

Progress Report August 2009

LNE/G-MED: Sharing a Passion for Progress

LNE-GMED North America provides you with periodic updates on the status of various regulatory and quality related issues. As a service to help you best determine your current and future certification needs, we provide you with the following updates:

EUROPEAN ENVIRONMENTAL POLICY & IMPACT ON MEDICAL DEVICES

The environmental impact of products has been an increasing concern for the European authorities. There are several European Directives and Regulations that have been introduced helping to improve "the green" production:

1. **Packaging and Packaging Waste Directive**
2. **Waste Electrical and Electronic Equipment Directive (WEEE)**
3. **Restrictions On the use of Hazardous Substances in electrical and electronic equipment (RoHS)**
4. **Energy using Products Directive (EuP)**
5. **Updated Batteries Directive**
6. **Registration Evaluation Authorization and Restriction of Chemicals (REACH)**

These regulations and Directives are or will impact in some way your business on many aspects.

1. Packaging & Packaging Waste Directives: 94/62/EC

The targets of this Directive are mainly to reduce the packaging and limit hazardous substances. The Essential Requirement in the Directive can be found on the following link: http://ec.europa.eu/environment/waste/packaging_index.htm

2. Waste Electrical and Electronic Equipment Directive (WEEE): 2002/96/EC amended

The Directive objective is to recover more ends of life equipment and the ability to remove any potentially harmful components, subassemblies, or parts before final disposal. All electrical equipment must be marked so that information is provided to customers and recyclers on how to disassemble the equipment and the presence of any harmful material. More information can be found on the following link that covers both WEEE and RoHS: http://ec.europa.eu/environment/waste/weee_index.htm

3. Restrictions on Certain Hazardous substances in electrical and electronic equipment (RoHS): 2002/95/EC amended

The RoHS is focused on the design of equipment and bans the use of some six substances: Lead, Cadmium, Mercury, Chromium (Cr6), 2 types of Bromine flame-retardants: (biphenyls and biphenyl-ethers). The RoHS does not yet apply to medical devices, but the EU Commission is currently reviewing this situation. More information can be found on the following link: http://ec.europa.eu/environment/waste/weee_index.htm

4. Energy-using Products Directive (EuP): 2005/32/EC amended

The objectives of this Directives are to improve the energy efficiency of product groups and to set eco-design requirements by examining carefully the life cycle of these types of products. This Directive may concern several types of medical devices. More information can be found on the following link: http://ec.europa.eu/enterprise/eco_design/index_en.htm

5. Batteries Directive: 2006/66/EC amended

This is an update to the current Directive. It now includes all batteries and sets higher collection and recycling targets. The producer (which includes the product manufacturer who has added a battery to his equipment) is responsible for financing the collection/recycling and providing information to the end user. There are some exemptions for medical equipment in life supporting situations. More information can be found on the following link: <http://ec.europa.eu/environment/waste/batteries/index.htm>

6. Registration, Evaluation and Authorization of Chemicals (Reach): EC 1907/2006

The objectives of REACH are to evaluate the safety, both from human health and environmental damage point of view, via a registration process that may then restrict or require authorization for the use of some chemicals. Chemical manufacturers and/or importers (in EU) will have to provide data, any necessary risk assessment and resulting risk management. All substances above 1 tonne usage per year will be registered with the European Chemicals Agency (ECHA). The final registration of these substances will be delayed until 2013 and 2018. You will not be allowed to use this substance until it is registered and there is a procedure to "pre-register" substances. The [European Commission](#) supports businesses affected by REACH by handing out - free of charge - a software application (IUCLID), which simplifies capturing, managing and submitting of data on chemical properties and effects.

More information can be found on the following link:
http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

Standards & Services

Standards

Medical device manufacturers are encouraged to use standards within their operations. Some are product specific whereas others are business related. In this last category, the ISO 14001 series on Environmental Management Systems aims at giving tools to assess the environmental impact and implement action plans to reduce this impact.

Among product related standards, not less than 6 are directly focused on addressing the requirements of the Packaging Directive.

In addition, the EU Commission now requests that environmental considerations are systematically addressed in all new standards and revisions of existing standards. Both ISO and the European Committee for Standardization (CEN) has provided guides for inclusion of environmental aspects in product standards such as: resource use, energy consumption, emissions to air, emissions to water, waste, noise, migration of dangerous substances, soil, accidents or misuse. It is expected there will be an environmental annex to most standards in the future.

Recently the Medical Electrical Equipment Standard EN 60601 has been updated by including a new collateral standard: 60601-1-9 Environmentally Conscious Design. This document requires the identification of environmental aspects and the determination of the level of significance for each of these aspects. This new standard also suggests typical phases (stages) of the product life cycle for electrical medical devices from the conceptual design to the EOL (End Of Life) management.

For any additional information please contact:

G-MED North America, Inc.
8070 Georgia Avenue, Suite 306
Silver Spring, MD 20910 USA

Phone: 301.495.0477
Fax: 301.589.9443
Email: GMEDNA@LNE-MED.com
www.LNE.EU

