EMC Authorization of Wireless Devices in the US and EU

IEEE EMC Society – Minneapolis Chapter Meeting

June 2, 2004

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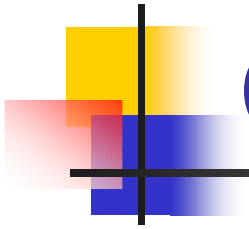
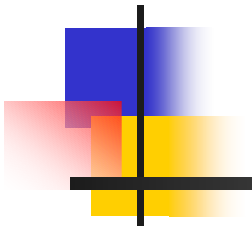


Overview

- ✓ Compliance Considerations
- ✓ FCC Authorization Process
- ✓ R&TTE Directive



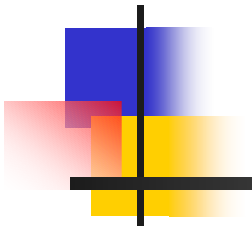
Compliance Considerations

Compliance Considerations

- Thoroughly investigate the applicable EMC specifications for your target market.
- Write a test plan.
- Make EMC a design consideration.
- Get expert help for rules interpretations, test plan writing, and EMC design strategies.
  - The best value is not always found with the lowest bidder!

Design Considerations

- The focus of EMC design: grounding, filtering, component selection, PCB layout, and shielding.
- Single solutions don’t exist; but rather a combination of suppression techniques are required.
- Don’t wait until the end of the design cycle to test.
- “One test is worth a thousand expert opinions” – *source unknown*



FCC Authorization Process

FCC Rules for Wireless Devices

Rules are found in Title 47 of the CFR. A sample:

Part 2 - Authorization and Measurement Procedures, Frequency Allocations, General Rules.

Part 15 - Receivers and Unlicensed transmitters (intentional radiators)

Parts 22 & 24 - Cellular Radio & PCS

Part 90 - Specialized Mobile Radio Service (Land Mobile)

Part 95 – Personal Radio Service (FRS, GMRS, CB, R/C), WMTS, & MICS

Part 101 - Fixed Microwave Radio Service

Rules can be found on-line at www.access.gpo.gov and www.fcc.gov/oet.

FCC Equipment Authorization Procedures

Until recently, there were five different equipment authorization procedures:

Type Acceptance - Required an application to the FCC. Applied to licensed transmitters.

Certification – Similar process to type acceptance. Applied to unlicensed low power transmitters that operated under FCC Parts 15 and 18.

Notification - Required an application, but no measurement data. Used for products with a good record of compliance, such as most receivers.

FCC Equipment Authorization Procedures

Continued:

Declaration of Conformity (DoC) - A self-approval procedure that requires no application to the FCC. The product must be tested at a NVLAP or A2LA accredited lab. Previously used for personal computers and peripherals only.

Verification - A self-approval procedure that does not require testing at an accredited lab. Used for non-residential devices operating under FCC Parts 15 and 18.

FCC Equipment Authorization Procedures

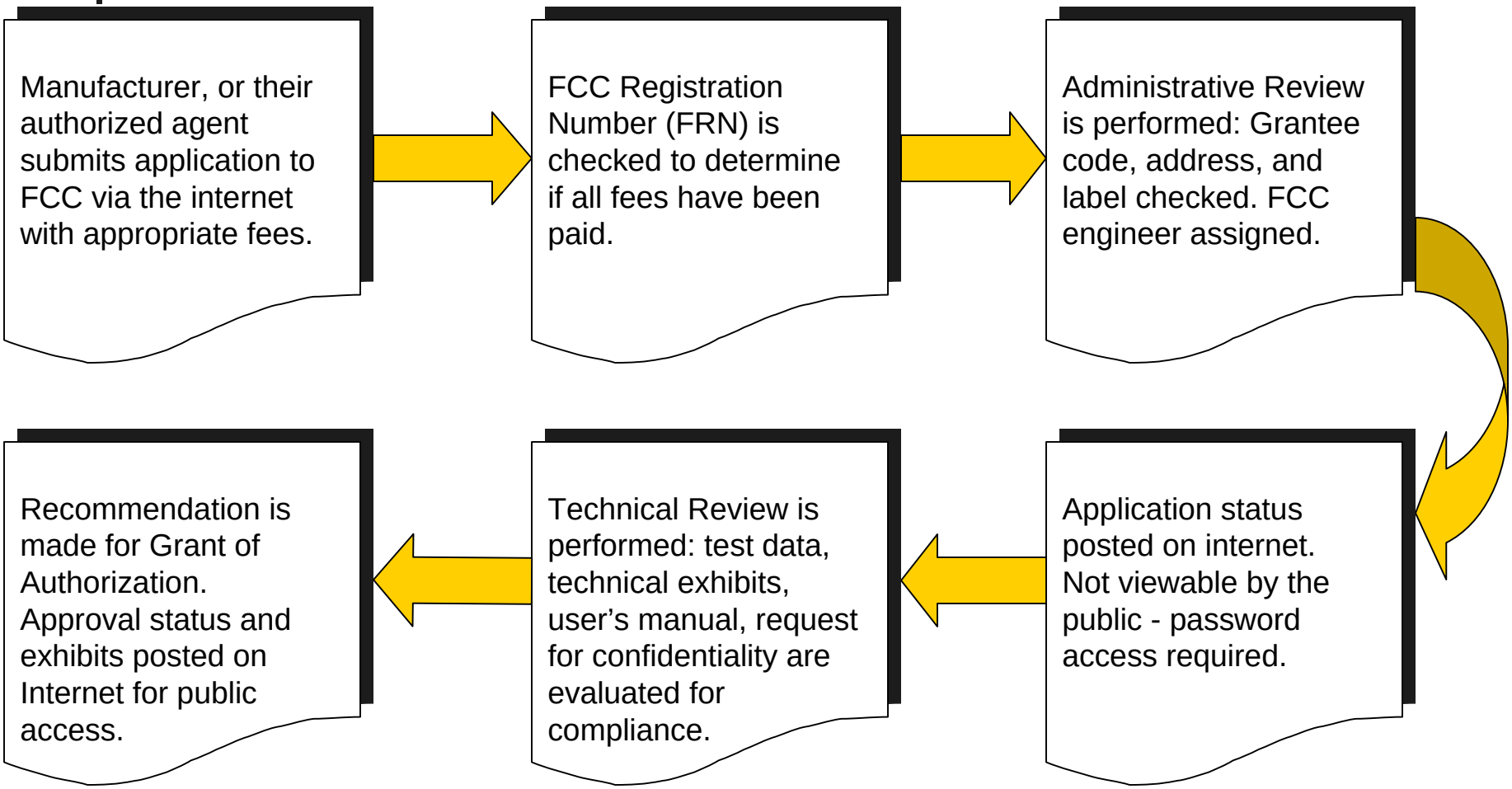
Now there are only three different equipment authorization procedures:

