Environmental Legislation and Medical Devices: RoHS, Batteries and WEEE

MediWales Regulatory Event
Cardiff, 19 Feb 2015

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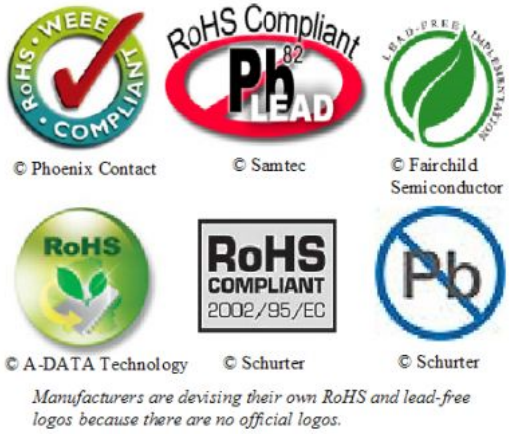
Agenda

- RoHS
- Batteries
- WEEE

RESTRICTION OF HAZARDOUS SUBSTANCES (ROHS)



Manufacturers are devising their own RoHS and lead-free logos because there are no official logos.

DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II)

RoHS – Why?

- 10 Million tonnes of EEE disposed of annually (EU)
- EEE waste stream growing rapidly
- EEE contains many hazardous substances that can be released into the environment on disposal

RoHS: The Story So Far….

- Directive 2002/95/EC
  (OJEC L37,13-02-2003)
- Article 95
- Six Banned Substances
- Effective from 01 July 2006
- Medical Devices (Category 8) exempt (until 2014)
- Application Exemptions Annex I
- Not a CE marking Directive
- No Conformity Assessment Procedure

‘RoHS-II’

- 2011/65/EU of 8 June 2011 (RoHS II)
  - OJ L 174, 1.7.2011, p. 88
- RoHS ‘Recast’
- Commission Proposal: COM(2008) 809/4, 03 December 2008
- Many changes
  - Medical Devices included from 22 July 2014!
  - IVD from 22 July 2016
  - AIMDs will be reviewed
  - ‘Everything else’ (Cat 11) by 22 July 2019

‘RoHS-II’

- ‘CE’ marking Directive
- Conformity Assessment Procedure (Module ‘A’*)
  - No Notified Body Involvement
- No change to list of banned substances from RoHS 1 (But Delegated Directive Drafted!)

***DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC**

RoHS II - 11 Categories

1. Large household appliances
2. Small household appliances
3. IT and telecommunications equipment
4. Consumer equipment
5. Lighting equipment
6. Electrical and electronic tools
7. Toys, leisure and sports equipment
8. Medical devices
9. Monitoring and control instruments
10. Automatic dispensers
11. Other EEE not covered by any of the categories above.

Banned Substances (Threshold)

- Lead (0,1 %)
- Mercury (0,1 %)
- Cadmium (0,01 %)
- Hexavalent chromium (0,1 %)
- Polybrominated biphenyls (PBB) (0,1 %)
- Polybrominated diphenyl ethers (PBDE) (0,1 %)
- Bis (2-ethylhexyl) phthalate (DEHP) (0,1 %)
- Butyl benzyl phthalate (BBP) (0,1 %)
- Dibutyl phthalate (DBP) (0,1 %)
- Diisobutyl phthalate (DIBP) (0,1 %)

New substances

Ban for Cat 8 and 9 from 22 July 2021, everything else from 22 July 2019

RoHS II Annexes

I. Categories
II. Banned substances
III. Exemptions (From RoHS I)
IV. Exemptions Cat 8 & 9
V. Exemption Application Data
VI. Declaration of Conformity
VII. Repealed Directives
VIII. Correlation Table RoHS I and RoHS II

RoHS II Summary

- Exemptions
  - Cat 8&9 Exemptions included in Annex IV
    - Validity ‘up to’ 7 years
  - However additional exemptions required and being progressed through political process.
  - Exemptions ‘expire’ after specified period
    - Up to 5 years for Cats 1-7, 10 & 11

Exemption 33

- Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators.

- Expires on 30 June 2016 for class IIa and on 31 December 2020 for class IIb.

