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Overcome the Challenges Posed by the RoHS Recast

Environmental regulations in the EU have gotten stricter for device makers.

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Medical device manufacturers have long had to follow complex rules governing the manufacture and sale of products, but until now, they have been exempt from environmental regulations regarding hazardous substances. That exception, however, is going to change. In June, the European Union (EU) adopted Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment. As of July 21, 2014, medical device makers will no longer be exempt from those regulations (the exemption will end for in vitro devices two years later). Compliance will be mandatory for any company planning to sell to the EU. This article will clarify the directive's requirements in a method that is easy to understand.

Background

The directive regarding the restriction of the use of hazardous substances (RoHS) and the Waste Electrical and Electronic Equipment directive (WEEE) have both been law for a number of years. However, enforcement of these directives has been weak and a significant amount of noncompliant products have entered the EU market. Manufacturers can expect enforcement to be tightened up as the recast directives take effect.

Often called the lead-free directive, RoHScovers electronic assemblies and electronic equipment. In addition to lead, the directive restricts the use of five other substances that are

Exemption Categories

Prior to the recast, there was only one exemption list. The new directive splits exemptions into different

considered dangerous—mercury, cadmium hexavalent chromium, polybrominated biphenyls (PBB), and polybrominated diphenyls. WEEE (the recycling directive) covers almost every type of electronic product and mandates that the original manufacturer of an electronic product take responsibility for the product's disposal. The manufacturer must pay for all costs associated with collection, transportation, and recycling, and ensure that the recycler is aware of the overall material content of the product.

Some items must be identified for separate handling. For instance, fluorescent tubes contain mercury and must be processed to remove the mercury prior to disposal. Batteries, cathode ray tubes, and LCD displays are also processed separately. Manufacturers must provide documentation that clearly identifies the location of offending materials within each product. For example, they may issue a recycling manual with each product that details the location of items that must be removed and treated separately during the disposal process. This manual can be a separate document made available to recyclers and consumers, or it can be included with the owner's manual.

Europe is getting serious about environmental protection. It will be very difficult for medical device makers to sell their products there without fully complying with the recast RoHS and WEEE directives. Other nations are also implementing their own similar hazardous materials legislation and requirements. China, for example, has mandated a

areas to cover explicit categories separately. The applications exempted from the restrictions specific to medical devices and monitoring and control instruments include the following.

Equipment using or detecting ionizing radiation:

- Lead, cadmium, and mercury in detectors for ionizing radiation.
- Lead bearings in x-ray tubes.
- Lead in electromagnetic radiation amplification devices—microchannel plate and capillary plate.
- Lead in the glass frit of x-ray tubes and image intensifiers, and lead in the glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons.
- Lead in shielding for ionizing radiation.
- Lead in x-ray test objects.
- Lead stearate x-ray diffraction crystals.
- Radioactive cadmium isotope source for portable x-ray fluorescence spectrometers.

Exemptions in sensors, detectors, and electrodes:

- Lead and cadmium in ion-selective electrodes, including glass of pH electrodes.
- Lead anodes in electrochemical oxygen sensors.
- Lead, cadmium, and mercury in infrared light detectors.
- Mercury in reference electrodes—low chloride mercury chloride, mercury sulfate, and mercury oxide.

Other exemptions:

- Cadmium in helium-cadmium lasers.
- Lead and cadmium in atomic absorption spectroscopy lamps.
- Lead in alloys as a superconductor and thermal conductor in MRI.
- Lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors.
- Lead in counterweights.
- Lead in single crystal piezoelectric materials for ultrasonic transducers.

declaration of materials, translated into the Chinese language, be included with products. It is to the benefit of manufacturers to learn about and comply with these stricter environmental regulations.

Recasting RoHS

RoHS is intended to eliminate the use of restricted materials in the production of electrical and electronic products. No more than trace amounts of those materials, which are typically used as chemical stabilizers and fire retardants, are permitted in certain products. RoHS was originally based on the WEEE directive and covers the same 10 product categories that the directive originally covered. These categories are as follows:

- Large household appliances.
- Small household appliances.
- IT and telecommunications equipment.
- Consumer equipment.
- Lighting equipment—including light bulbs.
- Electronic and electrical tools.
- Toys, leisure, and sports equipment.
- Medical devices.
- Monitoring and control instruments.
- Automatic dispensers.

Prior to the recast, categories 8 and 9 (medical devices and monitoring and control instruments) were exempt from RoHS requirements. In addition to ending those exemptions, the recast added an eleventh, catch-all category: other electrical and electronic equipment not covered by any of the mentioned categories. The recast also compressed the product categories covered by the WEEE directive, shrinking that list from 10 to five.

