Linking People to Knowledge!™

Global Compliance News

OCTOBER 2006 VOLUME 4, NUMBER 6

International Standards

New Releases:

CISPR 16-1-2:
Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-2: Radio disturbance and immunity measuring apparatus - Ancillary equipment - Conducted disturbances

IEC 60287-1-1:
Electric cables - Calculation of the current rating - Part 1-1: Current rating equations (100 % load factor) and calculation of losses

IEC 60364-4-44:
Electrical installations of buildings - Part 4-44: Protection for safety - Protection against voltage disturbances and electromagnetic disturbances

IEC 60825-4:
Safety of laser products - Part 4: Laser guards

IEC 61000-4-30:
Electromagnetic compatibility (EMC) - Part 4-30: Testing and measurement techniques - Power quality measurement methods

Table of Contents

SIMCOM's Assurance Service

Allows manufacturers to focus on their business while eliminating the burdens of China's CCC Certification System including #3 and technical exemptions as well as CCC Marking.

Click here for a demonstration.

Have an idea for an article?

Drop us a line:
articles@esimcom.com

SIMCOM International was the first Company in North America to be awarded the coveted Consultative Agent Status for China's Compulsory Product Certification System by China's Certification and Accreditation Administration.

IEC 61189-3:
Test methods for electrical materials, interconnection structures and assemblies - Part 3: Test methods for interconnection structures (printed boards)

IEC 61967-4:
Integrated circuits - Measurement of electromagnetic emissions, 150 kHz to 1 GHz - Part 4: Measurement of conducted emissions - 1 Ω/150 Ω direct coupling method

To purchase standards CLICK HERE!

SIMCOM Russian Training Courses

Take the guesswork out of the former Soviet Union's compliance schemes. Contact SIMCOM for details.

SIMCOM International
303 Perimeter Ctr. N.
Suite 300
Atlanta, GA. 30346

Phone
678-690-8540

Fax
888-582-3166

E-mail
service@esimcom.com

We're on the Web!
www.esimcom.com

Want to enroll a colleague? Click here

Hot Topics in December's Issue

SOUTH KOREA

Product Regulatory Compliance

Since the early 1960s, South Korea has achieved an incredible record of growth and integration into the high-tech modern world economy. In 2002 Economic policy undergone transparent and consistent restructuring. In 2004, South Korea joined the trillion - dollar club of world economies, where the government promotes the import of raw materials and technology. Many multi-national manufacturers are exploring the chance to get their products into South Korea Market.

In the next issue we will review Technical Regulations for the products imported into South Korea.

RUSSIAN FEDERATION

Mandatory Certification of Communication Devices

The Russian Ministry of Information and Communications reported that in 2004 the volume of investments in Russian telecommunications increased by 180%, while the market itself grew by more than 43% (and 38% in the first half of 2005).

The Article in the next issue will discuss Russian Government Decree 214, issued on April 13, 2005 and covering the Rules of Organization of procedures developed for Mandatory Certification of Communication Equipment and Devices in Russia.

Return to Table of Contents

RoHS - Keeping up with the World's Legislation

Restricted substance legislation has had a profound effect on manufacturers of electrical and electronic products. Over the past three years, most eyes and ears were focused on Europe - the genesis of Restrictions of Hazardous Substances (RoHS) and Electronic Waste Recycling (WEEE) began. With impetus from the EU, new RoHS and WEEE legislation has been created by: China, Japan, Korea, Canada and a few states in the US.

Manufacturers whose products are in non-compliance will suffer serious repercussions including: fines, market exclusion and damage to the company's reputation in some of the world's highest growth markets.

The only pragmatic answer is to implement specific steps to ensure internal and external procedures cover existing regulations, as well as upcoming regulations in countries, where regulations are in development. The following article outlines key legislation to allow manufacturers an ability to sell products on a global basis.

