The Engineer's Guide To Global EMC Requirements: 2007 Edition

Written by: Roland Gubisch, Chief EMC Engineer and Bill Holz, GMAP Program Manager, Intertek

Intertek Testing Services NA, Inc
70 Codman Hill Road, Boxborough, MA 01719

icenter@intertek.com 800-WORLDLAB www.intertek-etlsemko.com

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Introduction

Engineers everywhere would like to test their products only once for electromagnetic compatibility (EMC), using a single set of standards and placing a single mark on the products to allow them to be sold around the world. Unfortunately, that aspiration will not become reality any time soon. If anything, it is becoming even more elusive as companies pursue new global sales opportunities further afield. The challenges are no longer technical; increasingly, they are raised by regulators in government offices many time zones away.

The task of EMC testing for global markets is challenging indeed. Each country or region retains its right to determine:

- If EMC is a mandatory compliance aspect that must be met prior to placing products on the market
- Identification of the authority that will have jurisdiction over regulating EMC
- Determination of the technical requirements that must be met - whether emissions only (EMI), or both emissions and immunity (EMC)
- Identification of the standards required
- Compliance procedures and filings
- Determination of what test reports will be accepted
- Specification of any marks that must be applied.

This paper will review the regulatory issues of EMC compliance in selected regions around the world.

Background

EMC issues have been around since the early days of telegraphy and radio. Interference from solar activity caused "phantom telegraph operators" – telegraph output with no telegraph input – on long parallel transmission wires. The cure for this condition was occasional twists in the wires, which led directly to today's high-speed twisted-pair LAN wiring.

With the increasing popularity of broadcasting, and then with the use of electronic equipment in commercial and military applications, rules to prevent radio interference and equipment malfunctions became necessary. The result has been a succession of EMC standards and regulatory procedures worldwide. Some of the milestones are:

1844 Morse: telegraph
1892 Law of telegraph in Germany (EMC)
1895 Marconi: first radio transmission
1927 German Hochfrequenzgerätegesetz (High frequency device laws)
1933 CISPR founded as a special committee of the IEC, dealing with interference

1934 US Communications Act; FCC is established
1972 Altair 8800: first personal computer (PC)
1979 FCC Part 15, subpart J (digital devices)
1985 IEC CISPR 22 (Information Technology Equipment - ITE)
1989 EMC Directive, EU; mandatory 1-1-1996.

Personal computers and other microprocessor-based devices have triggered similar emissions standards around the world:

1979 FCC Part 15, subpart J
1985 IEC CISPR 22
1985 VCCI rules in Japan
1988 Canada Radio Act
1996 Australian EMC Framework
1997 Taiwan ITE EMI
1998 Korea ITE EMC
2000 Singapore EMI for telecom equipment

EMC as a mandatory compliance requirement

The first task is to identify the countries in which your company's products are to be sold. Then you need to determine what EMC compliance requirements (if any) must be met before the products can be marketed in those countries.

The overall scope of your efforts will be determined by the number of countries in which you wish to sell your products, of course. However, to keep this paper manageable – while providing a flavor of the issues to be encountered - we will limit the list to the following regions:

Americas:
- United States (US)
- Canada
- Brazil

Europe
- European Union (EU)
- Russia

Far East
- Japan
- Chinese Taipei (Taiwan)
- People's Republic of China.

Let's assume that with all of its products, your company always carries out complete EMC testing for the US and EU. Is that enough to allow you to place products everywhere in the

world? Unfortunately, it is not. Many countries that require EMC compliance also impose additional hurdles to market entry in terms of deviations to international standards, in-country testing or country presence. Fortunately, there are also simplifying arrangements and agreements that can leverage your EMC testing to cover larger geographical or market areas. They are found under the broad umbrella term MRA (Mutual Recognition Agreements or Arrangements).

Regulatory compliance procedures

Countries or regions that regulate product EMC will typically employ one or more of three procedures to determine compliance with national or regional requirements. The particular procedure may depend on product type.

- **Verification** – the product is tested to the applicable EMC standard(s) and brought to market bearing appropriate regulatory marks and/or statements under the vendor's or importer's authority (the "responsible party").

- **Declaration of Conformity** – the vendor or other responsible party declares conformity of the product to the relevant standard(s). Some jurisdictions require accredited testing (US) while others do not. The product may then need to be registered with the regulator (Australia, for example) or not (US for EMC). Regulatory marking and user information are a part of the process.