Certification – Applies to all transmitters and scanning receivers.

Declaration of Conformity (DoC) – Applies to most receivers, personal computers and peripherals, and residential Part 18 devices.

Verification - Used for non-residential devices operating under FCC Parts 15 and 18.

FCC Application Process



Past Problems with FCC Application Process

- Processing time was overly burdensome on manufacturers
- Authorization Process was too complex - many “opportunities” for delays
- Too much regulation of products with good compliance histories
- Not in harmony with international MRAs

Streamlining the Equipment Authorization Process

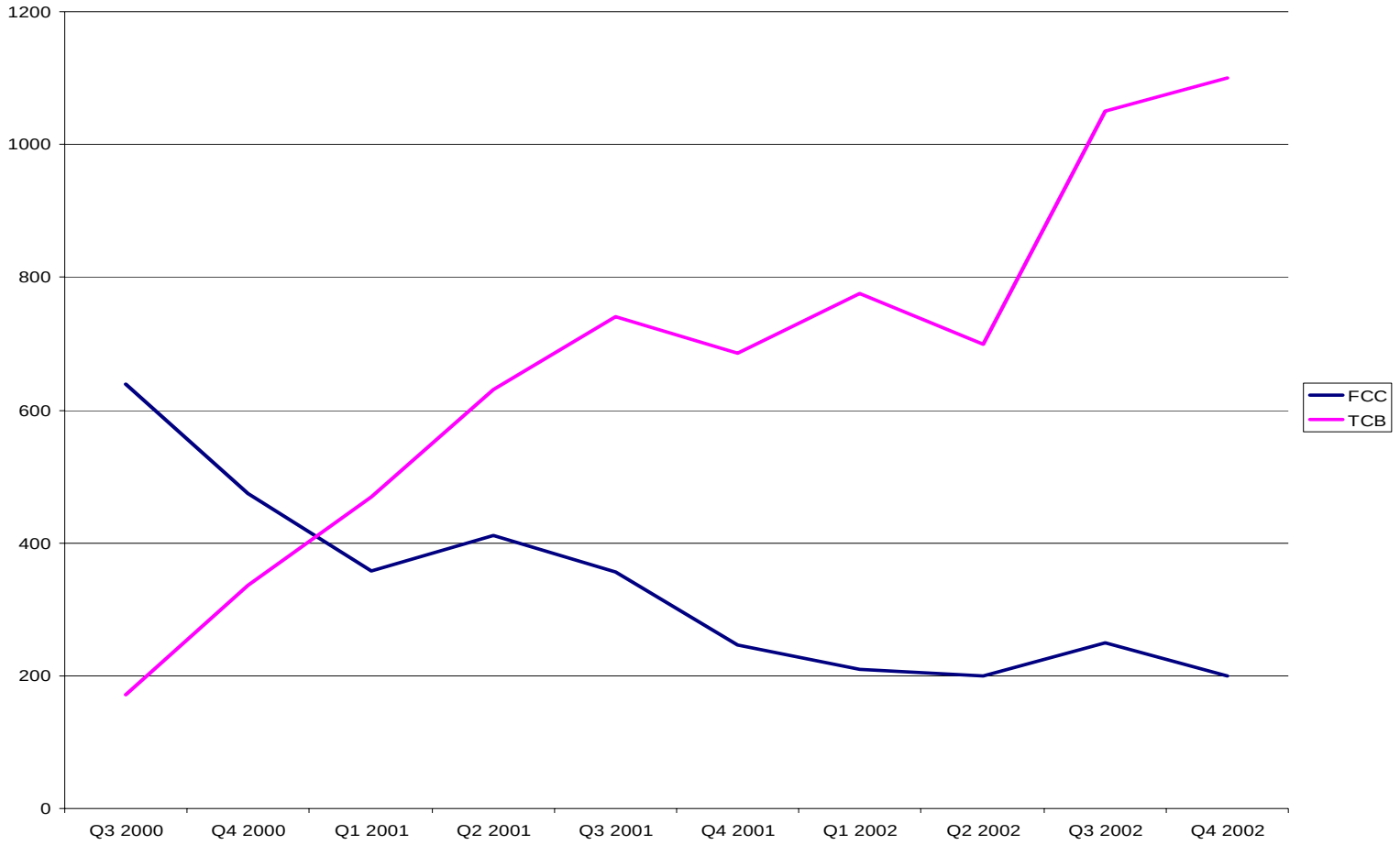
In Docket 98-68, TCBs were introduced:

- As an alternative to the FCC application process, designated private entities known as “Telecommunication Certification Bodies” (TCBs), can issue equipment approvals.
- Manufactures have the choice of using either the FCC or TCBs to certify products.
- TCBs function like the FCC by certifying a product based on the test results of one representative sample.
- TCBs parallel the product certification processes in other countries - an essential step in the MRA process.

TCB Advantages

- Manufacturers have more than one approval body to select from.
- TCBs provide a faster, more convenient option to the FCC's authorization system.
- Competition between TCBs has kept costs low and processing times fast.
- FCC is now able to direct more resources towards enforcement. TCBs grant more certifications than the FCC.

TCB Application Trend



Source: Julius P. Knapp, FCC, “FCC Conformity Assessment Program”, February 7, 2003, IRSC02030

TCB Qualification Criteria

- Accredited by NVLAP or A2LA to ISO Guide 17025 “General Requirements for the Competence of Calibration and Testing Laboratories”
- Accredited by NIST, using ANSI to perform the assessment, to ISO Guide 65 “General Requirements for Bodies Operating Product Certification Systems”
- Designated by the FCC

TCB Activities

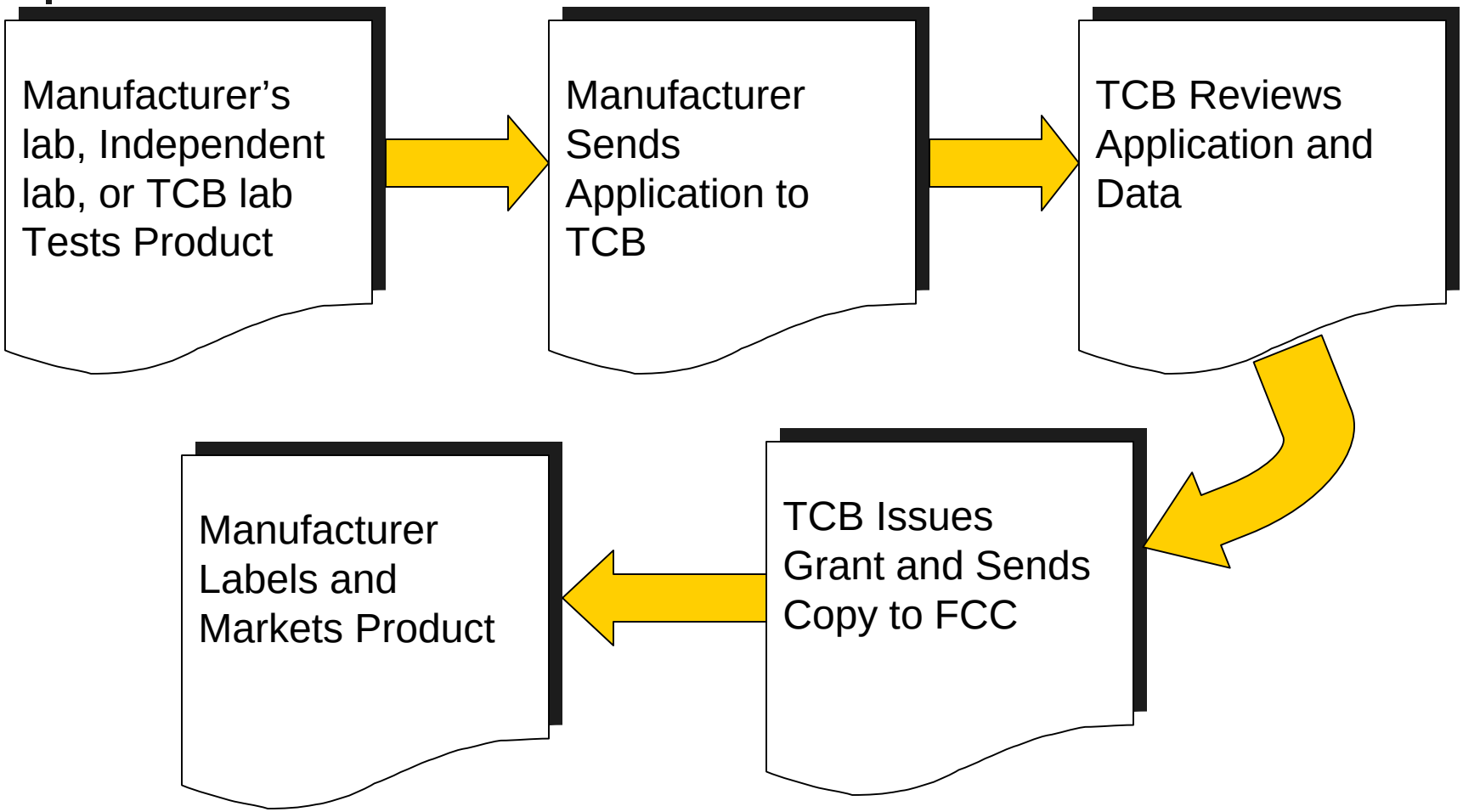
- TCBs certify devices in accordance with FCC rules and policies. See 47 CFR 2.960 & 2.962
- TCBs issue written grants of certification based upon applications that contain the same information currently required by FCC rules.
- The grantee remains responsible to the FCC for compliance.
- TCBs may either perform the testing themselves, or accept and review test data from manufacturers or other laboratories.