Europe

As of July 1, 2006, all 25 European Community Members, plus four EEA (European Economic Area) countries: Iceland, Norway, Liechtenstein and Switzerland have implemented RoHS. The RoHS Enforcement Guidance Document issued on May 2006 has two primary objectives:

"1. To assist Member States with national enforcement of the RoHS Directive
2. To provide clarity to industry on how producers may demonstrate compliance with its requirements."

The Guide describes the "Enforcement Process" including criteria for choosing or, sampling products under the following criteria:

- Market intelligence
- Random selection
- Products known to contain materials of high concern
- High volume products
- Short life products
- Consumer products unlikely to be recycled
- Notification of concern from external parties
- Notification of concern from other Member States

If concerns arise (for whatever reason) the Member State enforcement authority may take whatever actions are appropriate to the circumstances according to the powers assigned to them in national legislation; including the removal of the goods from the market.

RoHS Compliance Documentation is described in Section 2 of this Document. "While the overall approach to RoHS compliance is based on a Presumption of Conformity it is recognized that National Authorities will require self-declaration from producers as the key principle underlying the enforcement process."

1. Initial self-declaration;
2. More detailed assessment in cases where evidence from the producer does not assure compliance.
3. Detailed sampling and testing in cases of concern.

List of Typical Documentation:

1. Contact information (Point of contact within the organization that will deal with the RoHS enforcement request)
2. Company information (This should include the size of the organization, product range and approximate levels of sales)
3. Approach to compliance (This should be a general overview of compliance systems that the company has in place; suitable for proving compliance to the RoHS Directive)
4. An overview of the data quality systems (In cases where the producer relies significantly upon supplier information to demonstrate compliance)

Two Stage Compliance System:

Two routes are necessary to show "Best Practices" and demonstrate compliance:

1. Route A - Process-based Technical Documentation (Typical information relating to the producer's internal system to ensure RoHS compliance)
2. Route B - Product/Part-based Technical Documentation (Typical information relating to a product's/part's physical attributes that ensures RoHS compliance of a specific product)

Compliance Assurance System (CAS) is listed in the Table 2 and includes:

1. A definition of the purpose of the system, its essential requirements and Specifications. The specifications should cover compliance for internal and external processes.
2. A formally defined process to implement the requirements of the system; integrated within the organization's quality management systems.
3. A technical documentation system (paper and/or electronic) to support all processes and measures to assure conformity. The system should include requirements for training, work tools and infrastructure.

Evidence of Active Control of the CAS:

Results of internal and supplier audits to validate the Compliance System and/or processes; i.e., a supplier's ability to assure compliance:

- Evidence that the system is being followed including results of product specific conformance assessments comprising items such as: product assessments (including justification of RoHS categorization and use of exemptions), materials declarations, procurement, inventory and production controls and substance analysis where appropriate
- Overview of any internal data system used for the management of RoHS Compliance data
- Producers or suppliers warranties /certificates declaring that the use of the restricted substances is within the permitted levels
- Producers or suppliers completed materials declaration for each part (including revision for revised parts) and justification of RoHS categorization and use of exemptions. These declarations would be limited to the list of RoHS substances, not full materials declarations
- Analysis report for homogeneous materials in parts/components, (which could be the producers or suppliers own internal or external test results). The test results should refer to homogenous materials in parts/components.
- Those who use approach B only (SMEs) must also provide evidence that procedures are being followed to show that materials declarations have been assessed to determine if they can be trusted. Enforcement authorities will also need to see documented compliance procedures

It should be pointed out that testing (either nondestructive or destructive) to verify compliance with the requirements of the RoHS Directive will usually be seen as a last resort. However, the producers and/or the enforcement authorities may choose to carry out analytical testing of homogeneous materials in their products and/or specific components.

Sample selection and testing procedures are not yet formalized; however, one specific example of a standard procedure for analytical testing (which is being widely promoted for use by the IT, telecom and consumer electronics sector) is IEC 62321.Ed.1, 111/54/CD. The draft standard was recently rejected by vote; however it is widely believed issues in dispute will be rectified. Available as a draft, it includes an annex of guidance for: Disassembly, sample selection and application of test methods.