Aimed at portable (hand-held) devices which might experience rougher handling

What it means for you

- Medical devices will needed to be compliant from 22 July 2014
- Biggest issue ‘lead free’ solder
  - Tin/Lead (60/40) solder well understood
- Manufactures need to adopt due diligence in ascertaining composition of components
  (EN 50581 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances)
- Applies to everything in device as shipped not only electronic components.

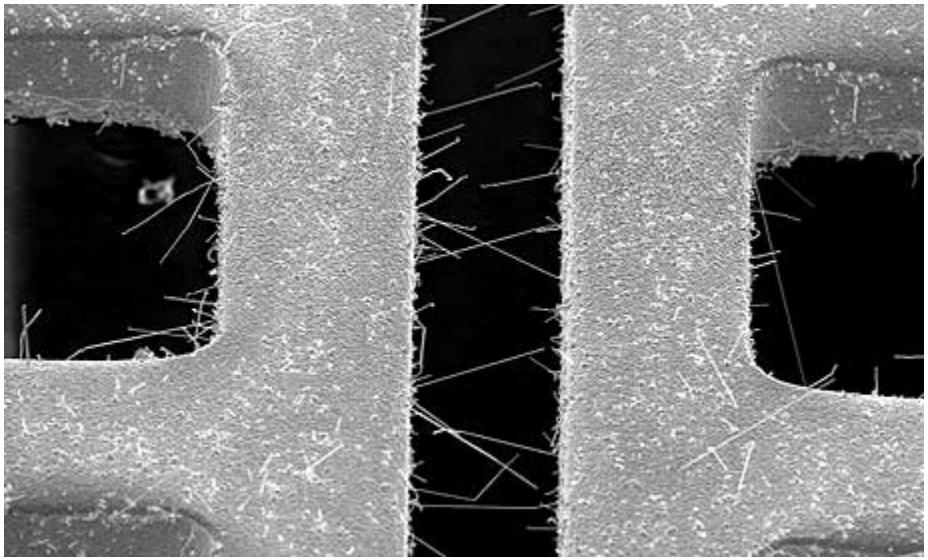
What it means for you

- Issues:
  - Lead free soldering uses higher temperatures (typically 40ºC more than tin/lead)
    - Higher stress for components (reliability)
    - Higher stress for substrates (process control)
    - Greater leaching of copper from components
  - Not all components may be available in lead-free versions
    - Some current products may need to be redesigned
    - Some current products may need to be obsoleted

What it means for you

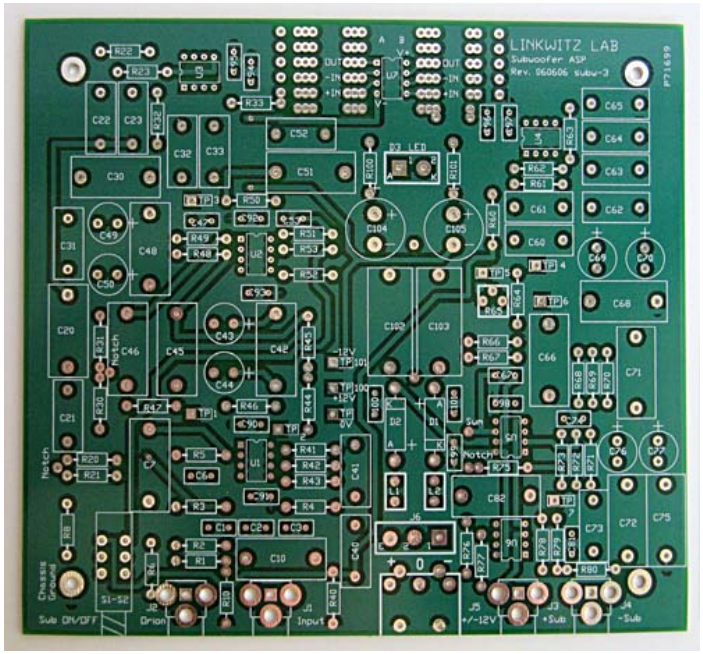
- Issues:
  - Large number of different lead-free solders available using different metal combinations and different ratios (e.g. tin/silver/copper)
    - Tin with Silver 3.0%/Copper 0.5%
    - Tin with Silver 3.1%/Copper 1.3%
    - Tin with Silver 3.5%
      - All have different strengths and weaknesses
      - Not all equipment manufacturers will use same solder
      - Optimal solder for electrical joints likely to be different from that for mechanical joints
  - Lead-free solder joints more difficult to quality control
    - Reliability (warranty claims)

