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Permit No. 110  
Frederick, MD  
21701

## Inside: Understanding the European Union R&TTE Directive



W A S H I N G T O N L A B O R A T O R I E S , L T D

## Proposed revision to the EMC Directive

Ten years after the initial deadline for compliance with the EMC Directive (subsequently pushed forward), the industry and regulators have learned many lessons.

Hence, a Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to electromagnetic compatibility has been issued on December 24, 2002, under reference COM(2002) 759.

This proposal is based on the results of the "SLIM" (Simpler Legislation for the Internal Market) process initiated in 1998 and of the Cost Benefit analysis performed in 2001.

Relying on the experience gained after 8 years of application of the current directive, this new proposal will bring a set of enhancements aiming at:

- Clarifying its scope by means of improved definitions, more clearly defined exclusions and inclusion of ready-made connecting devices;
- Regulating specifically fixed installations by means of a more appropriate regulatory regime;

- Enhancing clarity through more detailed essential requirements;
- Clarifying the role of harmonized standards;
- Simplifying the conformity assessment procedure, reduced to a single procedure for apparatus;
- Cutting "red tape" and increasing manufacturers' choice by abolishing compulsory third-party intervention where harmonized standards have not been applied but allowing in all cases for voluntary involvement of conformity assessment bodies for apparatus;
- Improving the tools for market surveillance through better traceability of the manufacturer.

The full text of this information may be found at:

[http://europa.eu.int/comm/enterprise/electr\\_equipment/emc/revision/proposal.htm](http://europa.eu.int/comm/enterprise/electr_equipment/emc/revision/proposal.htm)

W A S H I N G T O N L A B O R A T O R I E S , L T D

# T&E Update

Testing • Engineering • Consulting

Issue 20



## Understanding the European Union R&TTE Directive

By Greg Snyder

Wireless communications have increased world-wide over the last ten years at astounding rates. Aside from the normal cell and wireless phones almost every other aspect of normal day-to-day activities has been impacted by some version of wireless technologies available to consumers and businesses.

These untethered systems include wireless LANs, alarm systems, remote entry systems, meter readers, PDAs, video game controllers and keyboards.

Opportunities for growth of the industry has widened with the implementation of the R&TTE Directive, which was enacted by the European Union (EU) in April 2000. This directive removed significant barriers that previously prevented products from freely circulating within the EU (currently 15 members, with an additional 10 to be added by 2004).

The opportunity represented by this market makes it imperative for manufacturers to understand the R&TTE Directive and how it applies to their product.

This article aims to break up and analyze



Route" are akin to the EMC Directive process and are discussed in detail here (as most products will fall within one route or the other).

However, before choosing a route for compliance, the manufacturer must first understand the Essential Requirements of

the Directive, which are:

- Spectrum use (effective use so as to avoid harmful interference)
- Electrical Safety and health (as in Low Voltage Directive, 73/23/EEC)
- ElectroMagnetic Compatibility (as in the EMC Directive, 89/336/EEC)

In addition to these essential requirements, the Directive addresses other requirements that may be applicable to certain equipment (i.e. telecom equipment). These issues deal with such aspects as not causing harm to the network, privacy of data, avoidance of fraud, access to emergency services, and features for users with disabilities.

No matter which route to compliance the manufacturer or representative chooses, each requires the procedures of Annex II—

the different requirements of the R&TTE Directive and to provide concise understanding of these requirements.

The goal is to obtain the CE Marking. Several routes to complying with the R&TTE Directive are available to reach that goal. These routes are as follows:

1. Annex III: Standards Route ("easiest" path)
2. Annex IV: Technical Construction File (TCF) route (used for more complex cases and non-harmonized standards—requires a Notified Body)
3. Annex V: Full Quality Assurance route (Manufacturer can declare based on having a accredited Quality System)

The "Standards Route" and "TCF

## Understanding the European Union R&TTE Directive

continued from page 1

covering Internal Production Control—to be met. This Annex sets forth the legal requirements, production technical documentation, and manufacturing control as outlined below.