Taiwan

As a major electrical and electronic equipment manufacturing country, the EU's RoHS/WEEE Directives have had an affect in Taiwan. On June 1, 2006 Taiwan's Bureau of Standards, Metrology and Inspection (BSMI) under the Ministry of Economic Affairs announced a new set of regulations to govern designated laboratories responsible for: inspection and testing of hazardous substances.

BSMI will select qualified private laboratories to be in charge of inspection and testing work to ensure that electrical and electronic equipment containing lead, mercury, cadmium, hexavalentchromium, polybrominated biphenyls and polybrominated diphenyl complies with the requirements of the EU Directives.

Private laboratories that successfully pass accreditation by BSMI will be granted certificates to inspect EU-bound electrical and electronic equipment as well as parts and components that contain hazardous substances, at the request of domestic manufacturers.

Those manufacturers whose products are found free from the hazardous substances as set forth in the RoHS/WEEE Directives will receive inspection reports bearing BSMI emblems, which will enable them to easily export products to EU member states.

China

Just when the electronics industry thought that it had overcome the toughest regulatory hurdle with the EU's RoHS Directive; China announced new regulations for Restricted Uses of Hazardous Substances – with mandatory implementation on March 1st 2007.

After further scrutiny, most have discovered that China's RoHS regulation is not the same as the EU's. In fact, it is stricter.

Manufacturers who make "Electronic Information Products" (EIP) as finished goods or, internal parts and components are subject to China's RoHS requirements. The list of EIP products is extensive, covering common electronic items that are often used in industrial and household products.

China's RoHS Scheme imposes two stages of implementation, with compliance to the First Stage mandatory as of March 1, 2007.

The First Stage is a marking regimen covering all products qualified as EIP products. Information must be provided through labeling and language in the product "User Manual" as follows:

- The name of the toxic substance or element
- The "safety period" of the product (*the period when the electronic information product does not leak or mutate)*
- The amount of the substance or element
- The location of the substance or element
- The recyclability of the substance or element
- The name and content of the packaging material, including recyclables
- Place of origin of product

One of the marking requirements, described in Chapter 2, Article 13 requires listing the "toxic and harmful substances or elements" that are described in Chapter 1, Article 3 (4). This list is the same as the EU RoHS restricted materials list, but it also implies that other materials may be added in the future.

According to another marking requirement (Article 14), the manufacturer must define the materials used for packaging, confirming that only non-toxic, harmless, readily degradable and recyclable materials were used and providing information on the recyclability of the packaging material.

Labeling Requirements

MII and related technical groups have proposed a number of exemptions from product labeling requirements, which focus on several factors, including whether the size and functional limitations of the electronic information product make it impractical to mark on the product itself. MII and the related technical groups are making final revisions to the measures governing labeling and any possible exemption issues.

China's Second Stage Implementation will restrict the level of hazardous substance to the same levels as found in the EU RoHS Directive. The primary difference is that China will require testing of products to prove compliance and CCC certification. A formal list or, Catalogue will be published most probably in late 2007 or 2008.

Enforcement and compliance surveillance

Pre-market certification requirements constitute only one aspect of the enforcement and compliance surveillance system contemplated for China RoHS. The State Administration of Certification and Accreditation has a primary role with compliance and surveillance; though day-to-day surveillance will be carried out by provincial Commodity, Quality Inspection Bureaus, in a similar manner as it CCC Marking.

Penalty provisions applicable to the private sector are set forth in Articles 22 and 23 of China RoHS. Although the types of penalties for violations remain ambiguous, these penalties typically include warnings, fines, product seizures, product repatriation orders (for imports), import or manufacture prohibition orders or facility shutdown orders.

Understanding the implications of China RoHS for particular products and industry sectors will require patience, constant monitoring and explanations of the unique aspects of the Chinese legal system. Activity will no doubt intensify as we approach the initial effective date of March 1. Current projections, subject to change, are that MII and affiliated technical bodies will continue drafting implementing measures beyond the March 1st mandatory compliance date.

