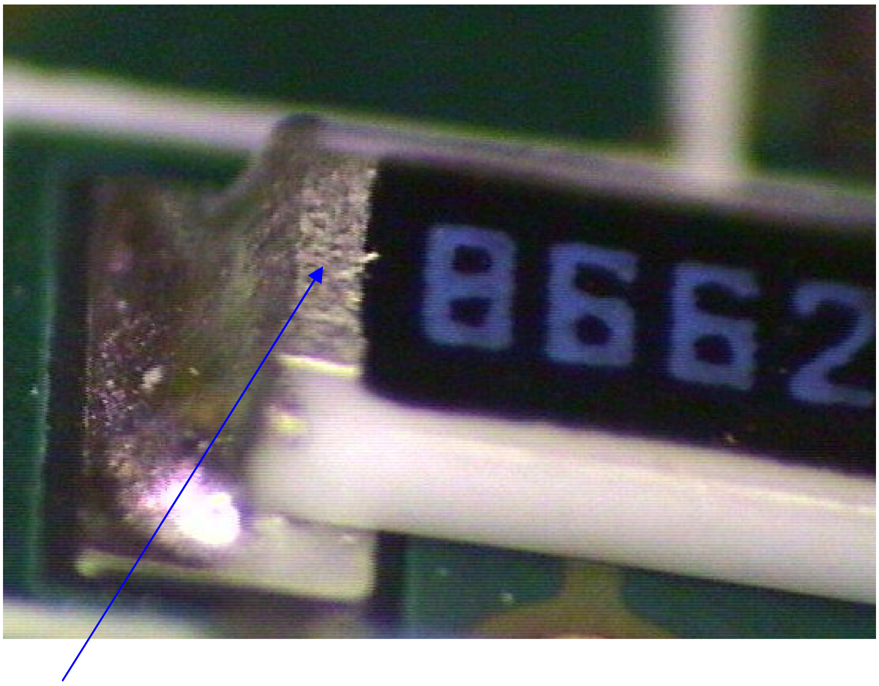

Figure 6. Tin/lead whisker on SnPb electroplated end termination of chip resistor

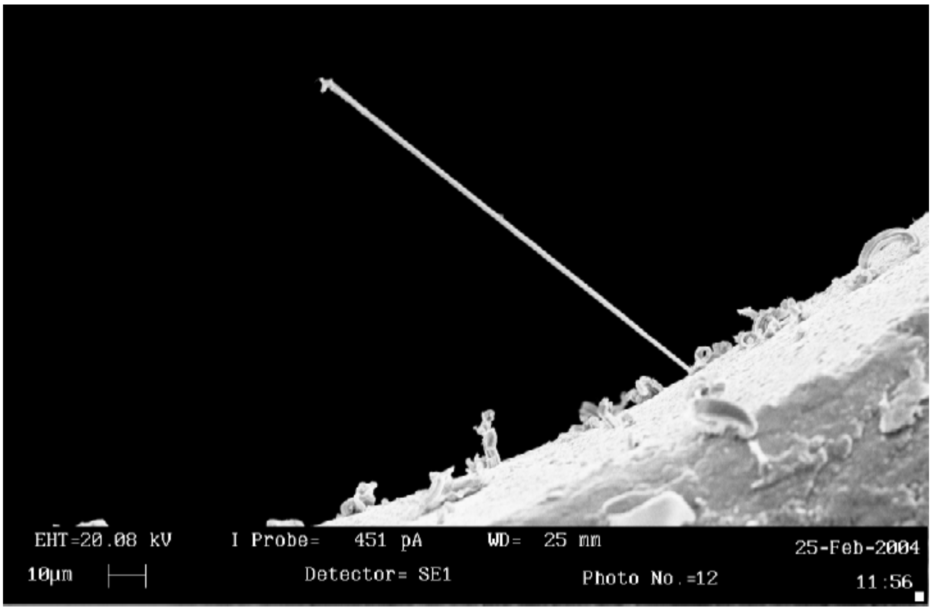

Figure 7. One long tin whisker and many nodules on an electroplated tin coating surface

This one long whisker could cause a short circuit but the nodules would not normally be expected to have an effect on reliability.

There have been some well publicised failures due to tin whiskers including the failures of satellites, missiles, heart pacemakers and power relays[40]. Recently a US nuclear power plant had to be shut down due to an electrical fault which was found to be short circuits caused by tin whiskers growing on a faulty batch of diodes produced in the 1990s[41].

Tin whiskers occur mainly on electroplated tin and tin alloy coatings but also on other metals such as zinc. Once the tin has been melted, such as in a hot dipped solder coating, whiskers are much less likely although they can occur. Tin whiskers can also form on "immersion" tin coatings but again are less likely, especially if the tin coating is very thin. At one time, whisker growth was thought to be much more likely on "bright" electroplated tin than on "matte" tin. Although this was true some years ago with the types of plating bath in use at the time, it is now known that tin whiskers grow on some types of matte tin coatings and can also be very unlikely on certain bright tin coatings.

8.2.1 Status of current research into tin whiskers

A lot of research has been carried out and is continuing into tin whiskers and this is summarised here.

For many years, the formation of tin whiskers has not been understood and research is being carried out to gain an understanding of the mechanism. Research is also being carried out to identify the

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[40] NASA website, http://nepp.nasa.gov/whisker/failures/index.htm.

[41] "Inadvertent Reactor Trip and Partial Safety Injection Actuation Due to Tin Whiskers" United States Nuclear Regulatory Commission Office of Nuclear Reactor Regulation, Notice 2005-25, August 25 2005.

main risk factors so that these can be avoided and also to develop accelerated tests to determine the risk of whisker formation.

Unfortunately, research into whiskers has frequently given contradictory and sometimes confusing results. This is usually because whisker research has been carried out using a variety on non-standard accelerated test conditions;: research results from tests with no nickel barrier should not be compared with data from tests with nickel barriers without appreciating the impact of the nickel. Research can be summarised by reviewing the variables that affect tin whiskers.

8.2.1.1 Strain

It has been suspected for many years that internal strain in electroplated coatings is the driver for whisker formation but this has been proven to be correct only fairly recently. The exact mechanism is not fully understood and there may be several underlying causes. It was at one time thought that "bright" tin was much more susceptible to whisker formation than "matte" tin coatings. Bright electroplated coatings may have more internal stress partly due to incorporation of organic compounds used to brighten the coating but recent research has shown that it is possible to produce bright tin with a low susceptibility and some matte tin coatings have been found to readily produce many long whiskers.

Measurement of strain within coatings is difficult but there is circumstantial evidence that strain is important. Strain relief occurs when metals are heated. It is well known that tin coatings are much less susceptible to whiskers after melting but there is significant anecdotal evidence that the soldering process also reduces the risk of whiskers. When surface mount components with tin coated termination coatings are attached to PCBs, the solder usually does not wet all of the coating but the remaining exposed tin rarely forms whiskers. Several manufacturers have reported (to the author) that, in their in-house whisker tests, only tin plated parts of components which were attached by hand soldering formed whiskers whereas tin on reflowed components had no whiskers. Some of the well publicised US military satellite failures occurred on tin coatings on components that had been attached using electrically conducting adhesives, i.e. there was no reflow.

Compressive strain can be induced by bending tin plated parts although some research is inconclusive. Whisker propensity testing is frequently carried out using specimens with bends to induce compressive strain. This can clearly increase the risk but in many reported tests using nickel barriers, no whiskers were produced, even on the tin surfaces which should be under compressive strain. Moyer et al. (FCI)[42] showed that even without a nickel barrier, the number and length of whiskers on tin on a bend were similar to tin on a flat surface whereas, where damage had occurred by wear, whisker length was significantly greater.

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[42] T. D. Moyer, "Designed Experiment to Determine the Reliability of Various Commercial Plating Baths and the key Factors Affecting Whisker Formation", IPC/JEDEC conference, Singapore, Aug 2004.

Damage to tin plating can cause compressive strain. Several connector and switch manufacturers have found that they can produce tin coatings which have a low risk of forming whiskers but when the surfaces are damaged by sliding contacts in connectors or within contacts in micro-switches, whiskers form at these locations.

Recent work reported by Huegel (Bosch)[43] found no relationship between macroscopic stress and tin whiskers. This work did show, however, that microscopic stresses within tin grains do influence whisker growth. One very recent publication[44] claimed that Sn-Mn alloy coatings under tensile strain form whiskers which is contrary to results with other alloys which only form whiskers under compressive conditions.

Galyon et al.[45] clearly show that whiskers grow where there is a compressive strain gradient which is highest at the substrate/tin coating interface and decreasing towards the outer tin surface. Strain relief is achieved by the formation of tin whiskers which grow at tin grain boundaries. Strain is highest at the substrate/tin interface because of the formation of intermetallics. Where tin is electroplated onto copper, there is a much higher diffusion rate for copper into tin than for tin into copper with the net result that tin copper intermetallic phases form, i.e.

$$\mathbf{11\ Sn\ atoms \rightarrow 2Cu_6Sn_5 + Sn}$$

$$\text{Molar volume of 11 Sn} = 171$$

$$\text{Molar volume of } 2Cu_6Sn_5 + Sn = 252$$

This represents a volume increase of 35% and as a result a compressive strain is produced. Furthermore, tin/copper intermetallic crystals grow at the tin/copper interface and between individual tin grains. Owing to this strain, tin atoms diffuse to locations where strain is lower which tends to be towards the surface of tin grains and away from the tin/copper interface. These tin atoms then become the base of tin whiskers and, as these form, the strain is relieved.

These results show why the use of a nickel barrier is effective. Tin/nickel intermetallics form much more slowly than tin/copper and also form as a regular thin layer at the interface which does not induce strain in the same way as irregular tin/copper intermetallic phase crystals. More importantly, as the rate at which nickel diffuses into tin is much slower than copper, more tin can diffuse into

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[43] W. A. Hügel, V. Kirchner, M. Nayeri, L. Henneken, and R. Keller, "Results from Whisker investigations and the corresponding conclusions", http://thor.inemi.org/webdownload/newsroom/Presentations/ECTC_2005/ECTC_05_2005_Whisker_Hugel.pdf

[44] K. Chen and G. D. Wilcox, "Observations of the Spontaneous Growth of Tin Whiskers on Tin-Manganese Alloy Electrodeposits", Physical Review Letters, 17 Feb 2005, http://scitation.aip.org/getabs/servlet/GetabsServlet?prog=normal&id=PRLTAO000094000006066104000001&idtype=cvips&gifs=yes

[45] G. Galyon, L. Palmer and R. Gedney "Theory closes in on causes of tin whiskers" Global SMT & Packaging, p10-14, Oct. 2005.

nickel thereby reducing the potential volume increase that occurs as a result of tin/nickel intermetallic growth and this reduces any compressive strain that would result.

Most components are fabricated by stamping out suitable shapes from electroplated sheet material. It is known that the stamping process can induce compressive strain and precautions are required to avoid whiskers if stamping is used. The Protin[46] study shows that maximum tin whisker length, in comparative tests on lead-frames produced by etching was less (~40µm) than on lead-frames produced by stamping (>250µm) - a process that is likely to introduce strain in tin plated layers.

Several accelerated tests use thermal cycling to determine susceptibility to whiskers. Cyclic strain is induced as a result of the difference in thermal expansion coefficient between tin and the substrate; the increased strain accelerates whisker formation.

8.2.1.2 Nickel barrier

Nickel barriers clearly reduce the risk of tin whiskers. There are numerous studies which show that tin electroplated over copper or copper alloys forms whiskers whereas the same tin coating with a nickel barrier layer (typically 1µm) produces either no whiskers or, if any are produced, these are short and unlikely to cause a short circuit although there are a few exceptions. One example showing the benefit of nickel (Moyer, FCI[42]) using copper lead-frames with 2µm nickel and 2µm tin produced no whiskers in accelerated tests whereas, without the nickel barrier, many whiskers were produced.

Whiskers will form under suitable conditions even if nickel barriers are used. For example, tin whiskers will grow if the tin coating is relatively thick, especially if plating chemistry is not well controlled. However many component manufacturers now produce products with thin tin coatings over nickel barrier layers.

The use of nickel is not straightforward and several problems can occur. The electroplated nickel barrier layer must be non-porous to avoid copper diffusion through a porous coating to form tin/copper intermetallic phases as if the nickel were not present.

The other potential problem is that most traditional electroplated nickel coatings are hard and relatively brittle. Component lead-frames and connector pins are manufactured from copper sheet which has been electroplated with tin or tin alloy. Pressing or stamping of the coated sheet is used to produce the shapes that are used to make the lead-frames or other parts and the stamped parts are often then folded to give the final shape. Stamping itself, if not carefully carried out, can induce compressive strain in tin coatings as well as the folding process. Distortion of the relatively brittle nickel can also cause cracks which expose the copper substrate to the surface. Cracks in nickel plating can cause copper to reach the tin layer more easily where intermetallics will form. This copper is also susceptible to corrosion and forms bulky corrosion products that spread over the surface. These products are electrically insulating and will hinder soldering. Therefore, until

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[46] EU Funded study into tin whiskers, final report:
http://www.europeanleadfree.net/POOLED/DOCUMENTS/a129869/Protin_Final_Report.pdf

recently, manufacturers of parts with complex shapes were unable to use a nickel barrier layer below tin coatings. However new electroplating processes have been developed which produce a more ductile nickel layer so that parts having these coatings can be shaped without crack formation.

8.2.1.3 Substrate

Research has also shown that the substrate is an important factor in the risk from whiskers. Tin deposited directly onto copper will form an irregular tin/copper intermetallic layer. Research has indicated that as this grows, this causes an increase in the strain in the tin coating which eventually causes whiskers. The intermetallic layer that forms on copper is produced relatively quickly and is irregular thereby causing strain in the tin coating. Tin forms an intermetallic phase with nickel much more slowly and this tends to be relatively uniform so that little additional strain is applied to the tin.

Research has also shown that the thermal coefficient of expansion (TCE) of substrates can influence tin whisker formation. Copper and tin have similar TCE values:- 16ppm/°C and 23ppm/°C respectively - so when the temperature changes the small difference in TCE results in only a small strain applied to the tin. Some components have nickel/iron (Alloy 42) lead-frames; this alloy has a much smaller TCE, 4.4ppm/°C, so temperature changes result in a much larger strain on tin than would occur on the equivalent copper lead-frame.

Bosch research[43] shows for tin on Alloy 42 substrates that a copper barrier layer can reduce whisker length in thermal cycling tests. However 5μm tin on an Alloy 42 substrate with a 4μm copper barrier layer produced long whiskers (up to 170μm) after 5 months storage at ambient. With thicker tin, the maximum length was less at 70μm. Results from the Protin study[46] also showed that a copper barrier layer over nickel iron substrates reduces the maximum whisker length significantly.

Research by Samsung[47] showed that tin electroplated onto Alloy 42 without a nickel barrier did not produce whiskers after solder reflow. They claim that this is because the reflow process induces tensile stresses in the tin which eliminates the risk of whiskers. Post baking did not, however, eliminate whiskers from tin on this substrate.

A variety of copper alloys are used to make connectors and other types of components. These alloys contain 97% or more copper plus minor alloying elements. Work carried out by Infineon, Philips, STMicroelectronics and Freescale Semiconductors[48] found that, in comparative whisker tests, the length of whiskers from tin electroplated onto Alloy C194 (Cu + 2.1 – 2.6 Fe + minor additions of P and Zn) was less than on Alloy K75 (Cu + 0.15 – 0.4 Cr, 0.02 – 0.07 Si + 0.01 – 0.04 Ti).

- Alloy C194 30°C / 60%RH, 2 months 80μm whiskers

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[47] S. Seyoung, et. Al, “Mitigation of Whisker by Reflow in Matte Sn Finished Alloy 42 Lead Frame Package”, Samsung Electronics.

[48] M. Dittes, P. Oberndorff, P. Crema and S. Chopin “A Two Step Approach for the Release of Lead Free Component Finishes with respect to Whisker Risk”, IPC/JEDEC 7th International conference, Oct. 2004, Germany.

- Alloy K75 30°C / 60%RH, 2 months 35µm whiskers

Unfortunately the tin coating on C194 was thicker than on K75 in these tests making a direct comparison difficult but these results do show that minor alloying additions can have a significant impact on whisker length.

8.2.1.4 Humidity and temperature

Tin whiskers are known to form in high humidity environments and some tests use high humidity to assess whisker formation. Why humidity affects whisker growth is not known but it is thought to be related to the surface oxide that forms on the tin surface particularly at grain boundaries. The tin oxide that forms at high humidity is more voluminous than oxide formed in dry air and this larger volume of oxide would apply strain to neighbouring tin grains. Temperature will have an affect on whisker growth rates as higher temperatures increase the rate of tin oxide growth.

8.2.1.5 Soldering Temperature

Reflow temperature may affect tin whiskers. Whiskers on tin plated components that have been reflowed are unusual. This may be because the heat from the reflow process removes stresses in the tin coatings. This implies that the higher reflow temperatures required for lead-free solders will relieve stresses more effectively that lead-tin solder reflow.

8.2.1.6 Tin alloy composition

Tin alloys are also susceptible to tin whiskers. Tyco, Molex, FCI and Amphenol[49] are collaborating on whisker research and have published comparative data on various tin alloys some of which is reproduced here:

Table 20. Properties including tin whisker propensity for selected termination coatings

Property	Tin	Sn/Cu	Sn/Ag	Sn/Bi	Sn/Zn	Au flash over Ni	Au flash over Ni/Pd
Plating process control	Straight-forward	Complex	Complex	Complex	Complex	Easy	Easy
Melting point (C)	232	227	221	~210	199	N/a	N/a
Solderability lead-free	OK	OK	OK	OK	Not known	OK	OK
Joint reliability	OK	stressed	stressed	brittle	brittle	OK	OK
Stress control	Good	No	No	Unknown	No	N/a	N/a

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[49] P. Elgrem, D. Dixon, R. Hilty, T. Moyer, S. Lal, A. Nitsche and F. Teuber, “Tin – The Finish of Choice for Connectors”, Nov 2003, http://www.amphenolcanada.com/ProductSearch/Generalinfo/Joint%20Position%20Paper.pdf

Property	Tin	Sn/Cu	Sn/Ag	Sn/Bi	Sn/Zn	Au flash over Ni	Au flash over Ni/Pd
Corrosion	Minor	Some	Some, especially with H_2S	Some	Major	Minor*	Minor*
Whiskers	Manageable	Risk	Risk	Risk	Larger risk	None	None
Cost	Low	Low	Medium	Medium	Medium	High	High

* Recent research has shown that corrosion of leadframes with these coatings is severe in the most corrosive atmospheres[38].

Clearly, the use of tin alloys does not eliminate the risk of whiskers and SnCu coatings may be worse than pure tin. Tin/bismuth coatings will produce whiskers but, in surface mount applications, this risk may be reduced or eliminated as its melting point is lower than tin and it is more likely to melt during reflow; melting significantly reduces the risk from whiskers. Alloy plating is however much more difficult to control than pure tin plating. If the composition is incorrect, solder wetting may be affected.

Coatings based on gold flash over nickel or palladium/nickel will not be susceptible to whiskers. However, most Category 8 and 9 products are produced in relatively small numbers and so manufacturers have no influence over the choice of component termination coatings that suppliers use. Most components are produced in very large numbers, mainly for low price consumer products, so price is a significant factor and therefore tin coatings are used instead of gold based coatings which are more expensive.

8.2.1.7 Coating thickness

It was originally thought that thicker tin coatings were superior with less risk of whiskers whereas recent research has shown that this is not always the case. These apparently contradictory findings are a result of original testing carried out without nickel barriers and more recently with nickel barrier coatings. iNEMI recommend the use of 2 µm tin coatings on a nickel barrier.

Several researchers have shown that for tin coatings plated directly onto copper with no barrier layer that as tin thickness increases, maximum whisker length decreases. For example in the Protin study[46], maximum whisker length at various tin thickness were:

Table 21. Effect of tin thickness on whisker length (Protin study)

Tin thickness on copper substrate (µm)	Max. whisker length (µm)
1.9	~ 200
4.2	~ 80
5.7	~ 40
10.6	~ 20

In another example of comparative tests (reported by iNEMI) without a nickel barrier showed the whisker length is inversely proportional to tin thickness:

Table 22. Effect of tin thickness on whisker length (iNEMI study)

Tin thickness on copper substrate (µm)	Whisker length (µm)
2.5	40
6.3	10
14.8	no whiskers

Research reported by Moyer[42] and confirmed by others shows that whisker propensity is less with thin tin coatings electroplated over nickel barrier layers (the opposite trend to that found without a nickel barrier).

2µm tin on nickel barrier	Average whisker length = 8.6µm
4µm tin on nickel barrier	Average whisker length = 15.1 µm

Work by Enthone[50] which investigated whiskers on tin coatings on copper substrates with nickel barriers produced whiskers from 3µm tin and thicker but almost no whiskers with 2µm and less. Tin thickness does however also impact on solderability. Solder wetting to very thin tin coatings can be poor, particularly after storage and so a compromise is suggested with 2µm tin thickness as thinner coatings gave poor solder wetting results in Enthone's tests.

8.2.1.8 Plating chemistry and impurities in coatings

This is probably one of the most important criteria. iNEMI have published results from tests carried out with matte tin coatings produced by two different electroplaters. Accelerated whisker tests were carried out with tin plated copper parts. Two different tin MSA (methanesulphonate) baths were used to produce thin tin coatings on copper without nickel barrier coatings.

Table 23. Effect of plating bath contamination on whiskers

Initial contaminant concentration (ppm)	Lead	Iron	Copper	Zinc	Nickel	Whisker length
Bath A	Not measured	5.2	0.7	0.6	0.4	"long" -some 60µm
Bath B	8.2	13.9	0.3	0.3	10	None

Which impurities are important in baths A and B is unclear. The higher iron content may promote or alternatively the nickel content may inhibit whiskers. Alternatively, the cause could be unrelated to these five impurities. Some component manufacturers claim that they fully understand the role of plating chemistry on tin whiskers and claim that they are able to produce tin coatings which do not

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[50] Chen Xu, Cookson Electronics.

form whiskers. Their understanding of bath chemistry is based on proprietary knowledge, which is unpublished and claims that no whiskers are formed are based on accelerated tests not field data.

During tests on whisker propensity (Protin study[46]), Infineon monitored the levels of lead, antimony, iron, copper and bismuth and all varied significantly (from 0 ppm to 780 ppm in one case) but no correlation with whisker length was found. Clearly the risk of whiskers can be affected by plating bath composition but factors other than impurities are important. It is now accepted by plating chemical producers that variation in composition of some bath types has very little affect on whisker propensity whereas small variations in other plating bath formulations has a marked affect. Tin plating chemical manufacturers have had some success in developing chemistries which are less affected by variation in plating bath chemistry and process conditions.

Studies of known impurities have not, to date, provided adequate information to determine if these affect tin film stress. Some impurities, notably copper, do increase stress levels and this usually increases whisker growth. Lead is known to reduce stress levels and does minimize whisker growth. Impurities may affect whisker growth by their effect on grain boundaries, changing grain size and crystal orientation.

Schetty (Technic Advanced Technology)[51] reports work carried out with a range of plating bath compositions which showed that whiskers were produced if the additive concentration was too low or if the plating bath temperature was too low. Moyer (FCI)[33] reports results from tests with three different tin plating baths. Small differences in the number of whiskers and maximum whisker length were found but may not be very significant statistically.

Philips, Infineon and STMicroelectronics[46] gives results of extensive research into tin whiskers including a study of the plating bath chemistry. They found that the following all have some influence on tin whiskers:

- Electrolyte chemistry
- Substrate surface (stamped or etched)
- Current density
- Bath temperature
- Contamination
- Drying procedure

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[51] R. Schetty, “Minimisation of Tin Whisker Growth in Pb-free Component Production Applications” IPC Conference, Shanghai, China, Nov 2004.

One tin plating chemistry manufacturer has stated that new tin plating processes are not very susceptible to impurities (unlike older formulations) and small quantities will not greatly increase the risk of whisker formation[52] as long as impurity levels are kept to within specified limits. Unfortunately, component users will usually have no way of knowing if this was carried out as there is no quick test that can be used to quantify this on a finished device.

8.2.1.9 Voltage bias

Accelerated testing with and without a voltage bias clearly shows that an applied voltage can affect tin whiskers although it is unclear why. Comparative tests by iNEMI[53] using bright electroplated tin showed that whisker length with a voltage bias was 135µm, whereas without the applied voltage the length was about 10µm. However with matte electroplated tin the effect of voltage bias was statistically insignificant.

8.2.1.10 Pre-baking components

Baking tin plated parts was used many years ago to prevent whiskers but this was discontinued when tin/lead alloys replaced tin coatings. Conflicting results have been obtained from research into the use of a "pre-bake" step. Pre-bake involves heating components or lead-frames immediately after electroplating tin onto copper substrates (no nickel barrier) at 150°C for about one hour. The intention is to relieve stresses and to build up a thin but homogeneous copper/tin intermetallic layer at the copper/tin interface. Copper/tin intermetallics that grow normally at ambient conditions form irregular structures which may induce stresses in the tin whereas the intermetallic layer after pre-baking is relatively flat and so does not cause stresses.

Philips[54] research with copper alloys C19400 and C7025 showed that tin coatings produced whiskers (C19400 was worse) but post-baked parts produced only very short whiskers. Work from Bosch[34] showed that post-bake of tin on several copper alloys reduced or eliminated whiskers. However, as already mentioned in Section 8.2.1.3, post-baking tin on Alloy 42 did not prevent whisker growth.

8.2.1.11 Crystal orientation

There is some evidence that tin crystal orientation can affect tin whisker susceptibility and so control of this could minimise the risk of whiskers.

X-ray diffraction (XRD) analysis of tin coatings has shown that there is a correlation between tin whiskers and small angles between crystal planes and the number of "low crystal angles" depends on

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[52] Private communication, Cookson Electronics.

[53] "Recommendations on Lead-Free Finishes for Components Used in High-Reliability Products, Version 3", iNEMI Tin Whisker User Group, May 2005, http://thor.inemi.org/webdownload/projects/ese/tin_whiskers/User_Group_mitigation_May05.pdf

[54] P. Oberndorff et al. "Whisker Mitigation by Postbake: Test Results" IPC Conference Amsterdam, Jun 2004.

the crystal orientation[55]. XRD is a bulk analysis technique which will give average values whereas Electron Back Scatter Diffraction (EBSD) is a micro-analysis technique which will give orientation information on individual grains. EBSD analysis of tin coatings has been carried out by Tsuji[56] who found a correlation between crystal orientation and tin whiskers. In 2002, Choi[57] found that the stress level in individual tin grains does vary. Egli of Infineon first observed that crystal orientation of tin crystals is related to whisker growth and found that the angular relationship between crystals is the dominant factor rather than the specific orientation. However, Galyon and Palmer[58] believe that freshly deposited tin coatings recrystallise to give different crystal orientations as whiskers grow from these different grains. Recrystallisation depends on many factors including micro and macro stresses in the film and it is quite possible that whiskers grow from certain crystal orientations.

One manufacturer[59] of tin plating chemistry claims that whisker resistant coatings can be produced with tensile stress in the deposit and has certain “preferred” crystal orientations which are less susceptible to whiskers. They point out that compressive strain caused by copper/tin intermetallics or by plating onto low TCE alloys such as Alloy 42 will increase the risk of whiskers in any tin coatings.

Although research with EBSD and other techniques is being carried at several labs, these techniques are not suitable as quality control methods to determine whisker propensity.

8.2.1.12 Conformal coatings

Research by NASA[60] and others with conformal coatings over circuit boards showed that whiskers can grow through these and potentially cause short circuits. The use of conformal coatings will however avoid the circumstances where long tin whiskers are produced at one location; these break off and float onto the terminals of fine pitch components causing a short circuit. Conformal coatings over the fine pitch components would prevent electrical contact from “floating” whiskers.

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[55] K. Whitlaw, A. Egli and M.Toben, “Preventing Whiskers in Electrodeposited Tin for Semiconductor Lead-Frame Applications”, May 2003, http://www.efsot-europe.info/servlet/is/251/15%20KeithWhitlaw.pdf?command=downloadContent&filename=15%20KeithWhitlaw.pdf

[56] K. Tsuji, “Roll of Grain-boundary Free Energy & Surface Free Energy for Tin Whisker Growth”, Sep 2003, http://www.unicon.co.jp/business/processing/Tin%20Whisker%20Growth%20ICP-JEDEC.pdf

[57] W.J. Choi, T.Y. Lee, K.N. Tu, N. Tamura, R.S. Celestre, A.A. MacDowell, Y.Y. Bong, Luu Nguyen, , "Tin whiskers studied by synchrotron radiation scanning X-ray micro-diffraction”, Acta Materialia 51, pp6253–6261, 2003, http://www.national.com/packaging/files/Synchrotron_Nguyen.pdf

[58] G. T. Galyon, “A History of Tin Whisker Theory: 1946 to 2004”, Jul 2004, http://thor.inemi.org/webdownload/newsroom/Presentations/SMTAI-04_tin_whiskers.pdf

[59] R. Schetty (Technic Inc.), “Suppression of Tin Whisker Growth through Optimized Tin Plating Chemistry Formulation Technistan EP”, Sep 2004, http://www.mill-max.com/rohs/Whisker%20resistant%20tin%20deposit%20letter%2004.pdf

[60] J. S. Kadesch, J. Brusse, “The Continuing Dangers of Tin Whiskers and Attempts to Control Them with Conformal Coating”, July 2001, http://nepp.nasa.gov/whisker/reference/tech_papers/kadesch2001-article-dangers-of-tin-whiskers-and-conformal-coat-study.pdf

8.2.2 Accelerated tests

A variety of accelerated tests are used in research on tin whiskers. These are based on combinations of humidity, temperature and temperature cycling. Some tests are carried out over relatively long periods, up to 6 months, but even the shortest is too long to be useful for quality control. In general, thermal cycling tests are useful where there is a significant TCE difference between coating and substrate. Where these are similar, such as for tin on copper, high humidity and elevated temperature are used.

The reliability of accelerated testing is not clear. The current improved understanding of how to produce tin coatings which have a low risk of whiskers is relatively new. These coatings have not been in service for very long so their behaviour over the next 20 years can only be estimated based on accelerated tests, and this inevitably is uncertain.

Research into a rapid test is being carried out. Various techniques are being investigated as possible techniques to determine crystal orientation and internal stress within tin grains. XRD and EBSD, discussed in section 8.2.1.11 are the most promising techniques at present.

In general, tests with tin plated onto copper substrates or copper alloys with TCE values similar to tin (with or without barrier layers) use high humidity to accelerate whisker growth. Assessment is usually with SEM. When low TCE substrates are used such as Alloy 42, tests using thermal cycling are recommended. Test procedures for all substrate types are recommended by iNEMI[61] and from the "Protin" study[46].

8.2.3 Risk minimisation

There are many factors which affect the risk of tin whiskers, many of which are not well understood. Therefore to guarantee no risk of whiskers, manufacturers would need to avoid tin coatings completely. However, as most equipment manufacturers purchase off-the-shelf components many of these will inevitably have tin plated coatings.

iNEMI has published methods to prevent tin whiskers[53]. One important characteristic of whiskers is their length. It is normally only long whiskers that cause short circuits and, frequently, whiskers are very short and would not cause a defect. iNEMI's recommendations include:

- Use nickel/gold or nickel/palladium coatings instead;
- Ensure that tin of ~2µm thickness is electroplated over a nickel barrier layer (porosity free nickel with minimum thickness of 1.27µm);

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[61] "iNEMI tin whiskers activities", http://www.inemi.org/cms/projects/ese/tin_whisker_activities.html

- Hot dipped tin and electroplated tin that has been melted is not normally susceptible however these surfaces have inferior solder wetting properties and the high temperature can damage some components. Immersion tin can be less susceptible;

- Tin plating bath chemistry is important. Generally matte tin is less susceptible than bright tin. However, some claim that bright tin coatings can be produced which have a low susceptibility. Also, some matte tin coatings can produce many long whiskers. Unfortunately there is currently no quick test for whisker resistance (the iNEMI tests take 6 months);

- Tin plating on low TCE materials such as Alloy 42 and Invar is much more susceptible to tin whiskers due to the strain caused by the TCE difference between materials. It is best to avoid tin plating these materials;

- Tin-bismuth has a reduced tendency for whisker formation, especially after reflow, due to its lower melting temperature. The bismuth content should be <3% and thickness <8 µm if used with SnPb. It is best to avoid this composition if used with SnPb reflow as Bi may build up in solder pot;

- Tin thickness – iNEMI recommends a thickness of > 8µm (without a nickel under-layer). Recent research has found that with nickel barrier coatings, relatively thin tin coatings are preferable;

- Compressive stress is the cause of whiskers and so tin plating with tensile stress is preferable to tin in compression. Do not bend or damage tin plated parts as this will cause compressive stress;

- Bias voltage is known to be detrimental to tin whiskers but the reason is unknown.

This review of scientific literature shows that the following criteria are important factors which affect whiskers:

- Coating thickness – ideally 2µm on nickel barrier;

- Barrier coatings – use nickel;

- Substrate – avoid low TCE alloys. Choice of copper based material important;

- Stress relief by reflow or post-bake;

- Plating chemistry – probably one of the most important factors;

- Coating composition – no advantage with alloys except SnBi, reflowed at high lead-free temperatures so that it melts. Effect of impurities not understood;

- Avoid damage to coatings;

- Conformal coatings – do not prevent whiskers forming but prevent loose whiskers falling onto and short circuiting fine pitch components.

It is accepted that very small whiskers are unlikely to cause short circuits and many of the whisker minimisation strategies described here will prevent the formation of long thin whiskers but short whiskers may occur. These are not a concern except in very high frequency circuits where they may act as aerials which can cause a variety of problems to sensitive electronics.

8.2.4 Commercial tin coatings

Since it became clear in the late 1990's that the RoHS Directive would restrict the use of lead in tin termination coatings and because of changes being made in Japan as lead was eliminated from electrical products, electroplated coating manufacturers and component manufacturers have been carrying out extensive research to develop tin coatings with a low risk of forming whiskers.

There are many electrical components now available only with tin plated terminations and their producers claim that there is no risk of whiskers unless the terminations are deformed or damaged (this induced compressive stress in the coatings)[59]. There is some evidence that whiskers do form on commercial component lead-frames although research published by National Semiconductors is with tin/copper coatings which may be more susceptible to whiskers than pure matte tin[57]. Several tin plating chemistries are commercially available where the manufacturers claim that these produce tin coatings which are "whiskers resistant". This does not mean that these coatings will never produce whiskers because other factors apart from plating chemistry (as discussed above) such as surface damage, Alloy 42 substrates, etc. can induce whiskers even with whisker resistant coatings. A small selection of examples of products which manufacturers claim are "whisker resistant" tin plating processes are:

- Technistan EP (Technic Inc.)
- Stan Tek BT 3000 (MacDermid)
- Stannostar® HMM2 LF (Enthone, Cookson Electronics)

8.2.5 Lead-free soldering reliability – main conclusions

Although an increasing number of products are being sold in EU which have been manufactured using lead-free solders, these materials are still relatively new and are not yet fully understood. The EU is currently funding several research projects under Framework 6 into certain aspects of this new technology. Five main issues have been identified and the main conclusions from these are as follows:

1. **Manufacturing defects.** Manufacturing defects occur with tin/lead processes and with lead-free processes but research has shown that the risk of defects increases with temperature and as lead-free processes are ~30°C hotter these are more likely. The cause of most of these defects is understood and techniques to avoid these should be well known to experienced

manufacturers. Most problems can be avoided as long as sufficient time and resources are available. Experience from manufacturers of equipment in Categories 1 – 7 and 10 is that this can take three years or longer to convert their product ranges to lead-free and eliminate defects and very complex products may take even longer.

2. **Thermal Fatigue.** Extensive research is being carried out but is as yet incomplete. Accelerated test results have been produced but there is no useful comparable field data yet available because lead-free solders are relatively new materials and have mainly been used to date in consumer and household equipment which does not experience high stress levels. Life prediction models are being developed but will not be ready for several years and useful field data should be available by 2010 – 2012 and so it will be possible to predict field behaviour in 5 or 6 years from now. Currently however, most researchers believe that lead-free solders will be reliable but data to adequately quantify this does not yet exist.

3. **Vibration.** Research has shown that at low g-forces and at high g-forces parallel to circuit boards, there is no difference between tin/lead and lead-free solders. However, at high g-forces perpendicular to circuit boards, lead-free solders will fail much sooner that their tin/lead counterparts due to flexing of the board and the more brittle nature of lead-free alloys.

4. **Corrosion.** Lead-free solders themselves are resistant to corrosion but lead-free circuit boards and components use less resistant coatings than tin/lead coated boards and components. Unexpectedly, recent research has shown that gold coatings are susceptible to corrosion in the most hostile environments. Further research is required although it should be possible to prevent serious problems in most environments with the possible exception of highly polluted atmospheres in chemical plant where costly additional protection measures for equipment may be required.

5. **Tin whiskers.** Extensive research is beginning to explain the mechanism for whisker formation and provide guidance on measures to minimise risk which is probably very low in most equipment if these measures are followed. Even if Category 8 and 9 equipment is not included in the scope of RoHS, manufacturers will still need to follow these measures as most off-the-shelf components now have electroplated tin termination coatings and alternatives are not usually available. Also, the Technical Adaptation Committee voted on 26th July 2006 to accept an exemption for the use of lead in termination coatings on “fine pitch” component lead-frames. This will allow the use of components with tin/lead termination coatings and avoid the risk of whiskers although component manufacturers may not produce all fine pitch ICs with these coatings.

8.3 Hexavalent chromium passivation substitutes

Hexavalent chromium is widely used on aluminium alloys, zinc plated and galvanized steel and on other metals. Several different types of hexavalent chromium passivation treatment are used but all are based on solutions containing hexavalent chromium with acids or alkali, accelerators, activators and other materials. Different formulations are used for different applications. Thin transparent coatings are usually used to protect electrical equipment that is used in most home, office and factory environments and these have very good electrical conductivity. Equipment used in more hostile conditions is coated with thicker, coloured (yellow, olive) coatings which have better corrosion resistance but inferior electrical conductivity.

Research has shown, however, that there is no one single alternative material that is a suitable substitute on all of these metals or even on all aluminium alloys. Research results are summarised here.

8.3.1 Properties of hexavalent chromium

Hexavalent chromium has been used for many decades in coatings on a variety of metals to prevent corrosion and improve paint and lacquer coating adhesion. This material has a unique combination of properties that make it ideal for this purpose. When a metal, such as aluminium, is immersed in an aqueous solution containing hexavalent chromium, a chemical reaction occurs at the metal surface and the surface is "converted" into a mixture of materials that provide very good corrosion resistance. These coatings are also called chromate conversion coatings. Unlike all other types, hexavalent chromium based coatings provide three essential characteristics; they are one of the most effective corrosion inhibitors, have self-healing properties when damaged and provide electrical conductivity.

Passivation coatings are complex mixtures of electrically insulating compounds (mainly metal hydroxides) but, when two treated metal surfaces are placed in contact, the microscopic high spots on the surfaces of metals break through the thin coatings giving electrical conductivity. This is possible only with very thin coatings if these are also effective as corrosion inhibitors. All metal parts in electrical equipment need to be earthed and this requires good electrical conductivity between adjacent metal parts. This is required to ensure electrical performance and safety but also to prevent electrically isolated parts and slots between parts behaving like radio aerials as this would cause interference problems, particularly in high frequency equipment.

Electrical equipment frequently emits electromagnetic/radio frequency radiation, which cause interference with other nearby equipment. EMI (electromagnetic interference) and RFI (radio frequency interference) can cause anything from annoying interference to radio and television reception to potentially dangerous interference with radio communications of the emergency services. For this reason, all electrical equipment must comply with the Electromagnetic compatibility (EMC) Directive (89/336/EEC and 2004/108/EC). Hexavalent chromium is particularly valuable as a tool in ensuring good EMC properties owing to the good electrical contact which can be achieved. Electrical conductivity with alternative electrically insulating coatings can be achieved if the coatings are removed from where the two metal parts are in contact but these untreated regions will then be susceptible to corrosion. This is particularly severe within crevices formed when two panels are connected as corrosion will produce electrically insulating by-products that prevent good earthing so that EMI and RFI shielding becomes ineffective. This will also adversely affect the performance of components with specific electrical properties such as antennas and waveguide components. Good corrosion resistance with good electrical conductivity is essential in some types of Category 8 and 9 equipment to maintain the shielding of very sensitive sensors and detectors used inside the housings. One example is relatively new medical equipment that is used to map brain activity. These use ultra sensitive detectors to detect the minute signals from brain activity and would not work without very effective shielding from the electrically noisy environments found in hospitals.

When a non-noble metal surface comes into contact with oxygenated water, corrosion occurs unless this is prevented by an inhibitor or physical barrier. Physical barriers such as paint coatings are effective but can be disrupted if corrosion occurs at the interface between the paint and the metal and this will often take place after there is damage to the paint coating. Corrosion is an electrochemical process and corrosion inhibitors such as hexavalent chromium prevent or greatly retard corrosion by affecting the electrode potential of the metal surface. Research has found that very small quantities of hexavalent chromium are very effective giving a relatively large shift in electrode potential. To be effective, the inhibitor must be in solution, albeit at very low concentrations. Therefore completely insoluble materials act solely as a physical barrier and have no inhibiting effect. If the solubility is too large, the inhibitor is soon washed away and becomes ineffective. The ideal combination of properties exhibited by hexavalent chromium are:

- Low water solubility combined with very effective inhibition at low concentrations;
- Chromate passivation coatings are hydrophobic;
- Possible to have effective inhibition with very thin coatings that can give low electrical resistance. The coating itself is electrically insulating but as it is very thin, it is easily broken through to obtain metal - to - metal contact;
- Self-healing properties. Where the coating is scratched, the gap fills with very dilute hexavalent chromium solution when water is present and this reacts with the exposed metal to repair the coating;
- Extremely effective corrosion inhibition;
- Powerful oxidising agent which reacts with metals to form thin, inert mixed oxide coatings;
- During inhibition, the chromium is converted from the hexavalent to the trivalent state. Trivalent chromium is a much less effective corrosion inhibitor but it can be converted electrochemically back to the hexavalent state (at a low concentration). Therefore, one of the most effective alternatives to hexavalent chromium is trivalent chromium.

