World-Wide Product Regulations and your International Vacation plans – What do they have in common?

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Agenda

- Executive Summary
- Local & USA Regulations
- International Regulations
  - Europe
  - BRIC
  - Asia
- Recommendations
Executive Summary

- Rapidly changing requirements are expanding around the world
- Utilize readily available sources to track the latest regulatory changes
- Leverage specialized expertise to address regulatory issues, as required
- Transition from a reactive to proactive program
- Implement a Design for Compliance program
- Maintain all necessary certifications based on the countries to where your products are being sold
- Comply with the law!
“The Greatest Paper Map of the United States You’ll Ever See”

http://www.slate.com/articles/arts/culturebox/2012/01/the_best_american_wall_map_david_imus_the_essential_geography_of_the_united_states_of_america_.html
Local Regulations

- Electrical Field Labeling
- NRTL Label
- Industrial Machinery
- Risk of Fire
- Risk of Electric Shock
- Seismic
- Testing (i.e. Hipot)

- NFPA 79 – Industrial Machinery
- UFC – Uniform Fire Code
- UBC – Uniform Building Code
- IBC – International Building Code
California Regulations

- Green Chemistry
  - Toxic Chemicals
    - Mercury Reduction
    - Lead in Jewelry & Toys
- Hazardous Waste
- Nanotechnology
  - i.e. nanosilver used as an anti-bacterial agent
- California RoHS
  - California Code of Regulations, Title 22
  - Displays >4”
- Prop 65 Warnings
  - Chemical Exposure
  - Cal/EPA
  - CA – Office of Environmental Health Hazard Assessment
USA Regulations

**USA Government/ Regulations**
- OSHA – Occupational Safety and Health Administration
- FCC – Federal Communications Commission
- EPA – Environmental Protection Agency
- DEA – Drug Enforcement Agency
- FDA – Food & Drug Administration
- TSCA – Toxic Substances Control Act
- CPSC – Consumer Product Safety Commission
- DoD – Military Standards

**International/ Transportation**
- DOT – Department of Transportation (DG)
- IATA – International Air Transport Association
- DG – Dangerous Goods
FDA Requirements

- To Protect the Public From hazardous or unnecessary exposure to radiation from electronic products
- US Manufacturers and Importers
- Radiation Emitting Products
  - Ionizing or non-ionizing radiation
- Sec. 1040.10 Laser products.
  - Class I
  - Class II <1mw
  - Class IIIa: 1–5mW
  - Class IIIb: 5–500mW
  - Class 4 >500mW
FCC Restrictions

- EMC/EMI
  - **FCC Part 15** – Radio Frequency Devices
    - Class A – Commercial
    - Class B – Residential
  - **FCC Part 18** – Industrial, Scientific, and Medical Equipment
  - FCC Part 22 – Public Mobile Services
  - Part 68 – Terminal Equipment

- Updates
  - SAR Testing (1.6W/Kg)
  - Post Market Surveillance

About the FCC:
The Federal Communications Commission (FCC) is an independent United States government agency. The FCC was established by the Communications Act of 1934 and is charged with regulating interstate and international communications by radio, television, wire, satellite and cable.
Top 10 OSHA Most Frequently Cited Standards

1. Scaffolding
2. Fall Protection
3. Hazard Communication
4. Respiratory Protection
5. LOTO (hazardous energy isolation)
6. Electrical Wiring methods
7. Powered Industrial Tools
8. Ladders
9. Electrical General Requirements – (Arc Flash)
10. Machine Guarding (clearing jams, amputation hazards)
CE Marking is Your Passport to Europe

- CE Marking
- Declaration of Conformity
CE Marking

- Machinery Directive
  - 2006/42/EC
- EMC Directive
  - 2004/108/EC
- Low Voltage Directive
  - 2006/95/EC
- R&TTE Directive
  - 1999/5/EC
- Standards
  - Make Reference to the latest standards
  - IEC – International Electrotechnical Commission
  - ETSI – European Telecommunications Standards Institute
IEC 61010 3\textsuperscript{rd} edition

Safety requirements for electrical equipment for measurement, control, and laboratory use

- IEC 61010 3\textsuperscript{rd} edition Published June 2010
- IEC 61010 2\textsuperscript{nd} edition Date of Withdrawal Oct 1, 2013
- UL 61010A–1, UL 61010B–1 and UL 61010C–1 will be withdrawn as of Jan 1, 2014
- Transition period: 2013 – 2018