Following typical rulemaking practice, the implementing measures would be issued in batches, after various industry groups have lobbied their interest with MII.

United States

Currently, there is no harmonized U.S. Federal Legislation or Program that covers Electronic Waste Recycling in all the States. Resolutions presented to the US Congress include:

- House Resolution (HR) 425 - The National Computer Recycling Act that proposes a Grant program to encourage municipalities, individuals and organizations to start e-waste recycling programs.
- House Resolution (HR) 320 or "TIER" Act of 2005– Tax Incentive to Encourage Recycling, amending IRS Code to provide tax incentives to manufacturers of cell phones, computers, televisions, etc. to start operating the recycling programs.
- Senate Bill S 510 - Electronic Waste Recycling Promotion and Consumer Protection Act that proposes to reduce and eliminate electronic waste (Computers, CRT's, display devices) through recycling.

None of these or, similar Bills were signed and it is difficult to predict whether the legislation will be re-introduced after the mid-term elections.

The State of California

California was the first state to seriously implement RoHS type legislation when the "California Electronic Waste Recycling Act 2003 (SB 20)" was signed. This Act represents a comprehensive recycling program established for waste collection reporting and collection procedures; whereby manufacturers and retailers are responsible for "Covered Electronic Devices".

"Covered Electronic Devices" presumed to be hazardous when discarded include:

- CRT and CRT containing devices
- Computer Monitors containing CRTs greater than 4"
- Laptop computers w/ LCD screens
- LCD containing desktop monitors
- Televisions containing CRTs or LCD screen
- Plasma televisions with screens greater than 4"

California Assembly Bill 3001, currently under consideration, proposes to add computers to the list captured by "Covered Electronic Devices". The California Department of Toxic Substance Control (DTSC) adopted regulations prohibiting the sale or offering of a "Covered Electronic Devices" in California if the device is also prohibited from sale in the European Union under the RoHS Directive. This regulation prohibits the use of the four RoHS heavy metals in "Covered Electronic Devices" – lead, mercury, hexavalent chromium and cadmium. The implementation of this regulation is currently scheduled for January 1, 2007. However, implementation and enforcement details need further clarification.

The California Assembly is considering Bill 2202, which would expand the scope of items subject to the substance restriction from "Covered Electronic Devices" to all product categories, as set out in the EU's RoHS Directive Annex IA. The proposed effective date is 2010. Enforcement procedures will be linked to the UK's recently released guidance document.

The State of Washington

The 2006 Washington State Legislature created the Electronic Product Recycling Law Chapter 70.95N RCW. Manufacturers of computers, computer monitors, laptop and portable computers and televisions must provide recycling services throughout the state at no cost to households, small businesses, small local governments, charities and school districts.

The Department of Ecology was tasked in creating the administrative rules for implementation of this new law. These rules require manufacturers of covered electronic products to go through the following steps:

- Register with the Department of Ecology,
- Pay an annual administrative fee to cover the agency's costs
- Brand their products sold in or into Washington State.

The rule requires retailers to only sell branded products. Collectors and transporters registration requirements are also included. The rule prescribes the enforcement process and associated penalties for non-compliance. This rule is being promulgated under the authorities granted to the department under ESSB 6428, passed by the Washington State Legislature during it's 2006 session, codified as RCW 70.95N. The rules currently being adopted are necessary in order to comply with the registration and fees due date of January 1, 2007 established in the law.

The department will be developing additional rules in relation to this new law throughout the upcoming year.

New York City

The New York City Bill that was signed into law on Dec 29, 2005 mandates the following:

- No new covered electronic device purchased or leased by any Agency shall contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers, except as provided by rules promulgated by the director.
- No new covered electronic device purchased or leased by any agency shall contain any hazardous substance in any amount exceeding that proscribed by the director through rulemaking.
- In developing such rules, the director shall consider European Union directive 2002/95/EC and any subsequent material directive issued by the European Parliament and the Council of the European Union.
- "Covered electronic devices" include display products only, not the same scope, as regulated in Europe.