Research into the composition of chromate conversion coatings has shown that, when the metal being treated is immersed in the chromate passivation solution, a chemical reaction between the metal substrate and chromate ions ($Cr_2O_7^{2-}$) takes place to deposit a mixture of metal hydroxides. For example with aluminium:

$$\mathbf{Cr_2O_7^{2-} + 2Al + 2H^+ + H_2O \rightarrow CrOOH + 2AlOOH}$$

The mixture of chromium hydroxide (CrOOH) and aluminium hydroxide (AlOOH) does not contain hexavalent chromium - chromium as CrOOH is in the trivalent state. However, in the next stage of the coating process, hexavalent chromium ions are adsorbed onto the trivalent chromium hydroxide. The quantity of hexavalent chromium in a coating will depend on the solution chemistry and the coating time and very little hexavalent chromium will be present in coatings produced after very short treatment times. The presence of hexavalent chromium in these coatings has been clearly demonstrated by various techniques including Raman spectroscopy which is able to detect "Cr^{3+} - O – Cr^{6+}" bonds. X-ray photoelectron (XPS) spectroscopy can also be used to detect hexavalent chromium and is a more sensitive technique but there is a risk that hexavalent chromium ions are reduced by X radiation to trivalent ions[62]. Those coatings which contain only trivalent chromium will act as physical barriers with little self-healing properties whereas those that contain hexavalent chromium are able to release chromate ions which act as an effective corrosion inhibitor but the corrosion resistance obtained with trivalent treatments is much better that would be expected from a very thin physical barrier alone. Therefore it would seem reasonable to expect that traces (well below the RoHS maximum concentration value) of hexavalent chromium are formed electrochemically which give rise to the observed corrosion resistance.

Analysis of chromate conversion coatings is not straightforward and it is possible, if care is not taken, to either oxidise trivalent chromium ions to hexavalent (to give a false positive result) or to reduce hexavalent ions to trivalent (to give a false negative result) during the test procedure and thereby obtain incorrect results. Research using Raman spectroscopy, XPS and other techniques clearly shows that hexavalent chromium is present in many types of these coatings and at concentrations much greater than 0.1% by weight but these techniques are unsuitable for quality control purposes. IEC has published a draft standard which includes a simple extraction and colorimetric procedure which is useful for testing electronic components[63].

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[62] "XPS Studies on Chromate Conversion Coatings on Zinc", X. Zhang et.al., Proceedings of the 15th International Corrosion Congress on Frontiers in Corrosion Science and Technology

[63] IEC TC111/54/CDV Procedures for the Determination of Levels of Six Regulated Substances (Lead, Mercury, cadmium, hexavalent Chromium, Polybrominated Biphenyls, Polybrominated Diphenyl Ethers) in Electrotechnical Products

8.3.2 Alternative coatings for aluminium

Research has been carried out over the past 20 years to identify potential alternatives to hexavalent chromium passivation. The scientific literature, patents and commercial information are reviewed and summarised here. Comparative accelerated test data is frequently published to compare panels treated with the test treatments with conventional chromate treatments. These are based on a variety of standard test procedures providing a range of severities:.

- Neutral salt fog test (ASTM-B-117): This is the least aggressive test. Severity is proportional to exposure time and tests up to 3000 hours are used. MIL-C-5541 requires 168 hours testing whereas MIL-PRF-23377 requires 2000 hours;

- SO_2 salt spray (fog): This is a more severe test used on painted alloys. The SO_2 creates an acidic environment;

- Copper accelerated acid salt spray (CAASS): This is a very severe test, usually used with aluminium;

- Tape (e.g. ASTM-D-3359): These tests are used to assess paint adhesion;

- Environmental testing: This is also carried out but, as this tends to take years to generate meaningful results, it is appropriate only for new product development. This involves exposing treated and painted panels to natural weathering at various locations, the most aggressive being maritime.

Coatings are assessed more realistically by field trials, however very little is published and data for only one or two years has been reported to date. This is because the alternatives have been developed only recently. Some US work has been carried out in which one side of an aircraft is treated and painted with CrVI based materials and the other side with chrome-free materials.

Passivation and other coatings are usually required to meet certain standards such as:

- MIL-C-5541E: This is for painted and bare aluminium (class 1A) or for low electrical resistance (class 3). Surfaces must pass 168 hour ASTM-B-117 neutral salt fog testing (limited number and size of corrosion spots permitted);

- MIL-PRF-23377H:. Standard for primer coatings; class C must contain strontium chromate and class N is chromate free. Coatings are expected to meet more severe corrosion testing requirements as the ASTM-B-117 neutral salt fog test is carried out for 2000 hours. With class C, no corrosion in the scribe is permitted (but permitted with class N). This standard also requires an Ilford corrosion test. This is a very severe test which measures paint delamination away from scribe lines which represent exposed metal due to scratches or other damage. Maximum filament lengths are specified. There are alternative MIL standards for primers such as MIL-PRF-85582 (water based primer, with or without chromate), MIL-P-53022 and 53030 are less demanding standards that do not require Ilford corrosion resistance;

- MIL-PRF-85285D. Standard for urethane topcoat; does not include corrosion testing. There are also other MIL standards for top coats. These coatings do not contain hexavalent chromium unless added as a pigment.

8.3.2.1 Comparison of titanium/zirconium based treatments and trivalent chromium treatments with hexavalent treatments

One of the more common alternative types of passivation treatments are based on titanates and zirconates as fluoro-salts. These are patented and are available from several manufacturers. They may be used on bare metal but are all intended for use with paint coatings. Most are not suitable where electrical conductivity is required.

These coatings are more difficult to use than chromates because they give “indifferent” colour changes. As a result, it is difficult to determine visually if the coating has been applied correctly. These chemicals must be diluted with deionised water unlike chromates which can be diluted with mains water.

Three examples of patents for Zr/Ti based treatments for aluminium are listed here although many other related patents exist:

GE Betz US 2004/0094235 A1, 20th May 2004. Based on Zr, Ti, fluoride, other acids and silanes under paint coatings. Intended for use on road vehicle wheels, tests include procedure from GM (more aggressive form of salt fog test) and Ilford corrosion testing. In comparison with chromate controls, good results are claimed:

Table 24. Comparison of corrosion data for caste aluminium wheels

Passivation Coating	Ilford corrosion (number of filaments and maximum filament length in mm along scribe)	Copper accelerated acid salt spray test (max. and average blister diameter mm)
Chromate control	8 / 3	1.0 / 0.5
Best chrome-free result	6 / 2	1.0 / 0.5

Chemetall GmbH US 6562148 B1, 13th May 2003, based on Zr, Ti and fluoride and examples are for AA6061 and AA5182 alloys. Treatment intended for aluminium which is to be painted and used in vehicles.

Henkel US 5,868,872, 9th. February 1999. Based on Zr, Ti, fluoride and phosphate for use under paint coatings. Not intended for aircraft use.

One commercial Ti/Zr/fluoride product (Alodine 5200) was evaluated in the Environmental Security Technology Certification Program (ESTCP) study[64] and data is available from other sources. Results from the ESTCP study treated metal without paint coatings by ASTM B 117 neutral salt fog corrosion test are shown in the following results:

Table 25. Comparative test results from ESTCP study

Surface treatment	On alloy 2024-T3, 168 hours	On alloy 7075-T6, 168 hours	On alloy 2219-T87, 168 hours
Alodine 1200 (CrVI)	10	10	5.4
Alodine 5200 (Ti/Zr/F)	3	6	0
TCP (CrIII) for comparison	10	10	9

Ratings from 0 – 10. 0 = very bad, 10 = very good.

Alodine 1200 is a US version of Alochrome 1200 and gives coloured passivation coatings containing hexavalent chromium.

Comparative test results from the ESTCP study and from other sources are given in the following tables. Treated surfaces with primers and topcoats were tested by neutral salt fog for 3000 hours:

Table 26. Comparative test results from ESTCP study

Coatings	Al 2024	Al 7075	Al 5083	Al 2219
Alodine 1200 (CrVI), MIL-PRF-85582 C2 (CrVI) primer then MIL-C-85285 topcoat	9.2	9.0	8.8	9.0
Alodine 5200 (no Cr), MIL-PRF-85582 C2 (CrVI) primer then MIL-C-85285 topcoat	9.0	9.0	9.0	9.0
Alodine 1200 (CrVI), MIL-PRF-85582 N (no Cr) primer then MIL-C-85285 topcoat	7.0	9.0	9.0	5.6
Alodine 5200 (no Cr), MIL-PRF-85582 N (no Cr) primer then MIL-C-85285 topcoat	6.4	8.8	8.8	6.0

Ratings from 0 – 10. 0 = very bad, 10 = very good.

The comparative test results in Table 26 show that Alodine 5200 (Cr-free) with a chrome-free primer gave good results on AL 5083 and AL 7075 in comparison with Alodine 1200 or 5200 with a chromate based primer but inferior results with AL 2024 and AL 2219. However, in the Ilford corrosion test (Table 27) carried out as part of the ESTCP study, the hexavalent chromium free system (pre-treatment and primer) fails the requirements of MIL-PRF-23377H.

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[64] Non-Chromate Aluminum Pretreatments, Phase I Report Project #PP0025 Aug 2003 Environmental Security Technology Certification Program (ESTCP) http://www.jgpp.com/projects/pretreatments/documents/phase_i_.pdf

Table 27. Ilford corrosion test results from ESTCP study on 2024-T3

Coatings	Percentage of scribe line affected	Maximum filament length (inches)	Criteria for MIL-PRF-23377H
Alodine 1200 (CrVI), MIL-PRF-85582 C2 (CrVI) primer then MIL-C-85285 topcoat	<10%	<0.0625	Pass
Alodine 5200 (no Cr), MIL-PRF-85582 C2 (CrVI) primer then MIL-C-85285 topcoat	10 – 50%	Up to 0.125	Borderline/pass
Alodine 1200 (CrVI), MIL-PRF-85582 N (no Cr) primer then MIL-C-85285 topcoat	50 – 75%	~0.25	Borderline/fail
Alodine 5200 (no Cr), MIL-PRF-85582 N (no Cr) primer then MIL-C-85285 topcoat	~100%	>0.25	Fail

Table 27 shows six week salt spray testing on Aluminium alloy (AlMgSi1) carried out by Henkel (manufacturer of passivation coating materials)

Table 28. Corrosion test data from Kresse and Nowak 1995 (Henkel)

Pre-treatment	**DIN 50021 salt spray, no paint coating**. (resistance in days to visible corrosion)	**DIN 50021 salt spray, no polyester powder paint coating** (paint creepage mm.)	**DIN65472 Ilford test, with PE powder paint** (proportional to area of attack, 20 = very bad, 1 = very good)
None	~1	>10	20
Yellow chromate ((CrVI)	~60	<1	5
Alodine 4840 (Zr/Ti)	~10	~1	5
Unsealed thin anodising	~20	~1	~1

Table 29 shows Ilford corrosion tests from Sintef Materials Technology carried out in 2003 on AA 6060[65].

Table 29. Ilford test results from Sintef Materials Technology

Pre-treatment	Length of Ilford corrosion (mm)
Chromate	0
Hot AC anodising	~0.2
Ti/Zr based treatment	~2.5
Silane based treatment	2.0

This work concluded that Ti/Zr/F based pre-treatments were inferior to hexavalent chromium but hot AC anodising could be a suitable alternative. Anodised coatings are electrically insulating however.

The US Navy has developed and patented (US 6,375 726, 23rd April 2002) what appears to be one of the most effective alternatives for unpainted aluminium alloys. The patent describes solutions based

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[65] (http://www.sintef.no/units/matek/norlight/seminars/norlight2003/Presentations/11%20Ol%20O%20Knudsen.pdf)

on trivalent chromium salts with fluorozirconate salts at controlled pH and optionally with thickeners to increase coating weight. Examples of data from the patent include:

On unpainted aluminium alloy 2027:

ASTM-B-117 neutral salt fog, 336 hours at 60°C treatment on bare metal alloy 2027 – T3 after 14 days, rating = 9 out of 10. (No comparative test with hexavalent chromium on unpainted aluminium is given in the patent).

On painted test coupons:

Table 30. Results of accelerated corrosion tests from US 6,375,726 B1. Tests with self priming topcoat (TT-P-27561)

Test	Coating on alloy 7075-T6	Results 1 – 10 (1 = bad, 10 = best) - scribed area, unscribed area, blistering
500 hours SO2	Hex chrome	5, 10, 10
	Trivalent chrome	4, 10, 10
2000 hour neutral salt fog	Hex chrome	10, 10, 10 (some corrosion in scribe but no undercut)
	Trivalent chrome	10, 10, 10 (No undercutting from scribe and 50% of scribed area has no corrosion)

The US ESTCP programme is assessing several commercial alternatives to hexavalent chromium passivation and uncoated and coated aluminium alloys are being assessed. Preliminary results show that trivalent chromium passivation (TCP) was the only suitable alternative to hexavalent chromium.

Table 31. Results of accelerated corrosion tests; comparison of hexavalent with trivalent chromium

Treatment	On alloy	ASTM-B-117 Neutral salt fog (336 hours) rating 1 – 10	SO_2 salt fog on scribed painted alloys* (500 hours), rating 1 – 10
Alodine 1200 (hex Cr)	2024-T3	10	8
Trivalent chrome “TCP”	2024-T3	10	8
Alodine 1200 (hex Cr)	7075-T6	10	7
Trivalent chrome “TCP”	7075-T6	10	8
Alodine 1200 (hex Cr)	2219-T87	10	6
Trivalent chrome “TCP”	2219-T87	10	5
Alodine 1200 (hex Cr)	5083-H131	5	8
Trivalent chrome “TCP”	5083-H131	9	8

* Various coatings used. Data is for MIL-PRF-23377 primer and MIL-C-85285 topcoat

Trivalent coatings, developed during the US study, are marketed by SurTec International under the trade name ChromitAL TCP. Other CrVI – free passivation treatments are available including Iridite NCP from MacDermid Industries. A comparison of the corrosion performance of two of these with a hexavalent chromium coating type on a range of aluminium alloys is given in Table 32 and 33.

Table 32. Salt spray corrosion performance of hexavalent and MacDermid chromium-free coatings on a range of aluminium alloys – time to first corrosion

	Time to first corrosion (hours)						
Aluminium alloy	**5052**	**6022**	**3003**	**1100**	**6111**	**6061**	**A356**
Substitute Coating (Iridite NCP)	+1000	+1000	+1000	+1000	+1000	+1000	576
Hexavalent coating (Alocrom 1200)	+1000	+1000	168	432	432	648	+1000

.From Iridite NCP datasheet, MacDermid Inc. 2005.

Table 33. Salt spray corrosion performance of hexavalent and trivalent coatings on a range of aluminium alloys – time to first corrosion

Aluminium alloy	AW6082	AW7075	AC4600 Sandblasted
Trivalent Coating	>480hrs	>480hrs	>480hrs
Hexavalent coating	480hrs	>480hrs	480hrs

From SurTec GmbH 2005[66].

Standard MIL-PRF-23377 also requires an additional “Ilford” test. In the ESTCP work, the TCP treatment gave almost equal performance to Alodine 1200 hexavalent chromium pre-treatment. Corrosion resistance in this test was very dependent on the choice of primer with hexavalent chromium types giving the best performance in this study although type 85582 type N (Cr-free) with TCP was almost as good as 85582 type N with Alodine 1200 but inferior to 85582 type C2 (Hex Cr based).

Table 34. Ilford corrosion test results with hex Cr and Cr – free primers

Pre-treatment	with CrVI primer (85582 C2)	Hex Cr – free primer (85582 N)
Alodine 1200 (Hex Cr)	1-1	2- 2 to 3 – 4
TCP	1-1	3- 3 to 3 – 4

Rating 1 – 1 = Ilford corrosion at <10% of scribe, length <0.0625 inches
Rating 2 – 2 = Ilford corrosion at 10 – 50% of scribe, up to 0.125 inches
Rating 3 – 3 = Ilford corrosion at 50 – 75% of scribe, up to 0.25 inches
Rating 3 – 4 = Ilford corrosion at <75% of scribe, over 0.25 inches

Therefore TCP with the hexavalent chromium-free primer does not meet the severe Ilford corrosion requirement of MIL-PRF-23377H although the performance of Alodine 1200 with this primer was a borderline fail.

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[66] Private correspondence from Surtech GmbH.

8.3.3 Electrical conductivity of trivalent passivation on aluminium alloys

This is a particularly important characteristic of passivation coatings. The surface resistivity of coatings on new equipment and after many years in the field must be sufficiently low to meet the requirements of the EMC Directive, to shield very sensitive electronics and to meet other electrical requirements. In the ESTCP study, electrical contact resistance was measured on as-coated 6061-T6 alloy and after ASTM neutral salt fog exposure for 168 hours. Only Alodine 1200 (hexavalent chrome) and TCP (trivalent chrome) passed this test with resistance values < 5 milliohms per square after exposure. The electrical resistivity was found to increase during salt fog testing as shown below:

Table 35. Electrical resistivity results from trivalent and hexavalent chromium treatments

Treatment of Aluminium alloy grade 6061	Before salt fog test mΩ/sq.	After 168 hours salt fog test mΩ/sq.
TCP	1.57	3.19
Alodine 1200S (30 second immersion)	1.48	1.98
Alodine 1200S (60 second immersion)	1.71	4.58

Note that electrical surface resistivity units are independent of area – so 1 mΩ/in^2 is the same as 1 mΩ/cm^2.

Alodine 1200 (or Alochrome 1200) is normally used to produce relatively thick passivation coatings with good corrosion resistance whereas most electrical equipment is treated with Alochrome 1000 types which gives thinner coatings which have lower electrical resistance but are less effective corrosion inhibitors.

There is very little independent published data apart from the ESTCP study. Work carried out in New Zealand[67] reports that a commercial trivalent chromium treatment on aluminium (Al5005) (SurTec 650) gave electrical resistance after 96 hour salt fog testing which initially appear to be at variance with the ESTCP results. However, the authors of this study have provided additional information[68]. The apparent variance is due to several differences in the way that the measurements were carried out and the authors believe that their results corroborate those from the ESTCP study and show that the trivalent chromium treatment is a suitable substitute for hexavalent chromium.

Data from MacDermid Industries showed that for electro-magnetic applications the electrical contact resistance of the Iridite NCP coating at <1.0mΩ/sq. compares favourably with that of the hexavalent coating Alochrome 1200 at <5.0mΩ/sq. making the coating acceptable for electrical grounding applications[69]. The contact resistance is measured to MIL-C-81706[70], by pressing a flat sample (with

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[67] R. Sommer and M de Liefde "Third report on RoHS compliant alternatives to hexavalent chromium for treatment of steel and aluminium", 25 Oct 2005. http://www.electronicssouth.com/ContentStore/Assets/7/41/Post%20first%20trial%20report%20on%20RoHS%20compliant%20alternatives%20to%20Hexavalent%20Chromium%20for%20steel%20and%20aluminium.pdf

[68] R. Sommer, private communication, 9 Jan 2006.

[69] Iridite NCP technical datasheet, MacDermid Industries.

[70] US Military Specification: Chemical Conversion Coating Materials for Coating Aluminium and Aluminium Alloys, Amendment 5, 13 Nov 1979.

chromium conversion coating applied to both sides) between two flat polished copper contacts, applying a pressure of 1380kPa (200psi). The area of the upper electrode is 25mm^2 and the area of the lower electrode should be larger. To meet the requirements of MIL-C-81706 class 3 (specification for electrical and electronic applications where low resistance contacts are required) the contact resistance of aluminium alloy panels with conversion coating applied must be <5.0mΩ/sq. as coated and <10.0mΩ/sq. after 168 hours of salt spray exposure. These results are compared with those for the hexavalent and trivalent coatings marketed by SurTec as shown in Table 36.

Table 36. Summary of electrical contact resistance measurements from aluminium alloys coated with chromium conversion coatings supplied by MacDermid Industries and SurTec GmbH

Product	Coating type	Contact surface resistance after coating	Contact surface resistance after 168 hours of salt spray exposure
MacDermid Iridite NCP	Chromium free	<1.0mΩ/sq	<10.0mΩ/sq
MacDermid Alocrom 1200	Hexavalent type	<5.0mΩ/sq	<10.0mΩ/sq
SurTec 650 ChromitAL TCP	Trivalent type	0.25mΩ/sq	0.51mΩ/sq
SurTec 655 Yellow Chromate	Hexavalent type	0.27mΩ/sq	0.73mΩ/sq

Conclusions regarding trivalent chromium treatments

Trivalent chromium appears to be one of the best alternatives to hexavalent chromium although it gives inferior results in Ilford corrosion tests with chromate-free primers. There is limited electrical resistivity data but this does indicate that trivalent coatings may be suitable as a substitute for hexavalent chromium. However, this is a new treatment, and no field data has yet been published because its use in products has been for much less than two years. Extrapolation of salt fog tests to predict field performance could be unreliable until these products have been used in relatively hostile conditions for at least five years. Trivalent chromium based coatings are commercially available and are being used in some products within Categories 1 to 7 and 10 that will need to comply with the RoHS Directive but these are almost all used in home or office environments.

8.3.4 Other treatments

Silanes – There are several products based on organosilanes available commercially (Oxsilan AL – 0500 and Oxsilan 9800) and some commercial products may contain these compounds as minor ingredients. Silanes are used as adhesion promoters so improve paint coating adhesion. In ESTCP tests, the AL-0500 product performed poorly but the 9800 performed well in more recent tests carried out in New Zealand[71].

Permanganate – Chemically similar to chromate, as both of these are powerful oxidising agents. Metal treatments based on permanganate are available commercially (Sanchem Safeguard 7000) but independent tests have shown them to be very inferior to chromate and so not suitable as drop-in replacements.

Conducting polymer – These are being developed by the US Navy and others but are not commercially available. One type tested on 2024-T3 (MIL-C-5541) in salt spray tests passed 800 hours. Currently research is ongoing with chromate-free primers. Research with conducting polymer films has shown that they do have some corrosion inhibiting properties.

Cerium based pre-treatment – Cerium is a rare earth element but the only one with a stable tetravalent state and it is in this state that it has corrosion inhibiting properties. A lot of research has been carried out on cerium based pre-treatment for aluminium alloys. Although promising results were obtained initially, there are currently no commercial products based on this technology.

Cobalt based – Originally gave very promising results and reported to be superior to the Ti/Zr formulations. Cobalt however is a suspect carcinogen, is banned in Germany, and so is not an alternative. No commercial products are available except as anodising sealants.

A list of alternatives would not be complete without mention of the one material which may be as equally effective as hexavalent chromium. It is often the case, that elements in the periodic table that are adjacent on diagonals (one row down and one to the right) have similar properties. Technetium is in this position in relation to chromium and technetate ions have been shown to be effective corrosion inhibitors. Unfortunately, technetium is one of the few elements that does not occur naturally and is highly radioactive.

8.3.5 Commercial products for coating aluminium

Table 37 lists a selection of commercial metal treatment products with comments on test results if published.

Table 37. Commercially available metal passivation products for aluminium alloys

Product	Manufacturer	Comments	Performance compared to CrVI
Alodine 5200	Henkel	Ti, Zr, fluoride	Suitable alternative for some applications
Oxsilan AL-0500	Chemetall (was Brent)	Silane based	Gave poor results in ESTCP study
Oxsilan 9812	Chemetall	Silane based	Gave good results in tests carried out by RoHS and WEEE Specialists International (New Zealand)[71]
Permatreat 615M, 617M and 604A	Betz Metchem	Range of products based on Ti, Zr, fluoride	Gave poor results in ESTCP study
Safeguard CC-3000	Sanchem	Claimed suitable on bare metal and under coatings	US Air Force tests show that Safeguard is inferior on 2024-T3 but superior on 7075-T6 (336 hour salt spray, unpainted)
PreKote	Pantheon Chemicals	For use under primer and paint (organic constituents)	Poor in ESTCP study but good results in more limited USAF comparative study based on field service on Military Aircraft

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[71] R. Sommer, personal communication

Product	Manufacturer	Comments	Performance compared to CrVI
Iridite NCP	MacDermid	Probably fluorotitanate based	Datasheet states that it passes ASTM-B-117 (salt spray on unpainted metal) and ASTM-D-3359 (tape adhesion on painted metal).
SurTec 650	SurTec	Trivalent chromium based on US Navy research	ESTCP study found this to be the best alternative to hexavalent chromium and is performing well in commercial tests

8.3.6 Chromate based primers for aluminium

Passivated aluminium is painted with a primer then topcoat. The best protection has traditionally been obtained with a combination of chromate passivation and a primer containing a chromate, often strontium chromate which is specified in MIL-PRF-23377H class C. Research shows that hexavalent chromium-free passivation with hexavalent chromium-free primers give inferior performance to their hexavalent chromium equivalents although research is on-going.

Manufacturers claim that they can supply hexavalent chromium-free alternatives but published test results appear to be contradictory though it is not always clear which test methods or standards are being used. Clearly alternatives are available for some applications but may not meet the criteria of the more demanding MIL standards.

8.3.7 Anodising of aluminium

Aluminium is anodised by electrolysis in an acidic electrolyte. The aluminium metal surface forms an increasingly thick oxide coating that provides corrosion protection. Aluminium is anodised in sulphuric acid, chromic acid, boric/sulphuric (used by Boeing and others) and sulphuric/phosphoric acid combinations. Anodised aluminium is a porous oxide but this can be sealed to increase corrosion protection but is usually left unsealed if painted as this increases adhesion. Anodising can be carried out with AC and DC voltages at ambient or in hot electrolyte.

Anodising has been proposed as an alternative to hexavalent chromium passivation but corrosion protection is inferior. Research has been carried out by Sintef Materials Technology into various aluminium pre-treatments prior to painting. Resistance to Ilford corrosion was assessed. Hot AC anodising (in 15% sulphuric acid at 80°C) gave the best protection after hexavalent chromium but anodised coatings are electrically insulating.

Kress and Nowak[72] found that anodising provided inferior salt spray resistance (bare metal) to hexavalent chromium but superior protection against Ilford corrosion.

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[72] J. Kresse and A. Nowak "Alternatives to the Chromating of Aluminium and its Alloys" http://www.cleanox.com/int_henkel/hst/binarydata/en/pdf/ACFRIA0n972z.pdf

Research by US Air Force (Fort Worth, Texas)[73] has led to a change from anodising in chromic acid to thin film anodising in sulphuric acid. This met the criteria of MIL-A-8625 (type and class not mentioned in article) and as a result, all production at this site now uses chromate-free anodising.

For exposed aluminium surfaces a sealant is required to achieve corrosion protection. Two types are used for aircraft:

- Nickel acetate and nickel-free based (originally by Novamax, now owned by Henkel - Anoseals);
- Cobalt based and cobalt/nickel based (acetates) – approved by Rockwell and tested by Boeing (in 1997).

8.3.8 Conclusions for aluminium coatings

There is no single drop-in replacement for hexavalent chromium and each application needs to be assessed individually. For some applications, hexavalent chromium-free alternatives will exist and there are many published examples of where chrome-free alternatives have been evaluated and are now being used commercially in aerospace, automotive and architectural applications.

Aluminium alloy selection is important as some alloys have a better corrosion resistance than others and some of the substitute coatings are less effective on certain alloys. Chromate-free treatments and coatings may be acceptable on some alloys but not on other types.

The standard to which a passivation treatment or paint coating needs to comply is also important. Ti/Zr based pre-treatments followed by chromate-free primers are acceptable for standards that do not require Ilford corrosion resistance but fail to meet the criteria for MIL-PRF-23377H.

Accelerated testing may not represent field conditions and some commercial products are reported to give good results in field tests whereas in accelerated tests, they performed poorly. The accelerated tests and MIL standards were originally developed using chromate based systems and may not give reliable indications of field performance with other types of treatments and coatings. The main concern of Category 8 and 9 equipment manufacturers is the lack of field data with these new materials. Although accelerated tests are giving encouraging results, this type of test does not always simulate real life conditions accurately. Also, published tests have concentrated on corrosion and DC electrical resistance whereas equipment that has to meet the requirements of the EMC Directive often uses high frequencies. The Test and Measurement Coalition is, as a result of this lack of data, carrying out extensive trials to investigate the main substitute materials. This work is on-going but to date is giving encouraging results with trivalent chromium performing well.

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[73] "AFP4 Success Story: Replacement of Chromic Acid Anodize with Thin Film Sulphuric Acid Anodizing System", The Monitor Fall Vol. 8, No. 7, p30, 2003.

The most promising alternative appears to be those based on trivalent chromium as these give good corrosion resistance (in accelerated tests) and low electrical resistance on unpainted metal.

Thin film sulphuric acid AC anodising is a possible alternative to hexavalent chromium passivation which may give adequate performance for some applications.

There is very limited data available as many manufacturers do not publish their results and many of the substitutes for hexavalent chromium are very new. The limited published data shows that for some applications, the alternatives to hexavalent chromium are inferior and do not comply with certain MIL standards. However for products which manufacturers believe are in Categories 8 and 9, available substitutes appear to be suitable. This is not the case however for equipment used in the most corrosive environments such as production processes, oil refineries, chemical plant, etc. Equipment used as part of these “large-scale stationary industrial tools” is regarded as being outside the scope of WEEE and RoHS. To date therefore there is no data to support an exemption for hexavalent chromium passivation for Category 8 and 9 products.

One point that may help manufacturers is that the IEC water extraction test on parts treated with Alocrom 1000 (which gives thin transparent coatings) gives a negative result indicating that no hexavalent chromium is present despite it being used to produce the coatings. These coatings are extremely thin so this result may reflect the test’s inability to detect such small quantities of hexavalent chromium - not that there is less than 0.1% Cr(VI) in the surface coating. However, the IEC test is very sensitive and there is no reason to believe that this result is incorrect.

8.3.9 Substitutes for zinc coated steels

Substitutes for zinc coated steel are commercially available and have been developed primarily by the automotive industry as a result of the End of Life Vehicle (ELV) Directive 2000/53/EC. In vehicles, galvanised steel parts are usually painted to give very effective protection from corrosion. However, in electrical equipment, fasteners are not painted and treated panels are bolted together without paint coatings and the coatings should give good electrical conductivity. Trials with substitutes for hexavalent chromium on zinc coated steel have shown that most give electrically insulating coatings but trivalent chromium substitutes can give electrical conductivity.

Thick film trivalent coatings are now accepted as suitable replacements for hexavalent chromium based coatings on zinc coated steels and there are a wide range of products on the market from companies including MacDermid Industries, SurTec and Henkel[74].

Reviews from these manufacturers suggest that the corrosion performance of the trivalent coatings equals or exceeds those achieved with hexavalent coatings (Table 38 and 39) and that they have superior thermal shock resistance (Table 40). One independent report[75] suggested that trivalent

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[74] P. Hülser, (SurTec GmbH), “The ability to apply trivalent coatings in thicknesses comparable to hexavalent coatings had previously limited their corrosion resistance”

[75] Third report on RoHS compliant alternatives to hexavalent chromium for treatment of steel and aluminium, RoHS and WEEE Specialists (NZ) Ltd, 25 Oct 2005.

coatings cannot match the corrosion performance of conventional hexavalent coatings such as Henkel Alodine 1200. In this study the best trivalent coating type only achieved a salt fog rating of 82hrs, as opposed to 96hrs for the hexavalent treatment. However, this was the only available comparison of the conventional coating against an un-named trivalent treatment.

Direct replacement of hexavalent coatings by thick film trivalent coatings can be limited by colour specifications, since trivalent coatings are generally colourless. However, because of the thickness of coating used, dyes can be absorbed and this capability provides for colour matching of components.

Table 38. Comparison of hexavalent and trivalent coatings on 8µm zinc and zinc-iron plated steel panels

Hours to 5% white rust coverage	Zinc	Zinc-Iron
Trivalent coating	200	450
Hexavalent coating	200	450

Data from High Performance Alternative to Hexavalent Chromium Passivation of Plated Zinc and Zinc Alloys, Alan Gardner and John Scharf, MacDermid Inc., 2001 Society of Automotive Engineers.

Table 39. Comparison of hexavalent and trivalent coatings on zinc coated steel after neutral salt spray testing

Coating type	Hours to first attack	Hours to 5% white rust	Hours to 10% white rust	Total
Blue hexavalent	24	8	40	72
Yellow hexavalent	198	151	74	423
Trivalent coating	297	81	49	427

Data from Chromiting®, chromium (VI)-free Passivating Basecoat for Deltacoll on Zinc and zinc alloys, P. Hülser, SurTec GmbH.

Table 40. Time to white rust after thermal degradation of hexavalent and trivalent coatings on zinc, zinc-iron and zinc-nickel (12-15% nickel) plated steel panels

Time to 5% white rust coverage (hours)	Zinc	Zinc-Iron	Zinc-Nickel
Trivalent coating (before thermal shock)	200	480	100
Hexavalent coating (before thermal shock)	200	400	700
Trivalent coating (after thermal shock)	200	480	100
Hexavalent coating (after thermal shock)	20	40	480

Data from High Performance Alternative to Hexavalent Chromium Passivation of Plated Zinc and Zinc Alloys, Alan Gardner and John Scharf, MacDermid Inc., 2001 Society of Automotive Engineers.

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http://www.electronicssouth.com/index.cfm/RoHS%20and%20WEEE/Files/Third%20report%20on%20RoHS%20compliant%20alternatives%20to%20Hexavalent%20Chromium%20for%20steel%20and%20aluminium

For zinc coated steels only limited data is available on the electrical conductivity of trivalent treated surfaces in comparison to conventional hexavalent treatments. A study by SurTec Japan[76] showed that the point contact resistance of the two coating types was comparable at ~1-2Ω although the relationship between coating thickness and resistance was different for the two types. Whilst the contact resistance of the trivalent coating increased slightly with increasing coating weight the contact resistance of the hexavalent coating decreased significantly as the coating weight was increased. This was due to a measured difference in micro-hardness between the coatings. As the hexavalent coating thickness increased the micro-hardness of the layer decreased. The pointed probe used for the measurements was able to penetrate further into the coating layer reducing the measured contact resistance. Conversely, as the trivalent coating thickness increased the micro-hardness remained relatively constant and likewise the penetration depth of the pointed probe into the coating layer.

8.3.10 Substitutes for magnesium alloys

Rugged lightweight portable test equipment may be made from magnesium alloy. This is lighter than aluminium and stronger than plastics and so is ideal for products which are likely to receive impact shocks, for example by being dropped. The magnesium is normally coated and the most robust coating to protect the equipment is a rubberised coating. Good adhesion to the magnesium is achieved by hexavalent chromium coatings and adhesion is very poor without this coating. Research using trivalent chromium passivation has given good preliminary results, however, and so may be suitable as a substitute[77].

8.3.11 Impact on Electro-Magnetic Compatibility (EMC)

Category 8 and 9 equipment must meet the requirements of the EMC Directive and this is currently achieved in many products by shielding circuitry with aluminium panels, sometimes with special gaskets to avoid narrow gaps. These form a “Faraday cage” around the sensitive electronics and prevent emissions that would otherwise be illegal as well as protecting the sensitive circuits and sensors from external interference and ensuring the electrical performance of the design. This is necessary as there are many sources of interference including mobile phones, other equipment etc.

In the field, aluminium is susceptible to corrosion, particularly in equipment that is used in hostile conditions or is exposed to corrosive materials. Where corrosion occurs, it can form electrically insulating layers at joins destroying the integrity of the Faraday cage. Isolated panels and slots can then act as aerials transmitting electromagnetic radiation. This problem is worse for high frequency equipment as radiation can escape through very small gaps created by corrosion product build up.

The procedure used by manufacturers to maintain the Faraday cage is to prevent corrosion by using corrosion resistant coatings - hexavalent chromium based coatings have been the most effective and widely used materials. These are used because they both prevent corrosion and maintain electrical

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[76] Private correspondence.

[77] Private communication from Test and Measurement Coalition, unpublished research results

conductivity between panels. This is often believed to be because the coating itself is an electrical conductor but this is not true. The coatings consist of electrically insulating metal oxides but these are so effective as very thin coatings that when two panels are placed in contact, electrical conduction is made at many locations via the high points on the metal surface which break through the very thin oxides. Inevitably, these coatings are damaged but they also have a unique property that damaged areas self-heal. The mechanism is unclear but is probably due to migration of water soluble chromate ions from the coating to the exposed metal where it reacts to reform a thin coating.

Thin transparent coatings are most commonly used. While these do not have the best corrosion resistance, their electrical conductivity is very good. Manufacturers and researchers are not able to determine with certainty if these coatings contain hexavalent chromium. Standard colorimetric tests give either negative or inconclusive results either because there is no hexavalent chromium or because the tests are not sufficiently sensitive to analyse accurately the minute quantities of hexavalent chromium that are present.

Substitutes for hexavalent chromium are commercially available and some types give good performance in accelerated tests but these are new products so no field data is yet available.

Manufacturers have other options to meet EMC Directive requirements but all involve significant design changes. This might be possible for new products but would incur large costs for existing models and this might not be economically viable if the cost is greater than future profits from the product's sales in the EU. Options include[78]:

- Use interlocking designs for joins between panels to maximise interface area and minimise seams that can allow emissions from high frequency equipment;
- Include ground planes on PCBs;
- Place power and signal circuits on separate PCBs if possible, otherwise on separate areas of PCB (this also reduces immunity to external interference);
- Choice of microprocessors can reduce emissions.

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[78] D. Atkey (ERA EMC consultant), personal communication.

9. Commercial and legal issues affecting manufacturers and users

The RoHS Directive is already having an effect on producers of Category 8 and 9 products and this has been taken into account in this review. There is existing and proposed legislation that affects these products and this also needs to be taken into account to avoid any conflicts before including these Categories within the scope of RoHS.

Categories 8 and 9 were originally excluded from the scope of RoHS because of concerns over the reliability of substitute materials and their likely impact on users and the environment if unexpected failures were to occur. Reliability issues have been discussed in Section 8. Other issues that may affect EU manufacturers, users and the environment are discussed in this section.

9.1 Current commercial situation affecting Category 8 and 9 equipment manufacturers

The RoHS Directive is already having a significant impact on manufacturers of Category 8 and 9 products. The main influences on manufacturers are:

9.1.1 Changing components

The majority of mass produced electronic components are being changed to comply with RoHS and many have already been replaced by versions that do not contain the RoHS-restricted substances. This is already affecting manufacturers of Category 8 and 9 products. Many have expressed concern about the risk of tin whiskers from these components but in practice have little choice but to use these components as most are available with tin-plated terminations as the only option. Category 8 and 9 products can contain up to 25% of custom or specialist parts that are not used in equipment in the other eight WEEE Categories. Clearly, tin plating need not be used but some manufacturers have extensive stocks of non-compliant custom parts, which should be used rather than become waste and this will take many years in some cases. Also time for research is needed to replace RoHS substances.

Another current trend is the acceleration of early obsolescence. Most components used in mass produced household, consumer, IT and telecom products, are sold in very large numbers and so component manufacturers have been replacing these with RoHS compliant versions. Frequently, however, specialist professional Category 8 and 9 products utilise older types of components which are produced in relatively small numbers and which the component manufacturers find it uneconomic to develop RoHS compatible substitutes and so are deciding to stop production. Manufacturers of products made in relatively small numbers frequently make life-time-buys (see Section 10.21.2) to enable continued production. Last time buys are not popular and are seen as a last resort but cost of re-design of equipment in Categories 8 and 9 can be greater than expected future profits and so this is often the only option.

Early obsolescence is a problem for all types of equipment but is currently a significant problem for Category 8 and 9 equipment manufacturers as it is estimated that about 10 to 20% of components are custom built and are not used in products within other WEEE Categories where large volume requirements will usually ensure that the supply of components will continue. Older non-compliant components will eventually be used and so the effect of this will be less significant if manufacturers are given sufficient time before the inclusion of Categories 8 and 9 in the scope of RoHS.

9.1.2 PCB subcontractors

Most Category 8 and 9 manufacturers and almost all SMEs do not produce their own PCBs but use sub-contractors. PCB sub-contactors usually have customers in different sectors of the electronics industry and many will have some customers who need to comply with the RoHS Directive (products within Categories 1 to 7 and 10). Many sub-contractors have only one production line and so will have to decide if this will be tin/lead or lead-free. Several manufacturers of Category 8 and 9 products have told ERA that their sub-contactors will be changing over to solely lead-free technology and this trend is likely to continue. Some have accepted this and so will as a result have lead-free products in the near future but others are being forced to change sub-contractors. This can be a serious problem for manufacturers as new sub-contractors will have less experience than the original manufacturer and yields can be reduced, increasing waste, and reliability may also be affected. Many of the Category 8 and 9 manufacturers consulted have said that their sub-contractors will continue to make tin/lead products into the foreseeable future. This is because in Europe, there are many manufacturers in sectors that are outside the scope of RoHS such as aerospace, military, medical and "monitoring and control" whereas most IT, telecom, consumer and household products are made in the Far East. It is likely, however, that in the future an increasing number of PCB sub-contractors will make only lead-free soldered products.

9.1.3 Customers

Currently, equipment in Categories 8 and 9 do not need to comply with RoHS but several manufacturers have indicated that they are being forced to use lead-free solders wherever technically possible to meet customer requirements in the Japanese market. There is currently no legal restriction on the use of lead in Japan (although there are now marking requirements) but there are significant cost implications for equipment containing lead at end of life and so the Japanese market prefers lead-free products if they are available. Several manufacturers of Category 9 equipment have decided to replace RoHS-restricted materials wherever possible because of demand from Japanese customers.

European customers do not normally require RoHS compliance for Category 8 and 9 products but ERA has heard of several examples where local authority customers require RoHS compliance for analytical instruments (Category 9). This may be due to an incorrect understanding of the RoHS Directive but may be a genuine request in some cases.

Military and aerospace customers use Category 9 products but usually would prefer, and in some cases, insist that no changes are made owing to the protracted and costly nature of design changes and approvals in this sector. Although equipment used in aircraft or made solely for military applications, would be excluded from the scope of RoHS, dual use products will need to comply with RoHS when these Categories have been included in the scope of RoHS. This will affect both producers and their customers.

9.2 Compliance with other relevant legislation

Electrical equipment must comply with a wide range of regulations as well as the RoHS Directive and any changes that compliance with RoHS necessitates must not conflict with the requirements of other legislation. Frequently, even small changes made in order to comply with RoHS will require re-testing, reauthorisation and resubmission to notified bodies for licensing before the products can be sold. This process may need to be repeated in many other countries world-wide as manufacturers rarely make products solely for the EU market - particularly those sold in small numbers as are most Category 8 and 9 products. Compliance with equivalent legislation outside Europe is often very onerous and can be a much more lengthy process than in the EU.