Additional TCB Activities

- TCBs are responsible for the accuracy of the test data.
- TCBs verify that all FCC labeling requirements are met, including FCC ID.
- TCBs must submit electronic copy of all granted applications to the FCC.
- TCBs can approve permissive changes, regardless who originally certified the equipment.
- TCBs perform post-market audits of equipment they certify

Bottom Line - All TCB Actions Subject to FCC Review!

TCB Process Overview



TCB Prohibitions

TCBs are prohibited from the following activities:

- Granting waivers to FCC rules and regulations
- Certifying new technologies where FCC rules do not exist
- Enforcing FCC rules
- Granting transfers of control of Certifications
- Imposing their own requirements
- Issuing Grants for devices on the FCC Exclusion List

In cases of dispute, the FCC will be the final arbitrator.

Latest TCB Status Report

- In the United States
  - 20 TCBs
- In Europe
  - 11 TCBs
- Exclusion List
  - Simplified List to allow TCBs to certify more product types
  - Revised List issued July 17, 2002

Source: William Hurst, FCC, “FCC Recent Activity Report”, USCEL Meeting, Aug 19, 2002, Minneapolis, MN

R&TTE Directive

European Union

- Prior to May 1, 2004, 15 EU Member States: Belgium, Netherlands, Luxemburg, Germany, France, Italy, Finland, Sweden, Denmark, UK, Ireland, Spain , Austria, Portugal, Greece.
- On May 1, 2004, the EU added 10 Member States: Estonia, Latvia, Lithuania, Poland, Czech Republic, Slovakia, Hungary, Cyprus, Malta, and Slovenia
- Romania and Bulgaria hope to join by 2007. Turkey not currently active in negotiations.

European Economic Area

- European Free Trade Association (EFTA): Switzerland, Liechtenstein, Norway, and Iceland
- European Economic Area (EEA) = EU + EFTA.
- For many areas, EEA rules are the same as EU rules

Directive 1999/5/EC

- Radio and Telecommunications Directive (R&TTE)
- Effective April 1, 2000
- Compliance is based on a manufacturer's Declaration of Conformity
- A Notified Body gets involved when harmonized standards don't exist, otherwise they play a voluntary role.

R&TTE Directive Philosophy

- Scope: terminal equipment plus all radio equipment (including both harmonized and non-harmonized frequency bands)
- No national approval regulations
  - The Directive does NOT harmonize spectrum use!
- Provides free movement of radios unless a Member State has good reasons to bar products (usually due to spectrum issues)

R&TTE Directive - Philosophy

- Requirements are legal, not technical and are designed to safeguard the spectrum
- ETSI and CENELEC provide the technical translation of the requirements
- Harmonized standards are voluntary - manufacturers can use other methods.
- Compliance with harmonized standards gives a presumption of conformity with the Directive. Easiest Route to Market!
- Harmonized standards are published in the “Official Journal of the European Communities”

R&TTE Directive - Philosophy

- Unlike the FCC, there are no pre-market access controls on R&TTE products (no “certification” required)
- Post-market surveillance is the primary enforcement strategy.
- The market is largely self regulated
- Testing laboratories do not need accreditation.

Essential Requirements – Article 3

- Electrical Safety and health (e.g. Low Voltage Directive, 73/23/EEC).
- Electromagnetic Compatibility (as in EMC Directive, 89/336/EEC)
- Spectrum use (Must be used effectively to avoid harmful interference – technical requirements for most radios are in ETSI Standards).
- Operate in accordance with national frequency plans. See EFIS at **http://www.ero.dk**

Conformity Assessment – Article 10

- Main Principle: Manufacturer takes full responsibility and should test to verify compliance.
- The procedures described in Annex III or Annex IV are the most common compliance routes.