Canada

Since 2002 Canada has developed environmental protection regulations with provincial jurisdiction. In June 25, 2004, Canada's Council of Ministers of the Environment (CCME) endorsed 12 national principles to guide the management of electronic waste. These principles state that responsibilities associated with the management of e-waste are to be "primarily borne by the producers of the products" and management costs are not to burden taxpayers. Requiring producers to internalize life cycle costs provides incentives to design environmentally safe products.

Province of Alberta

Alberta is a leader in environmental management programs. The first provincial electronic recycling program in Canada was created in this province. As of October 1, 2004, televisions, computers and related equipment originally destined for Alberta's landfills are to be: collected, reused, recycled and/or turned into new products and economic opportunities for Albertans.

In the initial phase of the program, televisions, computer monitors, CPUs, laptops, electronic notebooks and printers are accepted for recycling. As of February 2005, an environmental fee, ranging from $5 to $45 is placed on each product in the program.

The Alberta Recycling Management Authority (ARMA) has a multi-stakeholder board responsible for overseeing mandated recycling programs in Alberta, including tire and electronic recycling.

Province of Ontario

The Waste Diversion Act 2002 established Waste Diversion Ontario (WDO) as a non-government corporation made up of business, municipal, government and non-governmental representatives to develop, implement and operate waste diversion programs for a variety of materials. The Ontario government directed the WDO to develop a program to prevent electronic and electrical equipment from going to landfills.

As a result the legislation called "Ontario Regulation 393/04 - Waste Electrical and Electronic Equipment" was filed on December 14, 2004.

In this Regulation the following language is used to define products covered:

"*Waste electrical and electronic equipment" means a device that is waste, that required an electric current to operate and that is:*

- Household appliance, whether used inside or outside a home, including any device listed in Schedule 1,
- Information technology equipment, including any device listed in Schedule 2,
- Telecommunications equipment, including any device listed in Schedule 3,
- Audio-visual equipment, including any device listed in Schedule 4,
- Toy, leisure equipment or sports equipment, including any device listed in Schedule 5,
- Electrical or electronic tool, including any device listed in Schedule 6, but not including a large-scale stationary industrial tool, or
- Navigational, measuring, monitoring, medical or control instrument, including any device listed in Schedule 7, but not including any implanted or infected medical instrument."

Each Schedule provides an extensive list of products that are covered by this Legislation.
In April 2006 plans to move forward with the first phase of the E-Management Program were announced.

Province of Nova Scotia

A RoHS type regulation is has been under draft status including "public consultation". A final regulation has not been announced.

Province of Quebec

A specially designated multi-stakeholder group is preparing Report for public consultation and review. It is necessary to point out that the industry is very active in the implementation of the E-Management Program in Canada. Leaders in Canada's consumer electronics and information technology industries have joined forces in Canada to create the non-profit organization, "Electronic Product Stewardship Canada (EPSC) founded in 2003. This organization is working closely with the Government to design and promote a stewardship program with a "shared responsibility model" involving government, manufacturers, retailers and consumers.

Japan

Japan is 15 years into an ambitious attempt to transform itself into a Recycling-Based Society through voluntary producer and consumer initiatives. METI (the Ministry of Economy, Trade and Industry) publishes guidelines for each business sector and commodity.

As the world's number one developer and manufacturer of electronic components and PCBs, the entire electronics assembly industry has begun to pursue aggressively the removal of lead from the manufacturing process. From the beginning, the target was to put in place is a removal of over 90% of lead by the end of 2003. This does not cover offshore manufacturing, affecting only domestic production. The Japanese Electronic Industry & Technology Association (JEITA) is already working hard on developing manufacturing processes which eradicate lead from production and are well down the line investigating tin / bismuth / zinc (Sn / Bi / Zn) alloy solders. They are also recommending the implementation of SAC305.
At this stage RoHS substances must be reported but are not banned.

