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The Medical Device Manufacturer's Guide to
The Recast RoHS Directive 2011/65/EU

Eva-Helena Ouchterlony

Head of Chemistry, Health and Environmental Services/Intertek Sweden

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Introduction

The European Union's RoHS Directive 2002/95/EU has undergone major changes in terms of scope, definitions, and newly introduced methodologies and procedures. The recast RoHS Directive 2011/65/EU, also known as RoHS 2, was published in the Official Journal in July 2011, and transposed into EU national law in January, 2013, and the former Directive has been repealed.

As a manufacturer, importer or distributer it is important to understand and fulfil the obligations of the recast RoHS Directive. This white paper will go through the main changes of the Directive and discuss its potential impact on industry.

Background

The former RoHS Directive, 2002/95/EU, entered into force in July 2006. The main purpose of the Directive was to restrict Lead, Cadmium, Hexavalent Chromium, Mercury and Polybrominated Biphenyls (PBB) and Polybrominated Diphenylethers (PBDE) in electrical and electronic equipment (EEE). The reason for restricting these substances is that they may be released into the environment where they pose a threat to human and animal health and the environment, especially when reaching the waste treatment stage. The potential risks are further increased if sub-standard recycling/recovery processes are used.

Since 2006, enforcement and market surveillance has shown that a high percentage of EEE entering the European market is non-compliant with the requirements of RoHS, i.e. the products tested have been found to contain concentrations of the restricted substances above the set legal limits.

The former RoHS Directive also posed challenges for the industry in the way it was written. It was considered complicated in terms of how to demonstrate compliance to the substance requirements and also in terms of definitions and the scope.

To define product categories in scope, the former Directive made a reference to Annex 1A of the WEEE Directive (2002/96/EC on Waste of Electrical and Electronic Equipment). The WEEE Directive in turn, gave the Member States a certain degree of freedom in interpretation when it came to adding products to the categories in scope. As a consequence, the scope of both WEEE and RoHS has varied between Member States. These differences in interpretations of scope as well as enforcement methodologies in the Member States have given rise to uncertainty as to what is covered by the legislation and added to the administrative burdens and unnecessary costs of manufacturers.

A revision mandate set out in the former RoHS Directive (article 6) and the Commission's commitment to developing a better regulatory environment have formed the basis of a review of both the Directive's implementation and its potential expansion in terms of new product categories as well as an adaptation of the substance list. The objective of the review was to improve the implementation and to harmonize enforcement of RoHS requirements while minimizing the risk to human health and the environment, decreasing the administrative burden, and increasing cost effectiveness.

Based on the review, a recast Directive was presented in 2011, containing substantial changes to address both the problems seen with the first RoHS Directive, as well as the implementation and expansion of the Directive.

Key Changes
The key changes to the recast RoHS Directive include:

- scope - the inclusion of new product categories
- the introduction of new terms and definitions
- the introduction of a methodology for review of existing restricted substances and the introduction of new restrictions
- a clearer procedure for granting exemptions
- alignment with the New Legislative Framework (NLF) including CE Marking

Scope Expansion

RoHS 2 is now a standalone Directive and has no link to the WEEE Directive. Instead, the categories in scope are listed in Annex I of the RoHS Directive.

The scope of RoHS still covers the eight product categories included in the original scope, i.e. categories 1-7 and 10 listed in the WEEE Directive (2002/96/EC). In 2006, a study was performed to assess the possible inclusion of categories 8 and 9 of the WEEE Directive, namely medical devices and monitoring and control instruments, into the scope of RoHS. The study supported the inclusion of the two categories, and the RoHS Directive now includes medical devices and monitoring and control equipment. Compliance dates for medical devices, in vitro diagnostics, and industrial monitoring and control instruments placed on the market are July 22, 2014, July 22, 2016, and July 22, 2017, respectively. Active implantable medical devices and devices critical to an implantable device's operation remain exempt from the 2014 compliance date.

An additional category, category 11, was also included into the scope of RoHS. This category, entering into force in July 2019, will cover electrical and electronic equipment not covered by the other categories. With the inclusion of category 11, the RoHS Directive will have an open scope, including all EEE unless specifically excluded.

