A Closer Look: RoHS 2 Compliance Process

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Regulations for the Restriction of Hazardous Substances (RoHS) 2 impact the ways in which companies do business, especially in the medical device industry. On July 22, 2014, when a company places a CE mark on medical devices, they are confirming all appropriate measures were taken to ensure each product meets the RoHS 2 directive, which includes conformity assessment, as well as meeting the requirements of all relevant CE Directives. The conformity assessment to RoHS directive must include a process demonstrating that the medical device does not contain any of the restricted substances—unless it is an active implantable or critical to an implantable device's operation. This requirement now includes medical electronic disposables, which were excluded in the previous RoHS revision.

It is the sole responsibility of the medical device manufacturer to compile the "technical file" that enables RoHS 2 assessment of conformity of the product. This means considerably more work for manufacturers, suppliers, and importers regarding the documentation and monitoring of medical devices. More specifically, this process demands a continuous exchange of information along the entire supply chain. For example, a Restricted Substance Control (RSC) Process must be implemented. This process includes the collecting of compliance data for every component of material in the design. The documentation produced has to be included in the technical file, and be kept available for ten years after the product has been placed in the market.

A Systematic Approach to Compliance

Manufacturers are responsible for providing specific information and documentation on demand to enforcement agencies, proving compliance with Restricted Substance Regulations, such as EU RoHS and REACH. Without the proper measures and documentation, a manufacturer is exposed to sanctions from these enforcement agencies including blocked shipments, blocked sales and negative brand perceptions. A Restricted Substance Control (RSC) Process should contain all applicable policies, manufacturing processes and records to demonstrate all reasonable steps have been implemented to assure products conform to RoHS. This system should be a risk-based approach to determine the amount of data collection, verification, testing or auditing required. The risk assessment also should be performed to determine the possibility that a restricted substance may be present in a product or article.

Product Planning and Design for Compliance

A documented strategy on the control of restricted substances is defined and appropriate for the purpose of the organization. Such a document is agreed upon by an organization’s top management. During this first step, the organization develops a corporate restricted substance compliance policy statement detailing the company’s commitment to and goals for achieving compliance. The statement can

be included in the Company's Quality policy or a more detailed restricted substance list (RSL). The objective is to have a formal document to respond to customer inquiries about substance compliance.

When designing a product for Restricted Substance compliance, design engineers should define, document, and maintain Restricted Substance requirements for products that cover all applicable Restricted Substance regulations. Requirements for these regulations request documentation in an Engineering Restricted Substance Specification. More specifically, such requirements need to be properly defined, including: substance restrictions containing the maximum allowable concentration; substance usage exemptions; objective evidence of compliance; part/product verification; and data storage and retention.

Design engineering is responsible for specifying compliant parts from approved manufactures. The manufacturer is responsible for the Restricted Substance compliance of the part and engineering is responsible to verify this compliance by obtaining and reviewing appropriate objective evidence of compliance.

The following list contains examples of acceptable objective evidence of RoHS conformance that may be available for commercial-off-the shelf (COTS) parts manufacturers:

- Restricted Substance capability assessment
- Manufacturer's RoHS or REACH Material Declaration
- Independent Lab Analysis of Chemical Composition
- Manufacturer Web Site RoHS or REACH Conformance Statement
- Manufacturer Data Sheet (specific to part number or series) with RoHS or REACH Declaration

Design engineering also needs to establish all custom/fabricated parts using Restricted Substance compliant materials and parts from approved suppliers. Engineering must work to make certain all selected parts and materials are properly defined as to be Restricted Substance compliant per the Engineering Restricted Substance specification or fabrication drawings.

The following list contains examples of acceptable objective evidence of restricted substance conformance for raw materials.

- *Metal Alloys* – Material certifications to recognized international standard from material supplier that specifies the elemental composition of the alloy
- *Metal Finishes* – Restricted substance certification from the finish manufacturer or plating supplier
- *Plastics* – Restricted substance compliance certificate from the Resin manufacturer. In addition, a certificate is needed for any colorants or other substances added during the molding process.
- Independent Lab Analysis of Chemical Composition

Risk assessment should be performed and documented to determine the possibility that a restricted substance may be present in a product or article.

Supplier Information

As part of a Restricted Substance Control (RSC) Process, suppliers are expected to take responsibility for the quality and material content of products supplied. Suppliers also need to assure that adequate tests and inspections are provided to meet specifications. Maintaining an overall effective process to satisfy requirements is a best practice to fulfill supplier responsibilities.

Supplier/manufacturer selection and approval procedures ensure the supplier base is capable of providing restricted substance compliance items as specified. Procurement procedures and processes also must be implemented to restrict the purchase of compliant items to approved manufacturers and suppliers.

Quality and supply chain management play a key role as they monitor compliance of supplier and manufacturer parts and materials. The procedures for this group within an organization include a combination of periodic supplier/manufacturer restricted substance Declaration of Conformance (DoC) collection and verification, capability assessments, and part testing. The frequency of data verification and testing will depend on several factors such as the supplier restricted substance capability assessment, age of the DoC on file, and the materials used.

Manufacturing Operations

To consistently manufacture Restricted Substance compliant products, manufacturing practices that maintain the integrity of inventories, work in progress, and finished goods during the product realization, manufacturing, and service life cycle are required. In addition, on-going audits and verifications that continually evaluate and improve the effectiveness of these processes ensure requirements are met.

Receiving inspection procedures and processes must be implemented that ensure supplied items demonstrate evidence of compliance.

Inventory management procedures and processes that ensure Restricted Substance compliant procured items, work in progress, and finished goods are properly identified, controlled and stored so as to segregate compliant and non-compliant items and to mitigate the risk of contamination with restricted substances.

Implementation of manufacturing control procedures and processes that mitigate contamination from substitution or contact with non-compliant items during assembly, test, packaging and related processes should be documented.

Employee training also is important to ensure they understand their roles and responsibilities for Restricted Substances compliance and how that contributes to continued product and procedure compliance.

Audit and verification procedures and processes are also necessary to assess with the effectiveness of the Restricted Substance Control (RSC) Process.

The Role of Analytical Testing

The employment of laboratory testing (non-destructive or destructive) to verify compliance with the requirements of required laws or directives will be used in many cases as part of an overall systematic approach. In order to obtain conclusive results of a product's compliance, producers may choose to carry out analytical testing of homogeneous materials in their products and/or specific components based on the risk that a restricted substance may be present.

An electronic product may be made up of hundreds or thousands of homogeneous materials, complete testing of the product is usually impractical. When implementing a testing process, a producer should focus on samples from known "high concern" materials. The internationally recognized standard, IEC 62321 specifies methods and recommendations for sample preparation and analytical testing for certain restricted substances typically found in electrical and electronic products.