To comply with the regulation JIS C 0950, effective July 1, 2006, METI requires the declaration of RoHS hazardous substances used in seven categories of electrical and electronic equipment:

- TVs,
- Personal computers,
- Microwave ovens,
- Refrigerators,
- Washing machines,
- Clothes driers,

- Unit-type air conditioners.

Japan RoHS covers the same six substances called out by the EU RoHS Directive; however, Japan does not ban products containing these substances. Instead, products that exceed the limits of restricted substances are labeled “R”, while the products that do not exceed these values are labeled “G”.

Japan's laws governing product take-back and recycling are among the most far-reaching and ambitious in the Asia region. Japan's recycling and other product stewardship laws cover a wide-spectrum of electrical and electronic equipment, including many components

Japan's policy and law initiatives in the areas of Design-for-Environment and product stewardship are also among the most aggressive in Asia. Japan has distinguished itself among the other governments in the region, and the rest of the world, by developing national policies to promote "sustainable development" through government, commercial and private recycling and other resource-use minimization efforts. As part of this system-wide policy development effort, Japan is adopting a number of laws that will constitute the country's legal system supporting a "recycling-based society."

The Electronic Industries Alliance (EIA), in coordination with the Japan Green Procurement Survey Standardization Initiative (JGPSSI) is in the process of updating the current Joint Industry Guide for Material Composition Declaration for Electronics Products (JIG 101).

South Korea

Effective August 11,2007 the “Act for Recycling of Electrical/Electronic Products and Automobiles” will restrict the use of hazardous substances in such products and promote recycling. The requirements include marking of the products based on the content of hazardous materials in order to improve recycling efficiency.

It will be manufacturers responsibility to collect and the material composition information and declare compliance to this Law. This information will have to be available to the authorized government surveillance officials upon request.

What does it all mean for the OEM?

Entire industries that have had minimal compliance requirements have quickly found that the rules have changes. In addition to managing their own products, most legislation requires monitoring and data collection from their supply chain. In addition, third-party involvement to assure collection, recycling, fee payments, etc. is now on the plate of the OEM.

Companies who focused only on the EU’s Directive under the belief it was the most strict or if in compliance could meet any country’s requirements; have unfortunately found themselves scrambling for cover. Those who believed it was enough to simply collect Certificates of Compliance; or, those who have been counting on exemptions to escape compliance must re-evaluate their internal processes and procedures – otherwise, they may find products being banned from sale or, at a minimum severe scrutiny when entering countries that have imposed environmental regulations.

Component manufacturers that have resisted requests for material declarations of their products and have only provided “Certificates of Compliance” or, vague assurances that they do not use restricted substances in their products may be forced to prove compliance through random testing.

Any manufacturer that utilizes electrical or electronic parts and components in end products, must reassess how they define and/or develop products to successfully compete in a global economy with increasing environmental requirements.

For further information or to schedule a conference with SIMCOM International please contact SIMCOM at: (678) 690-8540 **or** service@esimcom.com **or visit us at:** www.esimcom.com

Return to Table of Contents

China RoHS Document Bundle

SIMCOM is now offering a complete set of English version documents for China RoHS Compliance. It is comprised of **3 Laws and Regulations, 2 Administrative Documents and 9 GB RoHS Standards.**

This Package consists of all the information your company needs in order to comply with China's Restriction of Hazardous Substances Laws effective March 1, 2007

Click Here for more information.

CANADA

The 1989 US-Canada Free Trade Agreement (FTA) and the 1994 North American Free Trade Agreement (NAFTA) produced a dramatic increase in trade and economic integration in Canada. In this issue we will review Canada's Product Regulatory Requirements.

Power Requirements

Voltage 120V (single phase)
208V/240V (three phase)
Frequency 60 Hz
(*The neutral wire of the secondary distribution system is grounded)

The standard NEMA 5-15 plug and socket system (in Canada, CS22.2, No.42) is commonly used in the U.S and Canada. This plug is rated at 15 amps. Other NEMA plug and socket configurations permit power connections at higher amperage and voltage ratings. The standard NEMA 6-15 plug and socket system is designed specifically for 250V circuits. This pair has a straight blade configuration but NEMA calls out a system of locking pairs as well.