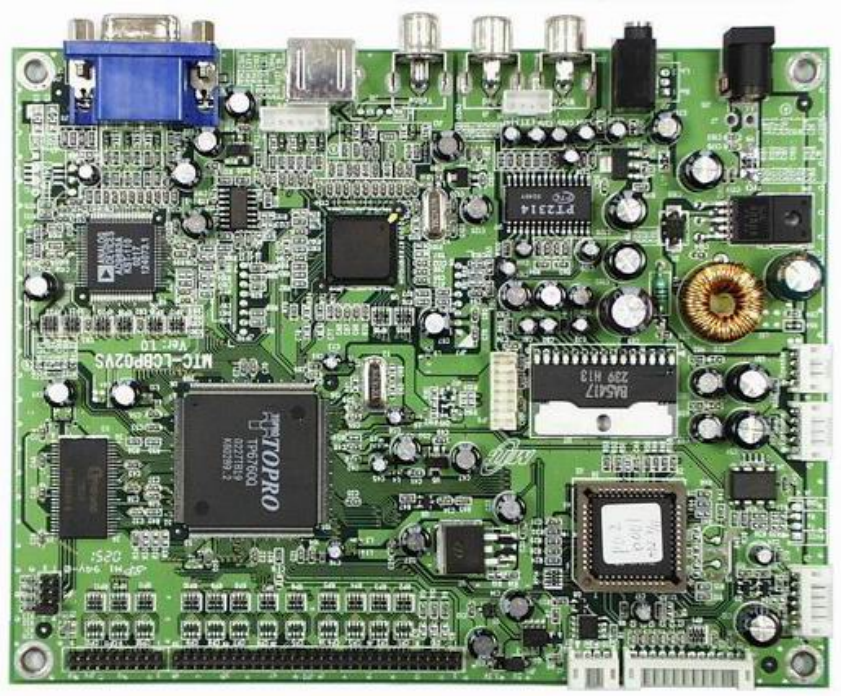
Lead Free Solder



What it means for you

- Issues:
  - Existing soldering equipment may have to be replaced/modified
    - Bench soldering equipment
    - Wave soldering equipment
  - Lead-free solder is more expensive than tin/lead
    - Cost increases (2-3 times for solder)


LINKWITZ LAB
Subwoofer ASP
Rev. 060606 subw-3
Sub ON/OFF
Orion
Input
+/-12V
+Sub
-Sub


TOPRO

What it means for you

- Cost of meeting requirements:
  - Capital
    - Major asset replacement/modification
      - Wave soldering machine
      - Soldering stations
  - Process
    - Additional quality control
    - Time (lead-free soldering takes longer)
    - Material (lead-free solder)
    - Training of staff
  - Risk Management!!

Questions?

BATTERIES….

DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

Batteries - Why

- Disposable Batteries in landfill are a significant source of chemical pollution

Batteries: The Story So Far…

- Directive 2006/66/EC (OJEC L266, 26-09-2006)
  - Amended by Directive 2013/56/EU (L329 10/12/2013)
- Article 95
- Imposes substance restrictions Hg, Cd* (* MDs exempt)
- Imposes substance labelling in some circumstances (Hg, Cd, Pb)
- Requires Producer registration (including for batteries incorporated into equipment)
- Requires data collection/reporting
- SMEs may be exempted from costs of collection of waste batteries.
- Requires labelling with ‘Crossed Out Wheelie Bin’:

Battery Removal

Directive 2013/56/EU

- Article 11
- Removal of waste batteries and accumulators
- Member States shall ensure that manufacturers design appliances in such a way that waste batteries and accumulators can be readily removed. Where they cannot be readily removed by the end-user, Member States shall ensure that manufacturers design appliances in such a way that waste batteries and accumulators can be readily removed by qualified professionals that are independent of the manufacturer. Appliances in which batteries and accumulators are incorporated shall be accompanied by instructions on how those batteries and accumulators can be safely removed by either the end-user or by independent qualified professionals. Where appropriate, the instructions shall also inform the end-user of the types of battery or accumulator incorporated into the appliance.