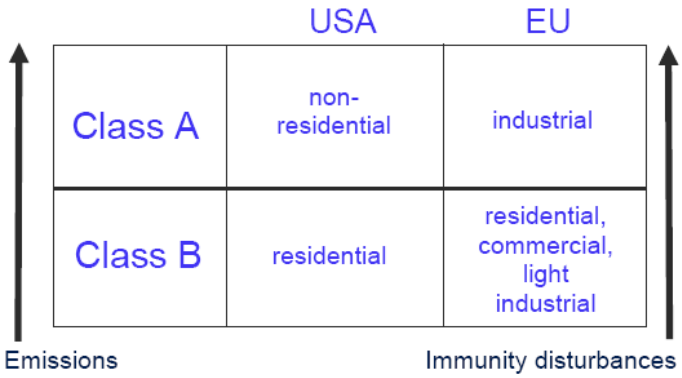
- **Certification** - the test report from an accredited or recognized laboratory, along with other technical information about the product, is presented to an independent third party for examination against the requirements. If the product complies, it is certified and listed with the regulator. The product may bear the certifier's mark. Product surveillance may also be a part of the certification process.

It's not always easy for the regulatory compliance engineer or manager to determine the applicable standards, compliance procedures and contact information for each target country or region. Fortunately, there are simplifying frameworks to lighten the burden .

Regulatory compliance frameworks

Mutual Recognition Agreements or Arrangements (MRAs) are multilateral agreements among countries or regions which facilitate market access for signatory members. MRAs can cover the mutual recognition of product testing, certification or both.

However, the existence of an MRA does not imply harmonization of the standards among the participants. For example, the interpretation of appropriate Class A or Class B emission limits in a commercial environment can differ between the US and the EU, as reflected in their respective standards and illustrated below:



Some of the terms common to existing MRAs include:

Agreement: Binding on participating parties

Arrangement: Voluntary participation

CAB: Conformity Assessment Body. A CAB can be *either* a tester or a certifier or both. In the case of US Telecommunication Certified Bodies (TCBs) and Canadian Certification Bodies, the certifier must also be an accredited test lab. The accreditation criterion for testers is ISO 17025 and for certifiers it is ISO Guide 65.

Phase I: The MRA partners agree to recognize each other's test reports

Phase II: The MRA partners agree to recognize each other's test reports and certifications (where needed).

One of the better-known MRAs is the agreement between the European Union and the US covering EMC, radio, telecom and several other product sectors. It has become a model for subsequent MRAs. Other MRAs in operation or pending that cover EMC and telecom include:

Canada:
With EU
In APEC Tel
In CITEL
With Switzerland
With Korea

US:
With EU
With EEA EFTA (Iceland, Norway, Liechtenstein)
With Japan
In APEC Tel
In CITEL

European Union: With US
With Canada
With Australia
With New Zealand.

Participating members of CITEL include Argentina, Brazil, Dominican Republic, Guatemala, Ecuador, Honduras, Mexico, and Paraguay. Participants in the APEC Tel MRA include Australia, Canada, Chinese Taipei (BSMI), Chinese Taipei (NCC, formerly DGT), Singapore, Korea, and Hong Kong.

MRAs are allowing testing and certification by CABs in one region or country to be accepted in another region or country – facilitating market access without additional testing. Regarding EMC, this is especially important when the destination country requires certification as a regulatory requirement.

Authority Having Jurisdiction over EMC

As you investigate each country to determine which agency has the EMC authority for your products, you should also be able to determine what those requirements are. Around the world, RF emissions or EMI is regarded as a potential threat to broadcast reception and to sensitive services such as radio navigation and radio astronomy. Therefore the spectrum or radio regulator in each country or region is usually charged with the widest responsibility for controlling EMI. Immunity, on the other hand, may be reserved as a performance issue for critical applications such as medical or military – and the regulator may differ in each case. The combination of EMI and immunity as EMC may also be used as a means to establish uniform trade rules across a region, as it is in the EU. The following is a brief overview of what you need to consider as you investigate the requirements for each country. We will use the US as a detailed example.