RoHS 2 Directive Scope

1. large household appliances
2. small household appliances
3. IT and telecommunications equipment
4. consumer equipment
5. lighting equipment
6. electrical and electronic tools
7. toys, leisure and sports equipment
8. **medical devices**
9. **monitoring and control instruments including industrial monitoring and control instruments**
10. automatic dispensers
11. **other electrical and electronic equipment not covered by any of the categories above**

Note: newly introduced categories are marked in bold

Medical Device Manufacturers and RoHS 2

Europe is getting serious about its environmental protection. It will soon be nearly impossible for medical device manufacturers to sell their products into the European Union without full compliance – something that is also catching on in China, Japan, India and other nations. This is part of a larger trend toward increased environmental regulation worldwide. You can be assured the authorities will be reviewing technical files for RoHS 2 compliance beginning July 22, 2014.

In the case of medical devices, which have increased testing and reliability requirements, the approximate yearly compliance cost is estimated to be 400-1600 million Euros. As a result, an important decision for medical device companies will be which products are still going to be available on the EU market after July 22, 2014.

Where to start?

Considering that it will take an estimated 18 months or more to complete testing and validation for the most complex products, while obtaining approvals under the Medical Device Directives may take an additional 12 months, manufacturers are urged to start planning for RoHS 2 compliance immediately.

Conformity information must be compiled into a technical documentation file based on requirements outlined in several legislative documents, standards, and industry best practices. This will require a continuous exchange of information in the entire supply chain.

Examples of documents included in a RoHS 2 technical file are:

- conformity risk assessment
- supplier declarations of compliance
- materials declarations
- results of supplier audits
- chemical analysis results

Examples of relevant resource documents include:

- 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) No339/93
- EN 62321: 2009, Electrotechnical products – Determination of levels of sic regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers), which is adopted from IEC 62321 (which also may 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 published March 1, 2012

Ideally, the requirements for technical documentation should be taken into account during the initial implementation of the restrictive substance control and during the conformity data collection. Taking an up-front approach will help medical device manufacturers avoid the need to re-do a portion of the conformity assessment due to incomplete or insufficient information.

Terms and Definitions

Article 3 of the recast Directive contains more terms and is more detailed than in its predecessor. As one of the intentions behind RoHS recast was to make the Directive easier to interpret, common definitions were deemed necessary to ensure the Directive's harmonized enforcement. Some definitions now included in RoHS were previously included in the Commission's FAQ on the former RoHS Directive and some of these definitions have also been modified since then.

An example of a newly introduced definition is "homogeneous material." This was previously not explained in the Directive. Also, scope-related definitions such as "cables," "spare parts," "large scale stationary industrial tools," and "large scale fixed installations" are included into article 3 (definitions). However, it should be noted that there still exist many question marks regarding for example "large scaled fixed installations" despite the attempt to clarify its meaning.

Substance Restrictions

No new substance restrictions have been added to the RoHS Directive. The substances restricted and maximum concentrations remain the same as before and are listed in Table1. One important change is that the restricted substances are now listed in an annex (annex II) to the Directive and not in the legal text. This makes it possible for the Commission to add substances to the list without having to make changes in the actual legal text. The maximum concentration values are listed in annex II as well.

Table 1: Restricted Substances of the RoHS Directive

Substance	Maximum concentration values per homogenous material
Lead	0.1 w/w%
Cadmium	0.01 w/w%
Hexavalent Chromium	0.1 w/w%
Mercury	0.1 w/w%
Polybrominated Biphenyls (PBB)	0.1 w/w%
Polybrominated Diphenylethers (PBDE)	0.1 w/w%

A methodology has been introduced for the review of existing restricted substances and the introduction of new restrictions. Article 6 of the Directive states that a review of the substance list, i.e., of annex II shall be considered by the Commission before 22 July 2014, and periodically after that. The review and amendment shall be coherent with other legislation related to chemicals and in particular REACH (i.e. Regulation (EC) No 1907/2006).

Substances made reference to in the Directive for possible future inclusion are "substances of very small size or internal surface structure" (nanomaterials) and the substances mentioned in recital 10, namely:

1. Hexabromocyclododecane (HBCDD)
2. Bis (2-ethylhexyl) Phthalate (DEHP)
3. Butyl Benzyl Phthalate (BBP)
4. DibutylPhthalate (DBP)

The four substances listed above are all included in the REACH Candidate List (Candidate List of Substances of Very High Concern for Authorization).

