RoHS Is a RoHS Is a RoHS . . .

Medical and *in vitro* diagnostic device manufacturers soon will need to comply with European requirements restricting the use of certain hazardous substances in electrical and electronic equipment.

Maria Donawa

On 1 July 2011, the recast of the Directive on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (2011/65/EU, otherwise known as RoHS II) was published in the *Official Journal* L174[1]. The recast directive entered into force 20 days later on 21 July 2011. This directive substantially updated and amended the original RoHS Directive (2002/95/EC; RoHS I) published in February 2003 and brought medical devices and *in vitro* diagnostic medical devices (IVDs) within its scope.

A list of 10 product categories was included in the Directive on Waste Electrical and Electronic Equipment (WEEE) and referenced in RoHS I. Medical devices appeared in Category 8; however, the directive excluded Category 8 products from meeting its requirements. This exemption for medical devices has been removed from the revised directive, so medical devices and IVDs must be compliant with RoHS II from 22 July 2014 and 22 July 2016, respectively.

Historical background

Like its predecessor, the RoHS II Directive aims to reduce the amount of toxic material entering the environment through discarded electrical and electronic equipment (EEE) and works in partnership with its sister WEEE Directive. The RoHS directives aim to solve the problem of toxic waste at the *start of pipe*, whereas the WEEE Directive is an *end-of pipe* solution.

Initially, the RoHS and WEEE directives shared the same equipment categories; however, with recent revisions to both directives from 15 August 2018, the new WEEE Directive will categorise waste EEE in line with existing collection and recovery processes, rather than in the same product groupings. RoHS II retains the original category structure, but adds Category 11 to cover any EEE not included in the original 10 categories. This will mean that although medical devices are in Category 8 for RoHS, they will be in Category 4 or 5 (depending on size) for WEEE.

The original RoHS Directive banned six substances from being used in EEE unless they were subject to a specific exemption. The six substances, together with the maximum concentration tolerated by weight in homogeneous materials, are:

- lead (0.1%);
- mercury (0.1%);
- cadmium (0.01%);
- hexavalent chromium (0.1%);
- polybrominated biphenyls (PBB) (0.1%); and
- polybrominated diphenyl ethers (PBDE) (0.1%).

These substances and maximum amounts are unchanged for RoHS II.

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Medical devices and RoHS

Medical devices were deliberately excluded from the scope of RoHS I, as it was recognised that banning the six substances from EEE may have undesirable impacts on reliability and durability of products until the behaviour of the various substitutes was fully understood. Such a problem for life-saving or supporting medical devices would not have been tolerable in the marketplace, hence the device exclusion.

It was recognised by the legislators that for some applications there would never be suitable alternatives to the banned substances. Consequently, provisions were made in the directive for specific exemptions. An application could be submitted to the European Commission for an exemption for a particular banned substance for a specific use. After examination of the application, if the proposed exemption was believed necessary, it was listed in an annex to the directive.

It was always understood that medical devices would be included within the scope of RoHS when the consequences of changing to alternatives for the banned substances were better understood and the risks appreciated. The inclusion of medical devices and IVDs within the scope of RoHS II, therefore, was not unexpected and was effectively communicated to all stakeholders during the negotiation stages of directive development. Nonetheless, owing to the complexity of bringing devices into compliance, a transition period ending on 21 July 2014 for medical devices and 21 July 2016 for IVDs has been granted.

The list of specific applications of the banned substances that were exempted from RoHS I, with current updates, is reproduced in Annex III of RoHS II. Because medical devices were excluded from the scope of RoHS I, no medical device applications are included in this list. During the period prior to publication of the revised directive, significant consultation took place between the device industry and the European Commission regarding exemptions for continued use of the banned substances for specific medical device uses. Some of the requested exemptions have not yet been granted, but may appear in future updates of the directive. The specific exemptions for medical device use that were granted are listed in Annex IV of RoHS II. It must be noted, however, that exemptions can be subject to an expiry period, so manufacturers should ensure they stay current with any amendments to the directive and apply in a timely fashion should an extension be required.