Conformity Assessment – Annex II

Annex II – Internal Production Control

- Per Article 10(3), this procedure is only available to telecommunications terminal equipment & receivers– not transmitters.
- Technical documentation is assembled to demonstrate conformity with the essential requirements of Article 3.
- Documentation covers design, manufacture and operation of the product – may include test reports

Conformity Assessment – Annex III

Annex III – Internal Production Control Plus Specific Apparatus Tests

- The requirements of Annex II, plus all the essential radio test suites must be performed.
- In the absence of harmonized standards, a Notified Body identifies the essential radio test suites

Conformity Assessment – Annex IV

Annex IV – Technical Construction File

- The requirements of Annex III, plus a Technical Construction File (TCF) that contains a Declaration of Conformity to specific radio test suites.
- A Notified Body reviews the TCF and issues and opinion

Conformity Assessment – Annex V

Annex V – Full Quality Assurance

- More complex, only some Notified Bodies are approved to perform this process
- The manufacturer must operate an approved quality system for design, manufacture and final product inspection.
- A Notified Body must assess whether the quality control system ensures conformity with the requirements of the directive.
- Subject to on-site surveillance by a Notified Body.

When to contact a Notified Body

- When harmonized standards don’t exist, a Notified Body prescribes a test suite.
- When a radio doesn’t meet harmonized standards, a Notified Body gives an “Opinion” based upon a review of the technical file.
- Manufacturers may voluntarily seek the “Opinion” of a Notified Body on any aspect of their technical file.

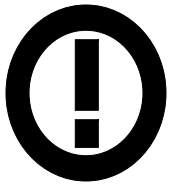
Notified Bodies and CABs

- Notified Bodies do not “certify” radios to the R&TTE Directive. Hence, not involved in the mainstream of standard products
- Conformity Assessment Bodies (CABs) are equivalent to Notified Bodies. Both are published in the “Official Journal” with their IDs

CABs are Equivalent to NBs

		e-mail: mer@metlabs.com **Web address:** www.metlabs.com **Tel:** +1-410-354-3300 **Fax:** +1-410-365-3313	
USA	0981	Northwest EMC 22975 Evergreen Pkwy, Suite 400 97124 Hillsboro, OR **e-mail:** dtolman@nwemc.com **Web address:** www.nwemc.com **Tel:** +1-503-844-4066 **Fax:** +1-503-844-3826	Annexes III, IV
USA	0982	PC TEST Engineering Lab, Inc. 6660 Dobbin Rd 21045 Columbia, MD **e-mail:** randy@pctestlab.com **Web address:** www.pctestlab.com **Tel:** +1-410-290-6652	Annexes III, IV

Product Marking

- Class 1 equipment: Unlicensed xmitters used in harmonized spectrum, or receive only.
  - CE mark + NB Number(s)
- Class 2 equipment: Licensed xmitters, or non-harmonized spectrum. Most radio products are class 2
  - CE mark +  + NB Number(s)

Source: Mark Bogers, US CAB Workshop, April 10, 2002, Arlington, VA

User Information

- Product marking on both packaging and in the user manual.
- Copy of Declaration of Conformity can be on the web or otherwise available with just a generic statement of compliance in the user manual
- On both the packaging and in the manual, the manufacturer must explicitly inform the user where the equipment is intended to be used
  - Actively marketing equipment where it cannot be used is a legal offence.

Source: Mark Bogers, US CAB Workshop, April 10, 2002, Arlington, VA

Technical Documentation

- To be kept at the disposal of surveillance authorities for 10 years after last product has been marketed.
  - Technical documentation described in Annex II, Point 4. Includes design drawings, schematics, theory of operation, design calculations, test reports

  Or,

  - Technical Construction File (TCF) described in Annex IV. Same as Annex II, Point 4 plus the DoC to specific radio test suites

European Perspective – Latest Status

European Commission reports a Positive Experience with the Directive

- Single Market for R&TTE has improved due to better administrative procedures and reliance on harmonized standards
- Simplified Procedures = reduced administrative tasks for manufacturers
- No visible increase in radio interference
- Efforts to harmonize standards have had positive results – however, the amount of standards could possibly be reduced.

Source: Mary Jo DiBernardo, NIST, “MRA Update”, USCEL Meeting, Aug 19, 2002, Minneapolis, MN

EU Rules for Wireless Devices

Text of R&TTE Directive:
http://europa.eu.int/comm/enterprise/rtte/dir99-5.htm

Frequently Asked Questions (General Info):
http://europa.eu.int/comm/enterprise/rtte/faq.htm

Interpretations of the R&TTE Directive:
http://europa.eu.int/comm/enterprise/rtte/interp.htm

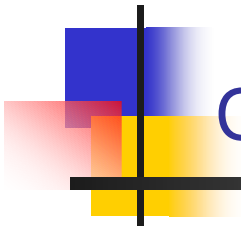
Harmonised Standards:
http://europa.eu.int/comm/enterprise/rtte/harstand.htm

ETSI Standards:
http://www.etsi.org/

European Radio Communication Office (Frequency Plans):
http://www.ero.dk/

How to Determine Spectrum Allocation in Each Member State

- See latest version of ERC / REC 70-03. Note that portions were updated Feb. 2004 (http://www.ero.dk/doc98/official/pdf/rec7003e.pdf)
- Use EFIS database (http://www.efis.dk/search/general)
- Contact spectrum authorities (http://europa.eu.int/comm/enterprise/rtte/spectr.htm)