### Legal Requirements:

Legal requirements mandate that the manufacturer declare that the product complies with the Directive via a written Declaration of Conformity and placing the CE Marking on the product. Additionally, it is required that the manufacturer must keep all technical documentation for a period of 10 years from the time the product was last manufactured. These requirements can be met by the manufacturer or by an authorized representative established within the European Union (EU). If neither the manufacturer nor the representative is in the EU then the person placing the product on the EU market is responsible for complying with the requirements of the Annex.

### Product Technical Documentation:

The product's technical documentation is used to assess the conformity of the product with the essential requirements of the Directive. The documentation must cover the design, manufacture, and operation of the device. Following is a list of what must be included:

1. Product description.
2. Conceptual design and manufacturing drawings, schematics, subassemblies, circuits, etc.
3. A description and explanation of the drawings and schematics as well as for the operation of the product.
4. A list of all standards that were applied, in full or in part to show compliance. If standards were not used or do not exist then a description and explanation of the solutions used to meet the essential requirements of the directive must be included.
5. Results of design calculations, examinations, etc.
6. Test reports.

7. A copy of the Declaration of Conformity.

### Manufacturing:

The manufacturer must ensure that all measures have been taken during the manufacturing process to continue to manufacture products that meet the technical documentation as described above and the product continues to comply with the requirements of the Directive.

### Routes to Compliance

#### The Standards Route

As listed earlier, the Standards Route covered is under Annex III. This route allows the manufacturer to test and evaluate the radio product to the essential radio test suites of harmonized standards for that particular type of device. A harmonized standard is one that has been published in the Official Journal for the R&TTE Directive. If a harmonized standard is not available, then the manufacturer must involve a Notified Body to prescribe the necessary test suite. When a Notified Body is consulted, the CE marking on the product must include the assigned number of the Notified Body. It is important to note that complying with a harmonized standard does not ensure that a product meets the essential requirements of the Directive, but it gives the manufacturer a “presumption of conformity” with the requirements.

In addition to standards being harmonized, frequency bands and device operation/intended use must also be harmonized between the member states. Although the R&TTE Directive has removed the barriers to trade, there still exists limitation in the frequency allocations and operation of devices within various member states. This is mainly due to history and the frequency bands already being used by other activities and services, such as military. When a frequency band is not harmonized, the manufacturer still applies the harmonized standard (assuming it exists), however, a separate process called Notification is required. This requires the manufacturer to “notify” in writing

the member state spectrum authority of the device. In addition the Equipment Class Identifier (ECI) or “Alert” symbol is required to appear on the label of the device signifying that the frequency band that the device operates in is not harmonized. Most frequencies, however, are harmonized and as new technology is developed these non-harmonized frequency allocation problems will diminish.

Once the device has been successfully tested, the manufacturer or authorized representative within the EU must prepare a DoC attesting that the product complies with the essential requirements and the appropriate CE Marking and the labeling must be applied to the product.

#### The Technical Construction File Route

The Technical Construction File (TCF) route to compliance is slightly more involved, as it requires the submission of a complete technical package to a Notified Body (NB) for review. This option is typically used when harmonized standards do not exist, such as in marketing new technologies, or when harmonized standards have only been partially applied. It should be noted that the TCF route may be chosen even if harmonized standards do exist for a product. Some manufacturers gain a level of confidence by submitting TCFs to Notified Bodies for review—a third party independent assessment. For formal submissions, a manufacturer may choose to consult with more than one Notified Body, but each body must be made aware of the other Notified Bodies that are involved.

A Notified Body's role includes identifying tests suites, reviewing the TCF, and issuing an opinion to the manufacturer. By mandate, the opinion of a Notified Body to the manufacturer must be given within four weeks of receipt of the TCF. At the end of four weeks or upon the receipt of the opinion from the Notified Body, the manufacturer or authorized representative within the EU can label the product and place it on the market. The label will have the CE Marking and the NB's number. Additionally, if the device operates on a non-

harmonized frequency band, then the ECI “Alert” symbol must also be placed on the label.

