

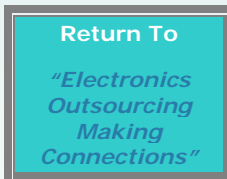
Sidebar

The Race to Compliance

EU Directives on Hazardous Materials Could Impact Medical Electronics Production

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Electrical appliances and electronic equipment sold in Europe will have to comply with new EU directives aimed at eliminating hazardous waste. Two directives of great concern to electronics manufacturers are the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Waste Electrical and Electronic Equipment (WEEE). As of 1 July 2006, RoHS will prohibit the sale of electronics-based products containing more than 0.01% of specific hazardous materials, including cadmium, mercury, lead, hexavalent chromium, polybrominated biphenyls (PBBs), and polybrominated diphenyl ether (PBDE). WEEE took effect on 13 August, 2005, and is intended to ensure that electronic products are properly disposed of or recycled after use. A component of the WEEE directive is the requirement that manufacturers must pay for the collection, treatment, recycling, and recovery of all electronics waste.



Medical devices, as well as monitoring and control equipment, are currently exempt from RoHS. According to the EU Commission, a 10- to 12-month study needs to be performed on both categories in regards to RoHS applicability. "This could push the decision to include these categories well into late 2006, with deadlines extending to 2008 or longer," says Geoffrey Bock, engineer and WEEE/RoHS specialist at TUV Rheinland of North America Inc. (Plymouth, MI, USA). Medical electronics manufacturers and other medical OEMs are lobbying to keep the exemption, as the potential impact of the RoHS directive could be costly and time-consuming. Other than reporting recovery and recycling rates until 2008, there are no exemptions for medical devices concerning the WEEE directive.

While materials such as PBBs or PBDE are rarely seen in electronics anymore, lead-bearing solder is still used to bond components onto PCBs, which poses a challenge for many suppliers to the medical electronics industry. ERA Technology, a UK-based consulting firm, recently stated in a report to the European Commission that the reliability of lead-free solders is being researched using accelerated testing. The report also said that "it is not yet known how to extrapolate accelerated test data to predict field performance...this will not be possible until lead-free solders have been in widespread use for at least five years."

Even with a reprieve from the EU, many medical electronics firms are moving toward compliance. Some EMS providers even started working on becoming compliant several years ago. "EDS Ireland adopted guidelines in 2001 to promote awareness on this issue, and we have evolved our processes to ensure compliance," says managing director Kenneth O'Hagan.

Paddy Turnbull, business development director for Europe at TriVirix, says the company is targeted to achieve a lead-free PCBA manufacturing facility for all customers that require lead-free products in compliance with WEEE and RoHS by June 2006. "We are approaching this on a customer-by-customer basis, using our supply chain to ensure that there is no loss in performance or compromise of device specifications," he adds.

Many manufacturers are sending out questionnaires to their suppliers to determine what types of materials are being used. DTX, a manufacturer of embedded computers, is in the process of surveying its suppliers regarding RoHS compliance and lead-free solder usage. The most important element, however, is consistency, says Phillip Gerard, executive vice president for sales and marketing. "We have to provide unchanged platforms to our customers. Every time they receive something from us, it has to be exactly the same as the last product they received from us."

In the end, though, it's up to the customers as to how much energy they want to expend on being compliant. As Ulrike Winter, director of marketing communications at Sanmina-SCI, says, "We can offer alternative components, but the customers have to make the final decision as to when and how they want to become compliant to RoHS and WEEE."