AMERICAS

US

- The Federal Communications Commission (FCC) establishes the compliance regulations for radios, digital devices and other unintentional radiators. It does not regulate immunity, except in a few special cases. Typical emissions standards are Parts 15 (RF devices) and 18 (ISM equipment). Some applications of digital devices are exempted from the FCC's technical standards, as is the case with test equipment, transportation vehicles, appliances, utilities or industrial plants. In many cases, such exempted equipment comes under the jurisdiction of other authorities, as noted below.
  Approval procedures: Verification for most unintentional radiators. No lab accreditation required. Some devices require Declaration of Conformity (DoC) and testing by an accredited lab in the US or MRA partner country. Some unintentional

radiators may be optionally certified by TCBs. For certification testing, the lab must be accredited and listed with the FCC either separately or through an accreditor.

- The Food and Drug Administration (FDA) Center for Devices and Radiological Health **(**CDRH**),** designates consensus device standards for medical devices. Typical EMC standards include: IEC 60601-1-2:2001+A1:2004 (general medical EMC); FDA MDS-201-0004 (1979) (*EMC for medical devices*); and ANSI / RESNA WC/Vol. 2-1998, Section 21, (*Requirements and test methods for electromagnetic compatibility of powered wheelchairs and motorized scooters*).
  Approval procedures: EMC report is submitted as part of device 510(k) filing, to FDA or an FDA-accredited person.

- Department of Defense (DoD), for military EMC. A common EMC standard is MIL-STD-461E (1999) *Requirements for the control of electromagnetic interference; characteristics of subsystems and equipment.*
  Approval procedure: EMC testing can be witnessed by DoD inspector; lab accreditation is helpful.

- Telecom network EMC varies by telecom network operator (ATT, Verizon, etc.), but most EMC requirements are based on GR-1089-CORE (2002) *Electromagnetic compatibility and electrical safety – generic criteria for network telecommunications equipment.*
  Approval procedure: EMC accreditation to GR-1089-CORE sections 2-4; network operator witnesses or accredits; equipment vendor submits test report to network operator.

- RTCA, for aircraft and equipment EMC. The standard RTCA DO160D *Environmental conditions and test procedures for airborne equipment* includes both EMC and environmental requirements. This standard is harmonized with the European EUROCAE ED-14D.
  Approval procedure: EMC report is submitted to FAA (Federal Aviation Authority); lab accreditation is helpful.

- SAE (Society of Automotive Engineers) EMC standard series J551/x, J1113/x is a start. However, the individual auto manufacturers (Ford, GM, DaimlerChrysler, Toyota, etc.) have their own EMC standards that differ from the SAE's standards.
  Approval procedure: EMC report is submitted by device vendor to auto manufacturer; lab accreditation is important.

This presents a fairly complex picture of regulations and regulatory authorities for EMC in the US. The table below summarizes some of this EMC information in a convenient format for comparison with other jurisdictions.

Jurisdiction	**United States - EMC**

Product type	ITE	Radio	Appliance	Medical
Authority	FCC	FCC	FCC exempt	FDA/CDRH
Approval Procedures	EMI only: Verification DoC: accredited Cert: accredited	Certification	N/A	Certification
In-country testing required?	No	No	N/A	No
MRA with US?	N/A	N/A	N/A	N/A
Marks	For DoC only: FCC logo	None	N/A	N/A

Canada

- The regulation of EMC in Canada is similar to that in the US. Industry Canada (IC) establishes the compliance regulations for radios, digital devices and other unintentional radiators. Typical emissions standards are ICES-003 (ITE) and ICES-001 (ISM equipment). Some applications of digital devices are exempted from IC technical standards, in a manner similar to the FCC. In many cases, such exempted equipment falls under the jurisdiction of other authorities, as noted below.
  Approval procedures: Verification for all unintentional radiators. No lab accreditation required.

- Health Canada (HC) designates consensus device standards for medical devices. It recognizes IEC 60601-1-2:2001+A1:2004 (general medical EMC).
  Approval procedures: EMC report is submitted as part of license application to HC. Class I device manufacturers require an establishment license; Class II, III and IV devices require a medical device license.

Jurisdiction	Canada - EMC			
Product type	**ITE**	**Radio**	**Appliance**	**Medical**
Authority	Industry Canada	Industry Canada	IC exempt	Health Canada
Approval Procedures	EMI only: Verification	Certification	N/A	Licensing
In-country testing required?	No	No	N/A	No
MRA with	Yes, Phase I	Yes, Phases I & II	N/A	No

US?				
Marks	Label info only	Label info only	N/A	N/A

Brazil

- The National Institute of Metrology, Standardization and Industrial Quality (INMETRO) is the 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 (an administrative approval) by the National Telecom Agency (ANATEL) and EMC is a factor in the approval. Both emissions and immunity compliance are required for telecom equipment; the standards reference IEC. Many but not all of the rules for short-range radio devices are identical to FCC rules.