Exemptions

RoHS annexes III and IV list a number of applications exempt from the substance restriction. Furthermore, annex V of RoHS introduces an application template of minimum information to be submitted with an exemption request in order to grant, renew or delete an exemption.

With the recast of RoHS, the exemption process has been amended and exemptions can only be granted if:

- The elimination or substitution via design changes or materials and components is technically or scientifically impracticable
- The reliability of the substitute is not ensured
- The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

An exemption can only be granted if at least one of the three criteria justifies the specific use of a restricted substance. Additionally, the availability of substitutes and socio-economic impact of substitution must be taken into account.

To further clarify the above the articles 3(25) and 3(26) of the RoHS Directive define *"availability of a substitute"* as *"the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in annex II "*(i.e. the restricted substances) and *"reliability of substitute"* as *"the probability that an EEE using a substitute will perform a required function without failure under stated conditions for a stated period of time."*

The Directive provides clear wording regarding the exemption timeline. The exemptions are temporary and each exemption has a validity period depending on the category of EEE. The newly introduced categories 8 (medical devices) and 9 (monitoring and control equipment) have a validity period of up to seven years. Exemptions for the categories already included in the former RoHS Directive will have a validity period of up to 5 years. An exemption can only be renewed upon request after a case-by-case assessment. Before amending annexes III and IV, the Commission shall consult stakeholders.

The aim of the proposed changes connected to exemptions is to create a Directive that is adapted to technical and scientific process and also make faster mechanisms for granting exemptions possible.

CE Marking & Alignment with the New Legislative Framework (NLF)

One of the most important changes of the recast Directive is that it has become a CE Marking Directive. This means that in order to affix the CE Marking on the EEE, a medical device manufacturer must meet the requirements of the RoHS Directive in addition to the requirements of other applicable CE Marking Directives (e.g. EMC or the Low Voltage Directive).

The CE Marking is the visual proof that a product has undergone a conformity assessment procedure and will, in the case of RoHS, demonstrate that none of the restricted substances exceed the set threshold values. The conformity assessment procedure should be carried out by the manufacturer and documented in the technical file of the equipment. Article 7 b of the RoHS Directive states that the manufacturer shall draw up the required technical documentation and carry out the internal production control (conformity assessment) procedure in accordance with Module A of Annex II in Decision 768/2008/EEC.

Decision 768/2008/EEC is part of the New Legislative Framework, published in the Official Journal in 2008, and constitutes a framework for the marketing of products in the European Union. It aims to improve compliance with EU legislation as well as the free movement of goods within the EU by including clearer definitions of, for example, economic operators (e.g., manufacturers and importers), clearer conformity assessment procedures, and obligations of economic operators.

As part of the alignment with the New Legislative Framework, in article 16, RoHS introduces presumption of conformity. According to article 16 of the Directive, material, components and equipment on which tests and measurements have been performed to demonstrate compliance, or which have been assessed in accordance with harmonized standards, shall be presumed to comply with RoHS requirements.

In response to article 16, a standard was quickly developed. EN 50581:2012 *"Technical documentation for the assessment of electrical and electronic products with respect to restriction of hazardous substances"* was harmonized under the Directive in the autumn of 2012. The aim of the standard is to specify the technical documentation that the manufacturer needs to compile as well as give guidance on how the manufacturer shall decide on relevant documentation for the technical file, what information to gather, and how to evaluate the information gathered.

In summary, medical device manufacturers have the responsibility to manufacture equipment that does not contain the restricted substances above threshold values, compile

the necessary technical file, draw up an EU declaration of conformity, and affix CE Marking. The other obligations of the manufacturer are listed in article 7 of the RoHS Directive and include, for example, the requirement to mark equipment with type, batch or serial number for identification purposes. The name of the manufacturer (registered trade name or mark) and address must also be indicated on the equipment or if not possible, on packaging or in a document accompanying the EEE.