9.2.1 EU legislation

Medical Device Directives

There are three related medical device Directives; the Active Implanted Medical Device Directive (90/385/EEC), Medical Devices Directive (93/42/EEC) and the *in-vitro* Medical Devices Directive (98/79/EC). In order for medical devices to be put onto the EU market, they must comply with the relevant Directive. Notified Bodies are responsible for reviewing the conformity of these medical devices and will issue a certificate before they can be sold in the EU. All new products must be tested for compliance with these medical device Directives. The technical file includes reliability testing and clinical trials, where appropriate.

Medical devices have specific EMC requirements as part of these Directives. Where existing products are changed in order to comply with RoHS, the manufacturer must inform the Notified Body that originally issued the certificate if substantial changes have been made. The Notified Body will assess the proposed changes and verify if these changes affect the conformity with the essential requirements of the Directive. This will be the case if the changes made are regarded as substantial and where the modification could affect reliability.

High reliability is an essential requirement for all medical devices and Notified Bodies would assume that modifications including the use of lead-free solders would not have a detrimental effect on product reliability otherwise the manufacturer would not be using it. This is particularly important for the most safety critical products such as implanted devices. Manufacturers of the most safety critical products would need to be certain that reliability had not been negatively affected by using alternative materials and so where any doubts remain, even if these are small, this could make achieving approval difficult.

Where an existing non-RoHS compliant product has to be modified to comply with RoHS, it may be necessary to carry out conformity assessment by a Notified Body. All medical equipment manufacturers that were interviewed for this review thought that any change including converting to lead-free solders would necessitate application to a Notified Body before the modified product could be sold. A Notified Body was consulted for this review and, in their opinion, as long as it is established that lead-free solders are equally reliable as tin/lead, this change would not require re-testing or submission of data to reapprove the product - nor would minor changes to a few passive components. However, a more significant modification such as using a different microprocessor would require testing and submission of data to a Notified Body.

The length of time that approval takes depends on how busy are the Notified Body, the complexity of the change and if adequate test data is available. This process can take as little as a few days but six months is not uncommon for more complex products. Some Notified Bodies are currently very busy and so it would be expected that an increase in workload that would result from the many changes that would be made to comply with RoHS will cause further delays so that, in some cases, approval could take up to one year.

There should be no conflict between the requirements of the RoHS Directive and the Medical Device Directives as long as:

- Sufficient time is allowed for development of compliant products (re-design if required), reliability and performance testing and approval;

- Substitute materials can be used to achieve equal or better reliability to those currently used.

Safety Directives

Product safety is regulated by the General Product Safety Directive (2001/95/EC) as well as the Low Voltage Directive (73/23/EEC) and certain products are also subject to other Directives such as ATEX (94/9/EC) – equipment used in explosive atmospheres. Changes to comply with RoHS must not compromise compliance with these Directives.

The UK Health and Safety Executive (HSE) enforces and is responsible for Health and Safety legislation in UK and has provided a detailed submission to this review. A lot of equipment in Categories 8 and 9 is safety critical and some has functionality that ensures health and safety. Therefore these products need to comply with legislation that stipulates their health and safety performance. The HSE’s view is that as the substances and components used in these products can affect reliability, any change to specification such as that engendered by RoHS has the potential to compromise safety. The HSE is aware of claims that the performance of lead-free solders are inferior to tin/lead solders although this has been investigated as part of this review and is discussed earlier in this report.

It is the HSE’s opinion, as well as that of many manufacturers, that until the reliability of lead-free solders is understood to the extent that that the risks of using it are no greater than with conventional tin/lead solder, an exemption should exist to allow the continued use of tin-lead solders in Category 8 and 9 equipment.

Electromagnetic Compatibility Directive (89/336/EEC) EMC

All electrical equipment must comply with the Electromagnetic Compatibility Directive 89/336/EEC (EMC) although medical devices have EMC requirements included in Directive 93/42/EEC. This Directive sets limits to the emissions of electromagnetic radiation from equipment that could affect other electrical products and limits the susceptibility of equipment to external interference. Products can be tested by manufacturers themselves (self declaration) or by Notified Bodies.

The main potential impact of RoHS on this Directive is from changing to substitutes for hexavalent chromium passivation coatings. If these are not suitable or applied incorrectly, products may not meet the requirements of this Directive. Manufacturers need to consider the performance of new products but these will also need to comply with this Directive after time in the field when surface corrosion may have occurred. The long-term performance of the substitute coatings needs to be determined before placing these products on the market to ensure continued compliance although substitute materials are available and appear to give acceptable performance. Until recently, no research had been carried out into the performance at high frequencies, commonly used in Category 8 and 9 products, but the Test and Measurement Coalition has reported preliminary results that indicate that substitutes give acceptable performance although this work is not complete and is continuing.

Marketing and Use Directive (76/769/EEC)

This Directive, which is related to the Dangerous Substances Directive (67/548/EEC), has been in existence since 1976. The Directive and subsequent amendments restricts a large variety of hazardous substances and is much more extensive than RoHS. This Directive usually places restrictions on preparations and articles containing specified substances as well as the substances themselves. It already includes restrictions for lead, cadmium and hexavalent chromium in certain applications some of which may be used in electrical equipment, for example lead in paints and cadmium in plastics. The Directive may restrict the use of a substance completely such as for penta-BDE and octa-BDE flame retardants or allow specific exemptions.

No conflicts between RoHS and this Directive should exist although some of the RoHS-restricted substances are specifically exempted from the Marketing and Use Directive. For example, cadmium pigments in safety critical applications is permitted by the Marketing and Use Directive but this would not be exempt from RoHS unless a specific exemption is accepted by the European Commission.

Eco-design of Energy using Products (EuP) Directive (2005/32/EC)

This new Framework Directive adopts a different approach to protection of the environment by regulating the design of products. It aims to reduce greenhouse gas emissions by encouraging energy efficiency and also to encourage manufacturers to look for less hazardous materials based on the full life cycle of the products. RoHS in contrast does not consider life cycle at all and is concerned only with avoiding hazardous materials arising in waste equipment regardless of the impact of substitutes on the product's life cycle. It is unlikely, at least initially, that Category 8 and 9 products will need to comply with this Directive as the numbers of products in most cases is too low and their impact on the environment is relatively small. The exception might be if there is a widely scoped Implementing

Measure (daughter Directive) concerning standby and off mode power losses. Bringing Categories 8 and 9 within the scope of an Implementing Measure would achieve most of the aims of RoHS as EuP requires manufacturers to choose the least hazardous materials wherever possible. However at least one Member State believes that this could not be enforced.

The medical industry is planning to adopt a compulsory eco-design standard (IEC 60601-1-9) which would achieve all of the aims of EuP as well as many of the aims of RoHS but materials restrictions would not be compulsory as cost may be considered.

Changing to lead-free soldering causes an increase in energy consumption in surface mount processes by an estimated 12%[79] because of the higher melting temperature of the most widely used solders. There would be an increases in energy demand because of the need for additional washing and drying of PCBs and there is an estimated increase in energy demand in wave soldering processes due to higher temperature of 15%. This is the same for products in all ten WEEE Categories.

Clearly, there are sometimes fundamental conflicts between the requirements of older legislation like WEEE and RoHS which only consider a particular part of the life cycle and EuP which reflects a whole life cycle approach. How such conflicts should be resolved has not yet been addressed to our knowledge.

Construction Products Directive (89/106/EC)

The scope of this Directive is not always clear but unlike with WEEE and RoHS, it is not up to manufacturers to determine if equipment is within its scope as this is defined by the Commission. CEN Standards are published which describe products within its scope. These include fire protection products that are installed in buildings but exclude security products.

Those products that are within the scope of the Construction Products Directive (CPD) must be tested and authorised by a Notified Body before use. Any equipment within the scope of both RoHS and CPD would need to be modified to comply with RoHS and then requires additional testing and evaluation by a notified body for CPD. ZVEI estimates that it can take up to two years for CPD authorisation. Whether fire protection products are also within the scope of WEEE is less clear because they are by definition part of a building and so may be excluded as a fixed installation. However there are likely to be some products within the scope of both Directives.

Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres (ATEX) Directive (94/9/EC)

Equipment that is used in flammable or explosive atmospheres must comply with this Directive. Notified Bodies are required to audit product designs, component choices, the product and quality systems. Changing a critical component requires re-testing which can take many months as there is usually a lack of availability of time at test houses and re-testing modified products can take six

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[79] Estimated by Electrovert

months or longer. One manufacturer stated that it can take two years to obtain authorisation after significant changes have been made to complex products.

VOC Solvents Directive (1999/13/EC)

This Directive aims to reduce emissions of volatile solvents. Equipment manufacturers will need to comply with this Directive but inclusion of products within the scope of RoHS could make this more difficult. Where manufacturers use wave soldering, there has been a trend towards water-based fluxes in recent years to meet the requirements of this Directive. However wave soldering with lead-free solders and water-based fluxes can be difficult and some manufacturers have been forced to revert back to solvent based fluxes in order to achieve good quality solder joints. On-going research is being carried out to develop better water-based fluxes that are suitable for lead-free and so this trend should be temporary. It is clear that changing from solvent to water based fluxes increases energy demand in addition to the increase in energy resulting from the change to lead-free solders.

Proposed REACH regulations

REACH stands for **R**egistration, **E**valuation, and **A**uthorisation of **Ch**emicals and is likely to affect manufacturers of electrical equipment if they use substances in their products or to manufacture these products, which are not already registered. The impact on Category 8 and 9 manufacturers is unclear but, as they use a large variety of unusual (mainly low volume) materials, they could be affected to a greater extent than manufacturers of other electronic products.

REACH is new and not well understood by manufacturers and some statements and claims received and included in the interim report may not be factually correct. While the final text of REACH has yet to be agreed, the main implications are:

- The chemical producer or supplier will normally carry out registration of most chemicals and registration will include all listed uses. Downstream users should provide information to chemical producers to be included in the list of uses - otherwise; they will need to register these themselves. They would normally do this only to retain confidential information.

- There is a lower limit for registration, which is 1 tonne/per producer/per year. This means that very unusual chemicals used in small quantities will be excluded.

- Substances of very high concern are considered differently with a requirement to obtain authorisation to use these. Manufacturers should not be using these substances unless there are no safer substitutes and most will already be restricted by the Marketing and Use Directive. It would be very unlikely that a manufacturer would have to change from a RoHS restricted substance to a substance of high concern.

- REACH includes “preparations” and “products” where the substance is released in use. For example, ink from a printer is released and so would need to be registered. Additives in plastics which are not released in the life of the product would not need to be registered unless the additive itself is incorporated into the plastic within the EU (and therefore must be registered as a use of this additive, not as a released substance).

Several Category 8 and 9 equipment manufacturers have recently stopped using PVC cable insulation because this frequently contains lead and they wish to pre-empt any future restrictions from the RoHS Directive. Manufacturers will need to ensure that the substitute materials not only comply with RoHS and the Marketing and Use Directive but also comply in the near future with REACH.

9.2.2 Legislation outside the EU

Electrical products are subject to regulations that resemble all of the EU regulations in the rest of the world.

Some countries accept the EU CE labels but many do not. Manufacturers of medical devices must submit applications for licences in USA, China, Japan, South Korea, Taiwan and many other countries and some of these have procedures that are more lengthy and onerous than in the EU. For example, manufacturer have reported that AIMD licensing in Japan can take four years and Class IIA medical device authorisation can take three years or longer in South Korea. This adds to the time required and the cost of compliance for Category 8 products so that manufacturers will be reluctant to modify existing models. Although they have the option of ceasing to sell non-compliant products in the EU or to make a compliant product for EU and non-compliant for other markets, most would find either option unacceptable as they are both uneconomic and so would be forced to modify products and apply for authorisation in all markets world-wide. The cost to EU producers will be significant unless products are included in the scope of RoHS only after sufficient time has passed for most existing models to be phased out and replaced by new models (that are RoHS compliant) when these are due for replacement.

9.2.3 Possible conflict between RoHS and other legislation

RoHS would conflict with existing EU Directives if products were less safe or less reliable as a result of changes made to comply. This would be in conflict with safety regulations and medical device Directives, the Construction Products Directive, ATEX, etc. if these are applicable. Also, if insufficient time were to be allowed for the collection of data and submission and evaluation by Notified Bodies for approval under these other Directives, producers would not be able to sell modified products legally.

Manufacturers need sufficient time to carry out research into issues that affect reliability as well as to produce the test data that is required by Notified Bodies. This research and collection of data will require more time than has been needed for products in the other eight WEEE Categories which in general need to comply with fewer Directives. Some producers will also need time to validate reliability and for some types of product, in particular for IVD, this is a lengthy procedure taking well over one year. The time for approval by Notified Bodies can take up to two years for certain product Categories although six months should be sufficient for most products.

Research, product re-design, product validation and testing and finally authorisation must be carried out sequentially. These steps are in total lengthier for safety critical Category 8 and 9 products than for most products in the other eight WEEE Categories. This is because i) models in Categories 1 – 7 and 10 are changed more frequently than industrial Category 9 and most medical devices so the need for re-design to comply with RoHS has been uncommon and ii) most Categories 1 – 7 and 10 do not need to comply with as many Directives that require stringent compliance testing so less testing and no validation are required. The time required to ensure that Categories 8 and 9 products comply with RoHS and with ATEX, safety, MDD and other Directives will as a result be longer than has been required for the other eight Categories. Note that servers and telecommunications network infrastructure equipment is in Category 3 and is safety critical equipment but this has a temporary exemption for lead in solders which is allowing a longer period for research, testing and authorisation.

In order to avoid harming EU manufacturers unnecessarily, timescales should also consider compliance with legislation in markets outside the EU. These timescales are varied depending on the type of product and the country. In many cases, timescales are similar to those in EU and approval will be carried out in parallel but several examples are listed in this report where the time required in certain countries is much longer than in EU.

The length of time required will need to be considered and it is clear that some sectors will require longer than others. If one implementation date is decided, this will need to be far enough into the future to allow producers who need the most time in that sector to comply, even though most manufacturers could have compliant products at an earlier date. This issue is discussed in more detail in the conclusions section.

9.3 Potential impact on Category 8 and 9 equipment manufacturers

Category 8 and 9 equipment manufacturers will be affected in a variety of ways by including these Categories in the scope of the RoHS Directive. The impact depends to a significant extent on the type of product. The following examples are used to illustrate how this Directive would affect various sectors of the electronics industry.

9.3.1 Large, relatively expensive high technology equipment such as X-ray, CT scanners, MRI, ultrasound, etc.

This sector includes a very wide variety of products mainly aimed at hospitals but also used by general practitioners and a few also by consumers. Some are relatively simple products and so would not require a long period of time to be converted to RoHS compliant versions but others are some of the most complex electronic products available including CT scanners, PET and MRI - all of which contain well over 100,000 component parts and cost several €millions.

Large and expensive medical equipment utilises state of the art technology and so manufacturers typically introduce new product designs every 3 to 5 years whereas some products in this sector are changed after much longer periods. Large complex products may take up to 7 years in development usually by refining and modifying existing equipment from previous models. A 100% new product would be very unusual. Also, these are very complex products which tend to be manufactured predominantly by relatively large enterprises that are more able to fund RoHS compliance than SMEs. Manufacturers of these types of medical equipment should be fully aware of the RoHS Directive and many are already planning for the future inclusion of Category 8. Their state of readiness is varied but most have concerns over the long term reliability of lead-free solders. Despite this, many plan to develop new products to comply with the requirements of the RoHS Directive to avoid having to re-design part way through the life of these products. This of course is on the assumption that additional exemptions will be permitted.

Siemens Medical, for example, plans to introduce new designs in 2006 that are built with lead-free solders but they have no plans to change existing models. If Category 8 is included in the scope of RoHS in 2012, many of Siemens' existing models of this type of product will have been phased out by this time, so avoiding the need to modify, test and reapprove most current models. This has the advantage that R&D staff can continue to work on new products and continue to produce state of the art equipment maintaining Europe's competitive advantage in this sector and also bring benefits to patients more quickly. Some other medical equipment manufacturers are also carrying out research into lead-free soldering but are taking a more cautious approach and have no intention of introducing RoHS compliant products until there is certainty that lead-free solders will be either equally reliable or more reliable than tin/lead solders.

Additional costs are incurred if existing products need to be changed. Where new products are developed and designed to comply with RoHS, the only additional costs are for research and for any increased component and material price increases. However modification of existing products incurs the additional cost of redesign, re-testing and re-licensing of existing products and this can be significant and would inevitably be passed on to users (e.g. hospitals). These costs would be avoided if existing products do not need to be re-designed and if those exemptions that can be justified are agreed. (See a discussion of these in Section 10).

Compliance by introduction of new RoHS compliant models without the need to modify existing ones will be possible in this sector if the date that Category 8 is included in the scope of RoHS is far enough into the future to allow the majority of existing models to be phased out at the originally planned date without having to be modified. RoHS compliance does introduce some added costs and additional work for any electrical product because in general, production costs are a few percent higher. New models in this sector tend to be incremental changes from earlier designs but compliance with RoHS will necessitate more drastic changes involving additional research and testing and so sufficient time is required for this research, testing and obtaining authorisation and this will have to be sufficient for the most complex equipment.

There are a small number of manufacturers who will have RoHS compliant Category 8 products in 2006–7. These producers tend to make simpler, less safety critical products but in a few cases products have been changed because the manufacturer did not realise that their products are currently excluded from the scope of RoHS.

Manufacturers in the medical sector who have suggested dates when inclusion of this Category in the scope of RoHS would be achievable, have proposed dates from 2010 to 2012 except for *in-vitro* diagnostics and implanted medical devices which are considered separately below. Most medical equipment manufacturers have said that they could achieve compliance by 2012. 2012 is six years from the date of this review. Manufacturers of products in Categories 1 – 7 and 10 of WEEE had ~3½ years between publication of the RoHS Directive in early 2003 and it coming into force on 1st July 2006 to comply. The longer period of six years allows time for the additional requirements (testing and authorisation) placed on medical equipment manufacturers which for technically complex products can be as much as 3 years or longer.

Clearly a few manufacturers in this sector could comply by 2008, many more by 2010, but the date imposed needs to consider those manufacturers who have the most complex products and who will need a longer period of time to comply. This is illustrated below - note that a similar situation exists with any other safety critical Category 9 product:

Figure 8. Timeline for inclusion of most medical devices in RoHS based on time previously allowed for Categories 1 to 7 and 10, and time required for new product introduction

2006	2007	2008	2009	2010	2011	2012
Now			Likely earliest date for an amendment to RoHS including Cat. 8 & 9			Most of Cat. 8 & 9 could comply with RoHS
Time for EU to amend Directive			~3½ years to comply after publication - same as was allowed for Categories 1 – 7 & 10			
3½ years to carry out research, re-design, process optimisation			~1½ years for testing		1 – 2 years for trials and approvals	

9.3.2 In-vitro diagnostics (IVD) equipment

In-vitro diagnostics (IVD) equipment is within the scope of Directive 98/79/EC. This sector is completely different to other medical equipment discussed in 9.3.1. From the date that a new product is launched, sales continue typically for 10 years before a new design is launched. New products may be quite different in their external appearance but internally changes are relatively small. This is because these products are very complex and must be very accurate and reliable so only fully tested components and circuit designs are utilised. Therefore new products may contain circuit designs with associated software that was developed 20 or 30 years previously. To continue production of these products, IVD manufacturers frequently 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.

Electrical equipment frequently utilises software and the time for rewriting software is usually much longer than changing circuit hardware designs. This is the case in all electronics sectors and IVD equipment is no exception and most IVD products have three sets of software operating on three levels:

- Desktop PC software – this is specific to individual IVD instruments
- Instrument control software
- Embedded software on microprocessors used on peripheral PCBs that serve specific functions

Redesign can necessitate rewriting software at all of these levels.

IVD products are sold typically in numbers of about 500 per year – so only 5000 in total over the 10 years of a typical design. About 38% of these sales would be in the EU. Numbers sold are much lower than for products in most other sectors. To illustrate this point, it takes 18 hours to manufacture all of the desktop computers required to operate 5000 IVD instruments, the total number of one typical model which would be manufactured over a ten year period. Design, testing, validation and licensing costs are significant and very time consuming for IVD instruments. One manufacturer, Bayer Healthcare, reports that a typical IVD instrument requires four years for this procedure and three years for a relatively simple product such as a blood gas analyser. This is of course in addition to the work to make the product RoHS compliant and assumes that an unlimited number of engineers are available, which will not be the case.

Table 41. Time that would be required to redesign a typical product to comply with RoHS

Design stage	**Time required (years)**
Hardware re-design	1
Rewrite software	1
System integration	0.5
Instrument revalidation	1.5
Re-licensing for the Medical Devices Directive	~1
Total elapsed time	**4**

Note: this example is for an immunoassay system.

Most of the steps in Table 41 have to be carried our sequentially hence the total cannot be less than 4 years. The most time consuming stage is instrument validation. This takes much longer than for any other type of product because these types of IVD instrument are used to carry out a large number of different tests and each one must be thoroughly validated after any modifications are made and before the data can be submitted to the Notified Body for re-approval. An automated immunoassay system might be able to analyse over 100 different substances using a different test procedure for each of these. All of these different tests will have to be laboriously and individually validated after modification of the instrument to ensure that the accuracy of all of these has not been affected detrimentally.

The example in Table 41 is of an ideal case where just one product needs to be modified. In reality, to comply with RoHS each manufacturer will need to modify most of their product range (excluding those they decide to phase out early) but they will have a limited pool of technical staff available to carry out this work. Members of the IVD trade association, EDMA, has estimated that to convert all products to comply with RoHS, re-test, validate, etc. could take eight years or longer despite a significant proportion of products being withdrawn from the EU market. Sales of existing products would be discontinued instead of being modified to comply with RoHS if the time between the date when the work listed in Table 41 is completed and when the product would normally be phased out and replaced is too short to fund the compliance costs. Future sales need to fund the costs incurred and, as sales are in small numbers, products that were launched more than five years previously are likely to be phased out if Category 8 is included in the scope of RoHS in 2012.

Typically in the IVD instrument sector, manufacturers have about 30 different models. EDMAs members have stated that 8 years will be required in their sector rather than the 4 years from Table 41 because the availability of trained engineers is limited; although there would be resources to change one product in 4 years, to change 15 or more in this time period would require more engineers than are available and a more realistic timescale would be 8 years. The remaining 15 (models/producer) could not be changed even with an unlimited number of engineers (which will not be available) as the time left after conversion to RoHS compliance before the planned phase out date is too short for sales to fund this work.

As an example to illustrate this - for a product launched in 2004 which would be due to be phased out in 2014 and if IVD products need to comply with RoHS in 2012, consider these two scenarios:

- Compliance work starts 2006 taking four years to complete, compliant product available from 2010, two years early but with only four years sales to fund cost of compliance.
- Compliance work starts 2006 taking eight years to complete, compliant product available from 2014 – too late for 2012 compliance date and after date when product is due to be phased out.

Even if EDMA’s estimate of 8 years is rather generous (and there is no evidence that it is inaccurate) it is clear that many of these complex products would have to be phased out in the EU if the date by which they are required to comply is too early.

Newer products could be changed to comply with RoHS but the cost, estimated to be €6 million per product (for the more complex models), would need to be funded in most cases by 5 or less years of sales, totalling as few as 2000 instruments of which less than 800 would be sold in the EU. This additional €6 million is an additional cost that would not normally be incurred in a product’s life if it does not have to be re-designed. If the manufacturer could not increase prices outside the EU due to the presence of non-RoHS compliant products in these markets, the sales price increase in the EU only would have to fund the total cost; this would result in a price increase of ~€8000 for each product, typically an increase of 7% on top of other compliance costs. Manufacturers in other sectors estimate this to be 1 – 4% (4% for more complex products sold in smaller numbers) making the total increase in cost about 10%. This is too large to be adsorbed by manufacturers and so would have to be funded by healthcare providers as higher sales prices. If the cost could be funded by world-wide sales, the price increase would be up to 6%. RoHS compliant products are not yet required outside EU and so it may not be possible to increase prices in locations where non-EU competitors do not have similar costs to meet, however many non-EU countries such as China, South Korea, Australia and some US States are likely to have RoHS type legislation soon after the EU.

In summary, the impact of early inclusion of IVD products in the scope of RoHS on IVD manufacturers and their customers would be greater than for other types of medical product because of the longer time scales required for re-designs. The impact could include:

- More significant loss of product diversity if IVD products need to comply by 2012 or earlier;
- Increased price of instruments (up to 11% if funded by EU sales only, otherwise up to ~6%);
- New product development would stop or be significantly delayed as technical resources are diverted to product modification;
- The healthcare providers main concern with IVD instruments is "cost per test". This has steadily decreased over the past decades due to technical advances but if R&D staff were diverted to existing product modification to comply with RoHS the cost per test is more likely to increase.

IVD equipment manufacturers are beginning to investigate RoHS compliant product development and plan to launch their first RoHS compliant products in the near future and will gradually phase out non-compliant older models.

9.3.3 Active implanted medical devices

Active implanted medical devices (AIMD) are within the scope of Directive 90/385/EEC and include heart pacemakers, defibrillators and insulin pumps. Many are manufactured in relatively large numbers, for example 100,000 per annum of one type of pacemaker product may be sold world-wide. These products are required to be the most reliable of all medical devices as unexpected failure can lead to death or serious injury. Hence, the design cycle for new products is very lengthy with most modifications that are incorporated into new models being small incremental changes to existing designs that are known to be very reliable. Typically, the time from concept to clinical trials is 6 to 8 years with a further 1 year for EU MDD licensing.

Medtronic is a US AIMD manufacturer and has stated that it would be technically possible to produce RoHS compliant versions although significant technical problems would need to be overcome. The reliability requirements of these products are very high and reliability data is required to obtain approval for sale in the EU under Directive 90/385/EEC, but this would be problematic without certainty over the long-term reliability of substitute materials. Usually for AIMD products, reliability statistics are based on field data from existing but very similar products. However, there will be no field data from lead-free soldered products for many years and until AIMD manufacturers can guarantee the reliability of lead-free solders in the field obtaining a licence will be very difficult.

The cost of changing AIMD products to comply with RoHS will be relatively expensive (owing to the need for extensive testing and trials) and it is likely that older models will be phased out early rather than make necessary changes to comply with RoHS, carry out trials and obtain approval from a Notified Body. Older models tend to have lower prices than new models and so the former are preferred by some healthcare providers in the EU although others choose the more advanced (but more expensive) models. The result of needing to purchase newer more expensive models and limits on healthcare budgets would result in smaller numbers of AIMD equipment being available to patients which could result in a negative impact on patient health and quality of life.

Manufacturers have said that inclusion of AIMD within the scope of the RoHS Directive is impractical before 2020. This is due to the difficulty of obtaining approval by Notified Bodies in the EU without field reliability data. They believe that by this date it will be known from other products whether lead-free soldering is as reliable as tin/lead. However, if the reliability of lead-free solders is sufficiently understood and there are no concerns, RoHS compliant AIMD could be available sooner than this date.

9.3.4 Consumer-type monitoring and control equipment such as thermostats and domestic smoke detectors, weighing equipment, analytical instruments, etc.

Category 9 products, except for industrial test and measurement equipment and some security products that utilise X-ray sources, could be modified to be brought within scope by 2012.

Consumer products are in general not complex products, are low in price and sold in very large numbers.

- Eurostat data for sales of electronic thermostats in the EU in 2002 was 33.6 million (this is much higher than one industry estimate and almost certainly includes thermostats used as components in other types of equipment);

- Eurostat data for multimeters in 2002 shows that 1.6 million were sold; sales would have been to both consumers and businesses.

The majority of manufacturers of these types of products are already carrying out research on the production of RoHS compliant versions and some RoHS compliant products will be available as early as 2006. Characteristics of this sector are:

- Product lives for consumer products are shorter than for specialist industrial products, typically of about 5 - 8 years;

- The cost of redesign can be spread over a larger number of products so that the resultant price increase will be minimal;

- Some products are safety critical such as smoke detectors and toxic gas detectors so high reliability is essential;

- Products are less complex containing fewer parts and most are not software based.

In summary, products of this type could be brought within the scope of RoHS sooner than other types of products and this could be achieved by 2012 and in many cases this could be earlier.

Manufacturers of weighing equipment sold primarily to retailers in large numbers are already working on RoHS compliance and some expect to have compliant products within two years (by 2008). The trade association for Fire safety and security products, Euralarm, has indicated that its members will be ready to change their products to comply with RoHS by 2010.

9.3.5 Security and safety equipment having X-ray sources

Security and safety equipment having X-ray sources are expensive and are sold in fairly small numbers. The impact on these manufacturers will be similar to that experienced by the industrial monitoring and control instrument manufacturers described in Section 9.3.6. The main difference is that these products include ionising radiation sources and are used in public places and so are subject to additional legislation requiring extensive testing to obtain approval. This can take typically up to 2 years and this time begins after the product has been designed, manufactured and tested. Therefore an additional two years will be needed for these products to avoid conflict with other legislation - 2013 or 2014 should allow sufficient time or these could be considered with those products discussed in Section 9.3.6.

9.3.6 Specialist industrial test and analysis equipment

The average product life of specialist industrial test and analysis equipment is about 10 years and can be as long as 30 years. The typical number sold of each model are as few as 2 per year (or less) and at most 10,000 units per year. Table 2 lists typical characteristics of products in this sector. The total number of different products in this sector is very large due to the variety of specialised types of instrument that are required by industry. Products are redesigned on average every 7 years although there is considerable variation. Most of the products in this sector are technically complex and so new product design or existing product modification has to be carried out by experienced and trained engineers. As the number of qualified engineers is limited, too early inclusion of these products in the scope of RoHS would have two effects:

- It would necessitate diverting R&D effort to product redesign to comply with RoHS and

- It would cause a proportion of products to be lost from the EU market where the number of available trained staff is insufficient to change these in the time period available.

Many products in this sector include components that are unique or unusual but contain a RoHS-restricted substance. This will require research to identify substitutes and to carry out reliability testing. One manufacturer (a member of the "Test and Measurement Coalition") has estimated that up to 3 man-years of effort could be required to replace only one material in a complex safety critical product.

Many Category 9 products need to comply with other Directives such as LVD, EMC, ATEX and Machinery Directives and testing and approval by third parties (Notified Bodies) is often required after modifications are made. Products will also need to comply with legislation in non-EU countries as most manufacturers will produce only one type of product for sale world-wide. Third party certification may also be required for some types of product. One manufacturer has estimated that the cost of additional testing and re-certification for one product modified to comply with RoHS could be as much as €1 million taking 2 or more years[80]. An unexpected impact of including Category 9 in the scope of RoHS is that it will affect products that are clearly Category 9 but are also used on board ships. Equipment that is part of a ship is outside the scope of RoHS (as there is no "ship" Category) but as manufacturers will produce only one version, the RoHS compliant product would need to be approved for marine use at additional cost and time.

Unlike IVD manufacturers, producers in this sector have a much larger number of product types on the market and so the time and effort that would be required to modify these would be even more significant. Insufficient additional staff with the required skills will be available as there is already a shortage of graduates with certain engineering skills within the EU. Therefore this would take a long time and many models would reach their normal end of life before they could be modified. As it would be impossible in practice to change all product designs by, for example 2012, this would result in many of these having to be withdrawn from the EU market early although sales could continue outside of the EU.

If the date that this sector is required to comply with RoHS is delayed beyond 2012:

- Less products will be withdrawn from the EU market and this would have less impact on product diversity;
- Only a small rise in the sale price of products would occur (and possibly no increase in some cases) as the additional cost of producing new RoHS compliant designs is much smaller than that of modify existing models;
- The ability to maintain leading edge technology by European producers would be maintained as R & D staff can concentrate on development of new products.

Many manufacturers have been consulted and have provided widely varying estimates for loss of product diversity as a result on including Category 9 in the scope of RoHS at an early date. They

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[80] Information from J. Lovegrove, AeA Europe.

claim that inclusion of Category 9 in the scope of RoHS in 2010 could result in up to 70% of some manufacturers' products being withdrawn from the EU market although the figure given by other manufacturers is less than 20%. This is quite different to the products discussed in Section 9.3.4, where very few early product withdrawals would occur. The Test and Measurement Coalition has provided figures for their members who represent 60% of this sector and have given different estimates based on whether certain exemptions are accepted.

Table 42. Estimates from industry of proportion of products that would be withdrawn from the EU market based on the date that Category 9 is included within the scope of RoHS

Options	2012	2018
With no new exemptions (unlikely)	40%-50%	5%-10%
With justified exemptions (discussed in Section 10 and listed in Table 71) and including "hexavalent chromium passivation" and Pb in solder	2%-10%	0%
With justified exemptions (discussed in Section 10 and Table 71) but excluding "hexavalent chromium passivation" and "lead in solder"	35%-40%	5%

The data in Table 42 is from the Test and Measurement Coalition and shows that the percentage of products withdrawn in 2012 would be less than 10% if all exemptions including one for lead in solders are accepted (until at least 2018). This is because without the need to change to lead-free soldering processes, most current product designs would not need to be modified. Most work including re-designs is required to change to lead-free solders.

With no exemptions for hexavalent chromium passivation or lead in solders, this industry sector has estimated that the proportion of products that would be withdrawn will be relatively high with a date of 2012 because 35 – 40% of current models that will still be available in 2012 will be too costly to modify or they will have insufficient engineers to carry out the work. In view of the recent test results the requested exemption for hexavalent chromium may not be required and so the impact on product withdrawals due to this should be much less although testing will need to be carried out.

The situation regarding an exemption for lead in solders is different. Research is likely to show by 2010 that this exemption will no longer be required. However the work required to modify thousands of existing designs to make them "lead-free" will be far too much to complete by 2012 and this is why the figure for products that would be withdrawn is so large. Manufacturers have estimated that by 2018, only 5% of current models will still be available and too costly to modify (more than future profits) as the majority of existing models could be phased out and replaced by new designs by this date.

Clearly there will be costs incurred as in all other sectors and manufacturers are already investing in research to identify RoHS compliant substitutes. The main concern though is that there are a very large number of product designs, many of which are sold in relatively small numbers and which will be costly to change and so many could be lost from the EU market as manufacturers determine that the cost of these changes could not be met by future sales.

Consider where the cost of compliance is €1 million per model. If 1 million units of this model are sold, the additional cost per unit is €1 - and so insignificant. However, if only 100 are sold each year for 5 years, the cost per unit is €2000 which in many cases will be too high as the average sale price of test instruments is €5200. Many are sold in even smaller numbers than this example although the cost of compliance for simpler products would be considerably less than €1 million.

Scope

The definition of equipment within this sector needs to be clearly defined to avoid different interpretations being used. One suggestion is based on reference to EN61010-1, "Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements":

"Products intended for use in industry that would normally be within the scope of European Standard EN61010-1 section 1.1 (a)".

This would include equipment normally tested to this standard even though customer requirements might result is other standards being used. This definition includes all of those products that are complex, safety critical and sold in small numbers to industry only and would exclude most simpler products that could be RoHS compliant by 2012. No definition is perfect, however, and this definition would include a small number of relatively simple products made in fairly large numbers such as lower specification multi-meters that could comply with RoHS by 2012 or earlier.

9.3.7 Summary of time needed to comply for different product types

Estimates provided by manufacturers for the length of time required to comply with RoHS and the earliest date for inclusion in the scope of RoHS (assuming that exemptions are permitted) are listed in the table below.

Table 43. Dates by which Category 8 and 9 equipment could be compliant with RoHS taking into account the most complex products

Product sector	Estimated date for full compliance
Medical equipment except for IVD and AIMD	By 2012
In-vitro diagnostics (IVD) equipment	By 2016 (allows 10 years for compliance from 2006)
Active implanted medical devices (AIMD)	Exclude
Category 9 products except for industrial test and measurement instruments and security equipment with X-ray sources	By 2012
Security scanning equipment	~ 2014
Specialist industrial test and measurement instruments	Manufacturers have requested 2018, 2016 may be reasonable but some products would be phased out in EU early without replacements

9.4 Cost of compliance

This has already been discussed for specific sectors in Section 9.3. Inclusion of Categories 8 and 9 within the scope of RoHS will inevitably have a cost impact on producers which in some circumstances will have to be passed on to users. Estimates by manufacturers of Category 1 to 7 and 10 products of compliance costs vary from ~1 to 4% of turnover. This is reasonable as costs include:

- Research, trials and testing of prototypes;
- Redesign and rewrite of software;
- Labour required for sourcing substitute components and materials;
- New process equipment and setting up and staffing systems for ensuring compliance;
- Staff training;
- Higher component and materials prices. Tin/silver/copper metal price is about 4 times that of tin/lead but ~90% of RoHS-compliant components are the same price as older non-compliant versions. However a small percentage are ~10% more expensive and most custom parts will incur a price increase;
- Lead-free soldering energy costs ~ 12% more due to higher melting temperature.

Compliance with RoHS will incur added costs but these will be greater where existing models have to be modified as the following describes:

> Development of new RoHS compliant product – **additional** costs are:
>
> Research, sourcing RoHS compliant components, investment in new equipment, staff training and setting up new procedures to ensure compliance.
>
> Modification of existing product to comply with RoHS – **additional** costs are:
>
> Research, sourcing RoHS compliant components, investment in new equipment, staff training and setting up new procedures to ensure compliance, re-design, software re-write, testing, validation, trials and obtaining authorisation from Notified Body if change is significant.

For the diverse reasons explained earlier in this report, the additional cost per product to modify it to comply with RoHS could be as high as 20% although most will be less than this and in the range from ~1 to 10%. In most cases these costs would eventually be passed on to users as all manufacturers in this sector will incur similar costs and so competition will not significantly inhibit price rises.

Many smaller EU based manufacturers sell the majority of their products in the EU and similarly, smaller US manufacturers sell most of their products in the USA. If Categories 8 and 9 are included in the scope of RoHS, the EU based manufacturers will have to modify their products as the EU is their main market but their US counterparts may decide not to do this if their EU sales are too small to fund the cost of making these products RoHS compliant. This could put smaller EU based manufacturers at a disadvantage as they would be less competitive in markets outside the EU where they have competitors who have not had to fund re-designs for RoHS compliance. If the EU producers are forced to recoup their costs only in the EU, price increases could be imposed only on EU users which would impact on EU competitiveness. Another possible result of inclusion of Categories 8 and 9 in the scope of RoHS is that manufacturers decide that re-design costs are too large and so withdraw the products from the EU market. This would also affect EU users who would want to use these products. The impact of inclusion of these Categories in the scope of RoHS will to a certain extent be negated by the adoption of RoHS-legislation world-wide. California, China and other States all plan to introduce similar legislation and so those manufacturers who modify their products in advance could gain an advantage over their competitors although this is difficult to quantify.

There may also be additional hidden costs to EU users and EU based industry:

- Healthcare providers all have limited budgets and so the increased prices for medical equipment will mean that less new equipment can be purchased with the resulting negative impact on health (see Section 9.6.1);

- In some cases, the need to divert effort from new product development to modification of existing products could result in a loss of technical superiority by European manufacturers over their non-EU competitors where this exists but this situation could be short term if the rest of the world adopts RoHS legislation. If this were to occur, it could harm EU industry and cause job losses;

- Early inclusion of Categories 8 and 9 in the scope of RoHS will cause a loss of product diversity as some older non-compliant products will be taken off the EU market. This will cause a loss of profits for the manufacturer but will also impact on EU users if they are unable to obtain essential equipment. One typical example is test instruments used to calibrate aircraft instruments which is discussed in Section 9.6.2;

- There has been a trend in the EU in recent years, to relocate manufacturing to low cost production areas and this is frequently outside of the EU (China, India, etc.). The decision to relocate could be made sooner if manufacturers find that it is necessary to upgrade their EU based production facilities by purchase of new equipment that is suitable for lead-free soldering. Many manufacturers have already found that it is more economical to move production to the Far East instead of refurbishing their existing plant and so this is closed with the resultant loss of employment and exports. Changes of this type will inevitably occur in the future to Category 8 and 9 manufacturers (some have already moved production) but the need to make lead-free products will result in these changes occurring sooner than they would otherwise.

9.5 Limitations on innovation

Many manufacturers have highlighted this issue, which is also a serious concern of DG Enterprise who is responsible for Medical Devices. Innovations are continually introduced into all products in all of the WEEE Categories. Restricted substances are unlikely to be used in new innovations in new products in Categories 1 to 7 and 10 and this will have not have a negative effect on human health, safety or the environment - the only impact would be the potential loss of some new features.

Category 8 and 9 researchers clearly will not choose to use hazardous substances in new innovations. Moreover, the direction of funding for new developments will not countenance even consideration of restricted substances if there is significant risk that they cannot be used over an extended period. However under some circumstances, physics or chemistry may dictate that lead, cadmium, mercury or other toxic materials would provide a significant technical advantage that could lead to new products which are beneficial to healthcare, safety or the environment. Examples, based on recent inventions illustrate how this might occur:

- Innovations in Category 8 are intended to give better and earlier diagnosis, more effective and successful treatment and completely new treatments. New semiconductor X-ray detector arrays based on cadmium telluride have been introduced in the last few years. These allow up to a ten-fold reduction in X-ray dose – clearly a health benefit to the patient and a reduction in risk to healthcare professionals. Also, the images obtained with these detectors are clearer so that earlier diagnosis is possible which improves survival and recovery rates. Another example of a beneficial innovation is MRI scanners, which rely on superconducting connections made from lead/cadmium alloys; **this technology, and its associated healthcare benefits would not have been developed if these metals were excluded from research**.

- Innovations in Category 9 provide better precision, accuracy, sensitivity, and discrimination, give earlier warnings of hazards such as pollutants, fire, etc and potentially reduce the risk to the environment and to safety. Improved control systems can also reduce energy consumption and greenhouse gas emissions. Continuous monitoring of water supplies for toxic pollutants such as cadmium at remote locations is possible using ion selective electrodes. These are used to analyse for cadmium and lead to enable pollution to be detected much earlier than would be possible using alternative techniques. **This would not have been possible if cadmium and lead were excluded as materials for research**.

As with products in the other eight Categories, substance restrictions could impose limitations on the development of innovative new products but where this occurs with Category 8 and 9 products, this could mean that potentially life saving and environmentally beneficial inventions would not be developed. It is impossible to predict future discoveries but there is no reason to assume that the discoveries that rely on hazardous substances will never occur - indeed, the above examples indicate precisely the opposite is likely.

Unfortunately there are few options available within the limitations of RoHS to allow unrestricted innovation. This problem is due to the intrinsic nature of “blue sky” research and development that may need to use a RoHS-restricted substance.