- The National Health Surveillance Agency (ANVISA**)** is the authority for medical equipment; EMC is also required.

Jurisdiction	**Brazil - EMC**			
Product type	**ITE**	**Radio**	**Appliance**	**Medical**
Authority	INMETRO	ANATEL	INMETRO	ANVISA
Approval Procedures	N/A	Certification and Homologation	N/A	Registration
In-country testing required?	N/A	Yes	N/A	No
MRA with US?	Pending	Pending	N/A	N/A
Marks	no	no	N/A	N/A

EUROPE

EU

With 27 member states, the population and economy of the EU exceeds that of the US. The EU has simplified the process of access considerably by identifying the "essential requirements" for almost everything that is placed on the market in the EU. The authorities having jurisdiction vary by product type, and each country has a Competent Authority for each product type or directive. For example, the Competent Authority for EMC in the UK is the Department of Trade and Industry (DTI). The specific "essential requirements" for your products will be listed in the directives that apply to your product. In most cases, the

directives will be "New Approach" directives for which CE marking signifies compliance and the applicable standards have been published in the *Official Journal of the European Union*. A good place to start for guidance on directives and standards is http://www.newapproach.org. The CE marking indicates that the equipment bearing the marking complies with *all* of the applicable "New Approach" directives.

- Most electrical/electronic products must comply with both emission and immunity requirements, according to both the current EMC Directive 89/336/EC and the new EMC Directive replacing it, 2004/108/EC. This includes appliances and many devices exempted from EMI regulation in the US and Canada. In addition, the safety standards for household appliances now require compliance with limits to the surrounding low-frequency electromagnetic fields according to EN 50366. This is a safety standard, not an EMC standard.

- The "essential requirements" for radio and telecom equipment under the R&TTE Directive 1999/5/EC include electrical safety according to the Low Voltage Directive (but with no lower voltage limit), RF exposure for radio transmitters and EMC according to the EMC Directive. For telecom terminal equipment, there are no more requirements. Radio transmitters must also comply with requirements for efficient use of the spectrum. Both spectrum and EMC standards for radio equipment are published by ETSI, the European Telecommunications Standards Institute.

- Medical devices are approved according to a classification scheme originating with the Medical Device Directive 93/42/EC and used as the prototype for other medical device regulations around the world, including Canada. The basic medical EMC standard is EN 60601-1-2:2001. The EMC requirements are modified by specific standards EN 60601-2-x to define particular test setups or higher or lower limits for particular EMC phenomena. EMC is also a factor for *in vitro* diagnostic medical devices (Directive 98/79/EC) and active implantable medical devices (Directive 90/385/EEC).

Jurisdiction	**European Union – EMC**			
Product type	**ITE**	**Radio**	**Appliance**	**Medical**
Authority	EMC Competent Authority	Spectrum Competent Authority	EMC Competent Authority	Medical Competent Authority
Approval Procedures	Verification. Notified Body opinion may be obtained	Verification. Notified Body opinion may be rendered.	Verification	Verification, DoC, Type Examination, Notified Body approval
In-country testing	No	No	No	No

required?				
MRA with US?	Yes, Phases I & II	Yes, Phases I & II	Yes, Phases I & II	Yes, Phases I & II
Marks	CE	CE, possibly Notified Body number, alert mark	CE	CE and Notified Body number where applicable

Russia

- The authority having jurisdiction for general product types is GOST, short for Gosstandart (State Committee for Quality Control and Standardization). It is the national standardization body in Russia. More then 60 EMC standards have become mandatory. Basic standards are harmonized with IEC and CISPR standards. The Harmonized Tariff Code (HTC) is the determining factor if EMC applies to your products. If your product requires EMC compliance, testing can be done in Russia or at accredited labs located outside of Russia. It is also possible (based on agreements) to utilize EMC test reports to the EU standards from accredited labs. If your product requires the GOST mark, both safety and EMC are included under the single mark. You will also need to determine whether any special warning statements need to be included in the user manual and on the packaging, along with any specific language requirements.