Defining The Products

The new directive clarifies the acronym EEE in an effort to further define the products that are subject to regulation and eliminate potential confusion. EEE is now defined as “electrical and electronic equipment.” This refers to equipment that depends on electric currents or electromagnetic fields to work properly, as well as equipment that generates, transfers, and measures such currents and fields. The equipment must be designed for use with a voltage rating not exceeding 1000 V ac and 1500 V dc. It must also have at least one intended function that is fulfilled by the use of electric currents or electromagnetic fields. The recast expands the reach of what had been considered electrical and electronic equipment, and requires compliance for all equipment types that are not specifically exempted.

Previously, a device could be exempt if electricity was not its main function, which meant a significant number of products were not regulated by the directive. Now, any device that uses electricity for any function falls under the scope of RoHS.

For example, a talking doll would previously have been exempt from RoHS, as its main function was always to be a plaything. Its ability to fulfill this function did not rely on

electricity; even if the talking feature did not work, it was still a doll with which to be played. After the recast, however, such dolls will no longer be exempt, because the talking feature requires the use of batteries and electronics. Category 8: Medical Devices A medical device is defined by the Medical Device Directive (93/42/EEC) as follows:

> "Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; or control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means…"

Directive 98/79 EC defines an in vitro medical device as follows:

> "Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state; concerning a congenital abnormality; to determine the safety and compatibility with potential recipients; or to monitor therapeutic efforts."

Active implantable medical devices, including those in which patients' lives are dependent, are specifically exempted. The EU will require RoHS compliance for all medical devices that are not implantable or critical to an implantable device's operation. To illustrate, an incomplete list of such products could include:

- Anesthesia equipment
- Analyzers, (blood, cholesterol, sugar)
- Blood pressure meters
- Defibrillators
- Dental equipment
- Dialysis equipment
- ECGs
- Electrical surgical tools (saws, etc.)
- Endoscopes
- Gamma cameras
- Hearing aids
- Hospital beds, electricity dependent
- Immunoassay analyzers (IVD)
- Intravenous drug infusion pumps
- Medical freezers
- Medical lasers
- Medical thermometers
- Operating theatre equipment
- Oxygen analyzers (respiration monitors)

- Pacemakers
- Scanners (CT, MRI. PET, etc.)
- Self-test kits - electrical types
- Surgical microscopes
- Ultrasonic equipment
- Ventilators
- X-ray devices

Medical products for which RoHS status requires further clarification include proton therapy facilities (which could be considered large-scale fixed installations), mobility products for the disabled (presently considered a form of transport and thus excluded); and nonelectric dependent hospital beds.

Changes Coming to List of Restricted Substances

Although no additions were made to the list of restricted substances, industry can expect that some changes may be made (or at least discussed) within the next three years. Among those substances are chlorinated flame retardants, PVC, chlorinated plasticizers, dioctyl pthalate (DEHP), benzyl butyl phthalate (BBP), and dibutyl phthalate (DBP). A full evaluation of the list will be required by 2014.

Exemption Changes

Some substances are exempted from RoHS, depending on the context of their use. For example, lead, cadmium, and mercury are can used in detectors of ionizing radiation, because if those substances were not included, the detectors would not be able to detect the radiation. Prior to the recast, there was only one exemption list. The new directive splits exemptions into different areas to cover explicit categories separately. See the sidebar, “Exemption Categories,” for a partial list of these categories.

A manufacturer that suspects one of its products on the market is not in conformity must immediately take corrective measures,

The recast directive provides definitive dates of expiration for each exemption. Exemptions for products in categories 8 and 9 may not exceed seven years; exemptions for all other categories may not exceed five years. Existing exemptions will be assigned expiration dates.

Although it is expected that all exemptions will be considered for renewal, exemption applications must be submitted 18 months prior to their expiration. This deadline gives the committee time to issue a decision six months before the expiration date.

The manufacturer, an authorized representative of the manufacturer, or any economic operator (that is, any legal entity that participates in getting the product to market) in the supply chain may file an

including withdrawing or recalling it.

application to receive, renew, or revoke an exemption. The revised directive requires the filing parties to provide at least the following information, as quoted from the revised directive:

> "a) The name, address and contact details of the applicant. b) Information on the material or component and the specific uses of the substance in the material and component for which an exemption, or its revocation, is requested, and its particular characteristics. c) Verifiable and referenced justification for an exemption, or its revocation, in line with the conditions established by the directive's adaptation of the annexes to scientific and technical progress. d) An analysis of possible alternative substances, materials, or designs on a life cycle basis, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives..."