Clearly, the opinion of the Notified Body is important but there are some functions that the body cannot perform. These include: prepare test reports, design equipment, sign DoCs, or act as an agent for the manufacturer. In the event that an unfavorable opinion is received from a Notified Body, it is the manufacturer's responsibility to notify all other Notified Bodies of the opinion. However, even if a Notified Body does not issue a favorable opinion, the manufacturer may still decide to sell the product that operates on a harmonized frequency band in the EU! The Notified Body's opinion is just that—an opinion. National authorities, however, may decide to have the product withdrawn from the market if they reasonably expect that the product could cause interference.

#### Quality Assurance Route

The last route to compliance is Annex V of the R&TTE Directive. This annex, labeled as “Full Quality Assurance” is more complex and not as popular as the previously discussed routes. What it means is that the manufacturer must have an accredited Quality System. This tacitly demonstrates that the manufacturer has the necessary procedures and systems in place to ensure compliance with the R&TTE Directive. Currently, only a few Notified Bodies are approved to perform this process.

Following is an overview of the requirements that a manufacturer must fulfill in order to comply with Annex V.

- Operate an approved quality system covering design, manufacture, final product inspection and testing.
- Allow a Notified Body inspection to ensure that the quality system is sufficient to ensure that products are produced to meet the essential requirements of the directive.
- Permit regular audits by a Notified Body for continued compliance.
- Make all quality documentation, technical locations, and documents available to the Notified Body

for inspection.

- Allow unscheduled Notified Body audit visits.
- Produce and retain technical documents referred to in section 3.2 of the directive and allow continued assessment of these documents by a Notified Body.
- Apply the relevant markings to products placed on the market.

Quality system approvals require that each Notified Body make available to all other Notified Bodies relevant information concerning the approval, including references to products issued and withdrawn. Once compliance is achieved, manufacturers can produce a DoC and place a product on the market

only if the equipment operates on a harmonized frequency band. If the device operates on a non-harmonized frequency band, the manufacturer has to wait until the notification process has been completed. As with all routes to compliance the equipment must be labeled with the NB number, CE Marking, and ECI “Alert” symbol (if non-harmonized frequency band).

The following table summarizes the routes to compliance along with the requirements of using a Notified Body and the marking of the product. The table summarizes the Essential process in complying with the R&TTE Directive.

Summary Table of R&TTE Directive Routes to Compliance.

Route to Compliance	Frequency Band Allocation	Notified Body Consulted	Marking/ Labeling	
Standards	Harmonized	No	CE Marking	
		Yes (Optional)	CE Marking NB number	
	Non-harmonized	No	CE Marking ECI (Alert Symbol)	
		Yes (Optional)	CE Marking NB number ECI (Alert Symbol)	
			CE Marking NB number	
			CE Marking NB number ECI (Alert Symbol)	
Technical Construction File	Harmonized	Yes	CE Marking NB number	
	Non-harmonized	Yes	CE Marking NB number ECI (Alert Symbol)	
		Harmonized	Yes	CE Marking NB number
			Non-harmonized	Yes

#### Notifying Authorities

Not all of Europe uses the frequency spectrum in the same way. For mainly historical reasons, the various communications bands have slight—and not-so-slight—variations in usage across the EU. If a manufacturer makes a product that operates on a portion of the spectrum that is not harmonized, then the manufacturer is obligated to “notify” the intended market's authorities that they will sell transmitting products in their country. This Notification process must be done 4 weeks prior to placement on the market. The process is relatively straight-forward.

The R&TTE Directive represented an unprecedented change in the way telecommunications and radio products can be approved for the European market. The Directive shifts the burden from the Certifying authorities to the Manufacturer through the process of Declaration of Conformity. With this shift, more flexibility is gained in the process, which improves access to the European market, broadens consumer choices, and speeds technological competition and innovation.