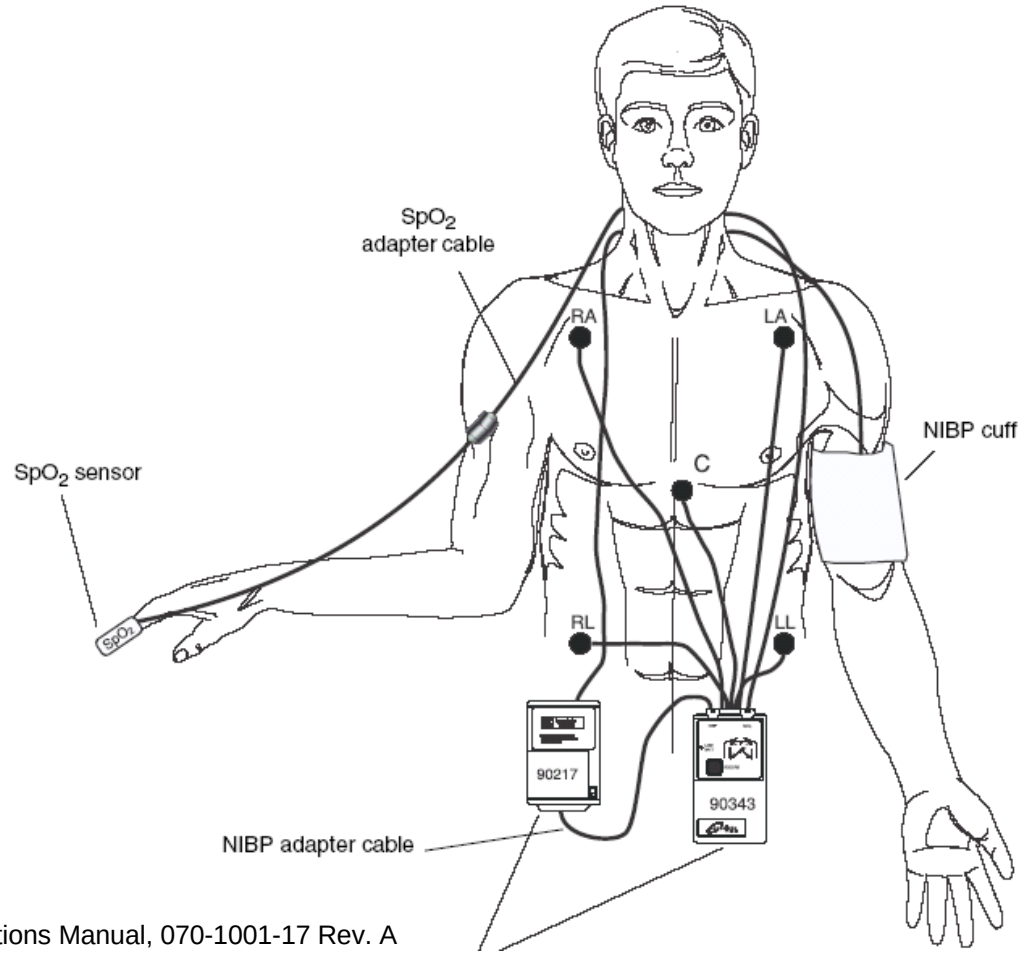


Overview of Wireless Medical Telemetry in the EU

Definition of Wireless Medical Telemetry

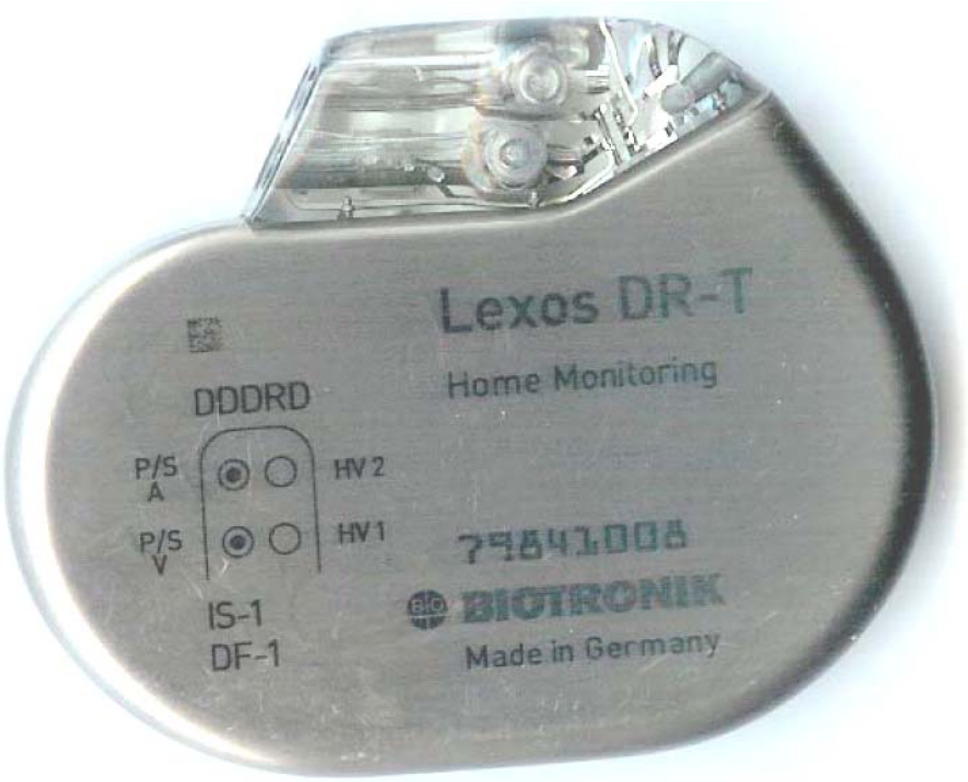
- Wireless medical telemetry is “The measurement and recording of physiological parameters and other patient-related information via radiated bi-or-unidirectional electromagnetic signals.” (**47 CFR 95.1103(c)**)
- Key advantages include greater patient mobility and improved comfort. In many cases, this speeds patient recovery times and shortens lengths of stay.
- One health care worker can monitor several patients remotely, thus decreasing health care costs.
- All types of communications are generally permitted; except for voice and video.