Changes

- Scope now covers both professional and non-professional products
- Test and measurement circuit requirements separated into a Part 2 standard
- Updates to clearances, creepages, solid and thin film insulation and molded and potted parts
- Temperature requirements modified due to EN563
- X-ray requirements modified to include intended and non-intended emissions
- New requirements for conformal coatings
- New requirements for risk assessment
- Added requirements for foreseeable misuse and ergonomics
IEC 62368–1 – Convergence of Technology (Computers and audio/video equipment)

- Audio/Video, Information and Communication Technology Equipment – Safety Requirements
- **Hazard Based Standard** replaces the current standards and merges legacy standards
  - IEC 60065 – Audio/ Video
  - IEC 60950 – Information Technology
- Move from the traditional, prescriptive approach to a new, hazard-based approach that emphasizes safety design in the early product development phase.
- New standard identifies several types of energy sources that can be represented by the three-block model including:
  - Electrical
  - Thermal
  - Kinetic
  - Radiated energy
- Mandatory in 2015
Multimedia Equipment (MME)
- Equipment that is Information Technology Equipment (ITE), Audio equipment, Video equipment, Broadcast receiving equipment, Entertainment lighting control equipment or combinations of these.

CISPR 32
- Electromagnetic compatibility of multimedia equipment – Emission requirements
- Replaces CISPR 13 & CISPR 22

CISPR 35
- EMC Immunity for MME
- Replaces CISPR 20 and CISPR 24.
EU RoHS Recast (2011/65/EC)

- Adopted by the European Union on Jun 2011
- Implementation and Adoption of CE Marking (Jan 2013)
- Changes in Categories:
  - Medical Devices (2014)
  - Monitoring & Control Instruments (July 2014)
  - In-Vitro diagnostic medical devices (July 2016)
  - Industrial Monitoring & Control Instruments (July 2017)
  - Other EEE (July 2019)
- Restricted Substances:
  - Lead, Mercury, Cadmium, Hexavalent Chromium, PBB, and PBDE
- Out of Scope
  - Large Scale Fixed Installations
  - Large Scale International Tools
European Chemicals Agency (ECHA) Regulates Chemicals:
- Carcinogenic, mutagenic or toxic to reproduction (CMRs);
- Persistent, bio-accumulative and toxic (PBTs)
- Very persistent and bio-accumulative (vPvBs)

Growing List of SVHC’s
  - i.e. CoCL2, DEHP, BBP, RCF (Ceramic Fibres)…

ECHA recommends thirteen Substances of Very High Concern for Authorization
CB Scheme

- National certification bodies of the IECEE member states have agreed to mutual recognition of CB test certificates
  - Electrical low-voltage products
  - Faster, cheaper market access to markets
- CB test certificate based on a type examination according to IEC standards
  - Does not include production monitoring
  - EMC tests can also be confirmed in a CB certificate.
- Participating states
  - Argentina, Australia, Belgium, Brazil, China, Denmark, Germany, Finland, France, Greece, Great Britain, India, Indonesia, Ireland, Israel, Italy, Japan, Serbia and Montenegro, Canada, Kenya, South Korea, Mexico, New Zealand, the Netherlands, Norway, Austria, Poland, Portugal, Sweden, Switzerland, Singapore, Slovenia, Slovakia, Spain, South Africa, Thailand, the Czech Republic, Turkey, the Ukraine, the United States, and the Russian Federation
Brazil: Update on Household Appliances Safety Requirements

- National Institute of Metrology, Standardization and Industrial Quality (INMETRO)
  - Authority with jurisdiction over the general safety of products as well as EMC
- There are very few general products that require safety for INMETRO certification and none that require EMC at this time.
- Radio and telecom products are certified and homologated
  - National Telecom Agency (ANATEL)
- Both emissions and immunity compliance are required for telecom equipment
  - Standards reference IEC
- The National Health Surveillance Agency (ANVISA) is the authority for medical equipment
Russia GOST Mark