- The authority for radio equipment in Russia is Glavgossvyaznadzor (Main Inspectorate in Communications). The application (with a detailed list of telecommunications equipment) should be submitted to the Certification Department of Goskomsvyaz (State Committee on Telecommunications and Information of the Russian Federation). The Department carries out a preliminary analysis to determine whether the equipment is compatible with the telecommunications technology currently used in Russia. After this technical review, two designated certification laboratories (of the 43 located across the country) will test the equipment "on type" and also for quality assurance. This will involve testing in the field and at the manufacturer's site. If the test results are successful, a Goskomsvyaz Certificate is issued and is valid for up to three years. Radio equipment sellers must obtain an additional permit from Gossvyaznadzor (The Russian Federation State Telecommunications Control) of the State Commission on Radio Frequencies (GKRCh) to use the radio spectrum and specific equipment on a specific frequency band in a specific area of Russia prior to the certification process.

- The Federal Service for Control over Healthcare and Social Development (Roszdravnadzor) is the main government agency responsible for registration of medical equipment, including foreign-made equipment. Applications for registration can include certificates of compliance obtained from other jurisdictions, such as:

- ISO 9001, ISO 9002, ISO 13485, and ISO 13488 certificates which should be notarized in the country of origin.
- Certificates of registration of medical equipment issued by a respective government agency in the country of origin, such as FDA certificates, EC Certificates (CE Mark) and Declaration of Conformity. All such certificates should be notarized in the country of origin.
- Electrical safety and EMC (electromagnetic compatibility) certificates, The Russian EMC standard corresponding to IEC 60601-1-2 is GOST R 50267.0.2.

Jurisdiction	**Russia - EMC**			
Product type	**ITE**	**Radio**	**Appliance**	**Medical**
Authority	GOST	Glavgossvyaznadzor	GOST	Roszdravnadzor
Approval Procedures	Certification	Certification, licensing	Verification	Registration
In-country testing required?	No	Yes	No	Yes
MRA with US?	No	No	No	No
Marks	GOST-R	No	GOST-R	No

FAR EAST

Japan

- The Ministry of Economy, Trade and Industry (METI) is responsible for appliance safety, including RF emissions (EMI). Immunity is not required. In 1999, the Electrical Appliance and Material Control Law was revised to become the Electrical Appliance and Material Safety Law (current law), which was implemented on April 1, 2001. Products subject to regulation are mandated to be labeled with the PSE mark. A wide range of products can be self-verified to the requirements and carry no regulatory marking. The RF emissions limits established for appliances are similar to corresponding CISPR standards, although deviations exist.

- EMI from Information Technology and Telecom equipment has been handled by a private, non-governmental, membership-based Voluntary Control Council for Interference by Information Technology Equipment (VCCI). The VCCI labeling has become so well accepted in some domestic markets that it has become a *de facto* regulatory gateway. With the new US/Japan Telecom MRA signed in February 2007, access to VCCI labeling will be available through either the membership route or by local accreditation to the VCCI standards based largely on CISPR 22.

- The authority for radio regulation in Japan is the Ministry of Internal Affairs and Communications (MIC). The technical requirements are contained in Radio Equipment Regulations dating from 1950 and have been updated numerous times since. Radio rules published by private certification bodies such as TELEC, or by industry associations such as ARIB (Association of Radio Industries and Businesses), are not to be confused with the official MIC technical requirements, although they may all seem very similar. The MIC radio rules are similar to corresponding FCC rules but there are many differences, especially with regard to frequency allocations.

- Medical products in Japan are regulated under the authority of the Ministry of Health, Labor and Welfare (MHLW). EMC requirements have been phased in over several years, with the last transition period for existing products just ended in March 2007 for Class I devices. The applicable EMC standard JIS T 0601-1-2:2002 corresponds to IEC 60601-1-2 first edition. This is soon being superseded by IEC 60601-1-2 2nd edition; the 2nd edition may be used currently with justification.

Jurisdiction	**Japan - EMC**			
Product type	**ITE**	**Radio**	**Appliance**	**Medical**
Authority		MIC	METI	MHLW
Approval Procedures	Registration	Certification, SDoC	Certification, verification	Licensing
In-country testing required?	No	No	No	No
MRA with US?	Yes, 2007	Yes, 2007	No	No
Marks	Class B: VCCI mark Class A: Kanjii text	Technical Conformity Mark	PSE or none	None

China (PRC)

- The People's Republic of China (PRC) has enforced EMC regulations since 1999, largely emissions only. Under the Compulsory Product Certification System (CPCS) implemented in 2002 and under the authority of the Certification and Accreditation Administration of the PRC (CNCA), a number of listed product categories must carry the CCC certification mark. The CCC mark includes provisions for indicating safety ("S") or EMC ("EMC") or both ("S&E"). The implementation rules for compulsory product certification specify the applicable procedures and standards by product

type, in a numbering format: CNCA-nnC-mmm:year. Examples are given in the table below.

