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# Global Compliance News

AUGUST 2006

VOLUME 3, NUMBER 6

## International Standards

### New Releases:

#### [CISPR 11:](#)

Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement

#### [IEC 60079-7:](#)

Explosive atmospheres – Part 7: Equipment protection by increased safety “e”

#### [IEC 60309-4:](#)

Plugs, socket-outlets and couplers for industrial purposes – Part 4: Switched socket-outlets and connectors with or without interlock

#### [IEC 60384-24:](#)

Fixed capacitors for use in electronic equipment – Part 24: Sectional specifications – Surface mount fixed tantalum electrolytic capacitors with conductive polymer solid electrolyte

#### [IEC 60603-7-7:](#)

Connectors for electronic equipment – Part 7-7: Detail specification for 8-way, shielded, free and fixed connectors, for data transmissions with frequencies up to 600 MHz

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## SIMCOM's New China 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.

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an article?

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[articles@esimcom.com](mailto: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 61008-1:](#)  
Residual current  
operated circuit-  
breakers without  
integral overcurrent  
protection for  
household and  
similar uses (RCCB)s  
- Part 1: General  
Rules

[IEC 61326-2-3:](#)  
Electrical equipment  
for measurement,  
control and  
laboratory use - EMC  
requirements - Test  
configuration,  
operation conditions  
and performance  
criteria

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standards \*\*CLICK  
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## **China's Final RoHS GB Standards Be the first to have Official Copies...!**

China has finalized the first GB standards for material declarations and a standard that describes maximum concentration values, (MCV) of the restricted substances. These standards will be mandatory to prove compliance to China's "Administrative Measure on the Control of Pollution by Electronic Information Products".

**SIMCOM International is the only American company to have advance copies, in English!**

These GB standards provide detailed instructions on how to meet China's RoHS Measure - with the first implementation deadline set for March 1, 2007.

**To purchase these standards go to:  
[www.esimcom.com/gbrohsstandards.asp](http://www.esimcom.com/gbrohsstandards.asp)**

**SJXXXX-X5 (Final numbering to be determined)**

**"Requirements for Concentration Limits for Certain  
Hazardous Substances in Electronic Information Products"**

**SJXXXX-X5 (Final numbering to be determined)**

**"Marking for the Control of Pollution Caused by Electronic Information  
Products"**

**Other important GB standards referenced in the core documents may be  
purchased:**

#### **GB 5296.2**

"Instructions for Use of Consumer Products & Instructions for Use of  
Household and Similar Electrical Apparatus"

#### **GB/T 16288**

"Marking for Recycling of Plastic Packages"

#### **GB 18455**

"Packaging Recycling Mark"

For additional information, contact a SIMCOM representative at 678-690-8540 or  
[service@esimcom.com](mailto:service@esimcom.com).

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## US Workplace Safety Requirements for Installed Equipment

The Consumer Product Safety Commission, (CPCS), estimates that the societal cost from: injury, costs to facilities and property damage due to faulty consumer products exceeds \$700 billion annually. For the complete report go to: <http://www.cpsc.gov/library/foia/foia02/os/costmodept1.pdf>

CPSC reported 1243 consumer products-related electrocutions in the US between 2000 and 2002. The highest percentage of deaths (15%) can be attributed to electrical installation materials (panel boards, circuit breakers, outlets, etc.). Another 15% comes from large appliances, such as water heaters, AC's, pumps, furnaces, clothes washers and dryers. 12% occurred, when metal objects (ladders, saws, poles) accidentally touched high-voltage power lines. Small appliances (microwave ovens, fans, cords) account for 8% of the deaths by electrocution.

Given the potential for harm, the Occupational Safety & Health Administration, (OSHA) forces all products that are used in workplace environments to bear a certification mark from a Nationally Recognized Testing Laboratory (NRTL).