Organizational Hierarchy

Federal Level - Federal government establishes minimum requirements
Provincial Level (Hydro Companies) - Grant Approvals to Federal Requirements
Authorities Having Jurisdiction – Must adhere to Provincial Mandates

Key Players

Standards Council of Canada (SCC)

- ✓ Grants National Accreditations
- ✓ Oversees all areas of safety

Certification Organization (CO)

- ✓ Accredited by SCC
- ✓ Responsible for Certification of products based on their compliance with National Requirements.

Testing Organization (TO)

- ✓ Accredited by SCC
- ✓ Conducts products tests based on the Canadian National Standards.

Standards Development Organizations (SDO) are responsible for: writing, harmonizing and maintaining Canada's National Standards. Provincial or Territorial Authorities enforce product compliance with national standards and local provincial/territorial requirements.

Legal Requirements

1) Product regulatory requirements are driven by the Provincial Authority, rather than by the Federal Government. Therefore, the requirements may differ depending on the Province, where they are to be used;
2) Mandatory certification is required for all products;
3) Electrical equipment cannot be offered for sale; unless the equipment is approved by Standards Council of Canada (SCC) accredited Certification Organization acceptable to provincial regulators;
4) Canada is bilingual - manuals and markings must be in both English and French.

Telecom Equipment

Telecom & Radio products require Industry of Canada approval and must demonstrate compliance to safety, EMC and telecom requirements. Testing may be conducted outside Canada by accredited testing organizations.

Medical Equipment

As of January 1, 2003, Canadian regulations require that medical devices be designed and manufactured under a registered quality management system (QMS) that meets the criteria of International Standards Organizations (ISO) standards 13488-03 for Class II devices and 13485-03 for Class III and IV devices.

The Canadian Medical Devices Conformity Assessment System (CMDCAS) (within the Therapeutic Products Directorate (TPD), in partnership with the Standards Council of Canada (SCC) were tasked with executing regulatory policy in that country. The SCC accredited organizations to register the QMS of medical device manufacturers. Only SCC-accredited registration bodies are eligible to register manufacturers for export into Canada.

As of July 15,2006, QMS of medical manufacturers must comply with CAN/CSA-ISO 13485-2003. Medical Devices in Canada are classified as Class I through IV according to their risk to the human body. Class IV represents the highest risk according to RBCS (Risk Based Classification System), under the jurisdiction of Therapeutic Products Division of Health Canada.

Classifications:

1) Class I: lowest risk devices such as wound care and non-surgically invasive devices, such as mechanical barriers;
2) Class II: low-risk devices including contact lenses and the majority of surgically invasive devices;
3) Class III: medium risk devices such as hip implants, glucose monitors and surgically - invasive devices

intended to be absorbed into the body or, that are intended to remain in the body for at least thirty consecutive days;
4) Class IV: high-risk devices such as pacemakers and surgically- invasive devices that diagnose, control or correct a defect in the central cardiovascular system.

Medical Devices must meet safety and performance requirements. The compliance data must be maintained at all times. Manufacturers are obligated to conduct risk assessment and identify the risks inherent in the device, eliminate or reduce possible risks or provide means protection from those risks.

All Medical Devices must have legible and permanent Labels containing the following data:

- Device Name/Model Number
- Manufacturers Name
- The control number for Class III or IV devices,
- Dimensions of the device
- Sterility information, where appropriate
- Expiration date
- Directions for use, storage, and disposal

If the device is sold to the general public, labeling information should be on the outside of the packaging (size permitting) and visible under normal conditions of sale. Labeling must be in either English or French, but manufacturers providing labeling in one language must be prepared to provide it in both languages. Required information (as shown above) on devices to be sold directly to the general public must be both in English and in French.