Under the present system, where a product is within the scope of RoHS a new innovation requiring the use of a restricted substance could be used only if an exemption were to be granted. Manufacturers’ experience with applying for exemptions is that this process takes at least one year.

Leading edge research is usually carried out by universities as short term contracts (1 – 3 years). The development of new technology, takes place in a competitive (and often highly commercially sensitive) environment, it is not possible for researchers and companies to operate with this type of uncertainty or delay but it does not appear that the European Commission is able to accelerate this procedure. Investment decisions require that acceptability or otherwise of the use of a restricted substance (where researchers suspect that no alternative will exist) in a particular application must be known before funds are committed. Even if an exemption already exists, the risk that it may be removed will also push the direction of research away from the use of restricted substances. So if a RoHS substance is determined to be essential and no alternatives exist, this line of research would be terminated.

As it stands, if Categories 8 and 9 are included in the scope of RoHS, manufacturers will be forced to avoid the RoHS restricted substances even if they believe that no substitutes exist in their research and so innovations that would otherwise potentially greatly benefit health and the environment would never be developed. Note that research carried out outside the EU will also be affected as RoHS-legislation in other countries tends to follow EU–RoHS.

Reliance on the current procedure to grant exemptions is too slow and uncertain for manufacturers and will result in the stifling of innovation. Moreover it only provides limited term exemptions. There are only two possible options to avoid inhibiting future innovation which are:

It would appear that it is not currently possible for the European Commission DG Environment to accelerate the exemption review procedure. If it is not possible to amend RoHS so that the review procedure for new exemption requests (for Categories 8 and 9) takes about one month, there are only two other options for avoiding inhibiting this type of beneficial innovation in the future:

a) Do not include Categories 8 and 9 in the scope of RoHS and control environmental impact and eco-design through a different mechanism (e.g. the EuP Directive and REACH regulations).

b) Include Categories 8 and 9 in the scope of RoHS but allow broad, non-time bounded exemptions or permanent exceptions such as for “sensors, detectors and electrodes” that would permit innovations in these areas. The disadvantage of this approach is that it is impossible to predict where new innovations will occur in the future.

9.6 Potential impact on users and the environment

The cost of implementation of the RoHS Directive has already been discussed in Sections 9.3 and 9.4 and will be borne by producers who, of course, will pass this on to their customers if this is possible. This will mean an immediate price rise if the costs are relatively large in proportion to the price of the product and this is most likely for products manufactured in small numbers. This is not unlikely as RoHS should affect all manufacturers in EU equally and so there will be no competitive pressures to prevent price increases where significant costs are incurred. The market for some Category 8 and 9 products would not support very large price increases and so these products would have to be withdrawn from sale.

Small price increases to products in Categories 1 to 7 and 10 would not pose a risk to consumer safety, health or the environment as these are not safety critical products. A significant price increase in Category 8 products in particular, but also possibly Category 9, could potentially have an indirect impact on healthcare provision, the environment and on safety.

Manufacturers of products in Categories 1 to 7 and 10 have only recently calculated the cost impact of RoHS on their businesses – estimates vary from under 1 to up to 4 % of turnover. Calculations carried out by the UK DTI confirm that the figure for the UK overall is about 2% of manufacturers turnover[81]. ERA has consulted Category 8 and 9 manufacturers to determine the likely cost to their businesses and the cost estimates are very varied depending on the type of product. The compliance cost for low cost products made in large numbers with new models being introduced on a frequent basis will be relatively small, possibly 2% or less of turnover and this could be absorbed by manufacturers. Most Category 8 and 9 products are different to typical consumer, household, IT and telecom products:

1. They are made in relatively small numbers, some in 100s in total or fewer per year.

2. They are complex products and will frequently need to be re-designed to comply with RoHS as some components will either not be available as RoHS compliant versions or cannot withstand the higher temperature required for lead-free solders. Re-design is not straightforward especially if software has to be changed.

3. Many manufacturers produce a large number of different models to supply their customers' needs.

4. Many products require authorisations and extensive validation and testing if modifications are made. This includes all medical devices. The time required for obtaining a licence for the various medical device Directives after all tests and trials have been carried out, could take up to one year in the EU but can be longer in the rest of the world (see Section 9.2.2). The cost

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[81] Regulatory Impact Assessment for the UK RoHS regulations, UK Department of Trade and Industry

of additional testing and re-licensing varies depending on the product but can be as high as €6 million for large in-vitro diagnostics analysers.

5. Many Category 9 products are manufactured unchanged for many years and some can be produced for up to 30 years. This is because these products are specified in various test and calibration manuals which users are either unable or would have great difficulty to change.

It is reasonable to accept that the cost of compliance for Category 8 and 9 products will be at least as much as Category 1 to 7 and 10 products and in many cases could be significantly higher (~10% for IVD products and possibly more for some specialised test instruments).

Where the cost of compliance is too high to be met by the market (likely for specialist low price products made in small numbers), these would be withdrawn and no RoHS compliant substitute would be available. These could continue to be sold outside Europe and this could detrimentally affect European industry and users.

9.6.1 Healthcare

Healthcare budgets are always limited but purchase decisions for new medical equipment depend on many factors. A local healthcare authority in UK was interviewed as part of this review. Their annual budget is £1 million, however each year, hospital staff ask for typically £3 million of new equipment and so demand is always greater than available funds. Frequently, healthcare providers will choose the most up-to date equipment to benefit from diagnostic benefits but the cost of service provision is also taken into account. The latest versions of high technology and high cost equipment such as CT, PET, etc. will always be purchased wherever possible and so older models tend to be phased out in Europe after only 3 to 7 years after their introduction although they may be sold in third world countries.

The impact of too early inclusion of Category 8 in the scope of RoHS would result in four effects.

- Manufacturers would be forced to change existing models rather than continue to develop new products which would be RoHS compliant. The cost of any re-design, revalidation, re-testing and obtaining approval for the second time would need to be recouped usually from increased prices. For products made in large numbers, no price rise is likely but for specialist products, price increases could be significant. As budgets are always limited, fewer new products could be purchased.

- Some models of products, such as heart pacemakers, are produced for long periods without changes due to their known reliability. Many of these older models are sold at lower prices than new models. As health authorities in European Member States will all have limited budgets for equipment, the effect of inclusion of Category 8 in the scope of RoHS would be to cause the withdrawal of some of these older products that either cannot be made as RoHS compliant versions for technical reasons or the cost of changing is too high. Health authorities will therefore be forced to purchase newer, more expensive products. This will potentially reduce the number of these that are purchased, which in turn limits the number of patients that can be treated, and this could affect patient health. Rises in price of medical equipment would sometimes result in decisions to delay buying new equipment so that older less reliable equipment is used for longer than was originally planned. This will also affect healthcare provision, as older machines are less reliable, diagnosis is more difficult as the benefits of new technology are not realised.

- Where the cost of modifications, testing and re-authorisation are too great, the product would be withdrawn having a direct effect on individual users. An example is a blood glucose analysis system designed for patients with impaired vision. Blood glucose analysers for sighted patients are sold in large numbers so that the relatively high cost of modifying these to comply with RoHS could be born by future profits without very large price increases. The specialist product designed for visually impaired patients is produced in much smaller numbers, however, and the total cost of compliance which is likely to be similar to the standard instrument would have to be funded by very few sales. This would require too large a price increase for the market to stand and so these would no longer be produced or sold in the EU, which would have a serious impact of visually impaired diabetes patients. This example is for one product currently on the EU market and there will be others affected in the same way.

- Two of the exemption requests discussed in Sections 10.2.2 and 10.4 do have substitutes but to introduce these would require the use of much more expensive materials. There are also technical reasons for the exemption requests and these are discussed in the relevant sections of this report but should these not be allowed, the more expensive substitute could be used but would affect two types of product in particular. In one case, the manufacturer has estimated that changing from lead to tungsten in surgical microscope will result in a price increase of 30%. This unusually large increase could negatively affect healthcare. In another case, the total cost of work to replace cadmium in K-edge filters for X-ray imager calibration is so high in comparison with the very small numbers sold that these instruments would be withdrawn from sale in the EU and hospitals would be forced to use older, less accurate technology.

9.6.2 Category 9 equipment users

Users of Category 9 products will be affected in a similar way. The following illustrative examples of Category 9 products illustrate the possible impact of too early inclusion in scope:

- High accuracy furnace combustion control – manufacturers will withdraw specialist products sold in small numbers if the cost of compliance is higher than future profits. The resultant loss of availability of products will reduce opportunities to maximise furnace efficiency, minimise global warming impact and evolution of pollutants such as $NO_{x.}$

- Equipment to monitor pollutant concentrations use state of the art sensor technology. Increased costs would limit the use of these products which could potentially have a negative impact on the environment.

- Aircraft instruments are routinely calibrated and these instruments are specified by the aircraft manufacturer and designs cannot be changed. The original instruments would have been designed when the corresponding aircraft was developed and as aircraft last for well over 30 years, the same design of calibration instrument has to be made during this time. As many of these products will not be new, it is inevitable that some components will not be available as RoHS compliant versions and so it will be impossible to build RoHS compliant versions of these instruments without significant redesign. Aircraft calibration manuals, developed when the aircraft were originally developed, do not permit redesign of the equipment that is used to calibrate aircraft instruments. Therefore, when the current equipment reaches end of life, aircraft instruments could not be calibrated if RoHS compliant versions are not available and so the aircraft would have to be flown outside the EU to countries where new but non-RoHS compliant equipment is available. This would cause a loss of jobs in EU and also aircraft that are normally used only within the EU would have to be flown elsewhere for calibration. This may seem to be an extreme example but this situation could be created.

9.6.3 Comparison with users of Category 1 – 7 and 10 equipment

The impact of the effects on users discussed above will depend on the length of time that Category 8 and 9 equipment manufacturers have to comply with RoHS and the impact will inevitably decrease with time. Users of Category 1 – 7 and 10 equipment are not being affected significantly by the inclusion of these Categories in the scope of RoHS on 1st July 2006 but there are several reasons for this:

- Most are relatively simple products although there are exceptions (some machine tools, vending machines, IT and telecom equipment);

- Servers and telecommunications infrastructure equipment is within the scope of an exemption for lead in solders and so manufacturers will have more time to solve technical problems;

- Most products are sold in large numbers and so producers can afford the resources required to modify products, although there are exceptions;

- Very few are safety critical (except servers and telecommunications infrastructure equipment, which has the exemption for “lead in solders”) and so do not need extensive validation, testing or authorisation.

From discussions with individual manufacturers of equipment in these Categories, some will not be able to produce RoHS compliant products on 1st July 2006 despite having had over 3 years to make changes. This is for a variety of reasons including starting the change process too late and difficult technical problems that have not yet been solved but also a number of factors outside of the manufacturers control such as; non-availability of promised RoHS compliant substitute components, no decisions on exemption requests that they require.

10. Requests for exemptions

Current exemptions

There are currently 21 published exemptions (23 if No. 7 is taken as three) to the RoHS Directive which have been accepted because there are no suitable alternative materials or designs available. A further 8 were agreed at the July 26th TAC meeting. Many of these will also be required for Category 8 and 9 products if these are brought within the scope of the RoHS Directive and these are listed in Table 44.

Table 44. Current exemptions to the RoHS Directive

Exempt. no.	Description	Used for cat.. 8 & 9?	Example applications
1.	Mercury in compact fluorescent lamps not exceeding 5 mg per lamp.	No	
2.	Mercury in straight fluorescent lamps for general purposes not exceeding: - halophosphate 10 mg - triphosphate with normal lifetime 5 mg - triphosphate with long lifetime 8 mg	No	
3.	Mercury in straight fluorescent lamps for special purposes.	Yes	LCD backlights
4.	Mercury in other lamps not specifically mentioned in this Annex.	Yes	AAS lamps, UV lamps
5.	Lead in glass of cathode ray tubes, electronic components and fluorescent tubes.	Yes	CRTs, passive components
6.	Lead as an alloying element in steel containing up to 0,35 % lead by weight, aluminium containing up to 0,4 % lead by weight and as a copper alloy containing up to 4 % lead by weight.	Yes	Many products
7.	— lead in high melting temperature type solders (i.e. lead based alloys containing 85 % by weight or more lead) — lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission as well as network management for telecommunications — lead in electronic ceramic parts (e.g. piezoelectronic devices)	Yes No Yes	Components Ultrasound probes
8.	Cadmium and its compounds in electrical contacts and cadmium plating except for applications banned under Directive 91/338/EEC (1) amending Directive 76/769/EEC (2) relating to restrictions on the marketing and use of certain dangerous substances and preparations.	Yes	Switches, connector coatings
9.	Hexavalent chromium as an anti-corrosion of the carbon steel cooling system in absorption refrigerators.	No	
9a	Deca-BDE in polymeric applications.	Yes	Plastic parts
9b	Lead in lead-bronze bearing shells and bushes.	Yes	Motor bearings
11.	Lead used in compliant pin connector systems.	Possibly	
12.	Lead as a coating material for the thermal conduction module c-ring.	No	

Exempt. no.	Description	Used for cat.. 8 & 9?	Example applications
13.	Lead and cadmium in optical and filter glass.	Yes	Endoscopes, microscopes,
14.	Lead in solders consisting of more than two elements for the connection between the pins and the package of microprocessors with a lead content of more than 80% and less than 85% by weight.	Possibly	Computing
15.	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit Flip Chip packages.	Yes	Processor ICs
Will be 23.	Lead in finishes of fine pitch components other than connectors with a pitch of 0.65 mm or less with NiFe lead frames and lead in finishes of fine pitch components other than connectors with a pitch of 0.65 mm or less with copper lead-frames.	Yes	Fine pitch ICs

Manufacturers and Trade Associations have requested many specific exemptions required for Categories 8 and 9 only. Those that are similar have been combined and are listed here as well as several more general exemption requests which will be considered separately.

Proposed new exemptions specific to Categories 8 and 9

Table 45. Requested new exemptions specific to Categories 8 and 9

	Definition of new exemption request	X-ray equipment	Sensors, detectors, etc.	Others
	Equipment utilising or detecting ionising radiation			
1	Cadmium in output phosphors of image intensifiers	x	x	
2	Lead, cadmium and mercury in ionising radiation detectors	x	x	
3	Cadmium in X-ray measurement filters	x		
4	Flexible copper cadmium alloy wire (until 2012)	x		x
5	Hexavalent chromium in alkali dispensers for in-situ production of photocathodes	x		x
6	Hexavalent chromium passivation coatings on aluminium and on zinc	x		x
7	Lead bearings in X-ray tubes	x		
8	Lead in electromagnetic radiation amplification devices: micro-channel plate, capillary plate and fibre optic plate	x		x
9	Lead in glass frit of X-ray tubes and image intensifiers	x		
10	Lead in shielding for ionising radiation	x		x
11	Lead in X-ray test objects.	X		
12	Lead stearate X-ray diffraction crystals	x		
13	Mercury in position switches of X-ray equipment	x		
14	Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers	x		x

	Definition of new exemption request	**X-ray equipment**	**Sensors, detectors, etc.**	**Others**
	Sensors, detectors and electrodes (plus items 1 and 2)			
15	Lead and cadmium in ion selective electrodes including pH electrodes		x	
16	Lead anodes in electrochemical oxygen sensors		x	
17	Lead, cadmium and mercury in infra-red light detectors		x	
18	Mercury in reference electrodes: mercury chloride, mercury sulphate and mercury oxide		x	
	Others			
19	Cadmium in helium-cadmium lasers			x
20	Cadmium in total residual chlorine monitors			
21	Cadmium pigments in ECG patient cables			x
22	Lead and cadmium in atomic adsorption spectroscopy lamps			x
23	Lead as PVC stabiliser until 2012			x
24	Lead in alloys as a superconductor and thermal conductor in MRI Lead/cadmium alloys as superconducting materials in MRI			x
25	Lead in counterweights	x		x
26	Lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons, (see also item 9)			x
27	Lead in single crystal piezoelectric materials for ultrasonic transducers			x
28	Lead in solder for bonding Peltier coolers to silver blocks in DNA multiplication equipment			x
29	Lead in solders for bonding to ultrasonic transducers			x
30	Lead in solders that are exposed to anaesthesia gases			x
31	Mercury in switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay			x
32	Mercury source for calibration of environmental mercury monitors – consumable			x
33	Specific Opto-coupler for IVD instruments			x
34	Lead in solders for array interconnections to photodiode CT detectors (until 2012)	x		
35	Lead in solders connections to micro-BGA area arrays (until 2012)			x
More general exclusions requested				
36	IVD and AIMD equipment			x
37	Lead, cadmium and hexavalent chromium in Medical Devices within the scope of Directive 90/385/EEC and class Iib and III of Directive 93/42/EEC	x		x
38	Lead in life time buy components			x
39	General exclusion portable emergency defibrillators			x

10.1 Sensors, detectors and electrodes

Several types of device that sense or detect use one or more of the RoHS restricted substances and so these could be combined and treated as one exemption. All exemption requests have been reviewed however. Some of the exemption requests for detectors are also related to X-ray equipment for which there are 15 exemption requests in total.

10.1.1 X-ray and γ-ray detectors

Exemptions for several types of X-ray and γ-ray detector have been requested; cadmium telluride, zinc doped cadmium telluride, lead iodide, lead oxide, mercury iodide and cadmium tungstate. These function in different ways and are used for different applications. There are many other types of X-ray detector that are in current use or are being developed which do not contain the RoHS restricted substances but it is important to understand the differences in characteristics and performance of each type to understand why these exemptions have been requested and determine whether they are justified.

There are two main types of X-ray detector which can be used to convert X-rays to digital signals; scintillator materials mounted on silicon photodiode arrays and semiconductor arrays. Cadmium tungstate is one type of scintillator material which is used predominantly for security X-ray screening, such as for checking luggage at airports, and in medical CT scanners. Semiconductor X-ray sensors are being used increasingly in a variety of applications particularly in medical X-ray imaging. The detection of high energy radiation is required not only for medical and industrial X-rays imaging, but also detection of γ-rays (PET scanners, isotope analysis, etc.) and also for detection of photons of other energies.

The most important characteristics of any type of X-ray detector are efficient absorption of X-radiation and conversion into a suitable signal. Physics dictates that X- and γ-radiation are most efficiently absorbed by elements which have high atomic number. The probability of interaction between a photon (X- or γ –ray) with an atom increases by the atomic number to the power of 4 and so this has a very significant influence on absorption efficiency. Low absorption efficiency can be compensated by the use of thicker layers of material but as the thickness increases, scattering of X- and γ-rays increases results in less spatial resolution and so a less clear image. Scattered radiation can also be lost so that the overall sensitivity is reduced. Therefore high atomic number elements like caesium (Cs), iodine (I), tellurium (Te), tungsten (W), lead (Pb) and mercury (Hg) are ideal for detectors although other factors such as density are also important.

Table 46. Relative absorption efficiency of elements commonly used in X-ray detectors

Element	Atomic number	Relative absorption efficiency based on atomic number
Silicon	14	1
Germanium	32	27
Selenium	34	35
Cadmium	48	138
Tellurium	52	190
Iodine	53	205
Caesium	55	238
Tungsten	74	781
Mercury	80	1066
Lead	82	1177

In Table 46, tungsten is inferior to lead but if the higher density is taken into account, tungsten absorption efficiency is similar to lead.

The optimum type of detector and its performance depends on the energy of the radiation and so different types of detectors are required for high and low energies. Low energy X-rays can be used for viewing low density materials whereas higher energies are needed for examination of high density materials. High energy radiation will pass through some types of detector such as silicon without interaction whereas low energy radiation is all absorbed with high detection efficiency by the same detector. Energy absorption efficiency is not the only important characteristic as the absorbed energy must then be emitted as light (from a scintillator) or electrons (from a semiconductor). The conversion efficiency for this process also varies with the type of detector. There are other significant differences between scintillator type detectors and semiconductor detectors. These are too complex to go into detail here but the main differences are:

- Scintillator detectors give a linear response to the radiation wavelength whereas semiconductors have a non-linear response with absorption maxima at characteristic wavelengths. This difference gives both advantages and disadvantages depending on the application.

- Semiconductor detectors are relatively new and are more difficult to fabricate than the well-established scintillator types. Cadmium telluride production is now routine and reliable but production difficulties for other semiconductor types currently limit their use.

- The efficiency of conversion of X-ray energy into an electrical signal can be as much as ten times greater with semiconductor detectors.

High detection and conversion efficiency are very significant advantages for diagnosis of illness as it allows a reduction in X-ray dose so reducing the risk to patients and workers. Also, the high detection efficiency results in thinner detectors which exhibit much less scattering and so give much clearer images which aid early diagnosis. These significant benefits are already leading to a gradual change from scintillator type detectors to semiconductor detectors which will continue in the future. Cadmium zinc telluride is now quite widely used and there is one product made in Japan which uses a mercury iodide detector. Lead iodide detectors are used for mammography because high spatial resolution is essential for early detection of very small tumours.

Scintillator type detectors

Scintillators emit visible light when exposed to X-rays. The emitted light is converted into an electrical signal by photomultiplier tubes or by silicon photodiodes. Scintillator films are deposited onto silicon photodiodes assembled as large arrays and are used to obtain two dimensional, real-time digital images. The visible light detection efficiency of silicon photodiodes is 70% at 450 nm increasing to over 80% at 1000 nm. At wavelengths < 450 and > 1500 nm, light conversion is less efficient and so scintillators that emit light in the optimum wavelength range are preferred. There are many different scintillator materials each having different properties and so all types will not be suitable for all applications.

Some of the main types of scintillator type materials used for X-ray and γ-ray detectors are:

Cadmium tungstate: Shortest afterglow (fastest decay in response after an X-ray is detected) of any scintillator and not damaged by high energy radiation unlike other scintillators. High atomic number so good X-ray absorption efficiency but the X-ray to light conversion efficiency is only half that of CsI. Used in CT scanners because of short afterglow and also for its high spatial resolution which can be better than the newer ceramic scintillators.

Caesium iodide (CsI), sodium doped: High sensitivity and has columnar structure. Relatively long afterglow, decay time too long for some techniques such as CT (this is reduced by thallium addition but this also reduces conversion efficiency and is a toxic material).

Thallium doped sodium iodide: Very sensitive, but hygroscopic and thallium is very toxic.

Novel ceramic scintillators: New ceramic scintillators are being developed which have superior performance to cadmium tungstate.

Ceramic scintillators are increasingly used to replace cadmium tungstate in new models by some medical equipment manufacturers but their use is restricted by patent limitations. The new ceramic scintillators cannot be used in current models of CT scanners as these require very significant design changes and the current models that use cadmium tungstate will be put onto the EU market until at least 2015. Table 47 summarises the main differences between the more common types of scintillator detector materials.

Table 47. Properties of selected scintillator materials, data from various sources

Material	Light output* photons/ MeV	Light output wavelength **	Afterglow % signal/time	Resistance to radiation	Examples of uses	Comments
CdWO4	15,000	540 nm	0.1%/3ms 0.002/30ms	High	CT and high energy applications	Fast processing, low afterglow at low energy and high energy stability
NaI(Tl)	38,000	415 nm	0.3 – 5% /6ms	Medium	Gamma cameras, PET	Light output wavelength too low and long decay time
CsI(Tl)	59,000	550 nm	0.5 – 5% /6ms	Medium	Most widely used	High efficiency and light output matches Si photodiode
BGO	9,000	480 nm	0.005%/3ms	High	High energy detection, PET	Fast scintillator but low conversion efficiency. Can be used to measure radiation energy
GOS	~30,000	430 nm – 512 nm***	<0.1%/3ms, 0.01%/30 ms	Good, improved by dopants	CT	Not single crystal so thick layers not possible
GSO	30,000 – >60,000	350 – 490 nm*			CT, imaging, PET, luggage scanners	Good energy resolution, fast response
LSO	30,000	420 nm	<0.1%/6ms	High	CT, PET	Fast response

* This is dependent on dopant levels and energy of incident radiation, temperature, etc. Published figures vary as these are based on different test conditions

** Optimum values to match silicon photodiode are >500 nm.

*** Peak wavelength and other properties depend on dopant elements used

LSO = Lutetium orthosilicate, GSO = Gadolinium orthosilicate, GOS = Gadolinium oxysulphide, BGO = Bismuth Germanate

The most commonly used scintillators are sodium iodide and caesium iodide (thallium doped) as these are very sensitive to X-radiation and have high light output. They do however have disadvantages; thallium is very toxic and they have long afterglow and so cannot be used where the time between sequential images is very short such as in computed tomography (CT). CT uses an X-ray tube and detector located on opposite sides of a large ring and these rotate around either the patient or luggage three times per second taking up to 1000 images / second in order to build up a computed three-dimensional image. Cadmium tungstate has a very short afterglow time (the time light emission continues after impact of X-ray) and so is used in CT scanners for medical and security imaging. The patient or luggage is located at the centre of the ring. The time to acquire each image must be very short otherwise this would mean that fewer patients (or luggage items) could be examined with one machine. For medical applications, the CT image must be built up quickly to avoid any movement by the patient that would otherwise occur and blur the image.

Another use for cadmium tungstate is for high energy radiation detectors where it is used because it is resistant to damage by high energy radiation whereas caesium iodide and sodium iodide are damaged and so degrade.

Alternative scintillator materials are now being used by some manufacturers as X-ray detectors in CT scanners including Hitachi who also manufacture ceramic scintillators. It therefore appears that suitable cadmium-free substitutes do now exist for this application. HighLight composite ceramic scintillator material is used by GE in some of their CT machines[82]. Research is also being carried out into the possible future use of semiconductor detectors such as cadmium zinc telluride. Semiconductors radiation detectors are increasingly used as they offer the advantage that X-rays and γ-ray are converted directly into electrical signals and can be up to 10 times more sensitive. These may eventually replace scintillator types of detectors for CT scanners.

At the moment, however, there does appear to be a need to allow the continued use of cadmium tungstate scintillator detectors although this requirement should not need to be permanent. Cadmium tungstate does offer distinct technical advantages over all other types as it has better spatial resolution, superior to that of ceramic types and so it will continue to have limited use in research CT scanners. The only suitable substitutes for cadmium tungstate are the new ceramic scintillators but these are all patented and not available to all users. One UK manufacturer has stated that they are unable to obtain these substitutes due to the patent situation and restricted supply and so the only material currently available with suitable performance is cadmium tungstate.

Semiconductor X-radiation detectors and their characteristics

A variety of semiconductor detectors are used and being developed for X- and γ-radiation. The most widely used currently are based on silicon and selenium. These are suitable for lower energy applications and are currently more widely used because large area arrays with good spatial resolution (very small pixel size) can easily be manufactured. Newer types of semiconductor are more difficult to make but cadmium telluride detectors can now be manufactured with good sensitivity and resolution and this is likely to be the fastest growing X- and γ-radiation detector material in the near future. Research into several novel heavy metal detectors based on lead and mercury is underway but only a few commercial products currently use these. The one exception is lead oxide which has been used for many years as an X-ray detector in the Plumbicon tube. The main types of semiconductor X-ray detector materials are listed in Table 48.

Good clear images cannot be obtained if there is significant noise and this increases with temperature. The signal to noise ratio required governs whether cooling of semiconductor X-ray detectors is required. This ratio depends on the band gap of the semiconductor and materials like cadmium telluride have larger band-gaps and exhibit less noise than silicon and germanium. Semiconductors with smaller band gaps are noisier at ambient temperature and so cooling is essential. Cooling with liquid nitrogen requires significant additional equipment and is energy intensive. Peltier cooling can

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[82] "Testing for life's sake", L. D. Maloney, Test and Measurement World, August 2005, p. 22

be used for silicon and selenium but some additional equipment and energy input are required. Cadmium telluride has a high signal to noise ratio and so can be used at room temperature.

Table 48. Semiconductor X-ray detectors, their atomic numbers and characteristics

Detector material	Atomic number	Comments
Lead iodide	82, 53	High atomic number so efficient X-ray adsorption therefore can be thin which results in better resolution and reduces radiation exposure. New detector material used for mammography.
Mercury iodide	80, 53	High atomic number so efficient X-ray adsorption, therefore can be thin which results in better resolution and reduces radiation exposure. Resistant to radiation energies >10 MeV. New potentially useful detector material but further research needed before it can be widely used in commercial products.
Cadmium telluride and zinc doped cadmium telluride	48, 52	High atomic number so efficient X-ray adsorption therefore can be thin which results in better spatial resolution. High radiation adsorption efficiency reduces radiation exposure either because lower X-ray doses are required for imaging or less radioactive tracers need be administers for PET. Does not require cooling.
Lead oxide	82	Used in Plumbicon digital video cameras. Similar Saticon cameras use selenium instead of lead.
Silicon	14	Needs cooling to eliminate noise, sensitive to low energy X-rays.
Selenium	34	Needs cooling but more sensitive than silicon.
Germanium	32	Needs cryogenic cooling with liquid nitrogen.

X-ray imaging with higher energy X-rays and γ-radiation detection for PET and nuclear isotope detection rely on materials with high atomic number for a high detection efficiency. At 10keV, a 1 mm thickness of either silicon and cadmium telluride absorbs almost 100% of the X-ray energy but at 100 keV, 1mm of cadmium telluride absorbs ~ 50% of the radiation while 1mm silicon absorbs only 1% of the X-ray energy. The relative adsorption efficiency of commonly used X-ray detectors[83] at intermediate energy levels is shown in Table 49.

Table 49. X-radiation absorption efficiency at 50 keV in detectors

Material	X-ray Absorption %
Cadmium telluride	~100 %
Caesium iodide scintillator	65 %
Germanium	~60 %
Silicon	~10 %

At higher X-ray energies, the absorption efficiencies of silicon, germanium and scintillator detectors are relatively poor in comparison with cadmium telluride. Lead and mercury iodide will be superior for high-energy radiation detection in terms of X-ray absorption efficiency because they have a higher atomic number than cadmium telluride.

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[83] Information from Eurorad http://www.eurorad.com/normal/index1.html

It is estimated that cadmium zinc telluride is up to ten times more sensitive than either silicon or the best scintillator type of X-ray detector and this has several advantages for both patient health and the safety of hospital staff:-

X-ray imaging: Much lower X-ray doses can be used because of the higher detector sensitivity. This reduces the risk to both patients and healthcare workers form damaging radiation. Also, detector thickness can be significantly reduced due to the high-energy adsorption efficiency and this reduces scattering of X-rays and so improves spatial sensitivity giving clearer images which improves diagnosis. Obtaining clearer images enable doctors to see smaller defects such as tumours and artery blockages and so start treatment earlier than would otherwise be possible. Earlier treatment is usually more successful, less invasive with quicker recovery and overall treatment costs are reduced.

Molecular imaging (nuclear medicine): One approach to diagnosis of illness is to inject radioactive tracers into patients and to use either PET or gamma cameras to determine where these are concentrated in the body. The radioactive isotopes themselves are hazardous materials and ideally, as little as possible should be used. Significant reductions in risk can be obtained by using more sensitive detectors with reduced doses of radioactive tracers.

Radioactivity detectors: The detection of harmful ionising radiation is important to prevent scrap metal from being contaminated with radioactive materials, to prevent terrorism, and in research into a wide variety of technologies. All of these are more likely to be more successful with the highest sensitivity detectors.

10.1.2 Infra-red detectors

Exemptions for four types of infrared detector have been requested; mercury cadmium telluride (MCT), lead sulphide (PbS), lead sulphide/oxide and lead selenide (PbSe). There are many other types of sensor used for measurement of infra-red radiation but all have specific combinations of characteristics. In this report, infrared radiation wavelengths in µm or nm are quoted. Some publications use wavenumber values which should not be confused with wavelength.

Infrared radiation (> ~0.8µm) detectors are used in infrared imaging cameras (for thermal imaging, detection of pollution, medical thermography, intruder detection, etc), fire monitors and detectors, moisture detectors, gas analysers, infrared spectrometers for chemical analysis of organic materials and for other applications. The choice of detector depends on the sensitivity, speed, the wavelength required to be measured and in some cases portability. Table 50 and Table 51 list examples of the different types of detectors (including some that are suitable only for visible and UV light) and their characteristics:

Table 50. Optical and infrared radiation detectors

Detector type	Materials used	Wavelength range μm	Performance	Comments
Semiconductor	Mercury cadmium telluride (MCT)	4 – 20	More sensitive than thermal detectors, very rapid response time	Usually requires cooling. Only commercial semiconductor detector for “long infrared” (8 – 20 μm)
	Indium antimonide	1.5 – 6	More sensitive than thermal detectors, rapid response time	Requires cooling
	Lead sulphide and selenide	0.9 – 5.5	More sensitive than thermal detectors, rapid response time	Can be used without cooling
	Lead oxide/sulphide	0.4 – 2.0	High resolution and spectral response. Used because of its electrical conductivity	Room temperature operation
	Germanium	0.8 – 1.8	More sensitive than thermal detectors, rapid response time	Requires cooling
	Indium / Aluminium gallium arsenide and variations	0.8 – 1.6	More sensitive than thermal detectors, rapid response time, InGaAs used in infra-red cameras	Usually requires cryo-cooling
		Plus novel detectors for 3 – 5 and 8 – 12		Novel detectors for 8 – 12 μm research only, not commercially available yet
	Platinum/Silicon	~ 3 to ~ 5	Lower quantum efficiency	Requires cryo-cooling, used in infra-red cameras
	Mercury manganese telluride	Similar to MCT	Lower sensitivity than MCT	Contains mercury
	Lead tin telluride	Similar to MCT	Lower sensitivity than MCT	Contains lead
Photodiode	Silicon (and enhanced silicon for UV)	0.2 – 1.0		Not for infrared
Photomultiplier tubes	Glass, some types use hexavalent chromium	0.2 – 0.85	10 x more sensitive than semiconductor detectors	Very sensitive in UV and visible ranges (not infrared) but are relatively bulky. Rapid response time
Thermocouples and thermopiles	Bi/Sb	All infra-red	Less sensitive and slower response than semiconductors	Used with diffraction grating to scan wavelength range
Pyroelectric detectors	Lithium tantalite, lead zirconium titanate*	0.85 - >20	Respond to change in temperature	Pulsed radiation required, respond faster than thermocouples but less sensitive than semiconductors
Thermistors	Vanadium oxide, silicon	All infrared	Respond to change in temperature	Used for night vision equipment, less sensitive than semiconductors
Thermal	DTGS	All infrared	Used in lower price infrared spectrometers	Sensitivity lower and response time slower than other types

Note: Infrared light covers the wavelength range 0.8 to >20 μm.

* Lead in electronic ceramic components are currently exempt from RoHS.

Table 51. Characteristics of infrared detector materials and some visible light detectors for comparison

Infra-red detector type	Approximate Wavelength range (µm)	Response time	Relative Sensitivity[84] (peak values)
Mercury cadmium telluride	4 – 20 or ~ 4 – 10 for high sensitivity type	Fast, 50 ns – 5 µs	5 x 10^9 (10^{11} for high sensitivity type)
Lead sulphide	0.9 – 4 (at 77K)	150 µs (at 0C)	10^{11}
Lead selenide	0.9 – 5.5 (at 77K)	5 µs (at 0C)	5 x 10^9
Indium Antimony	1.5 – 6 (at 77K)		2 x 10^{10}
Indium gallium arsenide	0.7 – 1.7 or 1.2 to 2.55		~10^{11}
Thermal detectors (DTGS)	All infrared range	150 µs to 10 ms	5 x 10^8
Thermistors	All infrared range	1 – 20 ms	< 10^8
Germanium photodiode	0.8 – 1.8	-	~ 10^{13}
Photomultiplier tube (for comparison)	Not suitable for infrared	1 – 10 ns	~ 10^{13}

Note: 273.16K = 0C.

DTGS = Deuterated triglycine sulphate.

Mercury cadmium telluride

Mercury cadmium telluride (MCT) was first developed in the 1970's as an infra-red detector and no substitute has yet been found that has equal sensitivity and speed over the same wavelength range. MCT is produced as single crystal wafers and as a thin layer deposited onto cadmium telluride wafers. It is reported that most of the MCT produced is for the military market (e.g. night vision) with only 1% being used in non-military applications. MCT is used for organic substance analysis, thermal imaging and in gas analysers such as those used to check vehicle exhaust emissions. Detectors are very small containing from 10 to 500 mg of MCT.

One of the main non-military applications is in infrared spectrometers as the detector for longer wavelengths. Organic materials are analysed by this technique for pharmaceuticals research, forensic science and for quality control of production processes to check purity. Infrared spectroscopy is carried out by passing infrared radiation through the sample or by reflection and, in either case; the organic material absorbs infrared light of certain wavelengths to produce an infrared spectrum. The wavelength and strength of absorption maxima are characteristic of the structure of the organic molecule and so this technique can be used to identify specific chemicals. Often, only minute quantities of material are available for analysis and so very high sensitivity detectors are essential. The useful wavelength range used for analysis of organic substances by infrared spectroscopy is usually from 2.5 to 16 or sometimes 20 µm. The region from 8 to 15 µm is known as the "fingerprint" region which is particularly useful for substance identification where the spectrum of the material to be identified is compared with libraries of infrared spectra. MCT is the only semiconductor detector that is sensitive to wavelengths between 6 (the upper limit for InSb) and

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[84] J. Chalmers and G. Dent ,"Industrial Analysis with Vibrational Spectroscopy", Royal Society of Chemistry, 1997.

20µm. Semiconductor detectors are very sensitive and also very fast which is particularly essential for Fourier transform infra-red (FTIR) spectrometers which are the most accurate and sensitive type of spectrometer on the market.

Fourier transform (FT) infra-red spectrometers give the best and most accurate results with complex substances and where very small quantities are available. FT infrared spectrometers are used because they have higher signal to noise and provide more accurate wavelength measurement. The light sources available in parts of the infrared region are relatively weak and the most sensitive detectors; photomultipliers, do not operate in this region. However analysis of minute traces of substances is possible by adding the data from many very rapid scans; genuine absorption peaks are added whereas random noise cancels itself out. This is possible only with fast and very sensitive detectors and MCT is the only type available in the wavelength range required for infra-red analysis of organic substances. One typical application is analysis of minute traces of contamination on silicon wafers. These are present in such small quantities that they cannot be detected by a single scan even with the most sensitive MCT detectors but can be analysed by adding multiple scans using MCT detectors. There are several slower and less sensitive detectors available such as DTGS which cover the entire infra-red range and these are used in lower priced scanning infrared spectrometers but this cannot replace MCT in the high specification instruments. MCT is the most expensive choice of detector for FT infra-red spectrometers because they have to be cooled with liquid nitrogen for maximum sensitivity but it is used because it is the only practical choice for the top-of-the-range instruments whereas DTGS is widely used in lower specification instruments.

MCT is also used as the uncooled detector in infrared imaging cameras where its very high sensitivity is utilised. It is used for automotive exhaust gas analysis without cooling because it is a fast detector, has high sensitivity and can analyse all of the gases present simultaneously.

Lead sulphide, lead sulphide/oxide and lead selenide detectors

These three types of infrared detector are used for limited, specific applications. The main use of lead sulphide is in moisture analysers (~3µm) and that for lead selenide is in fire detectors[85] and both are also used for optical pyrometers and gas analysis.

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[85] Technical information SD-12. Characteristics and use of infra-red detection, Hamamatsu.

Table 52. Comparison of characteristics of semiconductor detectors for infrared radiation in the range 1 – 6 µm

Semiconductor Detector	Type	Wavelength range (µm) *	Normal use temperature **	Peak sensitivity at typical operating temperatures **
Lead sulphide	Photoconductor	1 – 3.5 (maximum sensitivity at ~ 3µm)	Ambient up to 100°C	100 x 10^9 (at 25C)
Lead sulphide/oxide	Photoconductor	0.4 – 2.0	Ambient	-
Lead selenide	Photoconductor	2 – 6	Ambient up to 50°C	1 x 10^9 (at 25C)
Indium antimonide	Photoconductor or photodiode	1 – 5.5	-196°C or -60°C (depends on type)	100 x 10^9 (at -196C)
Indium gallium arsenide	Photodiode	0.7 – 1.7 or 0.8 – 2.6	-120°C or 25°C	70 x 10^9 (at 25C)
Indium arsenide	Photodiode	1 – 3.8	-196°C	700 x 10^9 (at -196C)

Figures from various detector manufacturers datasheets. Actual values depend on temperature and exact composition.
** From Hamamatsu datasheet, reference 85.

Lead sulphide is sensitive to infrared radiation in the range 1 to 3.5 µm. Indium arsenide and indium antimonide can be used in the same range but both need to be cooled to eliminate noise and obtain good sensitivity. There are two types of indium gallium arsenide detector and these are the photodiode type which can be used at room temperature. It would therefore appear that indium gallium arsenide is a suitable substitute for lead sulphide but this is not always possible. The first point is that arsenic is considerably more toxic than lead and is also a carcinogen.

An example application will be used to explain why lead sulphide cannot be replaced by indium gallium arsenide. Water vapour absorbs infrared radiation at several specific wavelengths and the important ones for water vapour analysis are:

- 1.45 µm – this is a weak absorption and is suitable for the highest water saturation levels
- 1.95 µm – this is a stronger absorption and is suitable for the standard water saturation levels
- ~2.95 µm – this is a very strong absorption and is used to measure the lowest water vapour concentrations.

Lead sulphide is sensitive to all three of these wavelengths whereas indium gallium arsenide is sensitive only to 1.45 and 1.95 µm as its sensitivity above 2.6µm drops steeply to zero (these have zero sensitivity at 2.8 µm and above) and so it cannot be used as a detector in moisture analysers that operate in all three concentration ranges.

Apart from the FT infrared spectrometers described above and similar less sensitive scanning infrared spectrometers, there are applications for spectrometers that are able to analyse in the ultraviolet, visible and near infrared wavelengths, all by one instrument. Some analysis laboratories need to be able to measure samples in all three wavelength ranges at high sensitivity and this is possible by incorporating three types of detector in each spectrometer. Applications include materials evaluation for flat panel displays, analysis of semiconductor wafers, analysis of anti-reflective films and measurement of the properties of optical systems. Each instrument needs to have three types of detector to cover the required wavelength range:

• Photomultiplier	~0.2 – 0.85 µm	(UV and visible region)
• Indium gallium arsenide	0.7 – 1.7 µm	(used to bridge gap between photomultiplier and lead sulphide)
• Lead sulphide	1.0 – 3.5 µm	(near infrared region)

Lead selenide has a broader wavelength range than lead sulphide from 2 to 6 µm and the only apparent substitute is indium antimonide which has a range of 1 to 5.5 µm. Indium antimonide however is always used at below 0°C and is normally cryogenically cooled (this requires liquid nitrogen with complex equipment). Lead selenide detectors can be used for analysis of hydrocarbons for vehicle emission testing and the detection of fuel leaks because hydrocarbons have a strong absorption peak at 3.4µm. Lead selenide is the only high sensitivity detector that can operate at room temperature at this wavelength.