### A History of Workplace Safety

In the 1890's when machines started to replace manual labor, the number of serious accidents caused by machinery grew. However, there were no safety standards for electrical machines, so the insurance industry's underwriters requested that safety standards be developed. This was intended to provide minimum safety criteria that could be used to underwrite policies. The eventual outgrowth was the creation of a non-profit safety standards writing organization named Underwriters Laboratory (UL).

Moreover, in order to be able to evaluate machines for compliance with the applicable new safety standards, the insurance industry needed a qualified laboratory. Again, UL organized a laboratory that became the only insurance industry, accepted laboratory for the next 50 years.

In 1970 MET Laboratories filed a lawsuit to deregulate testing laboratories. The suit made its way to the US Supreme Court, which ruled in Met Lab's favor. As a result, The Occupational Safety and Health Administration (OSHA) created The Nationally Recognized Testing Laboratory (NRTL) Program. The NRTL Program recognizes private-sector organizations as NRTLs; whereby recognition signifies that an organization has met the qualifications specified in the program regulations. A NRTL assesses equipment and materials against consensus-based standards of safety to assure workplace safety as required by OSHA.

For purposes of meeting the NRTL product-approval requirements per OSHA requirements, e.g., those under Subpart S of 29 CFR Part 1910, OSHA allows only equipment or, products that have been approved by a NRTL lab to be installed and used in a workplace. For additional information about a NRTL's scope of recognition, please visit: <http://www.osha.gov/dts/otpca/nrtl/index.html>

Laboratories Currently Recognized By OSHA as NRTL Labs:

- ✓ Applied Research Laboratories, Inc.
- ✓ Canadian Standards Association
- ✓ Communication Certification Laboratory, Inc.
- ✓ Curtis-Straus LLC
- ✓ Electrical Reliability Services, Inc. (ERS) (also known as ETI Conformity Services and formerly Electro-Test, Inc.
- ✓ Entela, Inc.
- ✓ FM Global Technologies LLC (known as FM Approvals and formerly Factory Mutual Research )

- ✓ Intertek Testing Services NA, Inc.
- ✓ MET Laboratories, Inc.
- ✓ NSF International
- ✓ National Technical Systems, Inc.
- ✓ SGS U.S. Testing Company, Inc.
- ✓ Southwest Research Institute
- ✓ TUV America, Inc.
- ✓ TUV Product Services GmbH
- ✓ TUV Rheinland of North America, Inc.
- ✓ Underwriters Laboratories Inc.
- ✓ Wyle Laboratories, Inc.

According to provisions of the General Industry Standards (Part 1910 of Title 29, Code of Federal Regulations - 29 CFR Part 1910), the following categories of materials/equipment (products) are required to be approved by a NRTL:

1. Electrical conductors or equipment (Subpart S of Part 1910).
2. Other...

The National Electrical Code® (NEC®) is published every three years by NFPA-National Fire Protection Association. Established in 1896, NFPA serves as the world's leading advocate of fire prevention and is an authoritative source on public safety. NFPA's 300 codes and standards influence every building, process, service, design and installation in the United States, as well as many of those used in other countries.

The most recent version of the NEC is: NFPA-70 2005 Edition. The next revision will be in 2007.

Although the National Electrical Code® (NEC®) only covers installations, it does require that products connected to electrical mains comply with national standards and:

- ✓ Be suitable for the intended service,
- ✓ “Approved” for that service
- ✓ Installed as approved

It is important to understand that NEC Code defines safe installations and does not cover product designs or maintenance. The product must be designed for compliance with the applicable safety standard and then installed in accordance with NEC.

### **NFPA 70E (2004): Standard for Electrical Safety in the Workplace (Revision in 2008)**

As NFPA 70 was developed and expanded to include many different locations, it became too complex, and thus did not cover all the needs of Occupational Safety and Health Act, Section 6 (b); which deals with employee safety in the workplace.

NFPA 70 E is an offspring from NFPA –70 and was created to be compatible with the OSHA requirements for employee safety in locations covered by the NEC.