Compliance Process

The new product manufacturer must submit a product sample and all necessary information to CO/TO, accredited for the specific product category by SCC. The product is tested and if found to be in compliance with the applicable National Canadian Standards, an Initial Plant Inspection is conducted. Upon successful completion of Initial Plant Inspection a listing mark is issued. The Certification Organization conducts four follow-up inspections per year and the Listing is valid for the life of the product, providing that follow-up inspections are satisfied. Canada participates in the CB Scheme and therefore, products with CB Test Reports and Certificates will be accepted.

NAFTA Certificates of Origin

Under the North American Free Trade Agreement (NAFTA), certain products, including most medical devices, that "originate" in Canada, Mexico, or the United States enjoy low or zero tariff rates when traded between these countries. In order to receive this preferential treatment, products that qualify must have a NAFTA Certificate of Origin.

For information on NAFTA Rules of Origin and the Certificate of Origin, visit the Department of Commerce Trade Information Center Website at www.tradeinfo.doc.gov Click on "Country Information" followed by "NAFTA" and then "NAFTA Certificate of Origin."

Market Surveillance

Provincial Authorities may randomly pull any product from retail shelves for inspection or, compliance to regulations.

For further information or to schedule a conference with SIMCOM International please contact SIMCOM at: (678) 690-8540 **or** service@esimcom.com **or visit us at:** www.esimcom.com.

Return to Table of Contents

INTERNATIONAL NEWS

China

"Technical Regulation for Safety of Simple Pressure Vessels" TSG R0003-2006 was issued by General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). The proposed adoption date is August 18, 2006. The proposed date, when this document comes into effect is August 1, 2007.

Description of content: This technical regulation lays down mandatory safety technical requirements for simple pressure vessels, which is composed of a cylindrical part of circular cross-section closed by outwardly dished and/or flat ends revolving around the same axis as the cylindrical part or two dished ends revolving around the same axis. The design pressure of the simple pressure vessels is less than 1.6MPa and the product of pressure and volume is less than 1000MPa·L. The simple pressure vessels contain air, nitrogen and vapor from medical distilled water, and with the design temperature not less than -20° and maximum working temperature not exceed of 150°. Carbon steel or austenitic stainless steel is used as the material of the simple pressure vessels. The purpose of this regulation is to ensure the safety of simple pressure vessels.

Purchase Document Here (Note: Document in Simplified Chinese, English Translation Available Upon Request).

Return to Table of Contents

Taiwan

Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs (BSMI) issued a notification for Electric shredders and other digital audio recording apparatus (HS Codes 84 and 85) for the Separate Customs Territory of Taiwan, Kinmen and Matsu. The announcement is in regards to intension to regulate electric shredder and other digital audio recording as commodities subject to inspection. As of July 1, 2007, all such products must be inspected by the Bureau of Standards, Metrology and Inspection, and must conform to the safety and EMC inspection requirements (except that the digital cameras and digital video cameras are required to comply with EMC requirements only) when imported or marketed. All the technical requirements for the aforementioned products are CNS standards that have been harmonized with relevant IEC or CISPR standards. This notice also provides the applicable conformity assessment procedures. The digital cameras and digital video cameras will be subject to Declaration of Conformity scheme, while others will be subject to a dual-track approach to conformity assessment procedures, namely Registration of Product Certification or Type-approved Batch Inspection.

Relevant documents: The Commodity Inspection Act, CNS 14408, CNS 14336, CNS 13439, CNS 13783-1
Click here for the full text regulation.

Return to Table of Contents

EU Publishes PPE Directive Guidelines

The EU's Commission publishes guidelines on Personal Protective Equipment (PPE) (89/686/EEC) to serve as a reference guide for manufacturers, national regulatory and enforcement authorities. The guide contains an updated Appendix for categorization of PPE and classifies groups of products not covered by the PPE directive. Click here to download a copy of the guidelines.

Return to Table of Contents

Standards Updated for EU's General Product Safety Directive

The EU Commission recently published a revised list of standards for the general product safety (2001/95/EC) necessary to demonstrate conformity. Click here for a list of standards.

Return to Table of Contents

Need Global Compliance Training? CLICK HERE