The applications where **lead sulphide** and **lead selenide** are most difficult to replace are in battery powered instruments such as fire detection and portable analysers. This is because these two sensors can be used at room temperature (and above) whereas all of the apparent substitutes require cooling (otherwise they suffer from excessive noise). Cryogenic cooling is impractical in small portable or battery powered instruments and Peltier cooling, suitable for temperatures down to about -50°C consumes too much power to be practical with battery power. The other advantage of lead sulphide and lead selenide is that they are photoconductors. These are simpler to use than photodiodes requiring simpler control circuits which have fewer electronic components.

Lead sulphide/oxide detectors are used in portable battery powered infrared imaging cameras. These have very high sensitivity and so can be used to detect defects in semiconductor crystals, measure very high temperatures and they are used for revealing “hidden images” on ancient documents and pictures that may be obscured by layers of dirt. The use of sulphide with oxide gives electrical conductivity and this allows the detector array to be scanned to produce high-resolution infrared images. No other infrared detector has a sufficiently high electrical conductivity for this application. This detector operates at ambient so no cooling is required (therefore suitable for battery power) and they detect both visible and infrared light (0.4 – 2.0 µm), ideal for high resolution cameras; there are no other detectors that operates in this range.

In conclusion, there are no suitable substitutes for the four types of semiconductor infrared detectors reviewed in section 10.1.2 for those applications where they are currently used.

10.1.3 Oxygen Sensors

Lead is used as an electrode in electrochemical oxygen sensors and these are manufactured in very large numbers. These sensors are used in a wide variety of applications and are particularly useful in portable equipment and where space is very limited. They have the advantage that no power supply is required. They are used for example by the fire services to monitor oxygen concentrations in which their personnel operate such as in burning buildings where it is essential that immediate warnings of low oxygen concentrations are identified. They are also used with Self Contained Underwater Breathing Apparatus (SCUBA) equipment to monitor oxygen levels, in incubators for premature babies, in process plant to prevent explosions from flammable gas/oxygen mixtures and in testing of automotive emissions.

Electrochemical oxygen sensors are essentially small fuel cells which use oxygen as fuel to generate current and the size of the current is proportional to the oxygen concentration. These fuel cells have a very small orifice to control the flow of gas into the cell. Within the cell, an electrochemical reaction occurs.

At the cathode, which is typically gold or platinum:

$$\mathbf{0_2 + 2H_2O + 4e^- \rightarrow 4\,OH^-}$$

At the lead anode:

$$\mathbf{2Pb + 4\,OH^- \rightarrow 2PbO + 2H_2O + 4e^-}$$

The overall the reaction is**:**

$$\mathbf{0_2 + 2Pb \rightarrow 2PbO}$$

The lead anode is consumed in a way that is similar to a battery and so these devices could be and some are used as batteries.

Lead was chosen as the best anode material for these sensors many years ago. Lead has one main advantage that it does not corrode in the cell spontaneously and so does not produce a current in the absence of oxygen. Lead is used with to the platinum cathode so that the cathode has the correct electrode potential for oxygen reduction. Sensors based on lead have a reasonably long life and can be used typically for 1 to 2 years. Another advantage of this type of sensor is that they do not consume power and so the batteries used in portable oxygen meters have long lives. The sensors are robust and can withstand vibration and shock without damage. They are not suitable, however, for use with hot gases

To determine if this exemption request is justified, two issues that have been investigated which are a) substitutes for lead and, b) alternative types of oxygen sensor.

Substitute materials

Many other metals could in principle be used but all suffer from disadvantages that prevent this. The most obvious candidate is zinc.

Zinc: Zinc has a suitable electrode potential and electrochemical oxygen sensors with a zinc anode would work. However, zinc is a much more reactive metal than lead and corrodes spontaneously. This greatly shortens the life of the sensor and gives a continuous but variable background current so that low oxygen concentrations are impossible to measure. Zinc anodes are used in alkali batteries which in many respects are similar to oxygen sensors except that the "fuel" is provided by the cathode. A lot of research has been carried out with alkali batteries to prevent zinc corrosion and various methods are utilised but only one is totally effective. Zinc anodes in cylindrical cells contain indium, lead and other materials to inhibit corrosion but these are not totally effective and so these types of batteries have to be vented to allow the hydrogen by-product to escape. Alkaline button cells with zinc anodes are sealed as corrosion is minimal but this is achieved by the addition of about 1% mercury to the zinc and mercury is more toxic than lead. One battery manufacturer, Varta, sell an "oxygen sensor" which uses a zinc/mercury anode. However, Varta intend this product primarily as a power source and it is not suitable for oxygen concentration measurements and its working life is months rather than years.

Tin: Tin is similar to lead electrochemically but when it oxidises, it forms an inert protective oxide coating that prevents further reaction. This is called "passivation" and will occur with many other metals such as nickel and copper.

Indium: Indium may be suitable although passivation may occur. However, this metal is produced in very limited quantities, only about 200 tonnes per annum, and there would be insufficient available to replace the estimated 10 tonnes of lead used annually in electrochemical oxygen sensors.

Aluminium: Aluminium has not been considered because it also readily passivates. If this could be prevented, aluminium would be unsuitable as it would react violently with the electrolyte.

Cadmium: This has been used and would be technically suitable in electrochemical oxygen sensors, however cadmium is more toxic than lead.

Nickel, copper, iron: These are unsuitable because when connected to platinum or gold they give a cathode electrode potential that is not suitable for oxygen reduction and so the cell would not operate. The cathode's electrode potential can be changed by imposing a voltage from an external power supply and then a wide range of anode metals could potentially be used but addition of the power supply adds weight, materials and uses additional energy and these would make the sensor unsuitable for many of its current applications.

Gold, platinum, silver: These do not oxidise and electrode potentials are too close to that of the cathode.

Alternative types of sensors

There are several alternative types of oxygen sensor commercially available and all have their advantages and disadvantages. Some could replace electrochemical sensors in certain applications but there are some where there is no substitute. The main alternatives are as follows:

Paramagnetic sensors: These have been used for many decades and are widely used. They rely on the relatively high magnetic susceptibility of oxygen which has paramagnetic behaviour. Sensors consist of a suspended glass dumbbell which rotates in a magnetic field according to the oxygen concentration of the surrounding gas. There are no consumables and these can measure oxygen in the range from 1 to 100%. Their main disadvantages are their larger size and much higher cost, 10 to 20 times that of electrochemical sensors. As they use a suspended dumbbell they are inevitably more susceptible to orientation, vibration and shock although one manufacturer has recently launched a portable paramagnetic oxygen sensor. They can also give large errors if other paramagnetic gases are present and cannot be used close to MRI equipment due to the powerful magnetic field.

Potentiometric sensors: Most metals cannot be used in place of lead in the electrochemical sensor because they give the cathode an electrode potential that is unsuitable for oxygen reduction. However, by controlling the cathode's electrode potential with an external power source, any metal could be used as the anode. In commercial potentiometric sensors, silver is used as the anode and gold as the cathode. These sensors are suitable for measurement of oxygen in gases and dissolved in liquids and orientation is not important. However, they suffer from a relatively short life because in use the composition of the electrolyte changes although their lifetime can be similar to electrochemical sensors. They rely on an aqueous electrolyte which can dry out. Their main drawback is that they are more complex in design, require control electronics and require a constant power supply to operate. Currently these cannot replace lead anode type electrochemical sensors for all applications but research is being carried on various types of potentiometric oxygen sensors so this might be possible in the future.

Zirconia sensors: Zirconia sensors are designed for measurement of oxygen in gases and operates at 700°C. Their main uses are in flue gas monitoring and engine management because they can operate at higher temperatures than other types of oxygen sensor. They therefore consume power to maintain their operating temperature and their accuracy can be poor as their response is affected by a variety of other gases.

10.1.4 Reference electrodes

Reference electrodes are used for chemical analysis of solutions, for corrosion measurements and *in-vitro* analysis for medical applications. These include electrodes based on mercury such as the calomel electrode and which were at one time widely used in laboratory equipment such as in pH electrodes. For pH measurement and as reference electrodes these have mostly been replaced by electrodes based on silver/silver chloride although calomel electrodes are still commercially available. Silver/silver chloride replaces calomel as it is mercury-free but also as it is more stable and reliable.

However, it can be detrimentally affected by sulphides and can be unsuitable as a reference electrode for chemical analysis of chloride or silver concentrations.

The problem with sulphide can be overcome by the use of a suitable barrier and commercial silver/silver chloride electrodes for use in sulphide environments are available.

Calomel reference electrodes

Calomel reference electrodes contain mercury and mercurous chloride in equilibrium in a solution containing chloride ions. Silver/silver chloride electrodes are very similar with silver and silver chloride in a chloride solution. Several special electrodes have been developed to overcome the problems with standard calomel and silver chloride reference electrodes for certain specific applications where calomel and silver chloride electrodes are unsuitable.

An exemption request has been received for Calomel electrodes but silver/silver chloride is being used by many manufacturers as a substitute. The main practical difficulty is that the electrode potentials for these two electrodes are different. This is not a problem with new equipment as this can be adapted to account mathematically (e.g. via software) for the difference. Sales of Calomel electrodes to users of existing equipment would also not be a problem as these are being supplied as spare parts to replace broken electrodes for repair of Category 8 and 9 equipment put onto the EU market for the first time before the date that these Categories are included in the scope of RoHS; in this respect they are consumables (or spare parts), and so will be outside the scope of RoHS. Therefore an exemption for Calomel electrodes does not appear to be justified.

Low level mercurous chloride electrode

These are used to monitor chloride concentrations in water directly. The electrode potential of this electrode varies with chloride concentration and the voltage reading is directly proportional to the chloride concentration. Calomel electrodes and silver chloride electrodes cannot be used for this application as the mercurous chloride junction and the silver chloride junction are designed to have a constant potential and are stabilised by storage in sealed reservoirs with a solution containing a high concentration of potassium chloride. Small changes to the potassium chloride concentration have a minimal effect on reference potential so that the chloride concentration in the test solution has no effect on potential. Calomel and silver chloride electrodes cannot be used to measure chloride concentrations directly as they are designed to have fixed potentials against which other electrodes such as pH and ion selective electrodes or a corroding metal can be compared. Most low level chloride electrodes are used as components of large-scale stationary industrial tools such as power plant and manufacturing plant. However a small number will be used as portable analysers and each will contain about 1 g of mercury and very small numbers will be Category 9 products. There is no alternative technique for directly and continuously monitoring chloride concentrations.

Mercurous sulphate electrode

These can be used to measure sulphate concentrations directly as their potential is proportional to the surrounding sulphate concentration. They can also be used as reference electrodes in systems where chloride diffusing out from the electrode cannot be tolerated. There is no equivalent stable silver sulphate electrode and silver/silver chloride electrodes release chloride ions.

Mercuric oxide electrode

These are the only reference electrodes that are stable in strongly alkaline solution and give stable reference potentials for corrosion measurements etc. There is no equivalent silver oxide electrode. Very few are sold in the EU as these are a very specialist product but there is no alternative reference electrode that is stable in high pH solutions.

10.1.5 Lead in glass of pH electrodes

Electrodes to measure pH were developed in the 1930s using a special glass membrane. pH measurement electrodes are ion specific for hydrogen and so this exemption could be combined with the exemption request described in Section 10.1.6. pH is determined by measurement of the electrode potential across the membrane in which sodium ions exchange with hydrogen ions so that the potential reading obtained is proportional to the hydrogen ion concentration (pH is minus the log of hydrogen ion concentration). The glass membrane is a semi-porous sodium based glass but standard soda glass (which is lead-free) is unsuitable because its electrical resistance is too low. High electrical resistance sodium based glass was developed for this application and contains about 20% lead. Lead effectively increases the resistivity of glass which is one reason why it was also been used in X-ray tubes for many years. There are other types of lead-free glass which have either high resistivity (e.g. borosilicate glass) or contain sodium (soda glass) but there is no alternative lead-free glass that both contains sodium and has high electrical resistivity. These and other important characteristics are summarised in Table 53.

Table 53. Typical properties of various types of glass

Properties	Lead based soda glass	Borosilicate glass	Soda glass
Softening temperature (ideally low)	Low	High	Low
Electrical resistivity (must be high)	High	High	Low
TCE (needs to match body glass)	High	Low	High

Although there is no material substitute for the special lead glass used in pH electrodes, there is a relatively new electrode design that does not use glass membranes and so is lead-free. These are "Ion Sensitive Field Effect Transistor" (ISFET) pH electrodes. These use silicon devices called MOSFETs (Metal oxide semiconductor field-effect transistors) which have special coatings which are usually polymers but novel ceramic coatings may be used for certain applications. ISFETs have fast response, operate over the full pH range and are accurate. However, they have significant limitations, are not widely used and traditional glass pH electrodes are much more common although ISFETs are used in food and pharmaceutical analysis where broken glass is unacceptable and some are also used in IVD analysers. The limited acceptance of ISFETs is partly due to their higher price but also because their useful life is typically shorter that glass electrodes and they cannot be used for certain materials as these interfere with the MOSFET or chemically damage the membranes. There are a variety of circumstances where only the glass pH electrode is suitable. ISFETs are also relatively unstable, sensitivity degrades and they exhibit large drift in response with time requiring frequent recalibration. As a result they cannot be used on a continuous basis such as for process monitoring.

The glass pH electrode is a special type of ion-selective electrode sensitive to hydrogen ions. Exemption requests for two other types of ion selective electrodes have been considered in the next section.

10.1.6 Ion selective electrodes

Ion selective electrodes have been developed for chemical analysis of low concentrations of ions in solutions. These are designed to be specific for one type of ion so that the concentration of this ion can be measured in solutions containing several different ionic species. Therefore lead concentrations in aqueous solution can be measured using an ion selective electrode which has a lead sulphide membrane and cadmium concentrations can be measured with an electrode having a cadmium sulphide membrane. Lead and cadmium sulphides are chosen because these have extremely low water solubility and the membranes are doped with silver sulphide to create a semiconductor. The electrode functions by measurement of the difference in electrode potentials between each side of the membrane with one side is in a reference solution and the other in the test solution. When the electrode is immersed in water containing the ion being measured, the ion concentration is proportional to the potential difference between the two sides of the membrane.

This technique gives rapid and continuous measurement of ion concentrations. The equipment is small, portable and can be battery powered and so is used at remote locations to monitor levels of metal pollutants in rivers as well as in industrial process plant. There are no lead and cadmium-free substitute materials that could be used for measurement of these metals using ion selective electrodes.

There are several alternative analysis techniques suitable for lead and cadmium in solution but all use large laboratory-based instruments such as atomic absorption spectroscopy, inductively coupled plasma, ion chromatography and ion electrophoresis. None of these techniques are suitable for continuous monitoring of lead and cadmium at remote locations.

Each electrode contains ~ 0.1 g of lead or 0.1 to 0.4 g of cadmium and the quantities of these metals placed on the EU market annually from this application is estimated to be ~ 200 g of lead and ~ 60 g of cadmium.

10.2 Equipment utilising and detecting ionising radiation

Equipment that uses and detects ionising radiation includes:

- X-rays imaging – fluoroscopy, mammography, CT, etc.;
- Radiation measurement;
- Materials analysis such as X-ray fluorescence spectroscopy;
- Radiotherapy equipment – cancer treatment;
- PET, gamma cameras – medical imaging techniques that utilise sensitive radiation detection.

All of these products have similarities and 13 requests for exemptions have been made which relate to equipment associated with ionising radiation. These are:

Table 54. Exemption requests related to ionising radiation

Exemption request for application in equipment utilising and detecting ionising radiation	Applications in other types of Category 8 and 9 equipment
Lead in shielding for ionising radiation	No
Lead in counterweights	Also used in some other products such as surgical microscopes
Lead in frit glass for bonding in X-ray tubes and image intensifiers	Lead in frit glass also used for and vacuum tubes used to convert UV, visible, infrared red light into electrons bonding laser tubes
Lead in X-ray test objects	No
Lead, mercury and cadmium in radiation detectors	Yes, related types of detectors used in other products
Lead in micro-channel plate radiation amplifiers	No
Lead stearate X-ray emission crystal for electron probe microanalyser	No
Cadmium X-ray measurement filters	No
Cadmium in output phosphors in image intensifiers	No
Copper-cadmium wire	Yes but not required beyond 2012
Cadmium radioisotope source in X-ray fluorescence analysers	No
Mercury in position switches (until 2012)	No
Hexavalent chromium in alkali dispensers used for image intensifiers, photomultiplier tubes, etc.	Yes but should be possible to replace by 2012
Lead in solders for array interconnections to photodiode CT detectors (until 2012)	No, not required beyond 2012

If the exemptions that are not required beyond 2012 and those required for other types of products are excluded, this leaves 7 or 8 exemptions that are specific to these types of product. These are discussed individually.

10.2.1 Lead in shielding for ionising radiation

Lead is used as shielding in several types of equipment including:

- Radiotherapy equipment which uses high energy X-rays, electrons or gamma rays;
- Medical X-ray machines (fluoroscope, CT, etc.) and PET;
- Proton therapy - ~ 5 machines per year with 20 tonnes lead in each
- X-ray security equipment, e.g. for screening luggage at airports;
- Industrial X-ray equipment for examination of internal construction of products;
- Equipment for radiation measurement. Shielding is required to block stray radiation.

Lead shielding has several functions including; as a barrier to block X-radiation to protect hospital staff and patients, as a collimator to control the radiation dose and limit the radiation exposure to patients, and to prevent stray radiation reaching sensitive detectors. Lead is used for several reasons:

- High atomic number and density – The thickness of shielding required is inversely proportional to the atomic number and material density. Therefore the thickness of lead required will be less than that of steel although thicker than tungsten.
- Parts made of lead are much easier to fabricate and to recycling at end of life in comparison with tungsten which is very difficult to fabricate and recover at end of life. This is due to tungsten's very high melting point and because it is a very hard metal which cannot be easily formed into intricate shapes.
- High energy radiation (> 6MeV) causes metals to become radioactive but the half life of radioisotopes created in lead are very short and so they become safe within only a few days whereas tungsten can remain radioactive for 6 years.
- The world's supply of lead is very large whereas that of tungsten is much more limited with most arising in China (76% of the world supply in 2002 was from China). There are some disused tungsten mines which have closed but these could not easily and quickly be re-opened.
- The market price of tungsten metal is much higher than either steel or lead but more importantly, due to the difficulty with fabrication, machined tungsten parts could be up to 100 times more costly than equivalent lead parts. As materials are a significant proportion of the sale price of medical X-ray and radiotherapy equipment, conversion to tungsten would result

in a large price increase. This would restrict accessibility of the latest technology in the EU as healthcare budgets are always limited and so this would have a negative impact on healthcare.

- If lighter metals such as steel were used instead of lead, much thicker sections would be required. There is however frequently very little space available for shielding so that this option is not technically feasible. For example, during some forms of treatment health workers need access to their patients. This would be severely restricted if thicker radiation screening had to be used. In another example, CT machines are already very large. Their size is determined by the size of all the component parts that are required and these include radiation shielding to ensure that X-rays are focussed where required only and to shield the very sensitive X-ray detector. Bulkier materials would necessitate a significant size increase to the CT machines.

Shielding for ionising radiation is used in several forms:

- Sheet and thicker sections as a barrier to X-rays;
- Machined and moulded parts of intricate shapes (difficult with tungsten);
- Lead-bearing transparent glass for viewing patients by hospital staff and for locating samples for industrial X-ray analysis. Lead is the most effective additive that can be added to transparent glass to effectively screen X-rays. Barium glass can be used in cathode ray tubes (with some lead) but is less effective and tends to be affected by moisture. Tungsten based glass does not exist;
- Flexible shielding with lead in rubber sheet to protect patients and staff;
- Various devices to improve X-ray images where lead is used for its radiation shielding properties. These include:
  - A grid structure with an array of alternating structure with lead (radiation absorbing) and aluminium (transmitting) used to eliminate scattered radiation that would otherwise blur the image;
  - As a layer of lead behind X-ray plates to absorb X-rays. This prevents back-scattered X-rays being reflected back into an X-ray photographic plate or digital array detector which would cause blurring;
  - Within X-ray tubes as lead-glass for shielding;
  - In glass of capillary plates used for X-ray collimation.

The characteristics of lead, tungsten and steel are compared in Table 55:

Table 55. Characteristics of radiation shielding metals

Characteristic	Lead	Tungsten	Steel
Density (g/cc)	11.34	19.25	7.87
Melting temperature °C	327.5	3422	1538
Relative thickness required (Lead = 1)	1	0.6	5
Time until radioactivity decays to safe levels (not applicable to lower energy equipment)	A few days	Up to 6 years	Years
World supply and consumption	Total production (including scrap recycling) equals consumption at ~ 6 million t p.a.	Supply 38,000 t (2002) Consumption 37,000 t in 2002 predicted to rise to 45,000 t in 2008 (Roskill)	Plentiful supply
Recent metal price € / kg	0.8	12.8 – 36	0.5 – 0.7

Several other materials have been proposed for radiation shielding. One alternative shielding material that has been suggested is depleted uranium. This would be effective but suffers from a variety of environmental problems; it is more toxic than lead and is more difficult to fabricate and to recycle than lead. Several composites based on tungsten are commercially available as radiation shielding materials. The characteristics of these compared to lead are summarised in Table 56.

Table 56. Comparison of lead and other materials for radiation shielding

Material	Equivalent thickness for 150 keV, 99% absorption	Characteristics of material	Advantages and disadvantages
Lead	2 mm	Ductile, easy to form into any shape, stable	Low cost, easy fabrication and recycling
Depleted uranium	< 2 mm	Corrodes readily, more toxic than lead, radioactive	Controlled substance, cost ~ 100 times that of lead, recycling very difficult and requires licensed permanent storage at end of life
Polymer-metal composite (57% tungsten metal)	2.6 mm	Hard brittle material.	Shapes made by extrusion but moulds are expensive. Polymer may be degraded by radiation, tungsten becomes radioactive from high energy radiation. Very difficult to recycle
Densimet alloy (tungsten)	~2 mm	Powder metallurgical material	Difficult and expensive to fabricate and recycle. Becomes radioactive from high energy radiation
Tungsten powder in polyamide composite	> 2 mm	Similar to polymer-metal composite	Difficult and expensive to fabricate and recycle. Would become radioactive from high energy radiation but cannot be used at >200 keV

In practice, steel, lead and tungsten are all used in equipment as shielding for radiation. Manufacturers try to avoid tungsten for all of the reasons listed above but are forced to use it at some locations to minimise the overall size of the equipment to allow good access by hospital staff to the patient as, in some cases, even lead is too bulky.

Although tungsten is not a hazardous material, unlike lead, the use of this metal does have a negative impact on the environment. The main impact is from the very large quantity of energy required to extract tungsten from its ore, to fabricate parts from ingot or powder and at end of life to recycle it. Tungsten has a very high melting point, 3422°C as opposed to 327.5°C for lead. Tungsten is also very hard whereas lead is soft and so cutting and forming of lead consumes much less energy than tungsten.

This exemption request is justified as the substitute material, tungsten, would have a negative impact on the environment due to the large difference in energy used which has an impact on global warming. The tungsten metal/polymer composites all suffer from the same disadvantages as the metal although parts can be made more easily such as by injection moulding, however this is practical only if a relatively large number of parts are required as fabrication of the moulds is expensive.

10.2.2 Lead used in counterweights

Lead is used as a counterweight in three types of products and the availability of substitutes for each of these are different:

- CT and other X-ray imaging equipment;
- Radiotherapy equipment;
- Surgical microscopes and industrial measurement equipment.

CT and other X-ray imaging equipment

These products extensively use counterweights to counterbalance suspended arms or in rapidly rotating equipment such as CT scanners to give an even distribution of weight in the equipment. These products were originally designed with lead as the counterbalance material because of its high density, easy fabrication and straightforward recycling at end of life. To replace lead with a different material within the same equipment would require a material with the same density or a higher density. There is however a very limited choice:

Table 57. Substitute metals as counterweight materials

Metal	Density g/cm^3	Possible limitations
Lead	11.4	For comparison
Tungsten, Tantalum	19.3, 16.6	Very difficult to fabricate and recycle, high cost for parts
Gold	19.3	Very high value poses risk of theft.
Thallium, Mercury	11.9 and 13.5	Toxic
Rhenium, Osmium, Iridium, Platinum	21.0 – 22.6	Very rare metals, insufficient supply and extremely expensive

Steel, brass, bronze, concrete and other metals are used as weights and counterweights in other products but all have lower density than lead and an item with the same weight would occupy a larger volume. Usually in existing equipment designed to use lead counterweights, there is insufficient space for lower density materials and so the only two options are either to allow a temporary exemption to allow lead counterweights to be used until such a time as all current models are due to have been phased out which is expected to be ~ 2016 or to use a higher density metal and the only practical option for this is tungsten. Tungsten weights are already used as a lead replacement as fishing weights but fabrication of parts and recycling at end of life are considerably more difficult and energy intensive for the reasons explained in Section 10.2.1. Tungsten is also available in limited quantities and so there may be insufficient available for this application, especially if its use as radiation shielding increases. Manufacturers estimate that the cost of fabrication of tungsten parts instead of lead parts is up to 100 times greater. This very large difference would inevitably have an effect on the selling price of equipment that needs to use a significant number of counterweights much greater than by replacing lead solders with lead-free.

New models, designed to include lower density counterweights could be designed and eventually replace current models but this will take many years for research, etc. A variety of materials could be used to construct equipment but these new designs would be completely different as it is not possible to replace lead by lighter materials. Manufacturers estimate that it would be possible to phase out the use of lead in CT scanners and other X-ray imaging equipment by 2016.

Radiotherapy equipment

These products use counterweights to counterbalance suspended arms which are suspended at precise positions over the tumours in patients. Because of the essential radiation shielding, these arms are very heavy. Manufacturers of radiotherapy equipment have the same issues and problems to resolve as manufacturers of CT and other X-ray imaging equipment but in addition, radiotherapy rooms have to be heavily shielded to prevent radiation leakage. They are therefore as small as possible and changing from lead to less dense materials even in new models is not a viable option as this would result in larger equipment which would not fit into the limited space available. As a result, the only alternative to lead is to use at least some tungsten and so price increases are inevitable.

Surgical microscope and industrial measurement equipment

These microscopes are used for precision surgical operations such as on the eye. They need to be physically small and positioned at precise locations over the patient with sufficient space around the microscope for the operation to be carried out. Counterbalances allow the relatively heavy microscope to be suspended over the patient but moved easily and precisely by the surgeon. Frequently the surgeon will move the microscope with his nose as both hands will be required for surgical manipulations. The reasons for the use of counterbalance weights in measurement instruments is essentially the same as in radiotherapy equipment. Up to 5 different counterweight shapes and many counterweights are used per instrument. The only viable alternative is tungsten as lower density materials would be unacceptable. Machining tungsten is very costly and energy intensive. Tungsten composites are used as fishing weights and may be suitable but some development work would be required. The main limitation for tungsten in this application is cost. Machined tungsten parts are about 100 times more expensive whereas tungsten composite parts would be an estimated 40 times more costly. One manufacturer of surgical microscopes has estimated that replacing lead by tungsten composites will increase the price of these products by 30%. Due to limited healthcare budgets, this could potentially have a negative impact on healthcare.

Counterweights - conclusions

The main issue with substitute counterweights is the different impact on the environment from lead and tungsten. Lead is toxic whereas tungsten is not harmful. However the energy and resources in materials required to fabricate tungsten parts and to recycle these at end of life is very much greater than lead which as a pure metal is very easy to fabricate and to recycle as is already normal practice. The use of tungsten would increase product prices considerably which inevitably would impact on healthcare provision.

Manufacturers of CT and other imaging equipment could in the longer term develop new models which use less dense materials such as steel as counterweights but these could not be used in existing models. A temporary exemption until 2016 would allow time for these changes to be made and avoid the need for tungsten. However in the products such as surgical microscopes where less dense materials cannot be used, the only substitute is tungsten. An exemption for the use of lead counterweights in surgical microscopes would avoid the need to use tungsten which would have a negative impact on the environment. Radiotherapy equipment manufacturers are prepared to use tungsten counterweights if lead is restricted but this will have a negative impact on the environment.

10.2.3 Lead bearings in X-ray tubes

Lead is used as a bearing material in certain types of X-ray tube and as a component of the glass used in glass X-ray tubes.

X-ray tubes consist of an anode and cathode enclosed within a vacuum. Electrons are produced by the cathode and as these strike the anode; X-radiation is emitted. The shape of the anode controls, to some extent, the direction of the X-radiation. X-radiation formation is a highly energetic process which also generates heat. This is conveniently conducted away from the anode in low power tubes but the localised heating in higher power tubes would cause damage to the anode. Overheating is avoided by rotating the anode and this is achieved within the vacuum of the X-ray tube with a lead bearing. The quantity of lead used in each tube is very small but research by manufacturers has not identified a suitable substitute material. Materials that have been considered are listed below.

Table 58. Bearing materials for X-ray tubes

Material	Performance
Lead	Good wear resistance, low torque although some lead particles produced
Organic lubricants; greases, PTFE, etc.	Not suitable for use in vacuum. Greases and oils produce gases which would be degraded by X-rays. Internal temperature of X-ray tube too high for polymer bearings
Gold	Poor wear resistance, torque increased to high value, produces metal particles
Silver	Poor wear resistance, torque increased to high value, produces metal particles
Indium/gallium alloy (liquid)	Liquid slowly flows out of bearing location so is lost from bearing. No particles but high torque
Molybdenum sulphides, etc.	Poor wear resistance, produces particles

The conclusion that lead is the only choice as a metallic bearing material that can operate without organic lubricants in a vacuum is the same as found by IBM for the coatings on their thermal conduction modules in their supercomputers. These also require a metal to provide long term wear resistant material with low friction properties in a vacuum and research showed that lead is the only option[86].

Alternative X-ray tube designs

Substitute bearing materials do not appear to be available. However, an alternative approach would be to redesign the X-ray tube to avoid the need for a bearing. Bearings are required in higher power tubes because the anode has to be rotated to avoid local over-heating. At least one manufacturer has developed a new design of X-ray tube which does not have lead bearings. This new type of tube can used in a limited range of new product designs whereas most X-ray equipment will continue to use tubes with lead bearings. These new designs have been patented so that competitors could not benefit from this invention and so could not utilise this approach to replace lead bearings. The development of completely new X-ray tube designs is not a trivial exercise and would require a great deal of research. One manufacturer claims that the time from concept to launch would be from 7 to 10 years and these could be used only in new models of X-ray imaging machines as they would not fit into existing designs. The timescale would therefore be 7 – 10 years plus time for testing, clinical trials and obtaining approvals from Notified Bodies. Therefore an exemption for lead bearings in X-ray tubes will be needed for at least 12 years (2018).

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[86] Information provided to ERA by IBM to support request for exemption 12 which has since been approved.

10.2.4 Lead in frit glass for X-ray tubes, image intensifiers, for vacuum tubes that convert electromagnetic radiation into electrons and for bonding laser tubes

This section combines consideration of several requests for similar exemptions for lead in frit glass. This is used in several X-ray related applications and in several other applications but for simplicity, these are reviewed together since the issues concerned are common.

X-ray and other vacuum tubes have been fabricated from glass since they were first invented. Glass has been used as it is relatively easy to fabricate precise shapes which can be evacuated. X-ray tubes have an anode and a cathode which are connected electrically by metal rods that are sealed into the walls of the glass tube.

Varieties of other electrical components are also made from glass and include light bulbs and photomultiplier tubes. Both of these types of device contain vacuum (or a very low pressure gas) and have metal connections that pass through the glass and both are made from lead-free glass. Forming a metal/glass seal where the Thermal Coefficient of Expansion (TCE) of the glass matches the metal conductors is clearly possible without lead glass as several glass manufacturers sell special borosilicate high resistivity glasses with TCE that matches tungsten, molybdenum and other metals. The largest special glass manufacturer in Europe, Schott, advertise two grades of special glass that are intended for X-ray tubes both of which are lead-free. X-ray and vacuum tube manufacturers do not now use lead-based glass except for two specific applications. One is in X-ray tubes where the lead is included for shielding ionising radiation and this would be covered by the exemption request discussed in Section 10.2.1. The other is as a sealing material for bonding glass to metals where the bond area is relatively large.

There are many types of lead-free glass available with a range of TCE values. Borosilicate glasses have low TCE and can be designed to match Kovar and molybdenum which are used to make electrical glass/metal seal connections where thin wires need to be sealed into glass of photomultiplier and X-ray tubes. Where higher TCE is required for bonding to higher TCE metals, soda glass has a higher TCE but cannot be used because its electrical resistivity is too low for use with high voltage vacuum equipment. Borosilicate glass has a high electrical resistivity, which is important for high voltage vacuum tubes, but has a much higher melting temperature than lead glass and its melts are more viscous so that it is considerably more difficult to make vacuum tight seals with low stresses that will not crack in use. Soda glass has a lower melting temperature and so is easier to fabricate but its electrical resistivity is too low owing to the higher alkali metal content.

Increasingly, new X-ray tubes are being developed which are not made from glass. Metal housings are used and the area where X-radiation emerges from the tube is made of beryllium metal which is transparent to X-rays. This avoids the need for the use of lead in glass but metal X-ray tubes are fairly new and could not be incorporated into older designs of X-ray imaging equipment some of which will continue to be placed on the EU market after 2012.

Frit glass for X-ray tubes, image intensifiers and vacuum tubes that convert electromagnetic radiation into electrons

Modern X-ray tubes, image intensifiers and "streak tubes" have metal bodies as these a robust and not easily damaged unlike glass. Some types of X-ray tube include glass parts bonded to the metal body (e.g. lead glass for shielding) and some types of image intensifiers use a glass phosphor screen with lead-glass fibre optic plate (FOP) collimator. Both of these require glass parts to be bonded to the metal body with a high vacuum seal. Adhesives cannot be used as all evolve gas in vacuum and are porous so will not maintain the vacuum. The TCE of the glass and the metal used will not be identical and so temperature changes will cause stresses on the glass which if too large will cause failure. This is not a problem where thin wires are sealed into glass as the stresses are relatively low but this increase proportionally with the dimensions of the seal. For large devices, stresses will be too high unless the TCE of materials can be very closely matched. Stresses are minimised by using metals with TCE close to that of the glass parts to be attached such as the FOP but a precise match is not usually possible. Stress reduction can be achieved by using a glass frit with TCE intermediate between the glass and the metal but very few glass materials have been found within the narrow range of TCE that also have a melting temperature that is sufficiently low as a bonding frit. This should normally below 500°C to avoid deformation of the glass parts. FOP are made of lead glass which is deformed at temperatures of ~500°C and the frit glass has to melt at ~450°C or less. Research has found that, if the frit glass is crystalline, it becomes amorphous after the bond is created. In its crystalline form, it can be melted and flow at < 500°C to form a robust bond. It is frequently necessary to carry out subsequent process steps close to these bonds which if re-heated, the now amorphous bond does not re-melt or distort.

Typical TCE values of the materials used in image intensifiers are:

Typical TCE of metal parts	9.6 x 10^{-6} ppm/K
Typical TCE of glass parts	four types used: 8.5, 6.8, 9.4, 8.9 x 10^{-6} ppm/K
TCE of lead-based frits	8.8, 6.8, 9.4 x 10^{-6} ppm/K

No crystalline lead-free frits with softening temperature < 500°C are available. One type has a TCE of 9.0 – 9.8 x 10^{-6} ppm/K but the working temperature is 500°C which is too high for FOPs which will soften and distort at this temperature.

High voltage vacuum tubes include photomultiplier tubes that are used for detection of UV, visible and near infrared radiation. One photomultiplier tube manufacturer consulted has stated that they are able to use lead-free glass in all designs except those used to detect UV light because glass is not transparent to UV. Therefore a UV transparent window is inserted into the lead-free glass tube and clear single crystal magnesium fluoride or calcium fluoride in the form of sheet is used and bonded to the glass tube body using a lead-glass frit. Lead-free borosilicate glass used for the tube body typically has a TCE of 3.3 x 10^{-6} ppm/K although special grades with higher TCE (~5.4 x 10^{-6} ppm/K) are available, whereas magnesium fluoride has a much higher TCE (13.7 x 10^{-6} ppm/K in one direction and 8.48 x 10^{-6} ppm/K in the direction 90° to this). Because of the large difference in TCE, this applies a large strain on the device when the assembly is cooled after attachment of the magnesium fluoride window. The stress is proportional to the bonding temperature and the TCE difference and so the stress can be reduced if either of these can be minimised. Lead-based frit glass has a significantly lower melting point (e.g. 380°C) than lead-free frits currently available commercially (~500°C) and so the bond is made at a lower temperature (120° less) which reduces stress. However, even if special borosilicate glass designed with higher TCE is used which is (5.4 x 10^{-6} ppm/K) this will apply a large strain on the fragile magnesium fluoride window unless the strain can also be minimised by using a low melting temperature frit that has a TCE intermediate between the TCE of these two materials. Only lead-frit glasses have both low working temperature and TCE of ~ 8 – 9 x 10^{-6} ppm/K.

Frit glass for lasers

Lasers are constructed from tubes with mirrors or windows at each end. One very important characteristic of lasers is that the tube has to be a very precise length and so the bond itself has to have very precise dimensions. Gas lasers contain special gas mixtures at very low pressure and so it is essential that the technique used to seal the windows and mirrors to the tube provides a robust and permanent gas tight seal. Laser light is induced by electrical excitation of the low pressure gas inside the tube. Argon lasers produce blue/green light and are used for a variety of medical applications but they also emit some UV light that darkens glass and so quartz windows have to be used. Helium-neon lasers also produce visible laser light. Argon and krypton lasers use high current excitation and so are frequently constructed from electrically insulating glass or quartz tubes whereas helium-neon lasers use low current excitation and so less fragile metal tubes are used.

Lead-free frit glasses and alternative bonding techniques

The scientific literature has been reviewed to determine if substitutes are available or will be in the near future. Adhesives are unsuitable as these degas in vacuum and the gas contamination is highly detrimental. Adhesives and all polymers are also porous to gases so will not maintain a permanent vacuum. Two possible alternative options have been investigated:

- Low melting temperature lead-free frit glass;
- Alternative glass/glass bonding techniques (suitable only for lasers which have glass or quartz tubes).

Lead-free glasses - There are many patents and publications describing low melting temperature lead-free frit glasses however most are intended as pottery glazes and most have melting temperatures of greater than 500°C and so are unsuitable. The problem with most types is that they are formulated with a TCE to match the material to which they are used. For example pottery glazes need to closely match the TCE of the pottery base[87]. In general, lead-free versions always melt at higher temperature that their lead-based equivalent. For example Schott has developed a lead-free frit glass with working temperature of about 500°C to replace a lead-based glass with a working temperature of 420°C that is used for fabrication of phototransistors[88]. One recent patent[89] describes a bismuth based frit glass with a melting temperature of less than 500°C which is intended for bonding plasma display panels and so would match the TCE of the display panel glass but not other equipment. This frit would be unsuitable for bonding borosilicate glasses to the metals used in vacuum tubes and lasers as it has too low TCE. To date, most lead-free frit glasses have melting temperature of ~ 500°C or higher making these unsuitable for some applications. There are very few crystalline lead-free frits with softening temperature of less than ~ 500°C and these do not have the correct TCE to be suitable for the applications described here.

Alternative bonding techniques – There is one alternative possible where glass is bonded to glass or quartz is bonded to quartz. This technique does not bond dissimilar materials such as glass to metals or glass to magnesium fluoride and so this technique is limited only to certain types of lasers which have glass or quartz tubes. This technique is called optical contacting or direct bonding and requires that the two surfaces to be bonded are both perfectly optically flat and perfectly clean. A good vacuum tight bond is difficult to achieve, especially if the mirrors have to be orientated to precise positions before bonding. The bond is formed by chemical reactions that occur at the glass or quartz surface but no material transport occurs and so no gaps can be tolerated. This is a difficult technique to master and inexperienced manufacturers would create a significant quantity of waste if they were forced to stop using lead-based frits. However research into this technique is continuing and recently NASA have published results that demonstrate “solution assisted optical contacting” using alcohol to allow the parts to be orientated prior to bonding[90]. Optical contacting is however unsuitable for metal bodied lasers.

Vacuum tubes may be regarded as “electronic components” and so no exemption for lead in glass of these devices would be needed. Exemption 5 of the RoHS Directive Annex is “**lead in glass of** cathode ray tubes, **electronic components** and fluorescent tubes” and this already allows the use of lead in glass of these specified components. Unfortunately “electronic components” are not defined by RoHS or WEEE but CENELEC publish specifications for a wide variety of equipment and components and “electronic components” are considered by their “Electronics Components Committee”. This committee is responsible for photomultiplier tubes, cathode ray tubes, image intensifiers and other components that require lead-based frit materials and so this could be used to define “electronic components”. This definition would not however include lasers or X-ray tubes for which this exemption is also required.

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[87] US Patent US6255239 and other patents cited.

[88] Schott AG www.schott.com.

[89] Asai Glass US Patent US 2006105898.

[90] www.nasatech.com/Briefs/Mar04/NPO30731.html.

In conclusion, lead-glass frits cannot currently be replaced by substitutes in certain applications. Exemption requests for lead-glass frits have already been submitted to the European Commission for several specific applications in Categories 1 – 7 and 10 and two have recently been accepted (No. 20 and No. 25).

10.2.5 Cadmium in phosphors of image intensifiers

Phosphors are types of scintillators which emit light when exposed to electrons. Image intensifiers are devices designed to increase the intensity of weak X-ray images and consist of a phosphor located on the inside of the input window of the device. A photo-emissive layer deposited onto the input phosphor converts light into electrons which are focused with a series of electrodes onto an output phosphor. The output phosphor screen is much smaller than the input screen and the image has a high enough intensity to be recorded with a digital camera. Some image intensifiers use FOPs to collimate light. The output image can be as much as 5000 times brighter than the input image intensity[91].

Cadmium zinc sulphide was a common phosphor material for both input and output phosphors but thallium doped caesium iodide and other proprietary materials are now increasingly used as the input phosphor as this gives superior performance. Replacing the silver-doped zinc cadmium sulphide output phosphor material is more difficult. It has to be deposited as a very thin layer (4 to 8 μm) and emit visible light with high efficiency and intensity – however manufacturers are looking for substitutes and some have already identified alternative designs and others expect to be able to replace cadmium zinc sulphide by 2012.