*Greg Snyder is the Chief EMC Engineer for Washington Laboratories.*

# New Medical EMC Standard At-A-Glance

Immunity Test	Basic Standard	EN 60601-1-2 Medical EMC requirements	
		1st edition 1993 Mandatory today	2nd edition 2001 Mandatory 2004
ESD	IEC 801-2 / IEC 61000-4-2 (5ns rise, 30 ns pulse)	±8kV air ±3kV contact	±2, 4 & 8kV air ±2, 4 & 6kV contact
Radiated Susceptibility	IEC 801-3 / IEC 61000-4-3 80% AM mod. @1kHz		
	Non-life support devices	3V/m 27-1,000 MHz	3V/m 80-2,500 MHz
	Life support devices	3V/m 27-1,000 MHz	10V/m 80-2,500 MHz
Electrical Fast Transients	IEC 801-4 / IEC 61000-4-4 (5ns rise, 30 ns pulse@5kHz)		
	AC power	±1kV wall plug ±2kV permanent	±2kV
	DC power	n/a	±2kV
	I/O (>3m)	±0.5kV	±1kV
Surge	IEC 801-5 / IEC 61000-4-5 (1.2µs/50µs Open 8µs/20µs Short)		
	AC power	line-to-line	±1kV DM
		line-to-earth	±2kV CM
Conducted RF	IEC 61000-4-6 (0.15-80MHz 80% AM mod. @ 1kHz)		
	Non-life support devices	n/a	3V/m
	Life support devices	n/a	3V/m outside ISM bands 10V/m in ISM bands
Power Frequency Magnetic Field	IEC 61000-4-8	n/a	10 A/m 50 and/or 60 Hz
Voltage dips and interrupts	IEC 61000-4-11	n/a	30% dip @ 0.5s 60% dip @ 100ms 100% dip @ 10ms 100% interrupt @ 5s



# ANNOUNCING

## 2003 Testing Workshop Series

The 2003 schedule of free workshops at Washington Labs is now set—plan now to attend at least one! These popular seminar/practical workshops will include demonstrations, guest speakers, the latest EMC and Safety compliance news, and lunch!

Customized seminars and/or practical lab programs are also available to meet your company's specific needs.

FEB.  
21  
2003

### EMERGING WIRELESS TECHNOLOGIES SPONSORED BY **Tektronix** AND WASHINGTON LABORATORIES 8:30 A.M. – 4:00 P.M.

You're invited to attend our winter workshop, which we're co-sponsoring with Tektronix who will provide a comprehensive overview of current and emerging technologies encountered in the Wireless Communications Sector. With the advancement of 3G technologies and the proliferation of products using wireless communications media, it is critical to understand the types and inter-relationships of the various technologies. Also included will be a [basic technical background required to understand measurements made at the RF Layer of emerging wireless technologies](#). In addition to the "nuts and bolts" of wireless technologies, the testing and certification requirements for wireless systems will be presented. With the harmonization of worldwide standards, more markets are available for these technologies.

Demonstrations of signals and measurements will also be provided to give attendees understanding of the measurement process and the critical parameters for designing and characterizing signals.

#### Topics

Overview of Wireless Technologies	Technologies	Regulatory and Certification
Current Implementation	802.11	Spectrum Usage
Driving factors affecting expansion	WCDMA	Worldwide Regulatory Compliance
Technical challenges	GSM	North America: FCC & IC
Markets and Projections	GPRS	Europe: Radio and
	Domestic Wireless Market	Telecommunications
	International Market	Terminal Equipment
	CDMA2000	Directive
	Bluetooth	
	Ultra-Wideband	
	Wi-Fi	Asia-Pacific Requirements

This workshop offers critical information for managers, engineers, and technicians involved in wireless technologies. Don't miss this informative workshop—it's FREE! And on-site at Washington Labs Test Facility in Gaithersburg, MD. These workshops have been very popular; space fills up fast—call today! Tuition and lunch are free!

### GAITHERSBURG LAB FEB 21, MAY 16, SEPT 12, NOV 14

#### EMC Testing and Measurements

Designing to Avoid EMC Problems Down the Road  
Watch as our Gaithersburg Lab engineers demonstrate several testing techniques that uncover EMC flaws in electrical and electronic equipment— problems which can be avoided before the testing stage. You'll have the opportunity to "get specific" with the engineering staff on particular problems you may be encountering with current R&D designs.