It consists of four parts:

- Safety Related Work Practices
- Safety- Related Maintenance Requirements
- Safety Requirements for Special Equipment
- Installations Safety Requirements

NFPA 70 E is not a design standard, but a product designer must be familiar with its requirements, if the product in question will be installed in a US workplace.

## Authorities Having Jurisdiction

Each state has a right to adopt the newest or previous edition of the NEC. They also have a right to add requirements to installations in their jurisdictions, depending on special conditions and considerations, such as: earthquakes, high humidity, frequent fires, etc.

## Workplace Equipment Approval – The Choice of “Listing” or “Field Labeling” Equipment

The NEC defined by NFPA 70, requires products covered under the NEC to be Listed or Labeled as described in Article 90-7, “It is the intent of the *Code* that ... the construction of equipment need not be inspected at the time of installation of the equipment ... if the equipment has been listed by a qualified electrical testing laboratory that is recognized as having the facilities described above and that requires suitability for installation in accordance with this *Code*.”

In addition NEC Article 110-2 indicates: “... equipment required or permitted by this *Code* shall be acceptable only if approved.” Approved is defined in the NEC as, “Acceptable to the authority having jurisdiction.” When you get your product listed by a “qualified electrical testing laboratory” the lab will conduct periodic inspections of your product at your factories approximately once a quarter to make sure the device they tested is what is being produced. If the device is modified, you will need to contact the lab to update your files.

The following definitions of labeled versus listed equipment from NFPA may shed light on what is needed to pass the muster of an AHJ:

**3.69 labeled:** Equipment or materials to which has been attached a label, symbol, or other identifying mark of an organization that is **acceptable to the authority having jurisdiction** and concerned with product evaluation, that maintains periodic inspection of production of labeled equipment or materials, and by whose labeling the manufacturer indicates compliance with appropriate standards or performance in a specified manner.

**3.72 listed:** Equipment, materials, or services included in a list published by an organization that is acceptable to the authority having jurisdiction and concerned with evaluation of products or services, that maintains periodic inspection of production of listed equipment or materials or periodic evaluation of services, and whose listing states that either the equipment, material, or services meets identified standards or has been tested and found suitable for a specified purpose. (NFPA 70)

In essence, numerous safety standards may be applied to a piece of equipment; however, the key will be to make certain the NRTL representative accepts whatever standard you have applied during their “field inspection” and then it is inherent upon the AHJ to accept the results of the NRTL lab. This is why close coordination between the AHJ and the NRTL engineer is valuable.

An engineer from a NRTL will visit the installation site, conduct an equipment evaluation for compliance with the applicable national standard(s), and then conduct all the necessary testing (mostly non-destructive). If the equipment complies, he/she will issue a Compliance Report that only refers to this particular piece of equipment (serial number will be included in the report) and place a “Serialized Field Label” on the equipment. The label number and equipment’s physical location will be documented in the report. This means that a new visit and re-evaluation will be required, if equipment is moved to another location. It also means that the label and report are not valid on a similar piece of equipment installed elsewhere.

Numerous industries have found field labeling to much more cost-effective such as the semiconductor equipment industry which produces very specialized equipment and on an overall basis, the safety of the equipment is driven by industry standards written by SEMI International – the primary trade association for the semiconductor industry.

Please note that although electrical inspectors are versed with NEC rules; they may not be familiar with product safety standards, (especially international standards or, industry standards) and thus cooperation is needed. To ensure that your equipment is accepted, it may be easiest to design equipment to applicable national standards; however, in all cases you must be able to demonstrate compliance by assessment of a NRTL lab either through the listing process or during field labeling exercises.