- **GOST**: Gosstandart
- State Committee for Quality Control and Standardization
  - **Purpose**: To protect health and safety of Russia's population by excluding potentially hazardous or unsafe products from entering the Russia's commercial space.
- **Requirements include**:
  - Technical product testing and expert evaluation by independent third party testing facility, accredited by the competent standardizing agency of Russia,
  - Federal Agency for Technical Regulation and Metrology, based in Moscow.
- **A violation of the certification terms is a violation of Russian laws.**
India RoHS

- GOVERNMENT OF INDIA – MINISTRY OF ENVIRONMENT
- Now published and will be effective from May 1, 2012
- Rules shall apply to:
  - Producer(s), distributer(s), collection centre(s), refurbisher(s), dismantler(s), recycler(s), consumer(s) or bulk consumer(s)
  - Companies involved in the manufacture, sale, purchase and processing
  - Electrical and electronic equipment or components
- Concerns
  - Collection of e-waste
  - ‘Extended Producer Responsibility’ (EPR)
- State Pollution Control Board or Pollution Control Committee
- CLP In India
  - On July 8, 2011 the Gazette of India published notification from the Ministry of Environment and Forests of the draft regulations for classification, packaging, and labeling of hazardous substances
China

- The People’s Republic of China (PRC) has enforced EMC regulations since 1999
  - Emissions only
- Compulsory Product Certification System (CPCS)
  - implemented in 2002 and under the authority of the Certification and Accreditation Administration
- CCC Mark
  - Administration Certification and Accreditation Administration (CNCA),
  - China Quality Certification Center (CQC)
  - Includes provisions for indicating safety and EMC
  - Medical devices fall under the authority of:
    - State Food and Drug Administration (SFDA)
    - Ministry of Health (MOH)
- China RoHS
  - Environmentally Friendly Use Period
South Korea

- KC Marking – Korean certification
- Priority: EMC Qualification
  - Testing by qualified Labs
- Radio Research Laboratory (RRL)
- Single Korea Certification mark
  - Integrates and unifies existing marks
- Testing of ITE products
  - KN22 with RRL Notice No. 2005–82 (Sept. 29, 2005)
  - Information Technology Equipment – Radio Disturbance Characteristics – Limits and Methods of Measurement
- Enforcement at customs
Japan

- VCCI – Voluntary Control Council for
  - Interference by Information Technology Equipment
  - CISPR 22
- Ministry of Economy, Trade and Industry (METI)
  - Responsible for appliance safety, including RF emissions (EMI)
  - Immunity is not required
- Electrical Appliance and Material Safety Law
  - Authority for radio regulation in Japan is the Ministry of Internal Affairs and Communications (MIC).
- Medical products in Japan are regulated under the authority of the Ministry of Health, Labor and Welfare (MHLW)
- Japan RoHS
- Japan Cartagena Act
Taiwan

- Bureau of Standards, Metrology and Inspection and Inspection (BSMI)
  - Registration of Product Certification
  - Measures Governing Registration of Product Certification
- Compulsory certification for certain products
  - Safety
  - EMC
- Energy Efficiency
- Existing Chemical Substance Nomination (ECN)
Vietnam RoHS

- Ministry of Trade of the Socialist Republic of Vietnam
  - Regulations for permissible toxic chemical content limits in electrical products
- Restriction on 4 heavy metals and 2 classes of flame retardants
  - Same 6 substances and limits as EU–RoHS
    - Pb, Hg, Cd, Cr (VI), PBB, PBDE
- 8 categories of electrical and electronic products

Issued: 10 Aug 2011
Effective: Dec 1, 2012
Democratic Republic of Congo

- Conflict Minerals
- Dodd–Frank Legislation
  - Gold, tin, tantalum, tungsten
  - Requirements for "independent private sector audit"
- Organization for Economic Cooperation and Development (OECD) has published Guidance
  - Conflict free smelter program
  - Reporting and disclosure
Canada

- Canadian Environmental Protection Act (CEPA
  - Canada Mercury Ban

- Industry Canada
  - Typical emissions standards are ICES–003 (ITE) and ICES–001(ISM).