Image intensifier designs vary considerable and each manufacturer has its own unique technology. One European image intensifier manufacturer that was consulted during this review already does not utilise cadmium in output phosphors and so their image intensifiers will not contain cadmium based phosphors in future designs. One Japanese manufacturer also claims to use a cadmium-free alternative. Image intensifiers are a relatively old technology which is declining, particularly in Europe where healthcare providers tend to utilise state-of-the-art technology to gain the diagnostics benefits that reduce treatment costs per patient. In some new X-ray imaging products, high sensitivity semiconductor detector arrays are utilised so that image intensifiers are not needed. It is likely that relatively few image intensifiers will be sold in the EU for new equipment (only as spares) after 2012 but manufacturers have not yet found substitute technology for applications that require the highest spatial resolution at low X-ray doses such as for mammography.

Some image intensifiers will be sold in EU after 2012 but manufacturers should not need to use cadmium based phosphors after this date and so an exemption would not be required if Category 8 is included in the scope of RoHS from 2012.

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[91] Introduction to electronic imaging http://ric.uthscsa.edu/personalpages/lancaste/DI-II_Chapters/DI_chap2.pdf

10.2.6 Lead in X-ray test objects

These are non-electrical metal parts which may be supplied with X-ray equipment and so would be regarded as accessories to the X-ray equipment. There are two types, one is used for calibration of the equipment to obtain as clear an image as possible, and the other has a letter "L" and a letter "R" which are placed onto the patient when producing an image to record which is the left side and the right side. Lead is used for several reasons:

- High atomic number and so effectively blocks X-radiation;
- Ductile material which is not easily damaged. Other high atomic number metals are hard and brittle and so thin sections easily fracture;
- Lead sheet can be easily and accurately etched to produce fine lines and other intricate shapes. Although it is possible to etch tungsten metal sheet, it would be impossible to etch the more flexible tungsten/polymer composites.

In conclusion, lead is the only high atomic number metal that is ductile and can be easily etched to give the fine structures required.

10.2.7 Lead in solders for array interconnections to photodiode CT detectors, and lead in solder connections to micro-BGA area arrays

Solder bonding CT detectors is a complex and difficult process. Furthermore, these detectors are attached to PCBs that experience up to 70 g-force and would not survive without additional support from a special under-fill material. Unfortunately, underfill development (as discussed in Section 8.1.4) for lead-free systems is in its early stages and as yet it is not possible to produce reliable bonds to photodiode arrays for CT. A significant amount of research is required but manufacturers have stated that they are optimistic that the technical problems can be solved by 2012 although not earlier. Therefore this exemption request would not be required if Category 8 is included in the scope of RoHS in 2012.

A new failure mode has very recently been discovered by one manufacturer when developing lead-free connections to micro-BGA area arrays. This also uses underfill but no suitable products are yet available for these arrays using lead-free solders. Voids form in the underfill which cause cracks in the component substrate as shown below:

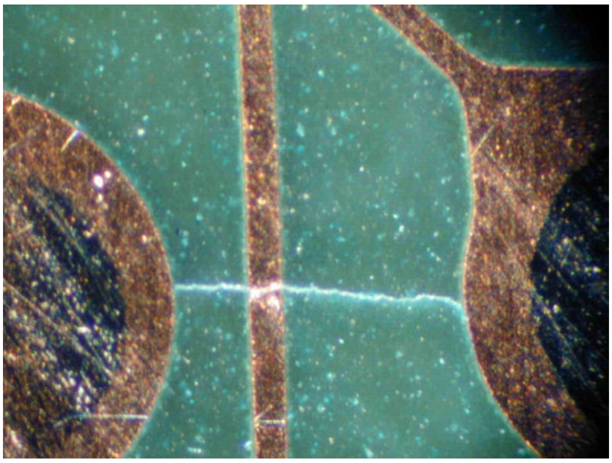

Figure 9. Cracks in array substrate that form during thermal cycle testing of lead-free products

These cracks form relatively quickly and are not seen in lead solder systems. Clearly research is required to find a solution to this new problem but manufacturers are optimistic that this can be resolved by 2012.

10.3 Lead stearate use in diffraction crystals for wavelength dispersive spectroscopy

Lead stearate $\{CH_3(CH_2)_{16}COO\}_2Pb$ is one of the traditional diffracting crystal materials used in wavelength dispersive spectrometers for light element analysis (atomic number, $Z < 11$).

Wavelength dispersive (WD) spectrometers are used in X-ray fluorescence spectroscopy (XRF) and electron microprobe microanalysis (EPMA). In XRF an X-ray beam is directed at a sample, causing excitation of atoms in the sample. Secondary electrons are emitted and subsequently X-rays, as the excited atoms return to their initial state. The energy of the emitted X-rays is characteristic of the atomic element from which they were emitted. In EPMA the sample is placed under an electron beam in a vacuum chamber. Atoms in the sample interact with the electrons in the beam producing secondary electrons and X-rays by the same process as XRF. In both techniques by measuring the wavelength of the X-rays the presence of an element can be confirmed and quantitative elemental analysis is possible.

Wavelength dispersive spectroscopy (WDS) is a serial technique. It measures the wavelength of emitted X-rays by utilizing Bragg's law to diffract the X-rays by a specific angle towards an X-ray detector, using a diffracting crystal. As the WD spectrometer can only measure one wavelength (or X-ray energy) at a time XRF and EPMA instruments may contain up to five individual spectrometers, enabling four elements to be measured simultaneously. Individual wavelength spectrometers are also produced for attachment to scanning electron microscopes (SEMs). Manufacturers of WD, XRF and EPMA instruments are shown below.

Table 59. Manufacturers of WDXRF and EPMA equipment

WD XRF manufacturers	EPMA manufacturers	WD spectrometer manufacturers for SEMs
Bruker (US/Germany) Rigaku (Japan) Oxford Instruments (UK) PANanalytical (part of Spectris group, UK) Thermo Electron ARL (US)	Cameca (France) JEOL (Japan)	EDAX (part of the Ametek group, US) Oxford Instruments Analytical (UK) Parallax Research (US) Thermo Noran (part of the Thermo-Electron group, US)

WD spectrometers typically contain a series of diffracting crystals. Different crystals are used over different X-ray energy ranges as each crystal is optimized for specific energy ranges. When required each of the different crystals is brought into alignment with the beam of emitted X-rays and used to diffract the beam to the X-ray detector. Lead stearate is one type of diffracting crystal used in the low energy/light element X-ray range.

Lead stearate has been used because naturally occurring crystals such as LiF are limited to the analysis of shorter wavelength X-rays because their maximum inter-planar spacings are small. Lead stearate or other pseudo-crystals (thin layer structures) have therefore been developed for the analysis of longer wavelength X-rays (lower energy).

Lead stearate diffracting crystals are produced by taking a suitable substrate such as mica or glass and dipping it into a trough containing a monolayer film of lead stearate floating on the surface of water. Lead stearate is characterised by a long chain molecule with the heavy lead atom at one end. The initial dipping results in the attachment of the lead metal with it's organic tail perpendicular to the substrate. Removal of the substrate from the trough results in a second layer being deposited in which the hydrocarbon tails are attached to the surface and a row of heavy metals form the external surface. The pseudo-crystal is then built up by repeated dipping. The organic tails of the molecules serve as light element spacers between reflecting planes of lead atoms. Different inter-planar spacings can be produced by using different organic molecules with varying chain lengths. Lead is used as it is a heavy atom with good reflectivity properties and lead stearate is a stable compound.

The quantity of lead used in each crystal is very small. The world market for dedicated WD XRF, EPMA instruments and WD spectrometers for attachment to SEMs is <200 units p.a. and the majority of these instruments will be shipped without lead stearate diffracting crystals[92]. **The estimated total annual use of lead in this application is therefore approximately 1 mg.**

Lead stearate crystals have poor durability and can be easily damaged, especially if the WD spectrometer is exposed to moisture or oil condensate. They are now being replaced by layered synthetic microstructure (LSM) crystals. These diffracting structures are built up by physical vapour deposition (PVD) of alternating layers of heavy and light elements (normally carbon and tungsten).

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[92] None of the listed WDXRF manufacturers are thought to still use lead stearate crystals.

The fabrication technique permits the deposition of layers with any value of spacing required and with material choices tailored to diffract X-rays of certain wavelength most efficiently.

LSM diffractors are typically ten times more efficient than lead stearate crystals, offering considerably improved X-ray count rates under the same instrument operating conditions. Higher order reflections that are observed with lead stearate crystals are also suppressed (a distinct advantage as higher order X-ray lines from metal elements may interfere with the light-element lines; e.g. the Al Kα$^{(III)}$ interferes with the O Kα peak and the Al Kα$^{(IV)}$ peak interferes with the N Kα peak). The only shortcoming of LSM crystals is the slight decrease in resolution at very low energies, although this can often be an advantage as the side effects of chemical shifts in wavelength are minimised; i.e. for quantitative analysis it avoids any problems associated with the element peaks having a different shape in sample and standard. The advantages and disadvantages of the different crystal types are given below.

Table 60. Comparison of different types of diffraction crystals

Diffracting Crystal Type	Advantages	Disadvantages
Lead Stearate	Offer the ultimate resolution at low energies Can detect chemical shifts in spectrum peaks	Poor durability – easily damaged by water or oil vapour contamination Do not suppress high order X-ray line reflections that may interfere with light element lines Crystal lattice spacing may vary with temperature
Layered Synthetic Microstructure	Durable and not easily damaged by water or oil vapour Suppress high order X-ray lines Up to ten times the sensitivity of lead stearate crystals Crystal lattice spacing remains constant over a wide temperature range	Do not have the ultimate resolution of lead stearate Difficult to detect chemical shifts in spectrum peaks

A comparison of the performance of lead stearate and layered synthetic microstructure diffracting crystals when analysing the light element boron is given in Table 56[93].

Table 61. Comparison of peak sensitivity and limits of detection for lead stearate and LSM diffracting crystals

Analysing crystal	Net Peak Intensity	Net peak to background ratio	Lower limit of detection (LLD)	Improvement over lead stearate crystal	
				Sensitivity	LLD
Lead Stearate	9	4	49750	n/a	n/a
LSM-160	112	33	4910	12.4	10.1
LSM-200	154	31	4320	17.1	11.5

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[93] Osmic Inc website (manufacturer of LSM crystals), http://www.osmic.com/products_ovonyx_xray_02.asp.

A comparison of the resolution performance of lead stearate and LSM type diffracting crystals is given in Table 58[94].

Table 62. Comparison of the resolution of lead stearate and other selected LSM diffracting crystals

Element	Peak energy (eV)*	Lead Stearate	LSM type 1 (W-Si multilayer)	LSM type 2 (Ni-C multilayer)
C(Kα)	277	5.4	8.8	10.7
N (Kα)	392	9.6	11.3	15.5
O (Kα)	525	12.4	13.6	20.4

* Full width of peak at half maximum height.

High resolution requires narrow peak widths; so these figures show that lead stearate gives the best resolution for light elements. Having very good resolution gives an added advantage that some molecular structure information (usually used for organic analysis) can be obtained which is not possible at lower resolutions.

Over 95% of wavelength dispersive instruments use LSM because of their good stability but the continued usage of lead stearate crystals is confined to a small group of WD XRF and EPMA users who require the ultimate resolution offered at very low energies and the ability to detect chemical shifts in light elements that cannot be achieved with LSM crystals. For these users there are no current alternative crystals available.

10.4 Cadmium in K-edge X-ray measurement filters

Medical and other types of X-ray imaging equipment is regularly calibrated to ensure that the correct X-ray dose is used for particular applications. It is dangerous to use too high a dose and too little is less effective and may affect the clinical outcome. The device that uses these filters is relatively new and has two types of metal filter, one that is transparent to X-rays (e.g. aluminium) and the other opaque. Cadmium is ideal for the latter application for X-ray imaging equipment used for mammography (this requires certain precise energy levels). The X-ray energy is determined by the difference in energies passing through the pair of filters.

The manufacturer who requested this exemption has estimated that less than 10 g cadmium is sold in EU for this application annually. They also admit that it would be possible to modify the equipment design so that silver or indium could be used instead of cadmium. However, this change is not straightforward as significant changes to electronics are required and once these are carried out, extensive testing would be required to guarantee accuracy. The manufacturer estimates that this would cost at least €500,000. As sales of this product are relatively small, this large cost could not be passed on to customers as a price increase and so they would be forced to remove this product from

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[94] G. Love and V. D. Scott, Journal of Microscopy, Vol. 201, Part 1, pp. 1-32, Jan 2001.

the EU market. This would affect users (hospitals) as the older alternative technology used to calibrate X-ray equipment is more difficult to use, calibration takes more time so that the equipment is not available for longer periods and, because of the complexity of the calibration procedure, there is a risk of errors being made.

10.5 Lead in microchannel plate (MCP), capillary plate (CP) and fibre optic plate (FOP)

These three devices, all containing lead, are used to amplify, collimate or focus electromagnetic radiation:

- Microchannel plate (MCP) amplifies electrons; for example in some types of X-ray image intensifiers;
- Capillary plate (CP) collimates X-radiation; these allow the use of lower X-ray doses so that the small amount of radiation that passes through the patient can be amplified to produce a clear image;
- Fibre optic plate (FOP) focuses visible light and is effectively a magnifying lens and as such is within the scope of the existing exemption for “lead and cadmium in optical and filter glass”. These are used in place of conventional glass lenses and as these are covered by an existing exemption, do not need to be considered further in this report.

MCP

The microchannel plate consists of an array of glass tubes arranged in the form of a disc. Each tube has a diameter of ~10 to 40µm and a few millimetres long. The internal surfaces are chemically etched to leave an electrically conducting surface (of lead metal) inside each tube and an electrical potential is applied along the length of each tube. This structure is fabricated from hollow glass fibres and must contain lead to provide the electrical conduction after etching the glass surfaces. MCP is used with photocathodes which emit electrons when exposed to light (such as from a scintillator or phosphor screen). The electrons are focussed electromagnetically by the MCP to amplify the signal. When one electron strikes the wall of a tube, many secondary electrons are emitted and as these pass along the tube, the signal is amplified. The gain can be 1,000 or 10,000 times. Although this is considered here as a new exemption request, these are electrical components used in medical devices and there is an existing exemption, number 5, of the RoHS Directive Annex, for “**lead in glass of** cathode ray tubes, **electronic components** and fluorescent tubes” and so a specific exemption may not be required.

CP

The capillary plate is also fabricated from lead-glass tubes arranged in an array, similarly to the MCP but each tube has a diameter, typically of 6 µm and is 1 mm in length. One CP may contain millions of tubes. A CP is used to collimate X-radiation and relies on lead, as a high atomic number metal, to absorb or reflect the X-rays, depending on their angle of incidence. At high incident angles, X-rays are absorbed (radiation shielding) and, at low angles, they are reflected and as a result collimated.

A relatively unusual additional function of the CP is to amplify X-radiation and this is achieved in a different way to the MCP. A potential is applied along the length of the CP tubes and when X-rays excite gas molecules in the tube to emit free electrons, these are amplified by the applied potential.

Lead has several functions in capillary plates including as shielding for ionising radiation and this application would be covered by the more general exemption for lead for shielding ionising radiation (as discussed in Section 10.2.1).

10.6 Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers

X-ray fluorescence spectrometers are analytical instruments used to determine the concentrations of elements in materials. There are a variety of types and designs and some are used for screening electrical components to determine whether any RoHS restricted substances are present. These instruments work by exposing the surface of the material which is to be analysed with ionising radiation. Small X-ray tubes are used in most instruments but the penetration depth of these weak X-rays is insufficient for one particular application. France has legislation which requires that any paint in buildings should not contain lead and that the paint should be analysed, to ensure that is absent, before the building is sold. Clearly it is not desirable to remove samples of paint, as this might be hazardous and damages the building, so analysis needs to be carried out in-situ by a non-destructive technique. The only accurate non-destructive technique available is X-ray fluorescence spectroscopy using portable instruments. Paint coatings are frequently too thick for X-rays from typical miniature X-ray tubes to have sufficient penetration so that they can give false positive results. Better penetration is obtained by the use of a cadmium radio-isotope as the source of ionising radiation and this is used in spectrometers used to check for lead in paint to comply with the French legislation.

The quantity of cadmium used in each spectrometer is extremely small (a few mg) and the main hazard is from its radioactivity, not the toxicity of cadmium. As these instruments use a radioactive substance they are closely regulated to prevent the release of the radioactive material. X-ray fluorescence spectrometers could use alternative radio-isotopes but the energy of radiation from cadmium is ideal for lead analysis and gives more accurate results than other radio-isotopes. Alternative radio-isotope energies either do not detected lead at all or detect lead only at concentrations that are much higher than the permitted maximum concentration. There are therefore currently no known substitutes for cadmium for this application.

10.7 Lead in single crystal piezoelectric materials for ultrasonic transducers

Ultrasound medical imaging is a very widely used technique to examine the internal organs of patients as well as the well known use for checking the health of babies in the womb. This technique is in principal very straightforward and utilises two arrays of ultrasonic transducers. One emits ultrasonic energy and the other detects the reflected signals from which the image is generated. The best ultrasonic transducers are piezoelectric materials containing lead such as lead zirconium niobate (PZN). Many transducers are made of ceramic composites and are very effective but the most sensitive types are based on single crystals of piezoelectric materials. The sensitivity of these devices depends on the efficiency at which the crystal converts signals into ultrasound and vice-versa. Typical figures are:

PZT single crystal	~90%
PZT ceramic composite	~70%
Best lead-free material	~50%

Lead in ceramic electronic components is one of the original exemptions to the RoHS Directive and would permit the use of lead in ceramic ultrasonic transducers. However, single crystals could not strictly be classified as a ceramic as ceramics are usually accepted to be multi-crystalline and multi-phase materials. The chemical composition of PZT single crystal and PZT ceramic is the same and an exemption for both is justified on the basis that lead-free substitutes give unacceptable performance.

Research into lead-free substitutes is being carried out. One current EU-funded project under Framework 6 is investigating potassium niobate as a possible substitute material. Pure potassium niobate has a much higher Curie temperature and so has low sensitivity at room temperature than PZN and so various dopants including bismuth are being investigated. At present, however, there are no commercially available lead-free substitutes with the required performance.

10.8 Lead in solders for bonding to ultrasonic transducers

Making electrical connections to medical ultrasound transducers is a difficult procedure. The transducers consist of an array of very small separate transducers (28 is typical) each of which needs an electrical connection. The transducer material is a ceramic or single crystal which is impossible to solder directly and so bonding is achieved by first depositing various metals onto the ceramic or single crystal surface. The bond has to survive the effect of ultrasonic vibration which applies very severe forces to the bond which must not fail.

Each manufacturer uses a different proprietary design for their transducers and has developed their own method for making the electrical connection. Each manufacturer consulted for this review uses a different bonding method and some manufacturers use different methods for different product types as the procedure used depends on a range of variables.

The types of solder used include high melting point solder (uncommon but an existing exemption), tin/lead, indium and indium/tin/lead solders but one manufacturer uses gold/gold bonds in one type of product. The PZT is not affected chemically by high temperatures but the piezoelectric properties can be affected. High melting temperature solders are unsuitable in many designs as the high temperature required (>300°C) damages other nearby components and materials as well as destroying the piezoelectric properties of medical transducers. Ideally, the solder should be ductile and flexible with a low melting point. Lead-free solders are relatively hard and inflexible which will be a disadvantage. Indium and alloys containing indium have two advantages as these are more ductile than tin/lead and are able to wet and bond to surfaces well, even to ceramics.

The most important characteristic of medical ultrasound transducers is their sensitivity (see Section 10.7). Piezoelectric materials have their molecular dipoles aligned in one direction; the temperature below which this becomes stable with the dipoles permanently polarised is called the Curie temperature or point. Piezoelectric properties are achieved by heating the ceramic to a temperature above its Curie point and applying a DC potential. This polarises the molecules in one direction and when the temperature is reduced to below the Curie point (with the DC potential still applied), the molecules are permanently polarised. However, this polarisation is lost if the material is re-heated near to and above the Curie point without the presence of the DC potential although depolarisation is not instantaneous and the rate of depolarisation is proportional to temperature. The most sensitive piezoelectric materials have relatively low Curie temperatures and in general, the lower this is the better the sensitivity. Manufacturers of piezoelectric materials for ultrasonic transducers all use their own proprietary formulations which have Curie temperatures typically from 160 to 200°C. Some piezoelectric materials can be soldered using traditional tin/lead (m.pt. 183°C) although the soldering temperature is typically 220°C but for a short time. Most lead-free solders (SnAgCu m.pt. 217°C) reach 240°C or higher and so the PZT is at a temperature above its Curie point for much longer which severely degrades its performance. SnAgCu is also harder than tin/lead and so damage to the brittle piezoelectric material is more likely if the equipment receives mechanical shock - for example if it is dropped.

The lower Curie temperature materials have to be soldered using special indium-based solders whereas the higher Curie temperature materials can use tin/lead as long as the material is hot only for a very short time. Solder wetting by standard lead-free solders (such as SAC) is slower than tin/lead and this combined with the higher melting point would prevent their use.

There are alternative low melting temperature lead-free solders but these are unsuitable:

- Indium/tin has a low melting point and can be electroplated as the alloy onto the flexible copper connectors used to bond to transducers. However, brittle indium/copper intermetallic phases will form which one manufacturer has reported results in early bond failure.
- Bismuth/tin is a reliable low melting point lead-free solder but bismuth cannot be electroplated to create the solder on the flexible connector. Also this alloy is hard and brittle and so damage to the brittle piezoelectric material is more likely if the equipment receives mechanical shock.

Conducting adhesives are not suitable as the bond is likely to deteriorate as a result of the ultrasonic vibration.

One manufacturer uses gold bump bonds similar to those used in flip chip devices and these connections are reliable. Modification of existing transducer designs to use gold bump bonds will be very difficult and requires lengthy research to redesign each transducer module. Transducer design is very complex and even very small changes can have a significant effect on “centre frequency”, bandwidth, “focal distance” and sensitivity, all of which affect performance and so changing to a completely different bonding method would be very complex and for most current designs would be technically impractical.

The current trend in ultrasonic transducer design is for smaller portable products. These have higher connection density and so are difficult to make without stressing the piezoelectric material. If dropped, which is not unlikely, the bonds should be flexible to prevent damage to the ceramic. Gold is a good conductor but is much less ductile than tin/lead or indium solders. Research is likely to develop RoHS compliant substitutes, such as gold bonding, in the future but this will take many years and it is not currently possible to predict when these would be available.

10.9 Lead in solders that are exposed to anaesthesia gases

Anaesthesia gases can be corrosive to metals and one manufacturer of equipment used with anaesthesia gases has reported that corrosion has occurred in trials with equipment produced with lead-free solders whereas no corrosion occurs with identical products made with tin/lead solders. The manufacturer has provided an image showing the corrosion.

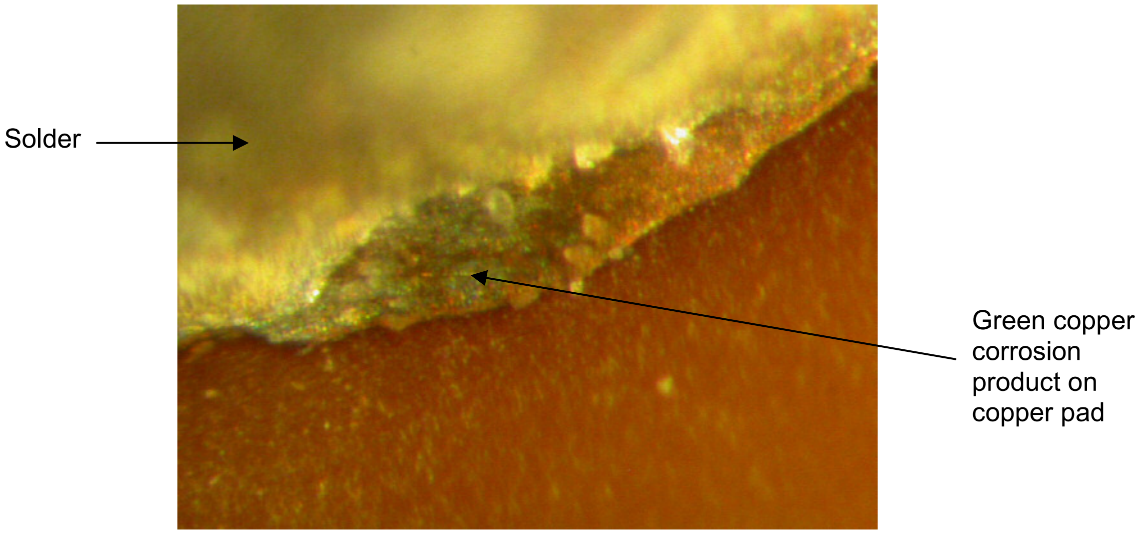

Figure 10. Corrosion of a copper pad at the edge of solder from equipment exposed to anaesthesia gases

It appears that the exposed copper pad has suffered from corrosion in the test but not the solder itself. Copper is susceptible to corrosion by a variety of gases and if allowed to continue this would cause a premature failure of the equipment.

It is a well known limitation of lead-free solders that their wetting properties are inferior to those of tin/lead solder. This results in the solder flow being more restricted and it is not uncommon for lead-free solder to fail to cover the entire copper pad and leave uncoated copper. This is much less common with tin/lead solder which flows more readily over copper. An exemption for lead in solders which are exposed to anaesthesia gases has been requested to avoid this problem but there may be alternative approaches to avoid corrosion and use lead-free solder:

- Use more aggressive fluxes and smaller pads to ensure complete solder flow over the entire pad;
- Use electroless nickel / immersion gold (ENIG) PCB coatings. These may be less susceptible to corrosion than copper but thorough corrosion tests would need to be carried out. As discussed in Section 8.1.7, corrosion phenomena cannot always be predicted;
- Use lead-free HASL coatings as lead-free solder does not appear to be susceptible to corrosion by these gases.

It is currently not possible to justify this exemption request as research is at an early stage and there is as yet no evidence that the potential alternatives such as those suggested here, are unsuitable. Further research is clearly required and manufacturers will need time to carry out this work. 5 to 6 years may be required as these are safety critical products and so, if Category 8 is included in the scope no earlier than 2012, this exemption should not be needed unless further unexpected test results are found. A temporary exemption should be permitted if Category 8 is included in the scope of RoHS before 2012 to allow time for this research.

10.10 Helium – cadmium lasers

These are used in various applications including Raman spectroscopy, fluorescence spectroscopy and analysis of biological materials. Helium – cadmium lasers have characteristic wavelengths of 325, 354 and 442 nm. The lower wavelengths are in the ultra-violet region which is not available from most other type of laser. Table 63 shows similar types of laser, some of which are also used for Raman spectroscopy, but note that most other types operate at higher wavelengths.

Table 63. Characteristics of lasers

Type of laser	Wavelength of output (nm)	Comments
Helium – cadmium	325, 354, 442	325 nm at 75 mW is possible
Helium – neon	Shortest is 594	Visible light only
Nitrogen laser	337	A common type of laser
Excimer	193, 248, 308, 353 depending on type	Ultraviolet lasers, used for surgery, etc.
Dye	Shortest wavelength is 390	Can be tuned by choice of dye
Cerium doped LiSrAlF	~280 to 316	Ultraviolet wavelengths but shorter than He-Cd
Semiconductor diode	Various but most >400	Research into ultraviolet diode lasers on-going

Raman spectroscopy uses various types of laser depending on the material that is being analysed. Raman spectrometer lasers range from 244 nm up to 800 nm. Helium-cadmium laser operating at 325 nm (in the UV light range) are used to examine a variety of biological materials and also for analysis of semiconductors. Most of the laser light that strikes the surface is reflected but some is converted into characteristic spectral lines that are used to identify the surface composition. The laser light can also cause an effect called fluorescence. This is a stronger emission of light over a broad wavelength range around the laser light frequency. Fluorescence is useful for semiconductor analysis but can be a problem if it hides weaker spectral emission lines. Shifting to a different laser frequency moves the characteristic spectrum but not the fluorescence frequency so that the spectrum can be revealed. Therefore Raman spectroscopy needs a range of different types of laser for analysis of a wide variety of materials and helium-cadmium lasers are particularly useful for semiconductor analysis for which a laser wavelength which is only a little higher or lower than 325 nm is much less useful.

No other laser available can produce light at 325 nm although there are some new commercial semiconductor laser diodes that approach this. Commercial semiconductor laser diodes are available at wavelengths down to 440 nm but the lowest research laser diode appears to be 375 nm. Research is on-going, however, to find laser diodes that operate in the ultraviolet region. These are being researched in the US for early detection of biological agents (from terrorist attacks). One technique being investigated is to "frequency double" laser light from a laser that operates at 650 nm. This gives light at 325 nm but is a research technique at present and is unlikely to be commercially available for many years[95].

Research into semiconductor laser diodes is at an early stage. Semiconductors based on aluminium gallium nitride p-n junctions have been developed at the University of South Carolina which can be designed to give light with wavelengths from 280 to 340 nm. This is emitted (non collimated and incoherent) light and not laser light and so is too weak for those applications which require helium – cadmium lasers. Novel UV semiconductor lasers are being developed by a US manufacturer but these operate from 360 to 375 nm so could not replace helium – cadmium[96].

Semiconductor laser diodes have several technical disadvantages over gas lasers such as helium – cadmium. Gas lasers produce light of a precise wavelength and this does not vary. The wavelength of light from diode lasers depends on the ambient temperature and is variable. This can be controlled but is a potential source of errors. Raman spectrometer manufacturers evaluate all types of lasers but have found that diode lasers are not sufficiently reliable for some applications and there are none suitable that operate in the UV region.

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[95] Tampere University of Technology website, http://tut.fi/optics/aoresearch/dlspektro/ .

[96] J. Carrano et al. "Ultraviolet light", Spie, OE magazine, p20, Jun 2003.

10.11 Lead and cadmium in superconducting electrical connections

Two related requests for exemptions have been received and reviewed:

10.11.1 Superconducting bonding for MRI magnets

Magnetic resonance imaging (MRI) equipment uses very powerful electromagnet coils as part of the medical imaging process. Nuclear magnetic resonance (NMR) spectroscopy uses essentially the same techniques for chemical analysis. The sensitivity increases with magnet power and manufacturers achieve this with minimal power consumption by the use of superconducting magnets.

Large magnet coils are made from niobium alloy wire which is superconducting at the boiling point of liquid helium (~4K or –269°C). Electrical connections are made to the coils using low melting temperature solder alloys which are also superconductors at ~ 4K. The alloy used by several manufacturers is "Woods" alloy which has the unusual property of melting in hot water (m.pt. = ~70°C). It contains both lead (25%) and cadmium (12.5%) and is used because it is a superconductor at 4K and remains so in the very strong magnetic field of the superconducting magnet coil. The superconducting magnet coil could be connected using lead/tin solders as these are also superconductors at 4K but Japanese research has shown that this superconductivity is lost in the presence of very powerful magnetic fields (this is a well known effect with conventional superconductors).

Lead/tin solders are suitable therefore in lower performance machines but the trend is towards increasingly powerful magnets as this gives improved diagnosis. There are cadmium-free (e.g. PbBi) and possibly also lead-free (e.g. using InSn) alloys which are superconductors at 4K but almost no research with these has yet been carried out for MRI applications and, as with all research, success cannot be guaranteed. It is very likely that they will not be suitable substitutes as their superconductive performance will be degraded in very high magnetic fields in the same way as tin/lead.

10.11.2 Superconducting bonds to SQUID sensors

Medical equipment has been developed for detecting the very weak signals produced by the brain, the heart or other organs. These use special SQUID (superconducting quantum interference device) sensors to detect extremely small signals. Machines designed to detect brain activity typically will have over 300 sensors located in an array that is used to map brain activity in three dimensions. SQUID sensors may also be used in specialist analytical equipment such as for measuring magnetic fields of minerals.

The sensors themselves are made on silicon wafers using semiconductor fabrication technology. Finished sensors are then mounted into neurological sensor arrays using lead tape bonds. The lead tape is connected by compression bonding to pads made of lead, indium and gold (lead as a superconductor, indium for ductility and good bonding and gold to prevent oxidation). The SQUID sensor array and associated lead bonds are then cooled to 4K with liquid helium where the sensor and lead bonds both become superconducting.

Lead is used for this application for several reasons:

- It is a superconductor at 4K, very few other metals are superconductors at and above this temperature;
- It is ductile and flexible and so not damaged during the cooling process. Introduction of boiling liquid helium is extremely turbulent and would damage any brittle materials;
- It forms a strong bond by cold welding to pads on SQUID sensors and to sensor array circuitry (for brain activity monitoring);
- Resistance to oxidation (niobium/tin can be cold welded but is brittle and readily oxidises);
- Soldering is used for bonding to SQUID sensors for heart monitoring (magnetocardiography) which has to be an alloy melting at ~200°C or less and be a superconductor at >4K. Only lead based solders have been found by researchers to exhibit both properties. Indium/tin may be suitable but has not yet been tested for this application although it has been used in Japanese research to make bonds to cryo-packages for Josephson junction devices[97].

10.11.3 Substitute superconducting materials for MRI and SQUID bonding

For bonding to SQUID sensors and bonding MRI and NMR magnets, a soft ductile metal is required which superconducts at 4K. The options available are given below:

Table 64. Superconducting and other properties of materials that might be used for MRI and SQUID sensor bonding

Metal	Critical temperature, T_c (K)*	Ductility, oxidation resistance
Niobium	9.46	Hard inflexible metal, readily oxidises
Lead	7.2	Ductile and flexible. Resistant to oxidation
Lanthanum	6.0	Hard inflexible metal, readily oxidises
Vanadium	5.38	Hard inflexible metal, readily oxidises
Tantalum	4.47	Hard inflexible metal, readily oxidises
Tin	3.72	Ductile and flexible. Resistant to oxidation but T_c too low
Aluminium	1.2	Ductile and flexible, resistant to oxidation and used for wire bonding ICs but T_c too low
Cadmium	0.56	Ductile and flexible. Resistant to oxidation but T_c too low but improves properties of Woods metal for MRI use
Gold	Not a superconductor at any temperature	
Indium tin (InSn) alloy	~ 6	Novel material which has not yet been evaluated

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[97] C. B. Burroughs et al., "Flexible Cryo-packages for Josephson Devices", IEEE Trans. on Applied Superconductivity, Vol. 15 (2), June 2005.

Metal	Critical temperature, T_c (K)*	Ductility, oxidation resistance
Lead Bismuth (PbBi) alloy	> 4	Novel material which has not yet been evaluated
Woods alloy	8.5	Superconducting in very powerful magnetic fields
Indium bismuth tin (InBiSn) (m.pt. 60C)	~ 6	Novel material which has not yet been evaluated

Note. 273.16 K = 0 °C. T_c = critical temperature at which it becomes a superconductor

The bonds to SQUID sensors are essentially wire bonds that are commonly used to make electrical connections to silicon chip circuitry in IC packages. Gold and aluminium are used for this application for ambient temperature connections but neither is a superconductor at 4K. All of the metallic elements that are superconductors at >4K are hard, brittle and readily oxidise except for lead.

Indium/tin and indium bismuth tin are low melting point solder alloys which have T_c > 4K. Their critical temperatures are in theory sufficiently high for use in cryogenic applications as a superconducting electrical connection although these are unlikely to be suitable in very powerful magnetic fields. These are new materials for these applications and to date have not been evaluated. A considerable amount of research will be needed to determine if they are suitable and if reliable equipment can be produced. This research is likely to take at least 10 years and may not be successful. Therefore at present no substitutes exist and none are likely to be available before at least 2016.

10.11.4 Lead as a thermal conductor at liquid helium temperatures

Closely related to lead used as a superconductor at liquid helium temperature, lead is also used as a thermal conductor at this temperature and in the same or similar equipment. Nuclear magnetic imaging and magnetic resonance imaging equipment use powerful superconducting magnets which are cooled to 4K in liquid helium. Refrigeration of the liquid helium is carried out within the instrument to minimise losses of helium which normally remains in the instrument throughout its life without significant losses. Lead is used as a heat sink in these products to cool the helium. Lead is chosen because, at these very low temperatures, most other metals become too brittle and so are easily damaged. Also, the thermal conductivity of lead at 4K is relatively high.

Possible suggested substitutes include: GdO_3, Er_3Ni and $HoCu_2$ but all are difficult to fabricate, are based on rare metals and will be difficult to recycle at end of life. Research is continuing into these and other potential substitutes but none are yet commercially viable.

10.12 Lead and cadmium in lamps for atomic absorption spectroscopy

Atomic absorption spectroscopy (AAS) is a well established analysis technique that is used to determine the concentrations of metals. This is widely used to analyse alloys, ceramics, plastics and other materials. The procedure used is to dissolve the test material in an acidic solution which is then sprayed into a hot flame.

The hollow cathode lamps used in AAS are vacuum tubes which contain the metal being analysed as a source of the appropriate radiation. Therefore, the lamp used to analyse lead, itself necessarily contains lead and likewise the cadmium analysis lamp contains cadmium. These are required so that light with the spectrum of the test metal, for example lead, only is produced. One strong line in the lead spectrum is chosen (one where any other metals present will not interfere) and this light passes through the flame where any vaporised lead will adsorb light of the wavelength chosen. The light that has passed through the flame is measured using a monochromated detector set at the correct wavelength. The intensity value is compared with intensity measurements obtained with test solutions containing the same metal (lead) at known concentrations. From this data the concentration of the test solution, and so also the original material can be calculated.

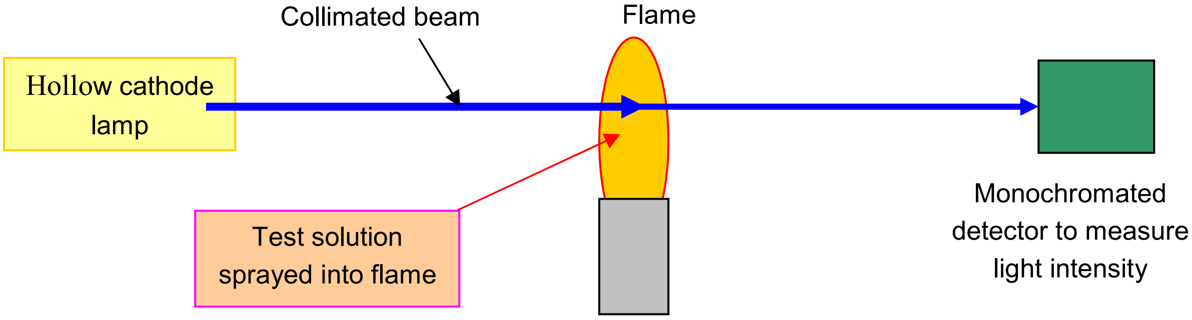

Figure 11. Atomic absorption spectroscopy

AAS is one of a small number of analytical techniques used to analyse metals. It has advantages and disadvantages over other methods but is the most accurate and reliable for certain materials. It is particularly useful for analysis of lead, cadmium and mercury.

The main alternative technique used to analyse metals in solution is called inductively coupled plasma (ICP) spectroscopy. In this method, the test solution is sprayed into a high temperature plasma. Light of a broad wavelength range is used so that many metals can be analysed simultaneously. This technique is particularly useful for metals with very high boiling temperatures as plasma has a much higher operating temperature than the flame. ICP is an emission technique and there are many more emission lines both from the element and from the matrix (other elements present) that can result in interference. AAS is a lower temperature absorptive technique and there are much fewer absorption lines available for any one element and a much lower risk of interference. AAS is therefore more suited to analysis of metals with lower boiling temperature such as cadmium, lead and mercury and which occur in complex mixtures with other materials.

This exemption request does not include mercury because Item 4 of the Appendix of the RoHS Directive includes an exemption for “mercury in other lamps…”. Lead and cadmium are essential in hollow cathode lamps for AAS analysis of lead and cadmium as there is no alternative available that produces light of only the required wavelengths. AAS as a technique cannot be replaced by alternative analytical techniques for accurate analysis of low concentrations of lead, cadmium and mercury where interfering impurities are in some samples also present. AAS is used for quality control, analysis of effluent solutions and analysis of environmental samples and so restricting lead, cadmium and mercury in this application would have a negative impact on the environment.

10.13 Hexavalent chromium in alkali dispensers for production of photocathodes

Photomultiplier tubes, image intensifiers (used in X-ray equipment) and several other devices are electrical components made of glass or metal which contain a vacuum and photocathode. The photocathode converts light into electrons which can then be amplified electrically. The photocathode is produced in-situ within the vacuum by a two step process. First a layer of antimony metal is evaporated onto the surface. The device is then sealed with a vacuum and containing a small device called an alkali dispenser. The alkali dispenser contains an alkali metal chromate and typically zirconium metal powder[98]. Chromate salts contain hexavalent chromium. The dispenser is electrically heated whereupon the zirconium reacts with the alkali chromate to release the alkali metal as a gas. Caesium chromate is commonly used and the reaction in the dispenser is:

$$\mathbf{4CsCrO_4 + 5Zr \rightarrow 2Cr_2O_3 + 5ZrO_2 + 8Cs\ (gas)}$$

The alkali metal gas reacts with the evaporated antimony film to form the photoconductive layer of CsSb. Photoconductor formation can be monitored by measuring the light sensitivity and alkali formation is stopped when this reaches a maximum value. At the end of this process, the alkali metal chromate may have all been consumed so that there is no hexavalent chromium in the final product (i.e. the reaction above has gone completely to the right). However, in practice, the reaction is stopped when the light sensitivity is at a maximum and some chromate remains in the alkali dispenser tube and so there is hexavalent chromium in the product that is put onto the market.

There are likely to be substitutes available for hexavalent chromium in this application although some manufacturers of medical equipment that use alkali dispensers were unaware of these developments.

- Japanese medical equipment manufacturers have not requested this exemption as they expect to have a substitute by 2012;
- Many photomultiplier tube manufacturers manufacture their own alkali dispensers and some are carrying out research into chromate-free substitutes. One UK manufacturer has stated that they are optimistic that they will have a substitute by 2010;
- At least one Austrian manufacturer, Alvatec Alkali Vacuum Technologies, advertises chromate-free vapour sources.

Therefore it appears that an exemption for hexavalent chromium in alkali dispensers will not be required beyond 2012 and possibly earlier.

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[98] Process originally patented by SAES Getters Spa, Italy GB 1,182,150.

