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HOW WILL THE EUROPEAN DIRECTIVE 'RoHS 2' IMPACT THE MEDICAL DEVICE INDUSTRY?

The European Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS Directive, 2002/95/EC)[1] has been recast and superseded by a new Directive (2011/65/EU)[2] published in July 2011. This new Directive maintains the intentions of the original Directive: minimising the amount of hazardous substances found in electronics, thereby protecting treatment operators during the recovery process after the same electronics have reached life capacity (i.e. waste).

Medical devices have reaped benefits from exclusion from the European Union's (EU's) first RoHS Directive. Nevertheless, as some medical device manufacturers know, the original Directive has impacted the supply chain and caused some complications due to availability of parts that have become end of life. The changes stemming from the new Directive are going to become significantly more complicated for medical device manufacturers.

'RoHS 2', as the recast Directive has become known, will no longer exclude medical devices. After 22 July 2014, all medical devices meeting the definition of electrical and electronic equipment will be restricted at a homogenous level from using lead, mercury, cadmium, hexavalent chromium, and two polybrominated flame retardants. There is an extended transition period for *in vitro* diagnostic (IVD) equipment (until 22 July 2016) and continued exclusion for active implantable medical devices.

Medical device manufacturers therefore have just over two years left to assess their current products and then re-design, re-qualify and re-submit for various legislative mandates (e.g. the US Food and Drug Administration). If a medical device manufacturer has not started this process, he is at an incredible risk of being barred from selling his product(s) in the EU after the date of compliance. The Consumer Electronics Association has published a report[3] that identified one of the leading causes of financial loss for companies resulting from the original RoHS Directive as the failure to get products re-designed, compliant and available for sale in time.

A closer look at the new RoHS Directive

Fortunately, from an industry perspective, no new substances have been added for restriction. At the same time, there is cohesion through the new RoHS Directive to align with restrictions originating from the EU's REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) Regulation[4]. Some substances that were under discussion through the RoHS recasting process are currently under REACH's Annex XIV authorisation list.

Medical devices will have specific application exemptions added to RoHS 2, along with exemptions that cover all electrical and electronic equipment. This means that medical device manufacturers need to identify if there are current uses in their products that require the RoHS restricted substances without the availability of viable alternatives. This is important since it will be needed to justify any request for exemption along with a number of other procedural activities identified in the Directive.

Placing medical devices on the EU market requires a conformity assessment procedure, according to the Medical Device Directive (MDD) and the IVD Directive (as applicable), which could require the involvement of a Notified Body. If such a Notified Body certifies that the safety of the potential substitute for the intended use in a medical device or IVD is not demonstrated, the use of that potential substitute will be deemed to have

clear negative socioeconomic, health and consumer safety impacts. From the date of entry into force of the RoHS 2 Directive, it should therefore be possible to apply exemptions for medical equipment even before the actual inclusion of that equipment in the scope of this new Directive.

Conformity assessment

RoHS 2 is a CE mark Directive. This means that the manufacturer's CE mark on each product will confirm that the manufacturer has taken all appropriate measures to ensure that the product meets the RoHS 2 requirements, including conformity assessment, as well as meeting the requirements of all other relevant CE Directives (e.g. the MDD). There has been little precedent for substance restrictions in CE marking except for some instances in the Toy Safety Directive[5].

Medical device manufacturers are already required to have the CE mark placed on their products due to the MDD, and the MDD requires the device manufacturer to perform a conformity assessment. When the RoHS 2 comes into force for medical devices, the conformity assessment will need to include a process demonstrating that the medical device does not contain any of the restricted substances (unless exempted). The conformity assessment for the MDD does not cover this activity and therefore must be expanded to include RoHS conformity assessment.

Part of the conformity assessment sets out requirements for internal production control with specific requirements for technical documentation, manufacturing, and conformity marking and declaration of conformity. Manufacturers must compile technical documentation that makes it possible to assess the product's conformity, including an adequate analysis and assessment of the risk(s).

Technical documentation

The technical documentation file created for complying with the MDD is not sufficient to satisfy the RoHS 2 Directive. Each technical file should contain the risk criteria and data needed to prove compliance to its respective Directive, and these criteria/data will differ. For RoHS 2, conformity information will be compiled into the technical documentation file based on requirements specified in several legislative documents, standards and industry best practices. Relevant documents include, *inter alia*:

- Directive 2011/65/EU;
- 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;
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;
- EN 62321: 2009, *Electrotechnical products - Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)*, which is adopted from IEC 62321 (which may also be used);
- IEC/TR 62476 Ed 1.0, *Guidance for evaluation of product with respect to substance-use restrictions in electrical and electronic products*;
- IEC 62474 Ed 1.0, *Material Declaration for Products of and for the Electrotechnical Industry* (this standard is currently at the final draft stage and is expected to be published as an international standard in early 2012).