### **Standards-Writing Bodies:**

Given the large number of product safety standards, it is important to understand something about standards-writing bodies. Many organization write standards and the following organizations have important roles in the creation of US standards (AS), international standards and industry standards:

ASTM (American Society for Testing and Materials)  
ASME (American Society of Mechanical Engineers)  
AWWA (American Water Works Association)  
IAPMO (International Assn. of Plumbing and Mechanical Officials)  
IEC (International Electrotechnical Commission)  
ISO (International Organization for Standardization)  
NFPA (National Fire Protection Association)  
NSF (National Sanitation Foundation)  
SAE (Society of Automotive Engineers)  
UL (Underwriters Laboratories, Inc.)

### **ANSI's Role in American Standards:**

If a standards-writing body wishes to have their standard recognized as an American National Standard, they must apply for acceptance to the American National Standards Institute, (ANSI). If a standard receives approval, a prefix is added to the title, i.e. ANSI/UL, ANSI/NSF. It is important to understand that an American National Standard does not automatically qualify as an international standard and in fact, the vast majority of standards written in the US do not become American National Standards.

**For further information or to schedule a conference regarding equipment compliance for workplace safety, please contact SIMCOM at: (678) 690-8540 or, [service@esimcom.com](mailto:service@esimcom.com)**

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## **China's Restriction of Hazardous Substances (RoHS) Will Your Company Be Ready?**

**Time is running out! China's RoHS regulations go into effect March 1<sup>st</sup>  
Numerous tasks must be completed soon...**

- ☑ Determining which Parts or Products are within the Scope of the Legislation
  - ☑ Collecting Data from Parts and Component Suppliers
  - ☑ Modifying Engineering Specifications
  - ☑ Establishing Purchasing Policies, including Amending Existing POs
  - ☑ Integrating Data into an Enterprise System to Assure Logistic Success
- 
- By starting now, you can meet the requirements of March 1<sup>st</sup>
  - Early preparation will assure legal entry into China – otherwise, product delays may cause millions in lost revenues
  - Implementing an integrated product lifecycle management system, (PLM) will create a solid foundation for other country's new, environmental regulations

### **SIMCOM's Integrated Approach to RoHS Compliance**

SIMCOM International is a global leader in regulatory compliance system integration. Our proprietary RoHS compliance system fully manages all primary tasks including: engineering specification preparation, sourcing policies and logistic interfaces. Early implementation will provide your Company with invaluable competitive advantages.

#### **Key Features**

- ◆ Automatic tracking of supplier's material declarations
- ◆ Validation processes to assure compliance to purchasing specifications
- ◆ Data exchange using leading industry protocols such as IPC-175X
- ◆ Integrated compliance at any Bill of Material (BOM) level
- ◆ Full integration with popular supply chain and manufacturing systems:
  - PLM Systems - Oracle, Agile
  - ERP Systems - Oracle, SAP

#### **Key Benefits**

- ✓ Eliminate the risk of having your products' access denied in key markets
- ✓ Build standardized compliance processes for multiple geographies
- ✓ Track compliance at the material, part and finished goods level
- ✓ Compress product development cycle times
- ✓ Lower overall compliance expense

**Change your Momentum – Contact SIMCOM today!**

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## The EU's Amended Machinery Directive 2006/42/EC

### **Important Chronology:**

The EU's amended Machinery Directive (2006/42/EC) came into force on June 29, 2006. Two- years from its publication or, by June 29, 2008 all Member States must transpose the amended directive into national law. By December 29, 2009 where Member State transposition has occurred, the Directive will be in full force without a transition period

Full text of the amended Directive may be found at:

[http://eur-ex.europa.eu/LexUriServ/site/en/oj/2006/l\\_157/l\\_15720060609en00240086.pdf](http://eur-ex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609en00240086.pdf)

### **HIGHLIGHTED CHANGES TO THE AMENDED DIRECTIVE**

1. Clarifications cover:
  - ✓ Machinery,
  - ✓ Partly completed machinery,
  - ✓ Lifting Equipment and Safety Components
2. Previous overlap with the Low Voltage and Lifts Directive has been eliminated;
3. The conformity assessment procedures for Annex IV machines has been liberalized:  
Full Quality Assurance (Module H), allows for self-declaration and the previous requirement to keep a Technical File with a Notified Body has been eliminated.  
[See: Article 12 (3) and (4)].
4. The amended Directive clarifies duties for partially-completed machinery manufacturers
5. The Directive's scope was expanded to: construction hoists and cartridge-powered tools (The latter having a 5-year implementation delay)
6. Annex I has been simplified while, overall structure and numbering remains