- Health Canada (HC)
    - Prevent dangerous products from being sold
    - Medical devices
      - Class I device manufacturers require an establishment license;
      - Class II, III and IV devices require a medical device license.
Electrical products exported into Mexico must meet NOM requirements
- Also mandatory energy efficiency requirements.
- Approval mark of NOM ANCE or NOM NYCE

Covers over 2,000 product categories, entering the Mexico
- Require evidence of compliance with NOM standards.
- Products requiring NOM Certification include:
  - Household refrigerators, freezers, gas heaters, cloth washers, air conditioners; small induction motors and motor operated tools; vertical and submersible water pumps; compact fluorescent lamps and wiring devices; telecom products that are data transmitters (digital, analogical, LAN or WAN systems) and those intended to be connected to the Public Telecom Network (PTN)
Australia & New Zealand

- Australian Communication Authority (ACA)
  - EMC framework
  - Radiocommunications Act
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
  - Regulations on industrial chemicals
- Australia Quarantine and Inspection Service Agency (AQIS)
  - Quarantine controls at our borders Import Applications required
Enforcement, Customs, Penalties

- USA
  - FDA Laser Compliance
  - Osha Fines ($20,000–$2M)
- France
  - CE Marking
- EU
  - WEEE/RoHS
- China
  - Special Goods Permits
- Australia
  - Chemical regulations
- Mexico
  - Mexico Customs and the Ministry of Health
  - Biological products

Penalties
- Varies by Country/Enforcement Agency
  - Germany – 50,000 Euros WEEE/RoHS
  - Product Removal
  - Lost Sales
  - Enforcement bodies can recover funds
**Tips & Recommendations**

- **Design for compliance**
  - Where are you shipping?
  - Incorporate into the development process
  - Eliminate the ‘how’ and ‘when’ is compliance achieved

- **Complete all required Deliverables**
  - Evaluations
  - Testing
  - Reports
  - Labels
  - Manuals

- **Meet applicable country requirements**
  - Shipment readiness check

- **Establish Regulatory intelligence**
  - Internet based Sources of regulatory updates
  - Leverage external experts to reduce learning curve
Conclusion

- Have you established an effective proactive regulatory compliance program?
- Do you have a well documented system with all required regulatory Deliverables?
- Do you meet Legal & Customer Requirements that cover multiple jurisdictions?
- Are all necessary Declarations, Certificates, Registrations, & Licenses complete?
- Do you have the Deliverables normally Checked by Customs?
- Ship It!
QUESTIONS?
References/ Links

- http://www.ul.com
- http://www.intertek.com/
- http://www.metlabs.com/
- http://www.bureauveritas.com
- http://www.siemic.com
- http://www.fcc.gov/
- http://www.trade.gov
- http://oehha.ca.gov/prop65/background/p65plain.html
- http://www.goglobalcompliance.com
- http://www.productrealizationgroup.com
- http://www.designchainassociates.com/
Countries That Require CE Marking

- Austria
- Hungary
- Poland
- Belgium
- Iceland
- Portugal
- Bulgaria
- Ireland
- Romania
- Cyprus
- Italy
- Slovakia
- Czech Republic
- Latvia
- Slovenia
- Denmark
- Liechtenstein
- Spain
- Estonia
- Lithuania
- Sweden
- Finland
- Luxembourg
- Switzerland
- France
- Malta
- Turkey
- Germany
- Netherlands
- United Kingdom
- Greece
- Norway
OSHA NRTL’s

- OSHA recognizes NRTLs
- NRTLs test and certify products as conforming to product safety standards
- Products certified, listed and labeled
- Product safety standards developed by US standards organizations (i.e. UL, ANSI, NFPA, FM)

Organizations Currently Recognized by OSHA as NRTLs

1. Canadian Standards Association (CSA) (also known as CSA International)
2. Communication Certification Laboratory, Inc. (CCL)
3. Curtis–Straus LLC (CSL)
4. FM Approvals LLC (FM) (formerly Factory Mutual Research Corporation)
5. Intertek Testing Services NA, Inc. (ITSNA) (formerly ETL)
6. MET Laboratories, Inc. (MET)
7. NSF International (NSF)
8. National Technical Systems, Inc. (NTS)
9. QPS Evaluation Services Inc. (QPS)
10. SGS U.S. Testing Company, Inc. (SGSUS) (formerly UST—CA)
11. Southwest Research Institute (SWRI)
12. TÜV Rheinland PTL, LLC (TUVPTL)
13. TÜV SÜD America, Inc. (TUVAM)
14. TÜV SÜD Product Services GmbH (TUVPSG)
15. TUV Rheinland of North America, Inc. (TUV)
16. Underwriters Laboratories Inc. (UL)