

Making Sense of the Changes in RoHS for Medical Devices & Control Equipment

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Significant changes are happening to European environmental regulations. While there has been a great deal of discussion and debate over the past few years, in June 2011 the European Union issued Directive 2011/65/ EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment. The new directive recasts Directive 2002/95/EC, and has come to be known in the industry as the RoHS Recast. While many of these changes seem confusing, compliance will be mandatory for any company that hopes to sell into that territory. This paper seeks to cut through the complications and lay a foundation that is easy to understand.

The directives regarding Restriction of use of Hazardous Substances (RoHS) and Waste Electrical and Electronic Equipment (WEEE) are not new to the world. Both directives have been law since 2003, but have featured required “compliance dates” that never materialized, or were not strictly enforced. Simply put, RoHS—often called the “lead-free” directive, covers electronic assemblies and electronic equipment and also restricts five other dangerous substances: mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyls.

WEEE—the “recycling” directive—covers most every type of electronic product manufactured and places the disposal responsibility of the products back to the original manufacturer, mandating free-to-the-consumer recycling of electrical and electronic equipment where manufacturer pays for all costs associated with collection, transportation and recycling. In addition, recyclers must be informed of the material content of many items.

All product manufacturers must inform recyclers of the product content. Some items must be identified for separate handling. For instance, fluorescent tubes exempted from RoHS contain mercury and must be processed to remove the mercury. Batteries, CRTs, and LCD displays are also processed separately. Documentation must clearly identify the location of these items in each product.

What do these changes mean to manufacturers that sell to European markets? It means that Europe is getting serious about its environmental protection and it will

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be very difficult for manufacturers to sell their products without full compliance—something that is also now happening in China, Japan, India and other nations.

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