**SIMCOM is please to offer a comprehensive report, which provides a comparative analysis of the old Machinery Directive with the Amended Directive. To purchase our exclusive, 10 page report, please use the link below:**

**[Purchase Amended Machinery Directive Analysis Report](#)**

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

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## Hot Topics in September's Issue



### Overview of Regulatory Compliance in Canada

As an affluent, high-tech industrial society in the trillion-dollar class, Canada resembles the US in its market-oriented economic system, pattern of production and affluent living standards. Since World War II, Canada's impressive growth in the manufacturing, mining and service sectors has transformed the nation from a rural economy into an industrial powerhouse. 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. Exports account for roughly a third of Canada's GDP. Canada enjoys a substantial trade surplus with its principal trading partner the US – which absorbs 85% of Canadian exports. Canada is the US' largest foreign supplier of energy, including oil, gas, uranium, and electric power.

In our September issue, Canada's place in the economic world will be reviewed with explicit details on its key product regulations.

### RoHS & WEEE – Keeping up with the Rest of the World!

For the past three years, eyes and ears were focused on Europe - where the world of RoHS and WEEE began. New RoHS and WEEE legislation has quickly spread across the globe, led by: China, Japan, Korea and California. In September, *Global Compliance News* will provide a comparative analysis of each major country's approach to environmental law - with "heads-up" information on new developments. Manufacturers must actively monitor global environmental legislation and SIMCOM's *Global Compliance News* is a free, cutting-edge solution to this inherent problem. Don't miss an opportunity to learn more!

### *International Compliance News*

#### Key RoHS Standard for the EU

The rules for RoHS are rapidly evolving globally. Recently a draft of an international standard outline the procedures for how samples are assessed by testing laboratories for chemical limits defined by the EU. This has been sent out for voting.

The standard is "IEC 62321, Ed.1: Procedures for the determination of levels of six regulated substances (Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls, Polybrominated Diphenyl Ethers) in electrotechnical products."

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## **Facelifts to the EU's three medical device directives**

The EU has published an updated list of standards to be used to demonstrate conformity with the medical device directives. Published in the *Official Journal* the list covers active implantable, in vitro diagnostic, and medical device directives.

In addition, the EU has submitted to the World Trade Organization (WTO) notice for updates to the three medical device directives. The purpose of the updates is to simplify the directives and to provide the highest level of protection for human health. The proposed date of adoption of these changes was not given.

The latest list of harmonized standards for purchase may be found at the following links: [Active Implantable](#), [In Vitro](#), and [General Medical Devices](#).

## **Additional Value for CB Scheme Reports**

When obtaining test reports for your products it is important for manufacturers to consider all markets of entry. CB Scheme reports tend to be more expensive, but have increased value with the increasing number of member countries. Recently Indonesia and Kenya became members with Uruguay, Columbia, and Dubai expected to join in the near future. The CB Scheme currently comprises 45 IECEE member countries, 58 certification bodies (NCBs) and 200 accepted testing laboratories (CBTLs).

## **EU Proposes New Regulations for Batteries and Accumulators**

The European Parliament and Council have proposed changes to the Battery Directive (91/157/EEC as amended by 98/101/EEC). One change is to introduce a new limit of 0.002% of cadmium in portable batteries. This change would apply to all portable batteries except those used in the following: emergency and alarm systems, emergency lighting, medical equipment, and cordless power tools. An attempt to change the level of mercury was made, but remains unchanged at this time. The reason for the change was for protection of the environment including pollution in streams. Implementation dates for the proposed changes has not been determined.

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