Major Changes in Compliance

The EU declaration of conformity is a declaration by a product's OEM that the device meets all applicable directives. It must be provided when the legal entity responsible for placing a product on the market has been asked to show proof of compliance. It is not a shipping label, but many OEMs attach it to the shipping information, which can ease the product's movement through European ports of entry. This document, as well as the requirement that every company selling to the EU must have a European delegate, could pose some significant challenges. Proof of compliance with RoHS must now be listed separately from proof of compliance with low voltage (LVD), medical device, EMC, and other requirements. Failure to meet all requirements will preclude a product from carrying a CE mark.

The European delegate, which is an entity that takes responsibility for a product's compliance with European directives and can be either a European third-party or an individual from a company division that is based in Europe, now must be listed on the declaration of conformity as a contact. The delegate has complete legal responsibility for the product's compliance with RoHS. It must keep the technical construction file and declaration of conformity on hand for at least 10 years, so that a challenge to a product may be immediately addressed. Because of this liability, delegates will look for the risk assessment and test reports, and will ask to be shown how the product complies with RoHS.

The revised directive also requires manufacturers to provide technical documentation that enables assessment of RoHS conformity for the product, including a conformity risk assessment and test reports. When test reports cannot be included, the manufacturer is expected to explain why test reports are not applicable for these parts. In addition, manufacturers are now required to maintain technical documentation, cite relevant

harmonized standards, implement internal production controls, and keep a register of all nonconforming products.

A manufacturer that suspects one of its EEE products on the market is not in conformity must immediately take corrective measures, including withdrawing or recalling the product and informing the competent national authorities of the member states. Manufacturers must also provide the details of the product's noncompliance and the corrective measures taken, such as keeping a register of nonconforming EEE goods, executing product recalls, and keeping distributors apprised. Further, after a reasonable request from a competent national authority, a manufacturer must provide all the information and documentation necessary to demonstrate the conformity of an EEE product, in the national language of the requesting body. The manufacturer must cooperate with the authority on any action taken to ensure compliance with the provisions of the directive.

Effect on Medical Device Manufacturers

Medical device makers will be obliged to source RoHS-compliant materials from their semiconductor and electronic component suppliers to ensure their equipment is compliant. Suppliers that provide the appropriate RoHS documentation with component parts will offer OEMs greater time- and cost-efficiencies. It is expected that some medical devices will require material changes to be compliant. This can be an expensive proposition. When new materials are introduced into medical electrical equipment, the equipment must be tested and recertified. This involves strict processes above and beyond those required by RoHS. EMC and product safety testing, being listed by the Nationally Recognized Testing Laboratory, and other requirements all contribute more cost to a product's production. Companies that produce all but the exempt medical devices must carefully analyze the costs and benefits and make some very tough decisions when considering selling into the EU.

Seeking RoHS Certification

While some manufacturers will not be able to comply with the recast directives and thus lose access to potentially lucrative markets, others will be in an ideal position to leverage their medical products' capabilities and their environmentally responsible processes into enhanced market share, provided they can meet the requirements in a timely and cost-efficient manner. There are a number of ways a manufacturer can accomplish this.

It is critical to choose the right certification partner, as this decision will greatly influence return on investment. Ideally, the manufacturer will be able to speed the process by working with a provider that can provide WEEE and RoHS certifications along with other necessary certifications.

OEMs should do everything they can to assure supplier-provided components are documented as RoHS compliant. Some certification providers have access to extensive part databases. This will facilitate the process of gathering and centralizing the required documentation, which can often dramatically reduce the cost of such an effort. Choosing a provider with such a capability will only benefit the manufacturer.

It can also be advantageous to select a certification provider with an extensive global presence. Such a provider should have access to the latest international standard updates and, if involved early in the design process, can help ensure that a product will comply with regulations around the world.

Ideally, the manufacturer should seek to work with an organization that can provide all the compliance services necessary for every desired market. The provider should also have a global network that is conducive to achieving certification on a near-local-basis, as well as the resources and acumen to enable prompt, cost-effective execution.

Conclusion

Due to increasing environmental awareness, the EU regulatory landscape is becoming ever more strict. With a few exceptions, every manufacturer selling to the EU market will need to reexamine its inventory to ensure compliance with the recast RoHS and WEEE directives. Medical device makers will need to decide if access to the EU market warrants investing in possible material changes and meeting multiple regulatory and legal requirements. Companies that partner with RoHS-compliant suppliers and competent global certification providers can expedite this process and open doors to larger market shares.