- The provisions set out in the first paragraph shall not apply where, for safety, performance, medical or data integrity reasons, continuity of power supply is necessary and a permanent connection between the appliance and the battery or accumulator is required.'

Particular Issues for Medical Devices

- Battery removal requirement problematic for some devices (e.g. AIMDs)
  - EU Commission opinion:
    - For Infectious devices: If life of battery expected to exceed life of device, no need for removability as device will become WEEE at EOL and WEEE exempts infectious devices.

Capacity Labelling

- The Directive calls for the capacity of batteries to be labelled. (Article 21.2)
  - *2. Member States shall ensure that the capacity of all portable and automotive batteries and accumulators is indicated on them in a visible, legible and indelible form by 26 September 2009. Detailed rules for the implementation of this requirement, including harmonised methods for the determination of capacity and appropriate use, shall be laid down in accordance with the procedure referred to in Article 24(2) no later than 26 March 2009.*
  - To date there are only regulations for secondary (rechargable) batteries.

Questions?

WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE)

DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)

WEEE – Why?

- 10 Million tons of WEEE thrown away each year in EU.
- WEEE Contains many hazardous substances (which can leach out causing pollution)
- Fastest growing waste stream
- Significant loss of (reusable and valuable) material

WEEE: The Story So Far…

- Directive 2002/96/EC
  (OJEC L37, 13-02-2003)
- Article 175
- Producer Responsibility for recovery and recycling of own products
- Medical Devices included immediately (except implanted or infectious)
- Effective from 13 August 2005
- Equipment must be labelled*:
- No recovery/recycling rate for MDs

*EN 50419

WEEE Recast

- Commission Proposal: COM(2008) 810/4, 03 December 2008
- Changes mainly of interest to Waste Industry however:
  - Recovery/Recycling Targets for MDs 75%/55%
  - Export controls on EEE for reuse (Annex VI)
    - The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal
- Publication in OJ L197, 27 July 2012
- Producers of EEE must register

