

RoHS Questions and Answers

When people discuss RoHS, they typically mean the European Union program found in directive 2002/95/EC as amended. In this program, products covered by the directive must meet requirements for certain substances. There are also RoHS regulations in other parts of the world including Asia/Pacific and California.

There are six elements or compounds covered by the EU directive. For five of them the maximum limit is 1,000 ppm (0.1%) while for Cadmium the maximum limit is 100 ppm (0.01%) by weight of homogeneous material. The elements or compounds are:

- Lead (Pb)
- Mercury (Hg)
- Cadmium (Cd)
- Hexavalent chromium (Cr⁶⁺)
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ether (PBDE)

The directive applies to certain classes of equipment defined in the Waste Electrical and Electronic Equipment (WEEE) Directive. Currently, two categories are exempt from the directive: medical devices and monitoring & measuring equipment. The EU has a proposal to bring these products into the scope of the RoHS Directive.

The RoHS directive applies to homogeneous material that could be mechanically separated. This means the requirements apply to individual components of a product, not the whole product. For example, if a plastic case contained 2,300 ppm (0.23%) of a polybrominated biphenyl (PBB), the whole piece of equipment, because of this one part, would not satisfy the RoHS requirement.

How do manufacturers manage the compilation of compliance documentation?

The standard method for manufacturers near the end of the supply chain is to analyze the bill of materials for the product to determine the components that can be mechanically separated. For each component ask the supplier for a declaration of conformity that the product satisfies the RoHS directive. Most OEM suppliers are prepared to provide the documentation.

For material further down the supply chain, the manufacturer may have to test the product. One method that has become popular is x-ray fluorescence (XRF) spectroscopy. In this method, an x-ray beam determines the elements in the material and their proportion. Modern XRF instruments are hand held, battery operated devices about the size of a hair dryer while others are bench top models.

The standard method is to assemble the supplier certifications or company test reports into a folder by component. Often, the same component can be used in multiple applications, so component files make record keeping easier. For any given product, an annotated bill of material can refer to the individual component files.

How are RoHS suppliers qualified?

RoHS suppliers are qualified by two characteristics. They have a program in place to collect and maintain the specific information required and they can provide a declaration of conformity when requested.

The most important characteristic is the ability to provide correct information supported by facts.

It is very important to remember that the RoHS requirements apply to parts, not to the supplier. In this sense, the requirements are more like the electrical or mechanical specifications of a part and less like the requirements for a Quality Management System.

What specifically should be requested of a supplier during a supplier audit that would demonstrate compliance due diligence?

There are two approaches. Some Notified Bodies provide a RoHS certificate. One example is the National Standards Authority of Ireland (NSAI) who operates a program in the US. They offer a certificate similar to a Quality Management System certificate for ISO 9001 or ISO 13485.

During a second party audit you would look for an established program (procedures, work instructions, forms, *etc.*) that the supplier effectively implemented. In particular, you would want to examine the files for the parts you purchase.

How is the RoHS requirement communicated to the supplier?

Technically, the RoHS requirement is an attribute of the part, not the supplier. You would communicate the requirement in the part specification. For an ISO 9001:2008 or an ISO 13485:2003 system you would include the requirement as part of the clause 7.4.1 Purchasing information. As a result, it will appear (perhaps by reference) on each purchase order.

In practice, you would already have this information as part of the product design, since you don't want to design in a part that does not meet the RoHS requirements.

What specifically is requested of the supplier concerning shipment of product?

When you qualified the part, you should have a declaration of conformity, test report, *etc.* that demonstrates the part satisfies the RoHS requirements. This documentation is in the part folder and helps you make an appropriate declaration of conformity to your customer.

Since you will not be able to determine RoHS compliance when you verify the purchased product, a Certificate of Conformance (CoC) would be appropriate. Typically, you specify this as part of the purchasing information, so it is on every purchase order. When you receive the part you will verify the CoC as part of your implementation of ISO 9001 or ISO 13485 clause 7.4.3 Verification of purchased product.