Wireless Medical Telemetry Device

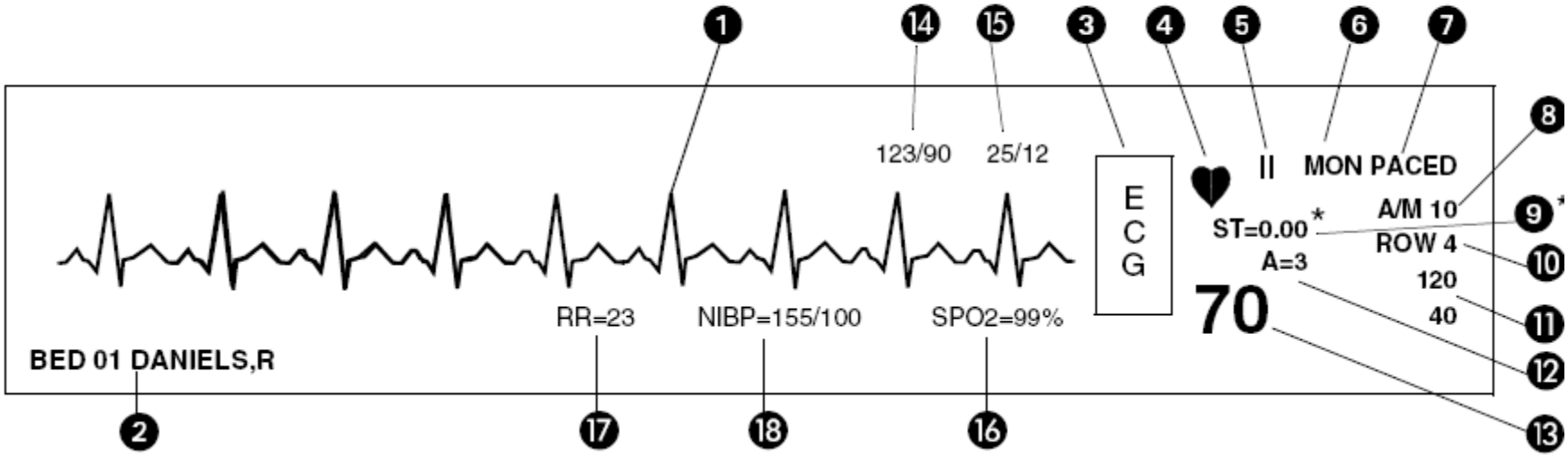


Spacelabs Medical, Operations Manual, 070-1001-17 Rev. A

Medical Implant Communication Device

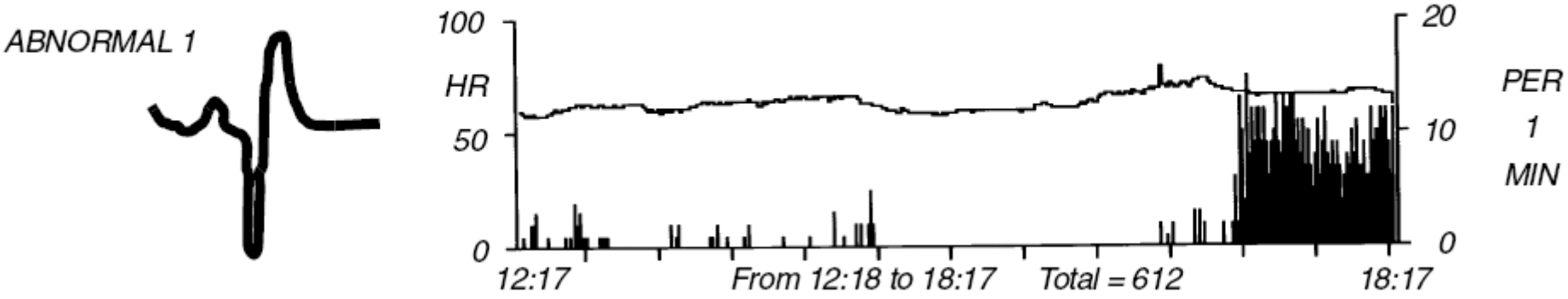


Patient Telemetry



Spacelabs Medical, Operations Manual, 070-1001-17 Rev. A

Analysis of Patient Telemetry



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Relation between R&TTE and Medical Devices Directive (MDD)