The requirements for technical documentation should be taken into account during the initial implementation of restricted substance controls and

during the conformity data collection. This up-front consideration of the requirements will help manufacturers avoid having to re-do a portion of the conformity assessment due to incomplete or insufficient information.

The old RoHS Directive did not include a discussion on standards to support compliance. RoHS 2 explicitly states that '[m]aterials, components and EEE [electrical and electronic equipment] on which tests and measurements demonstrating compliance with the requirements of Article 4 have been performed, or which have been assessed, in accordance with harmonised standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to comply with the requirements of this Directive'.

Not all International Electrotechnical Commission (IEC) standards have been adopted by the European Committee for Electrotechnical Standardization (CENELEC) but it is expected that if one were to follow the IEC standards, they will harmonise with adoption of the CENELEC standards. This can be taken from the fact that many of those who have helped create the IEC standards are also the same individuals working within the CENELEC body.

The expectation is that suitable CENELEC standards and a European Commission frequently-asked-questions document will be available in mid-2012.

Avoiding potential loss of market

The only way a medical device manufacturer is going to meet the challenges of the new RoHS Directive is to make sure the entire company works together. This means development, engineering, legal/regulatory, sales and senior management all have to be made aware of the RoHS 2 obligations, and agree on the timeline, the budget and the allocation of responsibilities.

The cost for RoHS compliance has been a topic of discussion for some time since there must be a net economic benefit between increasing costs to industry by restricting the use of hazardous substances, and the positive impact on health due to the reduction of exposure to hazardous substances. The European Impact Assessment[6] has stated the following:

> 'it is even claimed that cost of RoHS compliance for some complex products could be as high as 7-10% of turnover (new product) or 1-10% (modification of existing product)'.

In the case of medical devices and control and monitoring instruments, some of which are produced in low numbers or have critical applications and hence increased testing and reliability requirements, the approximate yearly compliance cost is estimated to be 400-1600 million Euros. A large part of this cost is attributable to the long development, testing and approval cycles of the more complex products. This is why a staged introduction for these products is proposed allowing the compliance conversion to take place in the framework of existing resources and product development cycles.

As a result, an important decision for companies will be which products are still going to be available on the EU market after July 2014. In fact, devices may need to meet the requirements sooner than July 2014 in response to professional tenders or other customers requesting RoHS compliant medical equipment well before the date of compliance to ensure effective supply of equipment for patient treatment.

Timing

Ideally, medical device manufacturers should have started the process for RoHS compliance already. Even the simplest medical device requires significant qualification and production control processes, so starting the RoHS programme now could still be too late. A report[7] prepared by ERA

Technology Limited on behalf of the European Commission states the following:

> 'For the most complex products, testing and validation can take 18 months or more and obtaining approvals under ATEX and the Medical Device Directives can take a year more'.
> [ATEX is the name commonly given to the legal requirements for controlling explosive atmospheres and the suitability of equipment and protective systems used in them.]

This suggests that about 30 months of time is required to transition the most complex medical devices to the new requirements. Therefore, medical devices manufacturers that have yet to begin their RoHS compliance programme may not meet the 22 July 2014 deadline. Any non-compliant products will be barred from the EU market after this date.

To put it simply, if you manufacture medical devices and have yet to implement an RoHS programme, this should be priority number one. This may seem difficult to justify because of other recent changes impacting medical devices (e.g. introduction of the third edition of IEC 60601-1[8]) but the RoHS programme will be supporting a CE mark Directive. Compliance must be achieved for **all** CE mark Directives impacting a medical device or the mark must be removed. Take every opportunity during internal meetings and discussions to introduce RoHS as a critical element during 2012 and 2013 development cycles.

The RoHS programme has no basis without a compliant bill of materials. This information needs to be gathered, assessed and then used for new product development. In parallel, medical device manufacturers need to establish their internal production control process as part of RoHS compliance to build their technical file. This process should follow standards that have been developed for RoHS compliance. To go down a separate path could lead to the medical device manufacturer being overburdened with having to demonstrate that a unique programme meets the requirements of the Directive.

Medical devices have a reputation for being one of the most innovative and complicated industries in the world. RoHS compliance will challenge this reputation further over the coming years.

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