‘Cooking’ Circuit Boards

Taizhou,China 2004

‘Recycling’ CRTs

Guiyu, China

Boy Carrying Electronic Scrap Lagos, Nigeria, 2005

‘Recycling’ Transformers Accra, Ghana, 2009

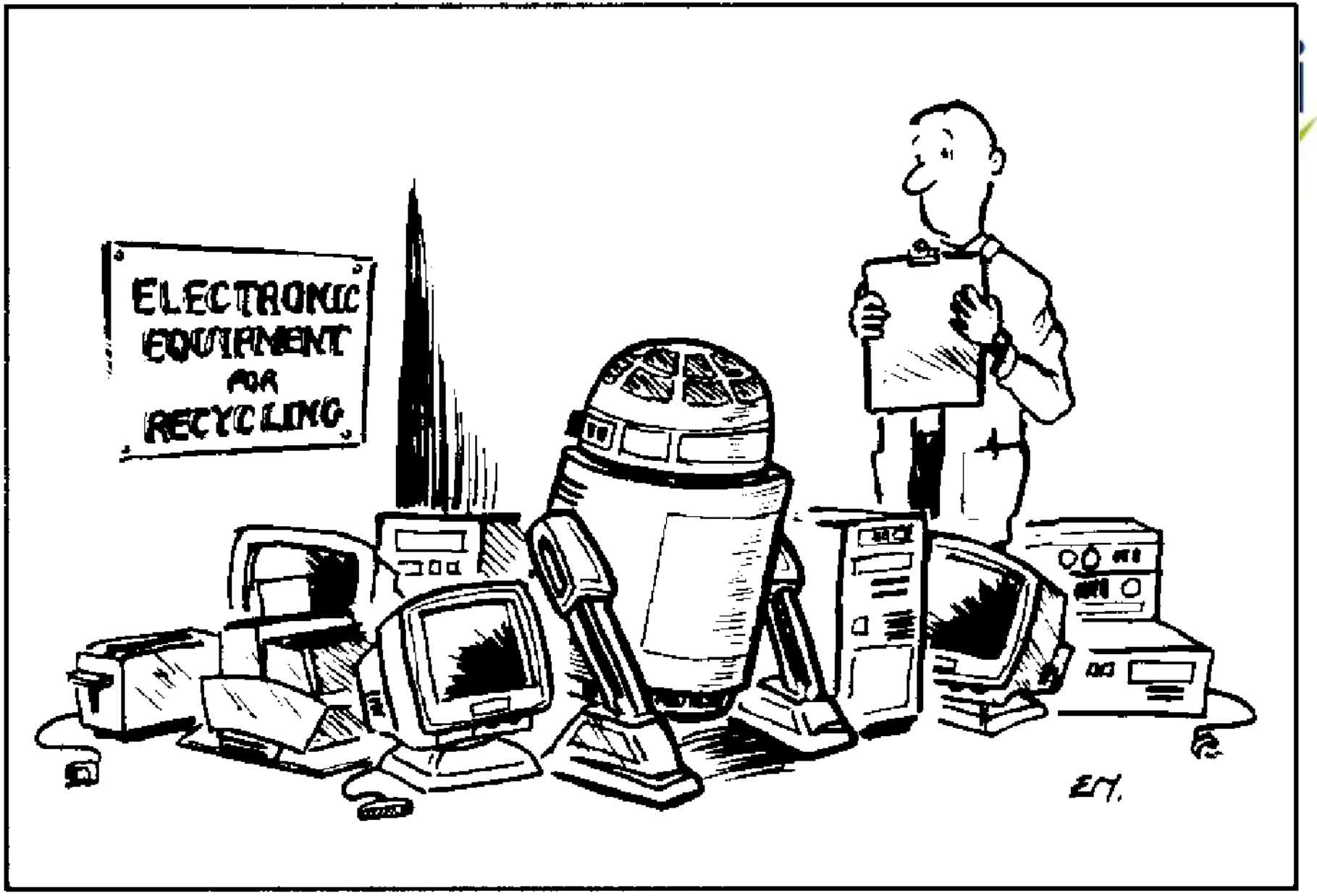
WEEE II
Export controls for EEE

- EU Commission concerned WEEE being shipped for ‘reuse’ to developing countries circumventing waste shipment legislation.
  - EEE shipments (Annex VI). Holder to have available:
    - (a) a copy of the invoice and contract relating to the sale and/or transfer of ownership of the EEE which states that the equipment is destined for direct re-use and that it is fully functional;
    - (b) evidence of evaluation or testing in the form of a copy of the records (certificate of testing, proof of functionality) on every item within the consignment and a protocol containing all record information according to point 3;
    - (c) a declaration made by the holder who arranges the transport of the EEE that none of the material or equipment within the consignment is waste as defined by Article 3(1) of Directive 2008/98/EC; and
    - (d) appropriate protection against damage during transportation, loading and unloading in particular through sufficient packaging and appropriate stacking of the load.
  - In the absence of appropriate documentation… …**Member State authorities shall presume that an item is hazardous WEEE.**

WEEE II
Export controls for EEE

- By way of derogation, point 1(a) and (b)
  - (a) the EEE is sent back to the producer or a third party acting on his behalf as defective for repair under warranty with the intention of re-use; or
  - (b) the used EEE for professional use is sent to the producer or a third party acting on his behalf or a third-party facility in countries to which Decision C(2001)107/Final of the OECD Council concerning the revision of Decision C(92)39/Final on control of transboundary movements of wastes destined for recovery operations applies, for refurbishment or repair under a valid contract with the intention of re-use; or
  - (c) the defective used EEE for professional use, such as medical devices or their parts, is sent to the producer or a third party acting on his behalf for root cause analysis under a valid contract, in cases where such an analysis can only be conducted by the producer or third parties acting on his behalf.

https://www.gov.uk/government/publications/weee-regulations-2013-government-guidance-notes


ELECTRONIC
EQUIPMENT
FOR
RECYCLING

Thank You.

ANY QUESTIONS?

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