- Radio approvals are under the overall authority of the Ministry of Information Industry (MII). The State Radio Regulation Committee (SRRC) Certification Center, under the MII, is directly involved in the approvals. Mobile terminals, including cellular base stations and handsets, are classified as terminal equipment and are so regulated. Quality assurance is also part of the certification process. PRC radio standards are drawn from FCC, TIA and ETSI, including EMC requirements.

- Many PRC standards are identical to international, FCC or ETSI standards. For example, the PRC standard GB4343 is equivalent to CISPR 14, and GB9254 mirrors CISPR 22. The IEC standards IEC 61000-3-2, -3-3 and 61000-4-x are references. Unfortunately, only in-country testing is permitted at this time.

- Medical devices fall under the authority of the State Food and Drug Administration (SFDA) and optionally the Ministry of Health (MOH). Medical devices are classified according to risk (I = lowest, III = highest) as with many other medical regulatory regimes. Implementation rules for medical products reference many IEC-particular medical electrical standards (IEC 60601-2-x). The SFDA requires type testing and factory audits.

Jurisdiction	**People's Republic of China - EMC**			
Product type	**ITE**	**Radio**	**Appliance**	**Medical**
Authority	CNCA	CNCA	CNCA	SFDA, MOH
Approval Procedures	Certification; see: CNCA-01C-020	Certification; see: CNCA-07C-031 for examples	Certification; see: CNCA-01C-016	Certification; see CNCA-08C-032 to 043 for examples; also Registration
In-country testing required?	Yes	Yes	Yes	Yes
MRA with US?	No	No	No	No
Marks	CCC	CCC	CCC	CCC

Chinese Taipei (Taiwan)

- The authority for safety and EMC for a wide variety of appliances and equipment in Taiwan is the Bureau of Standards, Metrology and Inspection (BSMI). RF emissions

(EMI) are regulated. Safety and EMC standards are derived from the IEC. For example, the limits in CNS 13438 are equivalent to CISPR 22.

- The National Communications Commission (NCC, formerly DGT) has authority over radio equipment. Many technical standards, especially for short range devices, are identical to FCC rules.

- Taiwan's Department of Health (DOH) regulates the importation of medical equipment.
  To market a medical device in Taiwan, the DOH pre-marketing registration approval must be obtained before the Board of Foreign Trade (BOFT) of the Ministry of Economic
  Affairs (MOEA) will issue an import license. The DOH, following many other economies, has grouped medical devices into three classes: I, II, III. EMC is required according to IEC 60601-1-2:2001, corresponding to the standard DOH-00003.

Jurisdiction	**Chinese Taipei - EMC**			
Product type	**ITE**	**Radio**	**Appliance**	**Medical**
Authority	BSMI	NCC	BSMI	DOH
Approval Procedures	DoC and certification	Certification	Certification, registration	Licensing
In-country testing required?	No	No	No	No
MRA with US?	Yes, Phase I	Yes, Phase I	No	No
Marks	Commodity inspection mark	NCC	Commodity inspection mark	No

Conclusion

This paper has provided a quick overview of what is required to ensure that EMC requirements are legally met for the countries in which you want to market your products. Although it is necessarily brief, it serves as a guide with which you can develop your own list of country requirements.

As you expand your list, you will be able to weigh the challenge of meeting compliance criteria and procedures for several nations simultaneously. Compliance has to be taken very seriously; the penalties for not complying vary from simple quarantine of your products at customs to severe measures such as monetary fines and even imprisonment.

If global EMC compliance issues are a recent challenge for your company, or if your current compliance staff are stretched thin, it may be beneficial to partner with Intertek-ETL Semko, a proven leader in EMC test and certification worldwide. We have more than 322 laboratories in 110 countries around the world, 20 of them in the US alone, In addition to MRA arrangements, we have special agreements with agencies and labs in many other countries including Israel, Brazil, Russia, and Belarus.

By working with a partner lab, it is easier to assemble a product- or technology-specific test and certification plan that maximizes your testing dollar and gives you the additional resources needed to seek global compliance. You have the security of knowing that the plan is defensible in the face of management scrutiny and traceable in case of an audit. And it can be modified easily as technology and business structures change.

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