### FREDERICK LAB MAR 14, JUN 6, OCT 17

#### Hands-On Safety Compliance

Join us at our lab in Frederick for hands-on practical workshops to assist you with Product Safety Compliance. You'll not only hear and learn about the design tips and information to help you with new product design to ensure safety—but you'll roll up your sleeves and work with practical demonstrations and test simulations—all geared to provide you with a 3-D picture of designing for compliance.

Each workshop will have a specific theme and guest speakers! Be sure to register early as positions fill up quickly. Call Ann or Katrina at 800-839-1649 or e-mail us at [info@wll.com](mailto:info@wll.com) to register today.

## Bluetooth Doo-Dads Slowly Emerging

After the hype and hoopla surrounding the introduction of Bluetooth, product introduction and implementation has been less than originally forecast. Partly to blame is the weakened economy and partly to blame is lack of consumer demand for wireless solutions.

However, some recent product introductions featuring Bluetooth show practical implementation of the short-range wireless protocol. (See our Bluetooth overview article in our newsletter available at: <http://www.wll.com/T&EUpdate1000.pdf>)

**Computing:** Hewlett-Packard's iPAQ Pocket PC h5450 is enabled with Bluetooth, the short-range wireless technology. It's also Wi-Fi-ready. Interestingly, it is the first handheld organizer with a biometric fingerprint reader designed to prevent it from being used by anyone but its owner. To unlock the machine, you must pass your finger across a narrow thermal sensor; the biometric technology confirms your

identity by measuring temperature differences between the ridges and valleys of your skin.

**Headsets:** Introductions at the 2003 International Consumer Electronics Show included Jabra's FreeSpeak and Sony Ericsson's HBH-20. Jabra's headset weighs less than an ounce. It has a small microphone and can be attached to either ear. Sony Ericsson released a similar Bluetooth headset, called the HBH-20, that transmits data within a 10-metre range and does not require line of sight.

**Automotive:** Delphi Corporation of Troy, Michigan has developed a wireless Bluetooth communications system for the new Saab 93 vehicle. The system is used to connect cellular phones and other wireless portable devices through the vehicle.

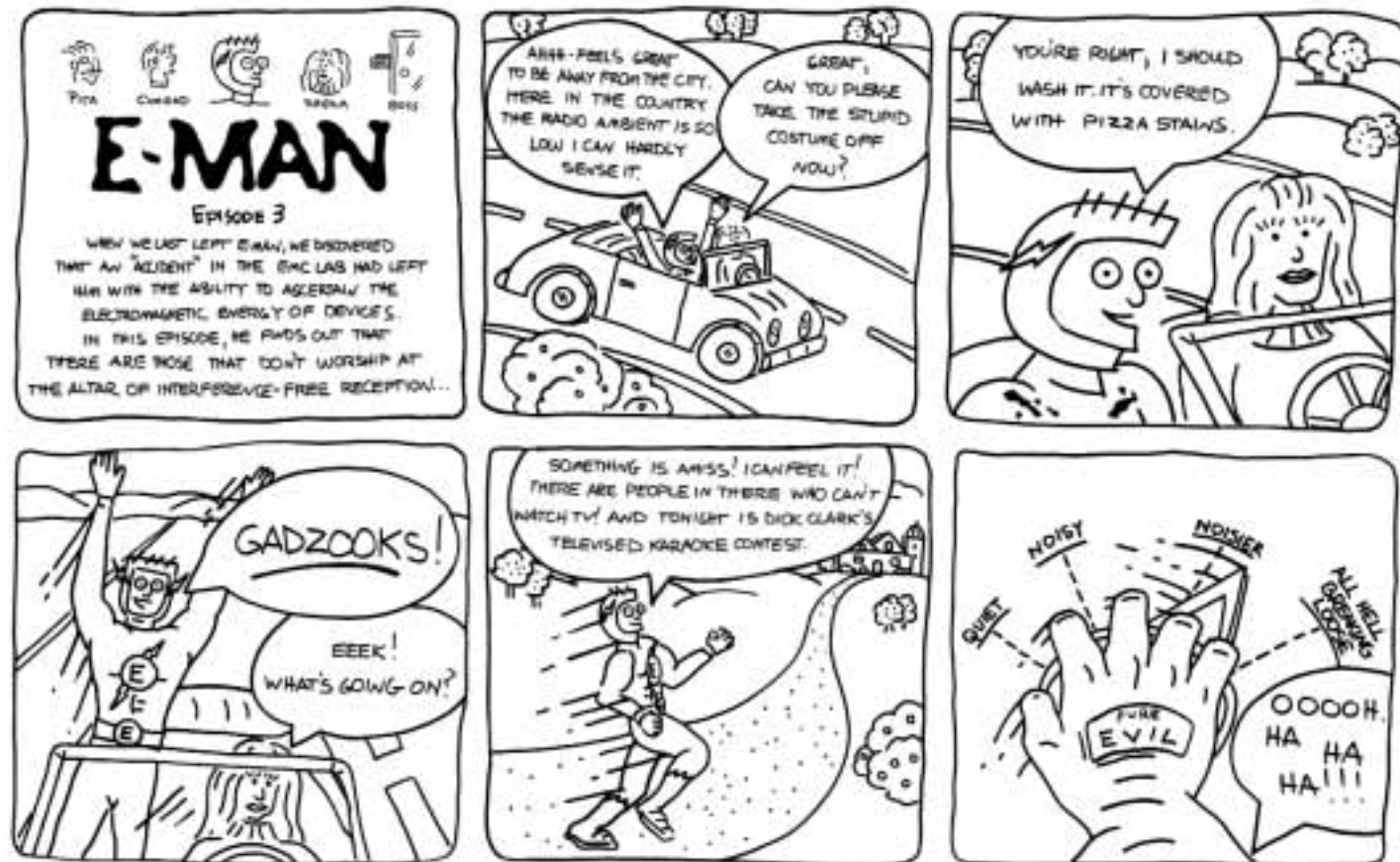
Credit: Bluetooth Web Site. See <http://www.bluetooth.com/news/news.asp>