10.14 Hexavalent chromium passivation

There is a detailed technical discussion of chromate passivation in Section 8.3. Several manufacturers have requested an exemption for hexavalent chromium passivation for Category 8 and 9 products and there has been one specific exemption request for hexavalent chromium coatings on metal parts of high sensitivity laboratory weighing instruments. These requests have been requested mainly because there is no long term field data for products that are used in conditions typical of Category 8 and 9 equipment and not because there is data that shows no substitutes exist. AeA has limited its request to equipment which operates at high frequency. All Category 8 and many Category 9 products need licensing or qualification if any design or materials changes are made and these require a certainty that the long-term performance of substitutes is satisfactory. Without field data, this is difficult to guarantee, but of course it is not possible to justify a request for an exemption without evidence that no substitutes exist.

Some types of Category 8 and 9 equipment rely on extremely sensitive electronics which will malfunction if not adequately protected for electromagnetic interference. This is one of the unique characteristics of Categories 8 and 9 that differentiate them from most if not all products in other Categories. Examples of particularly sensitive products are:

- Equipment which uses very sensitive SQUID detectors to detect minute electrical signals in the brain;
- X-ray detectors in X-ray imaging equipment;
- High speed analogue signal analysers which operate at very high frequencies.

Effective shielding is achieved using aluminium screens. Aluminium is an excellent electrical conductor but is susceptible to corrosion unless an effective inhibitor is used and hexavalent chromium passivation is usually used. For example, Alochrome 1000 is widely used in Europe which provides some corrosion protection but is very thin (<0.1µm) and so is easily penetrated to create a good electrical connection. Alochrome 1200 gives thicker coatings that are more effective corrosion inhibitors but has a higher electrical resistivity. One UK metal treatment sub-contractor has stated that 95% of electrical equipment uses the thinner Alochrome 1000 type of coatings[99].

An exemption would be justified if no suitable substitutes were available. However in this case, there is substantial evidence that substitutes are available commercially and that these give satisfactory performance although reliable independent test data is very limited (see Section 8.3). Lucent, however, has published a list of RoHS compliant substitutes that they will accept based on their own investigations with telecommunications network equipment and they will accept trivalent chromium

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[99] London Colney Anodising, personal communication

passivation coatings (called "plating" in this document)[100]. All Category 8 and 9 manufacturers who were consulted had not evaluated these substitutes yet and so there is no field or accelerated test data to evaluate these coatings under the very severe environmental conditions that some products are used. Since commencing this review, the Test and Measurement Coalition has initiated research into substitute coatings which is on-going but so far shows that some of the commercially available substitutes perform well.

There has been uncertainty within the electronics industry whether the thin transparent coatings (Alochrome 1000 type) contain hexavalent chromium at a concentration above the maximum concentration value (0.1 weight %). Research is being carried (for example by IEC [63]) to develop test procedures for thin passivation coatings but at present, only draft procedures are available. All industry test methods for coatings determine hexavalent chromium as "weight of Cr(VI) per unit area", not as concentration. It is also necessary to measure the coating weight (total coating weight per unit area) to calculate concentration but this is particularly difficult for very thin coatings.

ERA has carried out a series of tests on aluminium coupons treated with three types of passivation coating to determine if any hexavalent chromium can be detected using standard water extraction tests as proposed by the IEC using test procedure 59[63].

Table 65. Chemical analysis of passivation coatings on aluminium

Passivation treatment	Analysis result
Alochrome 100 (intended to give trivalent Cr only in coating)	CrVI not detected
Alochrome 1000 (hexavalent chromium treatment to give a thin transparent coating)	CrVI below detection limit in all test samples except where metal was treated for much longer than is normal
Alochrome 1200 (hexavalent chromium treatment to give a thicker yellow coating)	CrVI detected at 2.6μg/cm^2 in one sample

The problem with interpretation of a negative result is that this does not guarantee that no hexavalent chromium is present. Also this analytical method does not give results as concentration in the homogeneous material. Presumably, if hexavalent chromium cannot be detected, then legally this meets the requirements of the RoHS Directive.

It would be useful to compare the water extraction method with different techniques such as Raman spectroscopy or XPS. Tests carried out by the Test and Measurement Coalition on one type of coating gave the results in Table 66.

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[100] Lucent website http://scportal.lucent.com/pls/portal30/docs/FOLDER/DOC_CONTENTS/LUCENTSROHSRELIABILITYPOSITION/LUCENT+X-FREE+RELIABILITY+POSITION_0.PDF

Table 66. Comparison of Raman and XPS analysis of aluminium coatings

Sample	Raman analysis	Cr (VI) by XPS
5052 Aluminium with Alkalume treatment (similar to Alochrome 1200). Treated for 8 seconds to give a transparent coating	Hexavalent chromium not detected	1.44 atomic % = 19 wt % CrVI in coating
5052 Aluminium with Alkalume treatment (similar to Alochrome 1200). Treated for 120 seconds to give a yellow coloured coating	Significant concentration of hexavalent chromium detected	2.6 atomic % = 24 wt% CrVI in coating
Aluminium treated with Alocrom 1200, short treatment time to obtain thin coating. CrVI is readily detected by IEC test.	Not detected	~ 7 weight % CrVI in coating

Research by IBM using XPS confirms that chromate passivation coatings obtained with Alocrom 1200 contain significant concentrations of hexavalent chromium and that the concentration is similar in thick and thin coatings[101].

In conclusion, at present there is no technical data to support the need for an exemption for hexavalent chromium passivation coatings on Category 8 and 9 equipment. The situation with equipment that monitors or controls and is used as part of large-scale stationary industrial tools may be different as these environments can be more severe, but for the purposes of this study it has been assumed that products used in these circumstances are not in Category 9. Equipment used in very hostile equipments but which is not in Categories 8 and 9 is outside the scope of this review and so cannot been considered.

10.15 Cadmium pigments in ECG patient cables

Electro-cardiography (ECG) is a technique used to monitor the electrical behaviour of the heart. Colour coded cables are connected to specific locations on the patient and the colour codes used are standardised. Currently, polyamide cables are used with cadmium pigments used to obtain certain colours, in particular the red, orange, yellow and green. All of these colours can be obtained with cadmium-free pigments in alternative plastics but manufacturers have been unable to find cadmium-free substitutes based on the polyamide plastic insulation that has been used for ECG patient cables for many years. However, manufacturers have decided that they will develop substitutes which are expected to be available before 2012 and probably before 2010.

10.16 Flexible copper cadmium alloy wire (until 2012)

Copper cadmium wire is used in situations where an electrical connection is needed to parts of equipment that move. This wire has to be flexible and not fracture after many thousands of movements. Pure copper has excellent electrical conductivity but would fracture after repeated flexing. Copper cadmium is used because of its flex resistance, good electrical conductivity and tensile strength all of these characteristics are essential. There are now a few substitute alloys

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[101] IBM presentation. http://www.cstl.nist.gov/acd/RoHS/Presentations/Lau100605.pdf

available which could replace copper-cadmium. These have been developed by Fisk Alloys[102], based in the USA. The main substitutes are compared with copper cadmium in Table 67.

Table 67. Comparison of properties of flexible alloys

Alloy	Electrical conductivity %IACS	Tensile strength (hardened) MPa	Tensile strength (soft temper) MPa	Relative flex life (hard)	Relative flex life (soft)
Copper	100	414	221	2	2
Copper-cadmium C162	85	689	379	16	8
Copper-cadmium-chromium C18135	85	-	414	-	17
Percon 17	85	655	400	-	12
Percon 19	73	758	-	23	-
Percon 24	90	-	414	-	17

IACS = International annealed copper standard, metals conductivity in proportion to copper = 100%

The physical and electrical properties data indicate that there are cadmium-free substitutes. Medical device manufacturers will need to evaluate these as substitutes but expect that copper cadmium wire can be replaced by 2012.

10.17 Mercury in switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay

Mercury in switches, contacts, relays and thermostats has largely been phased out in most electrical equipment with big reductions in the quantity of mercury used as recently as 2004-5. New equipment is not designed with these switches unless research has shown that there are no substitutes and this would be very unusual and occur in very specific and limited applications. The few remaining position safety switches used in certain types of X-ray equipment will be phased out by 2012. One manufacturer and one distributor of mercury switches and relays and one user of mercury wetted relays have requested an exemption for these types of switches.

Fast and frequent switching of very high frequency circuits is very challenging and has traditionally been carried out with mercury wetted relays. In the past these contained several grams of mercury in each relay but the most advanced types now have as little as 10 mg per relay. The technical difficulty with switching very high frequency digital signals is that, when a mechanical switch closes, the metal contacts tend to bounce several times, unless the contact surface is mercury which is bounce-free. The “bounce” adds interfering “spikes” to the signal. Where very rapid and frequent switching is required, bounce is unacceptable. A second limitation of solid metal contacts, which are usually gold to give very low resistance is that it wears and eventually this results in an unacceptable increase in

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[102] E. S. Fisk, “Developments in Alloy Conductors”, Wire and Cable Technology International, Sep 2003.

contact resistance. The number of switch cycles before this occurs with gold contacts is typically 10^6 to 10^7 cycles but can be as high as 10^9 cycles with mercury wetted contacts as no wear occurs.

The main use of mercury wetted relays in the past was is in digital telecommunications but these have been largely phased out. Some are used in high frequency test instruments and in very high accuracy instruments which measure capacitance and loss.

Capacitance and loss measurement bridge

These are very high accuracy instruments made in very small numbers by a small US manufacturer and are used to calibrate standard capacitance and loss instruments. The equipment accuracy is achieved by the use of mercury wetted reed relays. This supplier also provides a reference standard which contains one mercury wetted reed relay and has sold about 10 bridges in EU per year over recent years and about half this number of standards. The total quantity of mercury in these products put onto the EU market per year is less than 2 g as each relay contains only 16 mg mercury. The manufacturer has carried out extensive trials with alternative non-mercury relays but all have much higher electrical resistance. The best alternatives use ruthenium switches. Ruthenium is a Nobel metal similar to platinum and a common high performance switch contact material. The performance of the instrument is limited by variations in resistance of the relays (not the actual resistance value). The variations in resistance measured by the applicant are:

- Mercury wetted reed relay	±1 milliohm (manufacturer quotes ±5 milliohms)
- Ruthenium relay	±30 milliohms

±30 milliohms is in fact very good and suitable for most applications but if these are used in these instruments, the accuracy would be degraded and they could not be used as reference standards or to calibrate other instruments. This manufacturer has not been able to identify a substitute and if mercury wetted reed relays in Category 9 equipment were not exempt, these products could not be modified to comply with RoHS and meet the technical specification and so could not be sold in Europe. This would have a negative impact on EU manufacturers who rely on these products.

Other mercury wetted reed relay applications

An EU distributor of mercury wetted reed relays has submitted a request for an exemption to the European Commission but states that these are used only in Category 9 products. Modern mercury wetted reed relays use much less mercury than previously and this can be as little as 10 mg per relay and a maximum of 20 mg. This distributor estimates that 215 g mercury was used in 2004 in this application in products sold in the EU although some of these may be outside the scope of Category 9. This distributor estimates that there were over 10,000 mercury wetted reed relay sales in 2004 but surprisingly, only two manufacturer has asked for an exemption for these components. This implies that manufacturers intend to substitute these for non-mercury alternatives and must have confidence that this will be possible. However technology is constantly developing with one of the main trends in Category 9 equipment is to use higher frequencies. Switching of very high frequencies is extremely demanding so that switch design and dimensions can have a significant influence over performance. High switching speed with zero bounce is essential.

New designs of mercury switch

California and other US States have banned the use of mercury in a wide range of products and this accounts for the current trend to replace mercury wetted reed relays wherever this is possible. The authorities in California review requests for exemptions for specific applications for mercury and has granted an exemption for a new mercury switch developed by Agilent Technologies. This has been granted due to its unique performance characteristics and because each contain 5mg or less of mercury.

The new Agilent switches

Agilent has produced an RF micromachined switch containing 5 or less mg of mercury. It has been called a Liquid Metal Micro-Switch (LiMMS). It operates by moving a small bead of mercury between two positions in a microchannel by means of heated gas in two small side chambers. The channels are formed in glass to a width of 0.15mm and a depth of 0.2mm.

As more information is transmitted by an increasing number of means of communications, a larger number of frequency bands are required. This is only achieved by moving to higher and higher frequencies as technologies are developed to be able to use them. In this way the bandwidth of all the equipment has to be increased. Equipment used to test high frequency telecommunications equipment must be capable of operating at frequencies up to ten times higher than transmission frequencies. One of the new applications which require a switch that is very fast with zero bounce and long reliable life is a device called a “bit error rate tester”. This is test equipment used for high frequency telecommunications testing and uses the Agilent LiMMS microswitch. Some satellite based communications systems operate in the 11 to 14 GHz region and are reported to be moving to 20 GHz. The current version of the switch can operate up to 18 GHz and the new version to 50GHz which will be needed in the near future.

RF switches require many other characteristics, including a low electrical resistance through the connections (contact resistance) to ensure minimum loss of signal and this switch is reported to have a resistance of less than 70 milliohm, which is a typical value for many types of contacts. High frequency signals behave differently from simple direct currents (DC) and changes in dimensions of materials can cause part of the signal to be reflected (and lost); this is referred to as the insertion loss. Insertion loss is quoted in decibels which should be as low as possible and the value for the LiMMS switch is better than 1 decibel (dB).

The speed of response of moving the mercury bead to actuate the switch (switching speed) is about 1 millisecond, which is faster than many other types of microswitches due to the small amount of material that is moved. The total life of about 10^9 switch cycles is also far higher than that obtainable from normal mechanical microswitches. There is also no contact bounce, which would introduce extraneous signals and other advantages over other types is that the power handling capability is high and the isolation between possible output circuits is high (high resistance when contacts are open).

Alternative switches and their characteristics

There are several alternative switches available which include field effect transistors (FETs), electromechanical switches, coaxial switches and standard RF MEMS switches. These clearly can replace mercury switches in certain applications but it may not be possible in all applications, particularly those which are the most demanding.

FETs are smaller and faster, but have higher leakage current, insertion loss, signal distortion, temperature variation and lower breakdown voltage. The breakdown voltage is the voltage at which the switch passes a current when it should be open. If the value is too low, the wrong parts of the circuit may become connected giving errors. Another disadvantage of FET switches is that they tend to introduce signal distortion as they act on the signal rather than just switching it. The way that these operate is that the signal passes through a semiconductor material which has a resistance that can be changed. Therefore there are no moving parts giving very high bandwidth and very long life but as the signal passes through a semiconductor, the “off” impedance is not high enough and distortion occurs when they are “on”.

Electromechanical switches have a high switching speed but lower bandwidth, isolation resistance, a shorter life due to wear of parts and inferior reliability. They are also a larger physical size which limits where they can be used.

Coaxial switches can be made with very precise dimensions as required for frequencies in the GHz range. At present they have greater bandwidth (40GHz) and isolation resistance than the micromachined switches but shorter life and lower reliability at higher switching speed. Switching time is longer and they are a much larger size.

Standard RF MEMS switches use small mechanical levers moved by electrostatic forces as miniature switches. They can be smaller and have higher switching speed than the new LiMMS micromachined switches, but the insertion loss, isolation resistance, reliability, hot switching, on-resistance stability and breakdown voltage are all inferior and so they are unsuitable for certain high performance applications. Hot switching is the ability to redirect a signal without first turning it off.

A detailed list of comparative data for the various types of switch are given in Table 68[103]. The LiMMS has the best or nearly the best performance for most of the parameters in the table and the data shows that these micromachined mercury switches have a unique combination of properties, which cannot be achieved by any of the other switches currently available.

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[103] Data provided by Agilent Technologies

Developments

The version in current production operates to 18GHZ and uses 1mg of mercury. A 50GHz version under development will use about 3-4mg. Less than 5mg will be required in any expected future development. The 50GHz version will have a higher bandwidth than any coaxial switch.

Trials on alternative materials

Mercury is the ideal choice because it wets other metals to provide good electrical contact but does not wet clean glass, plastics or ceramics, leaving a clean surface when it moves away and avoiding the possibility of leakage currents or short circuits. Other conducting liquids have been evaluated by the switch manufacturer but did not have the required properties including wetting to the contact materials but not wetting to glass, and stability of properties under temperature changes.

There are very few choices of metal that are liquid at ambient temperature. Pure gallium metal was evaluated early in the development, but it is molten only above 30°C, which would make it difficult to use. With gallium, the switch would have to be heated to ensure operation and this would consume additional energy. Also, the wetting by gallium to the contact metals is poor and would increase the contact resistance and shorten the life. Gallium tends to alloy with other metals and to wet glass and ceramics, giving the possibility of leakage currents or short circuits and so gallium is unsuitable. Gallium indium alloy is liquid at room temperature but wets all surfaces including glass and PTFE readily and so cannot be used for switching.

Potassium/sodium alloy is liquid at room temperature and although this does not wet glass, it is a very dangerous liquid which reacts violently with moisture and so would pose a very significant hazard during switch fabrication and use.

No suitable alternative liquids are known which have the unique combination of properties of mercury which are necessary combination for this class of high frequency switches.

Conclusions and Recommendations

Despite the relatively large number of mercury type switches used in Category 9 products, very few requests for exemptions have been received and this is undoubtedly because manufacturers are planning to change to mercury-free substitutes. There are however a small number of applications where only mercury-based switches meet all of the essential technical requirements, i.e. very high accuracy capacitance and loss measurement bridges which are used to calibrate lower accuracy instruments and test equipment used for very high RF frequency equipment, mainly used for telecommunications.

The total amount being used in the LiMMS switches is projected to be 50mg for 2006, 200mg for 2007 and 500mg thereafter, including that for use in later developments. The volume of mercury is not likely to increase dramatically. The State of California has assessed these switches and has allowed an exemption for this application. The quantity of mercury required for the very high accuracy capacitance bridge is only 2 g. A distributor of mercury wetted reed relays estimates that currently 215 g of mercury is used in Category 9 products but this is likely to decrease significantly as most equipment manufacturers are looking for substitutes.

The exemption should be restricted to limit the quantity of mercury used to only those applications where there is no substitute. Only one application for mercury wetted reed relays has been identified where no substitutes exist so presumably manufacturers can use substitutes for all other applications. Therefore the exemption need not cover other applications for mercury wetted reed relays unless these are brought to the attention of the European Commission and can be justified.

The LiMMS is a new product currently available from only one manufacturer and a very restrictive definition could prevent competitors making similar products which would have a negative impact on competitiveness.

ERA has considered ways to restrict this exemption as much as possible and two suggestions have been made. One is “MEMS” switches which can easily be verified. The capacitance and loss bridge and the applications for the MEMS switches will be products that are normally tested under European Standard EN61010-1, scope section 1.1 a).

A lower limit on frequency was considered but is probably impossible to enforce. This option was considered by the Californian authorities when considering the exemption to their legislation but was rejected. It would be advisable to require manufacturers to label mercury-containing relays and switches with the mercury symbol “Hg”. Two alternative wordings for this application have been suggested, the first being very restrictive and the second slightly broader but allowing other manufacturers to produce MEMS switches of different designs:-

Version 1 (Narrow but MEMS rf switches covered by patent)

Mercury wetted reed relays in very high accuracy capacitance and loss measurement bridges not exceeding 20 mg of mercury per relay and in high frequency MEMS RF switches and relays in monitoring and control instruments not exceeding 5 mg mercury per switch. All mercury switches and relays will be labelled with Hg to show the presence of mercury.

Version 2 (Broader allowing use of exemption by competitors)

Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay. All mercury switches and relays will be labelled with Hg to show the presence of mercury.

Table 68. Comparison of various types of switch

Parameter	FET switch	RF MEMS switch	Electro-mechanical switch	Coaxial switch	LiMMS
Bandwidth	50 GHz	20 GHz +	6 GHz	50 GHz	50 GHz (under development)
Insertion loss @ 18 GHz	1.5 dB	0.5 dB	Poor	0.4 dB	0.3 dB
Breakdown voltage	20 V	200 V	150 V	High	500 V
Power Handling Capability	0.5 W	10 mW	3 W	10 W	3 W
Signal Distortion	Poor	Very Good	Very Good	Very Good	Very Good
Temperature stability	Fair	Very Good	Very Good	Excellent	Very Good to Excellent
Size	1 mm^2	3 mm^2	60 mm^2	Very Large	50 mm^2
Isolation	25 to 40 dB	25 dB	Poor	80 dB	50 dB
Switching Time (settled)	10 µs	10 to 100 µs	200 µs	15 ms	1 to 3 ms
Lifetime (cycles)	1×10^{11}	1×10^8 to 1×10^9	1×10^5 to 1×10^8	5×10^6	1×10^8 to 1×10^9

10.18 Exemption requests for specific components

Two manufacturers have requested exemptions for specific components that are not currently available to them as RoHS compliant versions and their products cannot be re-designed to use alternative components. These components are:

High sensitivity military infra-red imaging modules – The infra-red detector may contain RoHS restricted substances, which is discussed in Section 10.1.2. The module in which these are supplied are constructed using lead-based solders. These are used primarily as a US military component and so the supplier is unable and unwilling at present to provide a version made using lead-free solders because the numbers of this specialist component used in non-military applications are too small for this to be economic. About 500 of these specialist products are sold in EU annually. Their military customers insist on lead solders being used. A non-military manufacturer (based in UK) uses these in very high accuracy infra-red imaging systems for process monitoring and for medical diagnosis. If they were forced to replace these with RoHS compliant detectors, these would be less accurate and unsuitable for the most advanced medical applications. An example of a medical application that requires these devices is imaging the circulatory system to diagnose damage caused by disease and an example of a process control application is detection of slag carry over on steel manufacture. A temporary exemption has been requested as it is likely that advances in infrared imaging detectors will progress and RoHS compliant versions with suitable accuracy will be available at some time in the future although it is not possible to predict when this will be.

LCoS - Liquid crystal on silicon (LCoS) displays are used in very small numbers in specialist medical equipment such as for tumour resection. RoHS compliant versions will be made and used in large numbers in the future in consumer electronics such as new front projection high definition TV but these are not currently available in the small numbers used for these medical products and so medical equipment manufacturers have to rely on specialist military equipment manufacturers. ERA attempted to contact the two main suppliers that medical equipment manufacturers have used in the recent past but no response was received from either. This is a difficult situation for the medical product manufacturer who wishes to make RoHS compliant products but is unable to buy RoHS compliant versions of this part. Also, due to several previous suppliers going out of business, they need to obtain sufficient parts to last many years. At present only non-RoHS compliant versions are available but manufacturers do not want to have to discard these to waste that remain when RoHS comes into force. The length of time this exemption is required is uncertain. One manufacturer claims that they need 10 years (until 2016) but the availability of RoHS compliant versions will depend to a large extent on the fledgling front projection high definition TV market.

10.18.1 Lead in solder for opto-coupler bar code reader for IVD instruments

Automated *in-vitro* diagnostics equipment uses miniature bar codes attached to test samples for identification. These are much smaller than the bar codes used on supermarket products so that standard barcode readers cannot be used. Manufacturers of the automated *in-vitro* diagnostics equipment have therefore developed their own novel bar code readers. One design utilises a diode laser and photodiode detector mounted in precise alignment for the laser light to reflect off the bar code surface to be detected by the diode. Precise alignment is essential as even micron size misalignment will cause errors in reading bar codes which could have serious consequences. The mounting medium has to be a plastic which is suitable for moulding to achieve the exact dimensions required, be optically transparent to the laser light and not be distorted when the part is soldered in place. Currently manufacturers use polyethersulphone plastics which meet all of the essential requirements. This has a glass transition temperature (T_g) of 225°C and so is not distorted by soldering with tin/lead. At temperatures above T_g, plastics become soft so that distortion is likely. Usually, this is unimportant but it is critical in this case as distortions of as little as a few micron could cause errors. Tin/lead soldering is carried out typically at 210 - 220°C which is below T_g but the melting temperature of all of the standard lead-free solders are higher that tin/lead and a typical soldering temperature for tin/silver/copper would be 240 – 260°C which is well above T_g and so distortion is not surprising. Possible substitutes have been considered:

Higher T_g plastic – from a search of the literature, the only plastic with higher T_g and optical transparency is polyimide which has a T_g of ~240°C. There are a few recent patents describing optically transparent polyimide but these do not appear to be available commercially as polyimide is usually yellow-brown in colour.

Low melting temperature solder – As discussed in Section 8.1, a few lower melting point solders are available. Tin/zinc alloys are susceptible to corrosion and, as *in-vitro* diagnostics instruments are frequently exposed to corrosive fluids, would not be suitable. Tin-bismuth and indium alloys have not been extensively testing and so long term reliability would be in doubt. A risk to reliability therefore exists with this option.

Alternative design – one competitor to the applicant uses a different patented design so would not need this exemption. However, as this is patented by a competitor, this technology would not be available to manufacturers who use the opto-coupler bar code reader. However an alternative technology is being researched for this application. This uses RFID identification on samples instead of bar codes and avoids the need for the bar code reader. This is the preferred longer-term option for users and so manufacturers aim to replace their opto-couplers with RFID readers which can be attached to circuitry using lead-free solders. Research to develop alternative designs, validate and test for reliability and obtain approval from a Notified Body is expected to take about six years. Therefore, if Category 8 is included in the scope of RoHS in 2012, this exemption should not be required and if *in-vitro* diagnostics equipment is included in the scope of RoHS from 2016, certainly will not be required.

10.19 Cadmium in total residual chlorine monitors

Total residual chlorine monitors are used to monitor the concentrations of dissolved chlorine in water. Chlorine is toxic but used for water disinfection and in a variety of manufacturing processes such as bleaching of paper. Water authorities set very low limits on the concentration of chlorine in waste water because of its toxicity and so emissions need to be monitored. The measurement process is not able to distinguish between chlorine and iodine and to differentiate between these, iodine has to be removed prior to analysis and this is carried out by passing the test sample through a column containing cadmium which chemically bonds to the iodine. Each column contains about 6g of cadmium but these are consumables and have to be periodically replaced.

The European Commission's FAQ guidance states that consumables are outside the scope of the RoHS Directive, so there is no need for an exemption for this application.

Manufacturers have stated that zinc is likely to be suitable as a substitute and, although research is continuing, they anticipate being able to replace cadmium from 2010.

10.20 Mercury for calibration of environmental mercury monitors

Environmental mercury monitors are used to detect and monitor very low concentrations of mercury in the atmosphere. These instruments are very sensitive and need to be calibrated on a regular basis to ensure that accurate data is produced. This can only be done by passing gas with a very precisely controlled concentration of mercury into the monitor which is then adjusted to give the correct concentration reading. The mercury vapour used for calibration is produced by an electrical product which is attached to the monitor. The mercury is retained in a ceramic container which may remain in the product for its entire life or is replaced when the mercury has been consumed, in a similar way to ink jet cartridges.

In this application, the mercury is a consumable and the European Commission's FAQ guidance states that consumables are outside the scope of the RoHS Directive so there is no need for an exemption for this application and manufacturers are free to continue to use mercury as calibration materials. There would be no possible substitutes for mercury in this application

10.21 General exemption requests

Manufacturers have requested the following exemptions:

i. Pb, Cd and CrVI used in medical devices within the scope of Directives 90/385/EEC and classes IIb and III of 93/42/EEC;

ii. Lead solder used in Category 8 and 9 products that are critical to safety and reliability of the end users applications;

iii. Pb, Cd and CrVI used in medical devices with super-cooled parts or modules (already discussed);

iv. Sensors, detectors and electrodes (exemptions for these already discussed);

v. Safety critical equipment;

vi. Life time buy components;

vii. An exemption to allow innovation.

Items i, ii and v are mainly concerned with the long term reliability of lead-free solders. An option would be to include a temporary exemption for lead in solders in these Categories until doubts over their reliability are resolved as discussed in Section 10.21.1. Alternatively, inclusion of these Categories could be delayed until this time. It should be noted that the reasons for the exemption for lead in solders in servers, storage, storage arrays and telecommunications network infrastructure is two-fold. Firstly, these are safety critical products but the majority do not experience severe environments (although some telecom products do). Secondly, some products include very large complex PCBs that are very difficult to produce and many of their manufacturers could not meet the July 2006 deadline and so requested more time. The main issue for some Category 8 equipment is PCB complexity (CT scanners, ultrasound imaging, PET, etc.) as most are not subject to environmental stresses but for Category 9 the main concern is very severe environmental stresses although some equipment, particularly the very high frequency products, use very large and complex PCBs.

Item iii has been discussed in Section 10.11 for superconducting materials but CrVI was also requested as this is used to prevent corrosion of shielding to protect very sensitive SQUID sensors. If, however, good and effective substitutes for hexavalent chromium exist, then the exemption for lead and cadmium as superconducting materials should be sufficient.

Item iv (sensors, detectors and electrodes has) already been discussed as several separate exemptions. Combining all of these into one inclusive exemption would significantly reduce the number of exemptions required for Categories 8 and 9 and give some limited flexibility which will allow innovation in this area. This is discussed in more detail in Section 13.4 of “Conclusions”.

10.21.1 Temporary exemption for lead in solders

The main concern of manufacturers of Category 8 and 9 equipment is with the reliability of products made using lead-free solders. It is clear that many manufacturers are already developing products within these Categories using lead-free solders and many plan to introduce new models that will comply with RoHS from late 2006 onwards (but most would not change existing models). Some who have carried out comprehensive testing believe that these lead-free products will be reliable and that they have solved all technical problems. Others are still carrying out trials and have technical problems that are not yet resolved. Some have stated that in their opinions, those manufacturers who are planning to introduce RoHS compliant Category 8 and 9 products in the near future are taking a risk as they do not believe that the long reliability of lead-free technology has yet been proven. The opinions of manufacturers would reflect the environments in which their products are used. Equipment used in conditions with minimal temperature fluctuations is unlikely to suffer from thermal fatigue whereas portable test equipment can be exposed regularly to large temperature fluctuations.

The technical issues with lead-free soldering technology have been thoroughly investigated as this is a fundamental aspect of this review but it is currently not possible to give a 100% guarantee that lead-free solders are always safe to use. Evidence indicates that they probably are reliable but without field data, it is impossible to be certain. Unexpected behaviour with novel materials does occur as illustrated by the unexpected corrosion discussed in section 8.1.7.

One possibility is to include Categories 8 and 9 in the scope of RoHS but with a temporary exemption for lead in solders. This exemption could be linked to the existing exemption for **"lead in solders for servers, storage, storage arrays and telecommunications networks"**. This exemption is planned to be reviewed in 2010 (four years after RoHS comes into force) and at this time there will be much more field data available to enable a more informed decision on the reliability of lead-free solders to be made. Currently there is insufficient field data to confirm field life predictions based on accelerated tests. If at this time (in 2010-2011) it is concluded that lead-free solders are reliable, then this exemption can be terminated so that servers, storage, storage arrays, telecommunications networks **and** Categories 8 and 9 equipment can be made using lead-free solders from a specified future date with the certain knowledge that unexpected failures are no more likely than they are with tin/lead solder.

10.21.2 Life time buy components

This has been discussed earlier in this report (page 32 (l)). Category 8 and 9 manufacturers utilise life time buys more often than manufacturers in other sectors of the electronics industry. Older component types that are purchased as life time buys are usually not RoHS compatible, often due to very small amounts of lead in the termination coatings. The European Commission is currently reviewing a request for exemption for "life time buy components" and, at the time of writing this report, the outcome is not known.

The main difficulty that Category 8 and 9 manufacturers will have changing existing equipment to comply with RoHS is the need to redesign products that utilise components that are not available as RoHS compliant versions and, as discussed earlier, most could not be redesigned economically and so could no longer be sold in Europe. This would not be necessary if non-RoHS compliant components could legally be used. Due to the relatively small numbers of Category 8 and 9 products of each model that are produced and the high cost of redesign (these issues are discussed elsewhere in this report), not being able to use life-time-buy components would result in products being withdrawn from the EU market and this will affect users (see Section 9.6). However, the majority of manufacturers would prefer not to use life-time buy components (these deteriorate in storage and eventually become unusable) and so would rather have sufficient time to make all necessary changes than rely on this as an exemption.

10.21.3 Portable defibrillators

Portable defibrillators are carried in emergency vehicles and then to patients by paramedics and it is normal practice in emergency situations to drop these on arrival. Measurements by manufacturers show that during transportation, g-forces of 40 g_{rms} are not unusual and when dropped can be 150 g_{rms}. These forces are unusually large but not unrealistic. JGPP research[37] indicates that these forces will be sufficient to cause solder joints to fail prematurely. Results from this research clearly indicate that there is a high risk that this will occur and this would be likely to prevent paramedics from resuscitating heart attack patients resulting in loss of life. It would therefore seem sensible to exclude portable emergency defibrillators that are carried in emergency vehicles from the scope of the RoHS Directive or at least allow the continued use of tin/lead solders.

Defibrillators used only within hospitals are not subjected to these stresses and so do not need to be similarly excluded or exempted.

Lead in solders used in Category 8 and 9 equipment that is carried in emergency vehicles and used in field emergency situations may need to be excluded for this reason although the only equipment highlighted by manufacturers as having a high risk of failures is portable defibrillators.

10.21.4 Exemptions or exclusions to allow innovation

This has been discussed in Section 9.5 and the issues will not be repeated here. Options for overcoming this problem are limited. Apart from excluding Categories 8 and 9 from RoHS or accelerating the exemption review procedure to less than one month, the only other option is to allow broad exemptions or exclusions (effectively exemptions with no time limit) that hopefully will include all of those areas where new innovations might occur that might require a RoHS substance. Of course it is impossible to predict what will be discovered in the future so this option has its limitations.

It currently seems unlikely that innovative discoveries relying on hexavalent chromium, PBB or PBDE will occur.

An innovation exemption need be for only Categories 8 and 9 products.

One area where this study indicates innovations will occur that rely on lead, mercury or cadmium is in sensors, detectors and electrodes. ERA proposes a single, broad exclusion :-

"Lead, mercury and cadmium in sensors, detectors and electrodes used in Category 8 and 9 equipment."

This would allow innovations in this area and combine at least six current exemption requests into one, all of which appear to be justified except the request for an exemption for Calomel electrodes. The amount of mercury used in Calomel electrodes is relatively small and decreasing as most manufacturers have already changed to mercury-free substitutes (which are technically superior) and use these only as spare parts.

It is impossible to predict innovations in other areas and although possibilities include radiation sources, and components in endoscopy capsules; all eventualities cannot be predicted.

11. Other issues

Various other issues have been identified which should be considered before introducing an amendment to the RoHS Directive. The current version of the RoHS Directive is unclear in several areas and an amendment to include Categories 8 and 9 within its scope presents an opportunity to clarify these points. Issues regarding scope are discussed in Section 4 and should also be considered under any revision of the Directive.

11.1 Legal basis

The RoHS Directive is an Article 95 Directive. As such, products within its scope sold in EU must comply with the same legislation in all 25 Member States to ensure that barriers to trade do not exist. Almost all types of Category 8 and 9 product sold in Europe are identical in all EU States; it would be impractical to make slightly different versions to comply with variations in Member State legislation that would occur if RoHS were not Article 95. Most types of Category 8 and 9 products are produced in relatively small numbers so having different versions in each Member State would be more difficult to achieve than for products in other Categories such as most household and consumer products.

Variations in national legislation can arise between Member States as a result of different interpretations of imprecise requirements. Definitions of terms may be interpreted differently to that which was originally intended and interpretations may differ between Member States if these are not clearly defined within the Directive. The definition of "put onto the market" has been interpreted differently by some Member States – see Section 11.2). The published definition adopted for "Large-scale stationary industrial tools" is broadly agreed by all Member States but there are some differences in interpretation. Determining which "fixed installations" are outside the scope of RoHS is far from clear with many differing interpretations being adopted by Member States.

11.2 Put onto the market

RoHS is a single market Directive which should ensure the free movement of goods between EU Member States. The definition of "put onto the market" should reflect this. The EC has advised that the definition of "put onto the market" should be based on the "Guide to Implementation of Directives based on the New Approach and the Global Approach"[104]. For RoHS, this implies that once a product is put onto the market in one Member State, it is viewed as being on the market in all EU States.

For example, if a new product is produced and put onto the market in one EU State before the date that RoHS comes into force, it does not need to comply with RoHS regardless of when it is sold. If, after the RoHS deadline, this product is transported from the first EU State into a second EU State, because of the single market principle, it can be sold legally in the second State.

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[104] Guide available at http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf

National RoHS legislation should reflect the single market principle but the wording used by some States is either unclear on this point or appears to interpret the market as their national market. The European Commission is currently checking conformity of the notified measures by Member States.

The single market principle is important because a significant proportion of Category 8 and 9 products are sold a long time after manufacture. It is common for products in these two Categories to be produced in the EU or imported into the EU and stored at one location for many months or several years in some cases before sale. These are often shipped to customers in other States when an order is placed. It is important for the free movement of Category 8 and 9 products that the EC's single market interpretation applies in every Member State.

11.3 Article 2.1 of the WEEE Directive

Article 2.1 of the WEEE Directive excludes equipment that is part of another type of equipment that is outside the scope of the WEEE Directive. This is clear but this statement is not included in Article 2 "Scope" of the RoHS Directive. The EC's legal services have stated that, in their opinion, this does also apply to RoHS - so the scope of both the WEEE and RoHS Directives are similar. Some manufacturers are unhappy with this legal uncertainty, which they believe places them in the position that their products could unknowingly be illegal and also might create inequalities in the EU market as this situation could be interpreted differently by Member States. This issue could be resolved by a simple revision to the RoHS Directive.

11.4 Spare parts

This has already been discussed in section 4.2. There are three issues that need to be addressed:

- Article 2.3 of the RoHS Directive will need to be amended if Categories 8 and 9 are included in the scope of RoHS to take into account the date from which these products are required to comply which is different to the date for Categories 1 to 7 and 10;

- RoHS does not define "spare parts". This could create differences in interpretation and inequalities in the EU market. Guidance for the EMC Directive however does include a useful definition[7].

- The wording of the current spare parts exclusion needs to be changed to account for temporary exemptions. An example will illustrate the issue; lead in solder in servers is currently exempt and so a server put onto the market in 2008 may use lead solders. It is normal to manufacture spare parts at the same time as the equipment using the same materials – this is essential as many of the components will 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 Article 2.3 only allows the use of spare parts for the repair of equipment put onto the market before 1st July 2006. This is not the intention of this Directive as the use of spare parts extends the life of equipment and so should be encouraged.

12. Discussion of options

After reviewing the RoHS Directive and determining whether it is possible to include Categories 8 and 9, there are several options that could be followed.:

Option 1: Continue to exclude Categories 8 and 9 and carry out another review in 2010 or 2012.

Option 2: Continue to exclude Categories 8 and 9 but encourage eco-design.

Option 3: Include Category 8 and 9 products within the scope of RoHS:

a. from a single specified date but with a list of justified exemptions and exceptions; or

b. from a number of different specified dates depending on the type of equipment but with a list of justified exemptions and exceptions.

12.1 Option 1: Continue to exclude Categories 8 and 9 from the scope of RoHS

The advantages and disadvantages of continued excluding Categories 8 and 9 from the scope of RoHS are summarized in Table 69.

Table 69. Advantages and disadvantages of continued exclusion of Categories 8 and 9 from the scope of RoHS

Advantages	Disadvantages
No need to amend the Directive or national regulations.	Missed opportunity to clarify aspects of Directive where there is confusion over requirements and differences in interpretation although this could be carried out without inclusion of these Categories.
No additional resources required to enforce RoHS regulations.	Most Category 8 and 9 manufacturers are working towards RoHS compliance. Exclusion of Categories 8 and 9 from the scope of RoHS would permit the minority of manufacturers who decide not to exclude the RoHS substances to continue to use these. This might be considered unfair those who have already taken steps to comply with the Directive.
The quantities of Category 8 and 9 equipment are relatively small, ~ 1% of all WEEE. Therefore inclusion of Categories 8 and 9 in the scope of RoHS would have a very small impact on the environment, particularly as many justified exemptions would be required and most manufacturers plan to modify their products to exclude the RoHS substances.	It is probable that countries outside EU will introduce RoHS-like legislation which will include products in these Categories. Japan and China may be the first but others will follow.

Advantages	Disadvantages
The use of the six RoHS restricted substances is already decreasing in Category 8 and 9 products. The reduction in the quantities of RoHS restricted substances in Category 8 and 9 products that would occur as a direct result of inclusion of these in the scope of RoHS would be relatively small if the reductions in use that are occurring anyway and the need for exemptions are taken into account.	The majority of manufacturers believe that these Categories should be included in the scope of RoHS - although after sufficient time to make changes to products.

12.2 Option 2: Continue to exclude Categories 8 and 9 from RoHS but encourage eco-design

Medical devices are manufactured to a compulsory international standard IEC 60601. Products must comply with this standard in order to have a CE label to show compliance with Medical Device Directives. The medical industry is currently working on IEC 60601-9-1 which will require manufacturers to consider eco-design as one of the criteria when developing new products. This would encourage the use of alternatives to hazardous substances where possible but without the need to request exemptions when no substitutes are available. This approach is consistent with the Eco-design of Energy using Products (EuP) Directive and in some respects is more beneficial to the environment than RoHS because the whole life cycle of products is considered. IEC 60601-1-9 would achieve most of the aims of RoHS as well as EuP but without risk to safety due to doubts over reliability, the need to consider exemptions, loss of product diversity or a negative impact on innovation. This standard differs from the approach used for granting exemptions to the RoHS Directive as it permits manufacturers to consider excessive cost as a criterion for design whereas exemptions to RoHS cannot be granted by the European Commission on this basis.

There is no equivalent standard for Category 9 although many Category 9 manufacturers are currently working towards RoHS compliance where possible. However, an implementing measure under the EuP Directive for measurement and control instruments (for those that are produced in relatively large numbers) could be introduced. Such a measure would need to be subject to a study and meet the prescribed eligibility criteria. However some EU Member States do not believe that this approach would achieve the same reductions in use of restricted substances nor would it be possible to enforce.

12.3 Option 3: Include Category 8 and 9 products within the scope of RoHS

An amendment to the RoHS Directive could be published including Category 8 and 9 products with an enforcement date which takes into account the time that Category 8 and 9 manufacturers will require to fully comply without harm to EU industry, health, safety or the environment.

The enforcement date could be

a) a single date covering all of Categories 8 and 9 or

b) several dates chosen to reflect the time required to comply for different sectors as have been discussed in Section 9.3.

Whichever of these options is chosen it will be necessary to allow certain justified exemptions and exceptions.