CE mark required for RoHS II compliance

Perhaps the most significant change from the original directive is that RoHS II is now a CE marking directive. Thus, a manufacturer must follow a conformity assessment process, develop technical documentation and carry out internal production controls in line with Module A of Annex II to European Decision No. 768/2008/EC (the revised *New Approach* framework) before placing a CE mark on the product. However, the directive includes a derogation from this requirement when the conformity assessment procedure

from other applicable legislation is "at least as stringent." In those cases, compliance "may be demonstrated within the context of that procedure." Medical device manufacturers generally will be able to make use of this derogation, as the conformity assessment requirements of the medical device legislation will be considered "at least as stringent" as the RoHS II requirements.

To be in compliance with RoHS I, the manufacturer was expected to have evidence that it had exercised due diligence in establishing product compliance in the event of questions from regulatory authorities. Demonstration of compliance with RoHS II has been made easier, however, with the publication of European standard EN 50581:2012, Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances, which provides a template for collation of the necessary evidence. EN 50581 became a harmonised standard with regard to the RoHS II Directive in November 2012, so meeting the standard will provide a presumption of conformity to the relevant parts of RoHS II.

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Having completed all the necessary conformity assessment requirements, a declaration of conformity must be raised to cover both the relevant medical devices directive and RoHS II. Alternatively, two separate but linked declarations may be raised, but bear in mind that two CE marks may not be placed on the device.

It should be noted that there is no Notified Body involvement in the conformity assessment to RoHS II. That is, Notified Bodies assessing manufacturers for compliance with the medical device directives should not need to be involved in the conformity assessment required by RoHS II.

Component supply

As mentioned previously, manufacturers must exercise due diligence in establishing that components are compliant with RoHS, unless they are covered by an exemption for that particular application. In most cases, this will involve simply obtaining a certificate from a qualified supplier for the component in question. At the same time, if the manufacturer has any reason to believe the certificate is in error, or if no certificate is available, the manufacturer is obligated to investigate further. This may need to include testing of a sample component by a laboratory. Alternatively, it may be easier to obtain a similar item from another supplier who is able to provide the necessary certification. In preparation for conformity assessment, suppliers, therefore, will need to be contacted to establish the RoHS status of components being purchased. Most suppliers should be sufficiently familiar with the demands of RoHS I to enable them to provide the required information for RoHS II.

Manufacturing issues

One of the biggest challenges for manufacturers in meeting RoHS requirements almost certainly will be the change from tin/lead to lead-free solders. Lead-free solders typically have a melting temperature 40°C higher than tin/lead, resulting in higher thermal stress on components and substrates during the soldering process. Considered together with any unfamiliar phenomena associated with lead-free solder, such as tin whiskering, becoming RoHS compliant may have an adverse effect not only on device reliability and durability, but also on the production process itself. In extreme cases, it may even lead to the need for a redesign of certain aspects of the product and requalification of compliance with device specifications.

Staff training also will be an important part of the adaptation to RoHS requirements, not just for production staff, but also for service staff, whether in-house or in the field. Spare parts also will have to be managed properly. Although it will be permissible to repair noncompliant devices with a compliant spare part, the reverse will not be permitted. Consequently, spare part inventory will need to be carefully managed to ensure adequate separation between compliant and noncompliant versions of the same part.

Transitional arrangements

By now, manufacturers should have decided which devices are going to be made RoHS compliant and which, if any, will be made obsolete. The directive allows noncompliant devices to be placed on the EU market until 22 July 2014 for medical devices and 22 July 2016 for IVDs. These devices can be in the distribution chain until 22 July 2019. Taking full advantage of these transitional periods, however, may conflict with customer expectations for the availability of compliant devices.

Should readers require additional assistance, guidance has been provided by the European Commission,[2] Eucomed[3] and COCIR.[4]

References

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