## Standard Update for the R&TTE Directive

Just a reminder, EN 301-489-1 V1.3.1 becomes mandatory August 1, 2003.

The standard has increased the radiated immunity frequency range to 2000mHz.

This reflects the increased use of spectrum.



## Everyone's Helping Hands

Employee Spotlight—Lavern Robinson



in the Big Apple, and a stint with the Department of General Services there, she moved her family to Gaithersburg, Maryland. There she enjoys the "peace and quiet" that the big city didn't offer. She also worked in administration for Health Gap Medical Services in Washington DC before coming to Washington Labs.

"I wake up and enjoy coming to work here. That makes a big difference" Laverne says of why she likes her job at Washington Labs. "I have a lot of independence and it's a very easy-going atmosphere with great clients."

A self-proclaimed workaholic, Laverne keeps busy with her church and her three children: Nicole aged 22, Wayne aged 15 and ten-year-old Annette. Parents take note: Lavern assures us that she is very organized at home too and finds that you have to keep everyone on task or there's chaos!

*I wake up and enjoy coming to work . . .*

"Welcome to Washington Labs"—our customers can always count on being welcomed with a wonderfully happy face and voice. And we all know how important that is to a front office. We're fortunate to have Lavern Robinson as our receptionist and administrative assistant extraordinaire.

Lavern started with us in 2000 as a temp and we quickly discovered that her personality, organization skills and quick-study nature were exactly what we needed so she became a full-time employee that same year. One of her many responsibilities is logging incoming and outgoing equipment to ensure the right products are tested and/or sent to the right people.

In addition to the phones and mail, Lavern assists the Accounting Department with accounts receivables and the Marketing Department with the quote and mail communication. And when she's not assisting everyone else, she takes care of a bushel of miscellaneous office responsibilities that everyone needs but can't seem to get done themselves.

Lavern came from Kingston, Jamaica in 1974 to live with her mother in Brooklyn, New York. After 20 years

Lavern is a joyful person and gets great satisfaction out of her church life at the Emmanuel Brinkow Seventh Day Adventist Church. She is an usher, greeter, hospitality committee member and extremely active in the Helping Hands group that ministers to the sick and shut-in. With the little free-time that she has, Lavern enjoys interior decorating, listening to jazz, and seeing a good movie.

If you need help, we all know who to call.

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