It will be easier for some sectors to change their entire range of products to RoHS compliant versions than others as summarised below:

- **Active implanted medical devices (in scope of 90/387/EEC)** – High reliability is essential for these safety critical products. It may not be possible to comply with Directive 90/387/EC until some time after lead-free solder reliability can be guaranteed to allow prototype development, testing and licensing. It is not known when this will be feasible and AIMD manufacturers have indicated that they could not develop RoHS compliant products until there is a guarantee of reliability so request a date of 2020 allowing five years after 2015 on the basis that by 2015, the long term reliability of lead-free solders will be known with certainty. This timescale would include time for development, testing and clinical trials and AIMD licence application. AIMD are currently excluded from WEEE, most could not be recycled at end of life anyway and account for a relatively small quantity of equipment and so it may be appropriate to permanently exclude this type of equipment.

- **In-vitro diagnostic medical devices (in scope of 98/79/EC)** –This is discussed in Section 9.3.2. Most products could either be modified or replaced by new products by 2016 but product diversity would be lost if the implementation date is much earlier than this.

- **Other medical devices (in scope of 93/42/EEC and a few other products)** – Typical product life for medical devices is 5 to 10 years and most medical device manufacturers are already carrying out development work to produce RoHS compliant products. Manufacturers in this sector have stated that 2012 is a reasonable date for implementation although a later date would be preferred for the more safety critical products in class IIB and III of Directive 93/42/EEC (see Section 10.24). Class IIB and III account for a small proportion of all electrical equipment in Category 8 which are the most safety critical and some utilise ionising radiation. However, when the reliability of lead-free solders is fully understood, there would be no need to differentiate these classes. As discussed in Section 9.3.1, 2012 allows the most complex products to be modified, re-tested and authorised and avoids the need for at least seven additional exemptions.

- **Consumer type monitoring and control instruments** – These have shorter lives and product designs are changed more frequently than industrial equipment. It is always easier to design new RoHS compliant products than try to adapt existing designs. It also allows technical staff to concentrate on new product development rather than changing existing designs with the risk of losing technical advantages over competitors. Manufacturers are already working on RoHS compliance with a few already having compliant prototypes. Most existing designs will have been phased out by 2010 so that predominantly new products will be manufactured after this date. Therefore it should be relatively straightforward for this sector to comply by 2012 and many could comply earlier.

- **Analytical instruments** – most manufacturers of analytical instruments have said that they could convert their product range to comply with RoHS by 2012. This will involve a great deal of work as it is not unusual for one manufacturer to have several thousand different products. However, the circuitry is in general not unusually complex.

- **Industrial monitoring and control instruments** – This sector consists of many small and a few large manufacturers each having a large range of products and designs many of which are sold unchanged for 10 to 30 years. Many are complex, high specification instruments which utilise high frequencies which are considerably more difficult and time consuming to modify than lower frequency equipment. Skilled technical staff capable of adapting existing products to comply with RoHS are limited in number and so it will take a considerable length of time to adapt, test and obtain approvals for all of the products in this sector. It is likely that in some cases, it will take longer to change all current designs (if this were possible) to comply with RoHS than the expected lives of these products. If the implementation date were to be 2012, then sales in EU of a large proportion of these types of products would have to be discontinued, as there would not be time or resources available to change them all. The number of products that would have to be discontinued early would be much smaller if the implementation date were 2018. This is discussed in Section 9.3.6 but one problem will be clearly defining products in this sector. Category 9 equipment intended for professional use would be too broad, as this would include many products (lower accuracy multimeters, digital thermometers, etc.) that could easily be modified earlier. A clear definition of products within this sector would be essential to avoid distortions of the EU market. One suggestion for a definition is to utilise the definition used in the EN Standard for the Low Voltage Directive:

  EN 61010-1 a) "Electrical Test and Measurement Equipment". *"Products intended for use in industry that would normally be within the scope of European Standard EN61010-1 section 1.1 (a)".*

> This definition excludes consumer products, thermostats, laboratory instruments, household electric meters, consumer type weighing equipment and equipment used in buildings but will include some lower specification test instruments such as multimeters which may be used by consumers as well as professionals. This definition would include all of those high performance Category 9 products which require a longer time period for compliance but will inevitably include some products that can be converted to comply with RoHS by 2012.

Category 8 and 9 manufacturers are already looking for substitute materials for the six RoHS restricted substances but the total time required for some types of products, due to complexity or safety criticality, will be longer than the time that has been allowed for Categories 1 – 7 and 10 because additional testing, validation, trials and approvals are required by other EU Directives and standards.

13. Conclusions

Article 6 of the RoHS Directive implies that the original intent was to bring Categories 8 and 9 within its scope.

13.1 Potential benefits of inclusion of Categories 8 and 9 in scope of RoHS

Although there is no scientific evidence that the use of the six RoHS-restricted substances specifically in Category 8 and 9 products has a negative impact on human health or the environment, the RoHS Directive was introduced to restrict the use of certain hazardous substances on the basis of the precautionary principle. No full life cycle assessments have yet been carried out although a life cycle analysis to compare tin/lead solders with lead-free solders has been published by the US EPA[105] and one for PVC stabilisers is underway but will not be complete until 2007[106]. However the six RoHS restricted substances are known to be hazardous substances and it is good eco-design practice to use safer substitutes wherever possible and many manufacturers are already doing this.

Legislation does however tend to encourage these trends. The recent large decrease in mercury use in EU is as a direct result of US State legislation. Frequently the use of non-toxic substitutes is no more costly than their hazardous counterparts and overall their use can be at a lower cost. For example, non-mercury switches cost less than mercury switches. End of life costs are reduced if hazardous materials are not present although the scope for this benefit is limited as many exemptions are justified and so these materials will be present although at lower concentrations. Overall, however, there will be an overall cost, at least initially, as a result of inclusion of equipment in the scope of the RoHS Directive[107].

Categories 8 and 9 should not be included in the scope of RoHS if there is an increased risk to human health, consumer safety or the environment; these risks have been fully investigated in this review.

13.2 Main conclusions

1. It will be possible to include Categories 8 and 9 within the scope of Directive 2002/95/EC although many additional exemptions will be required (discussed in Section 13.4) but only after manufacturers have been given sufficient time to carry out research, find alternative components and re-design products, validation and reliability testing and obtain approvals to comply with other legislation and industry requirements. The majority of manufacturers consulted expect that these two Categories will be included in the scope of RoHS and many are working towards RoHS compliance voluntarily although it is possible that some would stop if it were announced that these Categories would not be included. Many manufacturers

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[105] US Environmental Protection Agency website http://www.epa.gov/dfe/pubs/solder/lca/index.htm

[106] US Environmental Protection Agency website http://www.epa.gov/dfe/pubs/wire-cable/wirecable-factsheet.pdf

[107] Regulatory Impact Assessment for the UK RoHS Regulations. UK Department of Trade and Industry.

would prefer these Categories to be included in the scope to avoid unfair competition from free-riders but they all say that they would require sufficient time to make changes.

2. The quantity of Category 8 equipment sold in the EU estimated from data obtained from two State WEEE compliance schemes and from manufacturers' trade associations is in good agreement. Data from a third State gave a somewhat higher estimate. The quantity of Category 8 equipment sold in EU annually is estimated to be 30,000 tonnes.

3. The quantity of Category 9 equipment sold in the EU has been much more difficult to estimate. No data is available from EU Member States and very little from manufacturers. Manufacturers have difficulty estimating the quantity of equipment within Category 9 because the scope of this Category is not clear as different EU Member States offer differing opinions on individual products. The European Commission and some trade associations have provided guidance but this is inconsistent and interpretation is not straightforward. The data that has been provided is based on manufacturers' own interpretation of scope. Other data has been extrapolated from EU and UK Government Statistics but inevitably the final total will not be very accurate. However, the total quantity of equipment in Category 9 sold in EU annually is estimated to be about 30,000 tonnes - similar to the quantity of medical equipment. This total excludes equipment that manufacturers believe is outside the scope of RoHS as these products are part of fixed installations or part of large-scale stationary industrial tools. If these products are included, the total could be about 60,000 which is estimated from research published by ICER[9].

4. The scope of Categories 8 and 9 has been reviewed. Most difficulties are experienced with Category 9 for several reasons. It is not always clear if a product "monitors" or "controls" as these terms are not defined by the WEEE or RoHS Directives. Much "control" equipment is used as part of large-scale stationary industrial tools and so manufacturers have assumed that these are outside scope. The status of some types of laboratory equipment is very unclear. Confusion over scope could be a significant barrier to the free movement of goods through the EU if equipment is considered differently in some Member States to others. RoHS falls under Article 95 of the European Treaty and so individual products should have the same status in all EU States. Inclusion of definitions within the Directive itself has the advantage that this is legally binding and will promote harmonisation unlike guidance from the European Commission or from Member States.

5. The quantities of the six RoHS substances have been determined and listed in Table 70

Table 70. Total quantities of RoHS restricted substances in Category 8 and 9 equipment sold annually in EU

Substance	Category 8	Category 9	Category 8 + 9
Lead	1160 tonnes	>120 tonnes	1414 tonnes
Cadmium	1.8 tonnes	0.44 tonnes	2.24 tonnes
Mercury	~ 20 kg	~ 10 kg	~ 30 kg
Hexavalent chromium	-	-	0.3 – 0.8 tonnes
PBB and PBDE	-	-	~ 8 tonnes

More than half of the lead is used as shielding for ionising radiation for which there is no suitable substitute in many situations.

Most of the cadmium is used in radiation detectors for which no substitutes currently exist.

Most hexavalent chromium is used in passivation coatings where suitable substitutes do appear to exist

The estimated total for mercury may be low although the quantity used in Category 8 and 9 equipment within the EU has decreased very significantly since 2004 due to US legislation. The largest thermostat manufacturer in the world has replaced almost all of their mercury-based thermostats with mercury-free types in this time[108].

Manufacturers do not intentionally use PBB or PBDE as they specify plastics according to their flame retardancy specification and currently there is no data available for PBB, penta-BDE or octa-BDE. It has been estimated that less than 10 tonnes PBDE is used in Category 8 and 9 equipment and most of this is deca-BDE which is currently exempted from the RoHS Directive.

6. Manufacturers of equipment in Categories 1 – 7 and 10 had, in theory, 3½ years from the date of publication of Directive 2002/95/EC to the date it came into force. Manufacturers of the simplest products (made using hand soldering only) found that this was possible (in one example in less than one year) but more complex equipment does take much longer. For example a manufacturer of telecommunications base station modules has been working on RoHS compliance for well over 3 years. Manufacturers who have many different products are finding that the time required is proportional to the number of products as work is required for each model. A few have admitted that despite their efforts they did not meet the 1st July 2006 deadline. Most equipment in Categories 8 and 9 has safety, health or environmental requirements and so additional time will need to be permitted to allow for validation testing,

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[108] Honeywell www.honeywell.com

reliability testing and obtaining approvals. Testing of complex products can take 1 – 2 years and approvals in the EU for the Medical Device Directives, ATEX and several other Directives another 1 – 2 years although simple products can be tested and authorised in much less time. In practice, the time permitted must allow manufacturers of the most complex products to comply. Discussions with some sectors has shown that certain specific product types will need considerably longer to comply than others but the majority of manufacturers who make most Category 8 and 9 products would be able to comply by 2012. This is 3½ years (the time that was allowed for Categories 1 – 7 and 10) plus 1½ years for testing followed by another 1½ years for approvals. This timescale, starting from mid 2006, is illustrated by Figure 8. Those sectors requiring more time to achieve compliance could be dealt with separately as follows:

a. In-vitro diagnostics

b. Implanted medical devices

c. Industrial test and measurement equipment

7. Most Category 8 and 9 products are manufactured in relatively small numbers in comparison with most household, consumer, IT or telecom products. The cost of compliance per product arises from the total cost for research, redesign, validation, testing and obtaining approvals. Most of these costs have to be repeated for each type of product and are funded by future profits from each model. Where products are sold in very large numbers, the additional cost per product will be relatively low but where small numbers only are sold, the added costs will be much higher. For example, if the total costs were €1 million (not an unreasonable estimate for more complex products) and if 1 million items are subsequently sold, the cost per item would be €1. However some Category 8 and 9 products, especially industrial test equipment and in-vitro diagnostics equipment, are sold in much smaller numbers and so if, for example, only 200 were to be subsequently sold, the price would need to increase by €5000 to cover these costs which would be far too high for the majority of products. The average price of industrial test equipment is only €5160. This added cost means that many Category 8 and 9 products would have to be withdrawn from the EU market instead of being modified which would have a negative impact on EU users. The impact on users would be minimised if the inclusion of certain types of product in the scope of RoHS were to be delayed to allow older models to be phased out and replaced with new RoHS compliant models. As an approximate guide, as many as half of current product designs could be phased out if these Categories are included in the scope in 2010 but relatively few would be phased out if the date is 2016 or 2018. This delay is necessary only for *in-vitro*-diagnostics devices and for industrial test equipment although active implanted medical devices may need to be excluded for other reasons (see below).

8. Active implanted medical devices (AIMD) are the most safety critical of all medical products. These must be authorised for use by a Notified Body if any significant changes are made. Manufacturers of these products would need to submit test data to the notified body to demonstrate long-term reliability but this will not be available, as no suitable field data yet

exists for lead-free solders. Manufacturers can provide accelerated test data but, as discussed in this report, this cannot always be relied upon to predict performance in the field. AIMD manufacturers would therefore need to wait until suitable data is available before submitting requests for authorisation. There will be some data by 2012 from lead-free products in other Categories and so AIMD manufacturers could then (if this is conclusive) commence clinical trials and subsequently submit requests for approval. In view of the relatively small quantity of RoHS substances in AIMDs and the very high risk from unexpected defects, it would be advisable to either allow manufacturers much more time for compliance than those in other sectors or to exclude AIMD from RoHS permanently. These products are already excluded from the scope of the WEEE Directive and the European Commission, DG Enterprise department which is responsible for medical devices favours permanent exclusion of AIMD from the scope of RoHS.

9. Most manufacturers of Category 8 and 9 products are already carrying out research into RoHS compliance and some plan to introduce new models that comply with RoHS from late 2006 or 2007 but most will not change existing models unless forced to do so by legislation. These will however be eventually phased out and replaced with new compliant models.

10. Category 8 and 9 products use a wide variety of unique materials and components not utilised in the other eight WEEE Categories. Many of these could not be replaced and so exemptions will be required. The review of exemptions has shown that about 20 are justified. This number can be reduced by combining similar very specific exemptions into fewer broader exemptions. This is discussed in Section 13.4

11. The cost of compliance for Categories 8 and 9 is difficult to estimate but is likely to be higher than for the other WEEE Categories. Manufacturers of equipment in the other eight Categories have estimated that the cost is 1 – 4% of turnover depending on product complexity and numbers of each model sold. For Categories 8 and 9, the cost could be as much as 7 to 10% of turnover due to the additional test and approval costs. Costs will be considerably higher in those sectors where very small numbers of each model are sold (see conclusion 6 above) and depend on when these Categories are included in the scope of RoHS. If the date of inclusion is too early, average prices could rise by 5% which would add €2.7 billion to EU healthcare expenditure. Since healthcare funding is restricted, product price increases would result in fewer or less advanced new equipment being purchased with a resultant negative effect on healthcare provision.

12. Any amendment to the RoHS Directive needs to amend the date definition in Article 2.3. Guidance to the EMC Directive gives a useful definition of spare parts.

13. There are sometimes fundamental conflicts between the requirements of older legislation like WEEE and RoHS, which only consider a particular part of the life cycle, and EuP which reflects a whole life cycle approach. How such conflicts should be resolved has not yet been

addressed to our knowledge but taking into account the results of an impact assessment should be beneficial.

13.3 Conclusions concerning lead-free soldering technology

A principle reason why Categories 8 and 9 were originally excluded from the scope of the RoHS Directive was concern whether safety critical products made using substitute materials would be reliable. The material of greatest concern, solder, has been thoroughly reviewed in this study.

Despite extensive research since the early 1990s, no "drop-in" replacement for tin/lead solder has been found and probably does not exist. Several solder alloys are now available commercially and are used in an increasing number of products but almost all of these are not safety critical. It is clearly possible to manufacture equipment with lead-free solders but Category 8 and 9 equipment manufacturers need to be certain that products made with these materials will be no less reliable than the tin/lead counterparts.

There are many technical issues that manufacturers will need to understand before production of reliable products will be possible. Manufacturers however continue to have questions about the long-term reliability of lead-free products with several as yet unanswered questions:

- What is the thermal fatigue performance of solder joints in the field over 20 years in hostile conditions?
- How will new "whisker resistant" tin coating perform in the field over 20 years in hostile conditions?
- How will vibration over the long term affect reliability?
- Will corrosion be an issue?

Manufacturing defects could also be an issue but evidence from manufacture of many "lead-free" products over the last few years shows that as long as these are understood and sufficient time and resources are allowed for process optimisation, manufacturing defects can be avoided.

Almost no useful field data from lead-free soldered products that have been manufactured during the past five or so years is available and would be of limited value for Category 8 and 9 products. Most of the first lead-free products were consumer equipment and also some air conditioning equipment has been made with lead-free solders for over five years. If consumer products fail early due to lead-free solder defects, this is unlikely to be recorded as consumers tend to use these products for less than 5 years and if they fail after the warranty has expired, they are normally discarded, not returned to suppliers to failure investigation. Several Japanese manufacturers who have been making lead-free products for over five years were consulted as part of this review and they either responded that no increase in failure rates occurs or they could not provide any useful data. An important point is that consumer products (and air conditioning) are not subjected to severe environmental stresses so failures are unlikely even if lead-free solders were to have much shorter field lives when stressed.

This review has aimed to answer these questions because if they cannot be answered, Categories 8 and 9 products should not be included within the scope of RoHS without an exemption for lead in solders. A very large amount of research that has been carried out, the main conclusions of which are:

1. Accelerated thermal cycle testing has given consistent results which show that lead-free solders perform better than tin/lead when strain levels are low but they are inferior when strain levels are high. This result should be viewed with caution until it is possible to extrapolate accelerated test results to provide accurate field predictions.

2. Extrapolation of accelerated thermal cycling test results is not yet possible as lead-free solders have not been in use in hostile environments for a sufficient length of time to generate field reliability data. The only field data is for household and consumer products, for up to five years. Although no reliability issues have been found this information is inadequate given the high reliability required over long life times and in aggressive environments for Category 8 and 9 products.

3. Work is underway to develop prediction models to determine the field life of lead-free solders. This work is not yet complete but encouraging results are being obtained. Even where lead-free solders are found from accelerated tests to be less reliable than their tin/lead counterparts, they could still be used in equipment as long as the prediction model can show that field life will be significantly longer than the equipment is expected to be in service.

4. It is clear that lead-free solders and tin/lead solder have different microstructure and so their behaviour is different but research is beginning to understand these differences.

5. Manufacturers of new “whisker resistant” tin plating chemicals and component manufacturers who use these processes are confident that the risk of tin whiskers is low as long as the processes are carried out within their specified limits and the coatings are not distorted or damaged. Research has shown how whiskers can be avoided so the risk is low where these recommendations are followed. These conclusions are all based on research using accelerated testing; long term behaviour will not be known for 20 years as these coatings are new. The risk is mainly with fine pitch components and so the recently agreed exemption for lead in termination coatings of fine pitch components should remove this risk as long as component manufacturers offer this option.

6. There have been few reports of failures due to whiskers over recent years and these are all due to older types of tin coatings, not with modern whisker resistant coatings. These new coatings however, have not been in use for sufficient time to know with certainty if they will cause failures in the future.

7. Whether Category 8 and 9 equipment is included or not in the scope of RoHS will have only a limited effect on the risk from whiskers because equipment manufacturers usually buy mass-produced off-the-shelf components which have electroplated tin termination coatings. Too few components are purchased to be able to have an influence over which coatings that component manufacturers use. Where custom components are made, alternative coatings such as gold/nickel could be used to avoid the risk from whiskers.

8. The impact of vibration on lead-free solder joint reliability was not clear as there are many apparently contradictory reports – some indicating that lead-free is superior but others that lead-free is inferior. There are several anecdotal reports, mainly on the Internet, that lead-free solders are inferior but these claims are not substantiated by research. The main conclusion from research into the effect of vibration on lead-free solders is that at low g-force, lead-free solders and tin/lead solders perform equally well. At higher g-force, lead-free solders are resistant to g-forces in the x- and y- (in-plane) directions but failures occur where the g-force exceeds $9g_{rms}$ in the z-axis (out-of-plane) direction where tin/lead is more resistant to damage.

9. Recent research has shown that lead-free soldered equipment may, under the most severe environmental conditions, be unexpectedly more susceptible to corrosion than the tin/lead versions. This is not because of corrosion of the lead-free solder itself but is due to the need to change component termination and board coating materials. Surprisingly gold-based coatings give very poor protection in some circumstances. The most severe environments are experienced in chemical plant, oil refineries, etc which are regarded as large-scale stationary industrial tools (LSIT). Any monitoring or control product that is used as an integral part of LSIT would be outside the scope of WEEE and RoHS (based on European Commission's definition of LSIT[6]) and so this issue may be less important unless the scope of RoHS is broadened to include this subcategory. These research results show that unexpected behaviour may be experienced with new materials and where safety is important, sufficient time for research is essential.

Lead-free soldering is clearly a very complex technology with many potential failure mechanisms that could have an effect on long-term reliability. Many of these issues are understand and failures can be avoided as long as manufacturers understand these problems and know how to avoid them. There are, however, several aspects of lead-free technology that are not yet fully understood. Recent research into thermal fatigue, tin whiskers and vibration is giving a much better understanding of these potential failure modes so that in theory it should be possible to avoid failures by careful control of product design, choice of materials and production processes. These are not trivial matters and manufacturers will require a significant length of time to first understand these issues and then to implement design changes; many are already carrying out this research with new products although most are not changing current models.

This review has examined in detail the risks of using lead-free solders on long-term reliability because this could negatively impact safety and the environment. Indications from research and accelerated tests are that reliability is not significantly reduced in most situations but the predicted life with lead-free solders will be reduced where there is high strain in solder joints or high g-force vibration in the z-axis direction. As this is known to be the case, the impact of these factors could be minimised in some cases by changing the design but it is important to be able to predict accurately the likely field life to have confidence in the safety of products. This is where there is still some uncertainty. Lead-free solders are different to tin/lead but the longest field life data for lead-free products is about 5 years and this is only for consumer, household and office equipment. Category 8 and 9 products are used for considerably longer than 5 years and often in relatively hostile conditions. Extrapolation of accelerated test results for thermal fatigue, tin whiskers and vibration is not yet sufficiently accurate to completely eliminate all risks and these will be accurate only after long term field data becomes available so that the relationship between tests and field behaviour is known. Long-term behaviour is already well understood with tin/lead solders because they have been in use for over 50 years whereas lead-free solders are relatively new. With lead-free solders, extrapolation of accelerated test results is possible but only by the use of theoretical predictive models, which cannot be guaranteed to be accurate until long-term field data is available. This is of concern to manufacturers who produce the most safety critical products as well as to official national enforcement bodies who are responsible for the safety of equipment.

The earliest date by which it will be feasible to include Categories 8 and 9 within the scope of RoHS is estimated to be 2010. By this date, there will be another four or five years field data for lead-free solders as well as more research results. By 2012, any unexpected behaviour that causes lead-free solders to be significantly less reliable than current predictions estimate will be clearly demonstrated from experience with the very large number of RoHS compliant products that will be sold from 2006 onwards, such as laptop PCs, electric tools and household appliances.

The EC will be required to carry out a review of exemptions in 2010 (four years after RoHS comes into force) including exemption number 7.2 "Lead in solders for servers, storage, storage arrays and telecommunications network infrastructure equipment". One option to allow inclusion of Categories 8 and 9 in the scope of RoHS but to avoid the small potential risk from lead-free solders due to uncertainty over long term reliability would be to amend this existing exemption to include Categories 8 and 9 to read:

7.2 "Lead in solders for servers, storage, storage arrays, telecommunications network infrastructure equipment and equipment in Categories 8 and 9."

If the accumulated evidence in the review of exemptions to be carried out in 2010 indicates that there is no risk with lead-free solders, then this exemption can be terminated for all of these products including those in Categories 8 and 9. If however, the review shows that concerns remain, then the use of lead in solders can continue until the risk has been found to have been eliminated at a subsequent review (these should be carried out every four years).

This approach would allow Categories 8 and 9 to be included in the scope of RoHS at an earlier date without risk to safety or the environment but it will still be important to take into account the differences between Category 8 and 9 products and those in the other WEEE Categories when choosing a transposition date or dates.

13.4 Exemptions

All of the exemptions requested during the course of this review have been investigated. About forty different requests have been made covering a wide variety of diverse technologies including superconductors, radiation detection, soldering technology and many others. A few were found not to be justified, as substitutes already exist although in some cases manufacturers were unaware of these. Some would be required for a limited period to allow time to investigate and validate alternatives.

The European Commission has stated that it would not be feasible to include Categories 8 and 9 in the scope of RoHS if this is possible only with a large number of exemptions. A significant proportion of those requested do appear to be justified because of technical, environmental, safety or health reasons and these are listed below:

13.4.1 Justified Exemptions

All exemption requests have been reviewed but in some cases it has been possible to combine several into one and a total of 21 exemptions appear to be justified based on the criteria listed in Article 5.1 (b) of RoHS and another three should be considered for other reasons. This list could be reduced further by combining those exemptions that relate to "sensors, detectors and electrodes" and this will give a total of 17 exemptions or 20 if the additional three are accepted.

Exemption 3 in Table 71 has been included but would not be required if MCP and CP are defined as "electronic components" as these would already be covered by the exemption for "**lead in glass of** cathode ray tubes, **electronic components** and fluorescent tubes". One function of lead in CP is shielding for ionising radiation and so, if exemption numbered 5 in Table 71 is accepted, this exemption is unnecessary on this basis.

In item 4, vacuum tubes may also be considered electronic components and so no new exemption would be required for these but lasers, X-ray tubes and image intensifiers may not be regarded as electronic components and so an exemption to cover these would be required. As the status of these components is unclear, these exemptions have been included.

Table 71. Exemptions for Categories 8 and 9 that appear to be justified

	Definition of new exemption request	Comments
	Equipment utilising or detecting ionising radiation	
1	Lead, cadmium and mercury in detectors for ionising radiation	No substitutes with equivalent performance
2	Lead bearings in X-ray tubes	No substitute bearing material. Can be replaced by alternative designs but these could not be used in current X-ray machine designs

	Definition of new exemption request	Comments
3	Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate	No substitutes possible for various specific applications. Exemption not required for fibre optic plate as these are optical glass and so covered by an existing exemption. Also not required if MCP and CP are defined as electronic components (Section 10.5).
4	Lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons	No lead-free frits currently available with all essential criteria. If it is accepted that vacuum tubes are electronic components, the existing exemption for lead in glass of electronic components will cover these.
5	Lead in shielding for ionising radiation	Lead meets all essential requirements, main substitute tungsten has negative environmental impact
6	Lead in X-ray test objects.	No alternative materials that have combination of essential properties
7	Lead stearate X-ray diffraction crystals	Lead meets all essential requirements for limited applications where this is used
8	Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers	No substitutes possible in spectrometers used for lead analysis in paint coatings.
	Sensors, detectors and electrodes (plus item 1)	
1a	Lead and cadmium in ion selective electrodes including glass of pH electrodes	No substitute materials or designs available
1b	Lead anodes in electrochemical oxygen sensors	No substitute materials and alternative sensors not suitable for all applications
1c	Lead, cadmium and mercury in infra-red light detectors	No substitutes which meet the combinations of all essential performance criteria
1d	Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide	There are substitutes for calomel (mercury chloride) but not for low chloride, oxide or sulphate electrodes
	Others	
9	Cadmium in helium-cadmium lasers	Only laser producing 325 nm The only choice for high resolution of light element spectra
10	Lead and cadmium in atomic adsorption spectroscopy lamps	No substitutes possible
11	Lead in alloys as a superconductor and thermal conductor in MRI	Lead is unique as a ductile metal with high thermal conductivity at 4K
12	Lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors	No known substitutes, lead and its alloys are superconductors at 4K and in high magnetic fields
13	Lead in counterweights	Needed for surgical microscopes as substitute (tungsten) has negative environmental impact and also may affect healthcare due to high cost of tungsten. Needed for Medical X-ray and radiography equipment until 2016 although main substitute – tungsten has a negative environmental impact.
14	Lead in single crystal piezoelectric materials for ultrasonic transducers	Lead piezoelectric ceramics is already exempt but lead piezoelectric single crystals have superior performance but are not ceramics

	Definition of new exemption request	Comments
15	Lead in solders for bonding to ultrasonic transducers	Currently no substitutes, exemption will be required until at least 2016
16	Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay	Required for limited range of applications. A more restrictive wording is suggested in Section 10.17 but this may have a negative impact on competition within EU
17	Lead in solders in portable emergency defibrillators.	Due to a high risk of failure of lead-free solder joints
	Temporary exemptions required for reasons other than the criteria specified in Article 5.1 (b) of the RoHS Directive	
18	Lead in solders of high performance infrared imaging modules to detect in the range 8 – 14 µm	No RoHS compliant substitutes available for highest performance modules
19	Lead in Liquid crystal on silicon (LCoS) displays	No RoHS compliant substitutes available for medical equipment market
20	Cadmium in X-ray measurement filters	Possible substitutes could be used but too costly for product to be modified so would be removed from EU market

13.4.2 Exemptions required until 2012 only

Research is continuing into the following exemption requests but none are likely to be required beyond 2012:

Table 72. Exemptions requested that will not be required by 2012

	Definition	Reason
1	Mercury in position switches of X-ray equipment (until 2012)	Will not be required beyond 2012
2	Lead as PVC stabiliser in medical tubing	Will not be required beyond 2012
3	Cadmium pigments in ECG patient cables by 2012	Will not be required beyond 2012
4	Flexible copper cadmium alloy wire (until 2012)	Will not be required beyond 2012
5	Hexavalent chromium in alkali dispensers for in-situ production of photocathodes	Should not be required beyond 2012
6	Cadmium in output phosphors of image intensifiers	Cadmium in input phosphors have already been replaced by some manufacturers
7	Specific Opto-coupler for IVD instruments	Replacement technology should be available by 2012 **but not earlier**
8	Lead in solders until 2012	Withdraw if 2010 review shows no reliability concerns
9	Lead in solders for array interconnections to photodiode CT detectors	Replacement technology should be available by 2012 **but not earlier**
10	Lead in solders connections to micro-BGA area arrays	Replacement technology should be available by 2012 **but not earlier**

13.4.3 Exemptions requested that are not required, substitutes exist or there is insufficient information available

Table 73. Conclusions on exemption requests where these are either not required or insufficient information is required

	Definition	Reason
1	Mercury source for calibration of environmental mercury monitors	A consumable so out of scope of the Directive
2	Cadmium in total residual chlorine monitors	A consumable so out of scope of the Directive
3	Hexavalent chromium passivation coatings on aluminium and on zinc	Substitutes exist although long term test data is not yet available
4	Lead in glass of X-ray tubes	Glass used for radiation shielding only and so covered by exemption 8 in Table 71
5	Lead in solders that are exposed to anaesthesia gases	Requires further investigation but technical solutions to corrosion problems should be available given sufficient time for research
6	Lead in solder for bonding Peltier coolers to silver blocks in DNA multiplication equipment	Very little information received, requires further investigation. May not be a Category 9 product

14. Recommendations

1. Include Categories 8 and 9 in the scope of RoHS from 2012 except for:

   a) *In-vitro* diagnostic (IVD) equipment - include from 2016.

   b) Industrial test and measurement instruments - include from 2016 or possibly 2018. A clear definition of these products is essential, for example:

   "Products that would normally be within the scope of European Standard EN61010-1, section 1.1 (a). This would include equipment that is normally tested to this standard even though customer requirements might result in other standards being utilised".

   c) Active implanted medical devices - exclude permanently or delay inclusion until 2020.

   The date of 2012 provides the same length of time that was made available to manufacturers of products in the other 8 Categories (i.e. from February 2003 to July 2006) plus additional time required for validation and reliability testing and subsequent approval by Notified Bodies for compliance with other EU Directives (allowing for the more complex products) and other regulations and industry requirements. Also, by 2012, up to ten of the requested exemptions will no longer be required.

2. Provide a temporary exemption for lead in solders.

   ERA suggests the definition:

   7.2 "Lead in solders for servers, storage, storage arrays, telecommunications network infrastructure equipment and equipment in Categories 8 and 9."

   The current exemption will be reviewed in 2010 by the European Commission and could be removed if field data (and by this time over five years of this will be available) indicates that the reliability of lead-free solders is not significantly worse than current predictions based on accelerated tests. It is possible that by 2012, this exemption will not be required and so Category 8 and 9 products could be made using lead-free solders without additional risk. The period of time allowed for this exemption after it is terminated should be considered as changing products to lead-free versions is time consuming and two years would not be unreasonable for more complex equipment. Most manufacturers are already carrying out research into lead-free solders, even if they have no plans to sell lead-free products until all remaining doubts over reliability are allayed.

3. Provide exemptions for the requests listed in Table 71.

   These are justified, as currently no substitutes exist. Note, however, that research is being carried out to find alternatives and so all exemptions specifically for Categories 8 and 9 should be reviewed every four years and terminated when substitutes are commercially available. The Commission will require sufficient funding for independent consideration of the technical issues in a timely manner.

4. Provide exemptions for the requests listed in Table 72 until 2012 if Categories 8 and 9 are included in the scope earlier than this date.

5. Do not provide exemptions for the requests listed in Table 73.

   There is insufficient evidence to support these requests since manufacturers having carried out only very limited research. Note that manufacturers may discover in the future that more exemptions will be required and the European Commission will need to review these when required in a timely manner.

6. Provide a permanent exclusion from scope for "Lead, mercury and cadmium in sensors, detectors and electrodes used in Category 8 and 9 equipment".

   This will provide some limited scope for innovation which is potentially hugely beneficial to health and the environment but with minimal impact in terms of the quantities of restricted substances used.

7. Clarify the scope of Category 9 within the text of the Directive.

   The scope of Category 9 is very unclear and is causing difficulties for manufacturers. WEEE registration bodies have difficulty interpreting the intended scope and different decisions are made by Member States. This inconsistency is unacceptable given the Article 95 basis of RoHS which requires the same interpretation by all EU Member States. The amended Directive should explicitly clarify the intended scope for this Category explaining what is included and, equally important, which types of products are excluded. The definition in Section 4.4 with accompanying notes may be suitable:

   "Equipment whose primary function is monitoring, control, measurement or test;

   AND is placed on the market as a finished product;

   AND is not an integral part of a large-scale stationary industrial tool;

   AND is not part of another type of equipment that is outside the scope of Directive 2002/96/EC"

   Whether "laboratory equipment" that is within the scope of European standard EN61010-1:1993 should all be regarded as Category 9 should also be considered. This would have the advantage that decisions on the status of these products would be simplified although some laboratory equipment neither monitors nor controls.

8. Clarify the scope of Category 8 within the text of the Directive.

   The current scope of Category 8 is ***"Medical Devices (with the exception of implanted and infected products)"***.

   This definition is broader than the scope of electrical equipment with in the three Medical Device Directives as this also includes accessories and a few other types of equipment. An alternative definition suitable for RoHS could be:

   "Electrical equipment within the scope of the medical device Directives (Directives (93/42/EEC and 98/79/EC) and accessories specifically designed to be used with these products"

   This is clearer than the first definition.

9. Amend Article 2(3) to ensure that equipment outside of the scope of the Directive put on the market on / after 1 July 2006 but subsequently brought within scope can be repaired or upgraded with non RoHS compliant parts. The following wording may be suitable:

   "This Directive does not apply to spare parts for the repair and/or upgrade of electrical and electronic equipment which fall outside the scope of this Directive".

   At present if an exemption is removed, any product put on the market after the 1 July 2006 cannot be repaired using a spare part which made use of this exemption. This is clearly at variance with the intent of the Directive since it will result in equipment reaching end of life prematurely. To avoid this the following wording may be suitable:

   "This Directive does not apply to spare parts containing 'certain restricted substances' for the repair and/or upgrade of electrical and electronic equipment which fall inside the scope of this Directive where these 'certain restricted substances' were permitted to be used by an exemption when the equipment was put on the market".

10. Clarify the meaning of the following in the Directive to aid a harmonised interpretation across the EU and EEA. We suggest that the following would be helpful:

    a) Put on the market - make explicit that this has occurred when a product it is put on the market anywhere in the EU as per the "Guide to Implementation of Directives based on the New Approach and the Global Approach" and refer explicitly to this.

    b) Provide a definition of spare parts such as that used in the guidance to the EMC Directive[7].

    c) Transpose the text of Article 2.1 of the WEEE Directive into the RoHS Directive to make this understanding explicit.

d) Provide a definition of “part of” in the transposed Article 2.1 of the WEEE Directive.

e) Add the text of Article 2(3) of the WEEE Directive as a new clause in the RoHS Directive to make explicit the exclusion of equipment intended specifically for military and national security purposes.

Annex 1. List of contributors to this review

ERA would like to thank the following organisations for their input to this study with apologies for any omissions.

Type of organisation	Contributor	Comment
NGOs and research organisations	European Environment Bureau	representing: Ban Mercury Working Group Natural Resources Defence Council European Public Health Alliance Environment Network (EEN) Health Care Without Harm Europe (HCWH)
	CEA – LETI	France
	Intertek	Medical Device Directive Notified Body
	National Physical Laboratory (NPL)	UK
	RoHS and WEEE Specialists International	New Zealand
	Southend Hospital	Essex, UK
Government agencies	Ireland, Sweden, Denmark, Norway, Belgium, Germany, UK government	At the Expert Workshop and some subsequently
	European Commission, DG Environment	
	European Commission, DG Enterprise	
	NVMP	Netherlands WEEE compliance scheme
	NWML	UK RoHS enforcement
	El-Kretsen	Sweden WEEE compliance scheme
	UK Department of Trade and Industry	
	UK Health and Safety Executive	responsible for enforcement of safety legislation
Trade Associations	AeA Europe	US manufacturers
	COCIR	Medical
	CoGDEM	Category 9
	EDMA	Medical – IVD
	EUCOMED	Medical
	EUROM	Medical
	Euralarm	EU
	Gambica	UK
	JBCE	Japan
	JEMIMA	Japan
	Orgalime	Industrial equipment
	Spectaris	Germany
	Test and Measurement Coalition	(Category 9) includes Agilent Technologies, Fluke, Tektronix, Keithley, National Instruments, Anritsu
	ZVEI	Germany

Type of organisation	Contributor	Comment
Manufacturers	Andeen-Hagerling	US SME – Category 9
	Bayer	Multinational – IVD
	Beckman Coulter Inc	USA
	Bosch Sicherheitssysteme GmbH	Germany
	City Technology	UK
	Coherent Lasers	USA
	Design Chain Associates	USA (consultancy)
	Electron Tubes	UK SME - Category 8 and 9
	Elekta	UK - medical
	Emerson	Multinational – Category 9
	Endress and Hauser Group	Germany
	Eurorad	France
	GE	Multinational – Category 8and 9
	Hamamatsu	Japan
	Honeywell	Multinational – Category 9
	Infra-Red Associates	USA
	Key Med	UK subsidiary of Japanese Medical
	L3 Communications	USA – Category 9
	Land Instruments	UK SME
	London Colney Anodising	UK – SME (Conversion coating producer)
	Medtronic	US AIMD
	Motara	USA – Category 8
	Perkin Elmer	Category 9
	Philips Medical	Multinational
	Quest Technologies	USA
	Renishaw	UK – Category 9
	Roche	Germany
	Saint Gobain	France
	Schott Glass	Germany
	Servomex	UK
	Siemens Medical	Germany
	Siemens Schweiz AG	Switzerland
	Stanley Tools	UK – Category 9
	Taylor Hobson	UK – Category 9
	Teledyne	USA
	Thales Medical	France
	Thermo Electron	Mainly Category 9
	Tyco Electronics (Sensormatic)	Ireland - Category 9
	Varian	UK - medical
	Weston Aerospace	UK – Category 9

Annex 2. Indicative list of examples of Category 8 and 9 products and those whose status is unclear

Category 8 products in scope
Blood pressure meters (consumer types and professional types)
Blood analysers, e.g. cholesterol, sugar (consumer types and professional types)
Self-test kits - electrical types (consumer and professional types)
Oxygen analysers (respiration monitors)
Immunoassay analysers (IVD)
Endoscope
Ultrasound
CT scanner
PET
X-ray imaging
Medical thermometer
Dialysis equipment
Medical Freezers
Gamma Camera
Intravenous drug infusion pumps
Ventilators
Defibrillators
Pacemakers
Hearing aids
Surgical microscope
Hospital beds that rely on electricity for their main function
Electrical surgical tools (saws, etc.)
Medical lasers
ECG
Anaesthesia equipment
Operating theatre equipment
Dental equipment
“Medical” products whose status requires clarification
Proton therapy facility including particle accelerator
Veterinary products
Electric scooters used by disabled (as a transport product)
Hospital beds that are not dependent on electricity

Category 9 products in scope
Battery powered smoke detector (used in households)
Battery powered thermostat (used in households)
Carbon monoxide detector (used in households)
Weighing equipment except for households
Chemical analysis equipment such as spectrometers
Light meter
pH and conductivity meters
Chromatograph for chemical analysis
Equipment for calibration of other products
Portable digital thermometer
Surveying instruments
Voltmeters, ammeters, etc. not used as components within other products
X-ray imager for luggage (except those used for national security)
X-ray imager for examination of internal parts of products
Spectrum Analysers
Oscilloscopes
Network cable tester
Semiconductor parameter tester
Signal generator
Waveform monitor
Optical power meter
Roadside traffic warning beacons. Category 9 as the main function is "control (of traffic)" (not used for illumination therefore not Category 5)
"Monitoring and control – type products whose scope requires clarification
Smoke detector as part of alarm system installed in buildings
Household scales (included in Category 1)
Burglar alarm systems installed in buildings
Equipment used to prepare samples for analysis such as grinding equipment, mixers, extraction systems, etc.
Laboratory ovens
Laboratory centrifuge
Other laboratory equipment such as ultrasonic cleaners, fume hoods, distillation equipment, heating equipment, etc. (some could be regarded as Category 6)
Preparative chromatograph (Category 6?)
Petrol pumps (part of fixed installation, Category 9 or 10?)
Some types of CCTV monitoring equipment (or Category 3?)