The obligations of the importer, the distributor and of the authorized representative can also be found in the Directive. The importer must, among other requirements, ensure that the manufacturer fulfils its obligations in terms of conformity assessment, required documentation and record keeping, as well as marking and traceability requirements. The importer should also indicate on the EEE (or packaging/ accompanying documents) its name and contact information. The distributor has verification obligations, e.g., that the EEE bears CE Marking. For further information on the obligations of the economic operators, see Appendix 1 of this document.

Article 12 of the RoHS Directive also states that Member States shall ensure that economic operators, on request, are able to give information on the following to the market surveillance authorities for 10 years following the placement of the EEE on the market:

a) any economic operator who has supplied them with an EEE

b) any economic operator to whom they have supplied an EEE

Summary and Conclusion

In order to achieve a more efficient Directive with increased benefits for health and environment, the Recast Directive 2011/65/EU was transposed into national legislation in January 2013 and will in the long term include all electrical and electronic equipment, unless specifically excluded. To address issues regarding uncertainty of how to demonstrate compliance, a conformity assessment procedure, the use of Standards, Declaration of Conformity and CE Marking have been included in RoHS.

Ensuring and demonstrating product compliance will in most cases mean demonstrating compliance in the supply chain. However, with the alignment of the NLF and the clarification regarding how to demonstrate compliance, enforcement is made more feasible. Consequently, the recast RoHS Directive comes with the expectation that enforcement will increase.

For new products/product categories in scope, for example, medical devices, it is important to start the RoHS compliance work in time in order to meet the deadlines. Creating an infrastructure to produce and maintain correct technical documentation on RoHS compliance has proven time consuming, mostly due to complex supply chain communication all the way down to the homogenous materials of the EEE.

New challenges for the medical device industry may also arise if/when annex II of the RoHS Directive is amended, i.e. when a review of new and old substance restrictions is performed. A review of the substance list should be coherent with work done under other Union legislation and in particular, the REACH Regulation. It is recommended that RoHS and REACH compliance work, as well as work with other restricted substance legislation, is undertaken using a systematic approach to communication in the supply chain and staying up-to-date.

You can be certain that environmental regulation is here to stay and will become more stringent in the future given that there is:

- pending RoHS legislation in China
- EU REACH legislation restricting additional Substances of High Concern (SVHC's)
- New U.S. rules surrounding conflict minerals sourcing
- varying state-level bans on certain chemicals in the United States,
- simmering concern over the supply of rare earth minerals commonly used in electronics equipment

With the stakes high with potentially millions of dollars of revenue at risk, it is important to, at a minimum, design for conformance to avoid potential recalls, brand damage, costly redesigns, and scrapped parts – just to name a few costly roadblocks.

How Intertek Can Help

Working with manufacturers to ensure that electrical products meet the requirements of the European Directives that relate to them is a core activity for Intertek. Our engineering experts provide support and guidance at every point during the design process to ensure products comply with market requirements - from design review and pre-compliance testing, through full testing to standards and stringent professional assessment.

Whether you need advice on factory production control, on how to build a technical file or even on how CE Marking should be applied, we can help. From evidence to support your CE Marking and DoC activities or for a full product certification and Marking – or even working towards international market access via the IECEE CB scheme, Intertek has a compliance route to meet your needs and budget.

We are an EU Notified Body, a member of the IECEE CB scheme and a Nationally Recognized Test Laboratory for North America.

About Intertek

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Contact Us

If you would like to connect with an expert to answer your technical questions, or obtain a quote for a new testing project, contact Intertek at 1-800-WORLDLAB or icenter@intertek.com

Appendix 1

Obligations of economic operator as listed in articles 7 through 10 in the recast RoHS Directive:

Obligations of Manufacturer	Obligations of Authorised Representative	Obligations of Importer	Obligations of Distributor
1. When placing EEE on the market, manufacturers ensure that it has been designed and manufactured in accordance with article 4 (i.e. not contain the restricted substances no more than the allowed maximum concentration value by weight in homogenous materials)	1. Manufacturers have the possibility to appoint an authorised representative by written mandate. The following obligations laid down for manufacturers: "when placing EEE on the market, manufacturers ensure that it has been designed and manufactured in accordance with article 4 (i.e. not contain the restricted substances no more than the allowed maximum concentration value by weight in homogenous materials)" and the drawing up of technical documentation shall not form part of the authorised representative's mandate	1. Place only EEE that complies with the RoHS Directive on the Union market	1. When making an EEE available on the market, distributors act with due care in relation to the requirements applicable in particular by verifying that the EEE bears the CE marking, that it is accompanied by the required documents in a language which can be easily understood by consumers and other end-users in the Member State in which the EEE is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in points 7 and 8 of obligations of manufacturers and in point 4 of obligations of importers
2. Draw up the required technical documentation and carry out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC or have it carried out	2. An authorised representative performs the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following: -keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years following the placing on the market of the EEE, -further to a reasoned request from competent national authority, provide that authority with all the information and documentation Necessary to demonstrate the conformity of an EEE with the RoHS Directive -cooperate with the competent national authorities, at their request, on any action taken to ensure compliance with the RoHS Directive of EEE covered by their mandate.	2. Before placing an EEE on the market, ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer, and further ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in points 6 and 7 of obligations of manufacturers	2. Where a distributor considers or has reason to believe that an EEE in not in conformity with article 4 of the ROHS Directive (i.e. substance restrictions and applicable concentration), that distributor does not make the EEE available on the market until it has been brought into conformity, and that that distributor informs the manufacturer or the importer as well as the market surveillance authorities to that effect

Obligations of Manufacturer	Obligations of Authorised Representative	Obligations of Importer	Obligations of Distributor
3. Where compliance of EEE with the applicable requirements has been demonstrated (see above), manufacturers draw up an EU declaration of conformity and affix the CE marking on the finished product. Where other applicable Union legislation requires the application of conformity assessment procedure which is at least as stringent, compliance with the restricted substance requirements may be demonstrated within the context of that procedure. A single technical documentation may be drawn up	X	3. Where an importer considers or has reason to believe that an EEE is not in conformity with article 4 of the ROHS Directive (i.e. substance restrictions and applicable concentration), that importer does not place the EEE on the market until it has been brought into conformity, and that that importer informs the manufacturer and the market surveillance authorities to that effect	3. Distributor who consider or have reason to believe that an EEE which they have made available on the market is not in conformity with the RoHS Directive make sure that the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, are taken and that they immediately inform the competent national authorities of the Member State in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken
4. Keep the technical documentation and the EU declaration of conformity for 10 years after the EEE has been placed on the market	X	4. Indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer's name and address which are at least as stringent, those provisions shall apply	4. Distributor, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of EEE with the RoHS Directive, and that they cooperate with that authority, at its request, on any action taken to ensure the compliance with the RoHS Directive of the EEE which they have made available on the market
5. Ensure procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of EEE is declared shall be adequately taken into account	X	5. Importers, in order to ensure compliance with the ROHS Directive, keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof	X

Obligations of Manufacturer	Obligations of Authorised Representative	Obligations of Importer	Obligations of Distributor
6. Keep a register of non-conforming EEE and product recalls, and keep distributors informed thereof	X	6. Importers who consider or have reason to believe that an EEE which they have placed on the market is not in conformity with the RoHS Directive immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular of the non-compliance and of any corrective measures taken	X
7. Ensure that their EEE bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE	X	7. Keep for 10 years following the placing on the market of the EEE, a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request	X
8. Indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The address must indicate a single point at which the manufacturer can be contacted. Where other applicable Union legislation contains provisions for the affixing of the manufacturer's name and address which are at least as stringent, this provision shall apply	X	8. Importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EEE with the ROHS Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with the RoHS Directive of EEE which they have placed on the market.	X

Obligations of Manufacturer	Obligations of Authorised Representative	Obligations of Importer	Obligations of Distributor
9. Manufacturers who consider or have reason to believe that EEE which they have placed on the market is not in conformity with the RoHS Directive immediately take the necessary corrective measures to bring the EEE into conformity, to withdraw it or recall it, if appropriate , and immediately inform the competent national authorities of the Member States in which they made EEE available to that effect, giving details, in particular to the non-compliance and of any corrective measures taken	X	X	X
10. Manufacturers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE with the RoHS Directive, in a language which can be easily understood by that authority, and that they cooperate with that authority, and its request, on any action taken to ensure compliance with the ROHS Directive of EEE which they have placed on the market.	X	X	X