- Equipment coved by the MDD is specifically included in the scope of the R&TTE Directive (see Article 1.2).
- Several Directives cover Wireless Medical Telemetry devices: MDD, EMC, R&TTE, LVD
- MDD has more stringent EMC and safety requirements, than the R&TTE, EMC, and LVD directives. Therefore compliance with the MDD automatically yields compliance with most aspects of the R&TTE.
  - Even so, compliance with Article 3.2 of the R&TTE is still required.
    - ETSI Radio Tests

ETSI Radio Tests for Short Range Devices (SRD)

- Emissions
  - 9 kHz – 25 MHz: EN 300 330–2, EN 300 330-1
  - 25 – 1000 MHz: EN 300 220-3, EN 300 220-1
  - 1 – 40 GHz: EN 300 440-2, EN 300 440-1
- Immunity
  - 9 kHz – 40 GHz: EN 301 489-3, EN 301 489-1

ETSI Radio Tests for 2.4 GHz Spread Spectrum Radios

- Emissions
  - EN 300 328-2, EN 300 328-1
- Immunity
  - EN 301 489-17, EN 301 489-1

ETSI Radio Tests for Ultra Low Power Active Medical Implants (a.k.a. MICS)

- Emissions
  - EN 301 839-2, EN 301 839-1
- Immunity
  - EN 301 489-3, EN 301 489-1

Other considerations

- EMC requirements under Medical Device Directive
  - EN 60601-1-2
    - Immunity more stringent than EN 301 489-1, and sometimes tests are run with different modulations (types & frequency)
    - Additional requirements for EUT operating modes and configurations.
    - Exclusion Bands for RF tranceivers or receivers
- Highly advisable to co-ordinate a test plan with a Notified Body under the MDD to avoid unnecessary duplication of testing.

Sources for Presentation

- “New FCC Rules to Privatize Equipment Authorization and Implement MRAs”, presented by Art Wall of the FCC on Feb 10, 1999 at the EMC Globalization Workshop, Washington D.C.
- “MRA Update”, presented by Mary Jo DiBernardo of NIST on August 19, 2002 at the USCEL Meeting, Minneapolis, MN
- “FCC Recent Activity Report”, presented by William Hurst of the FCC on August 19, 2002 at the USCEL Meeting, Minneapolis, MN
- Title 47, Code of Federal Regulations
- “EU/US MRA CAB Training”, presented by Mark Bogers of the European Commission DG Enterprise on April 10, 2002 at the US CAB Workshop, Arlington, VA.
- Directive 1999/5/EC (R&TTE)

Excerpts from R&TTE Directive

R&TTE Directive – Article 1 Scope and Aim

Article 1.1 This Directive establishes a regulatory framework for the placing on the market, free movement and putting into service in the Community of radio equipment and telecommunications terminal equipment.

R&TTE Directive – Article 1 Scope and Aim

Article 1.2 Where apparatus as defined in Article 2(a) incorporates, as an integral part, or as an accessory:

a) a medical device within the meaning of Article 1 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices(1), or

b) an active implantable medical device within the meaning of Article 1 of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices(2),

the apparatus shall be governed by this Directive, without prejudice to the application of Directives 93/42/EEC and 90/385/EEC to medical devices and active implantable medical devices, respectively. ⇒

(Note there is very similar wording in Article 1.3 for Automotive Directives 72/245/EEC and 92/61/EEC)

R&TTE Directive – Article 2 Definitions

'apparatus' means any equipment that is either radio equipment or telecommunications terminal equipment or both; ⇒

R&TTE Directive – Article 3 Essential Requirements

Article 3.2 In addition, radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference. ⇒

Excerpts from EN 60601-1-2

EN 60601-1-2, subclause 36.202.3 a) 2)

Radiated RF electromagnetic fields

LIFE-SUPPORTING EQUIPMENT and SYSTEMS except as specified in 3) below or within the EXCLUSION BAND as specified in 4) below shall comply with the requirements of 36.202.1 j) at an IMMUNITY TEST LEVEL of 10 V/m over the frequency range 80 MHz to 2,5 GHz.

⇒

EN 60601-1-2, subclause 36.202.3 a) 4)

EQUIPMENT and SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation are exempt from the ESSENTIAL PERFORMANCE requirements of 36.202.1 j) in the EXCLUSION BAND; however, in the EXCLUSION BAND, the EQUIPMENT or SYSTEM shall remain safe and the other FUNCTIONS of the EQUIPMENT or SYSTEM shall comply with the requirements specified in 1) or 2) above, as applicable. EQUIPMENT and SYSTEMS shall comply with the requirements specified in 1) or 2) above, as applicable, outside of the EXCLUSION BAND.

EN 60601-1-2, Subclause 36.202.1 k)

If, for example, national radio regulations specify IMMUNITY requirements only for radiated RF electromagnetic fields, then the other IMMUNITY tests of this standard shall apply to the radio equipment. Note that according to 36.202.3 a), receivers of RF electromagnetic energy are exempt from radiated RF electromagnetic field IMMUNITY requirements in the EXCLUSION BAND of the receiver.

See Annex AAA, Subclause 6.8.3.201 a) 5) regarding the meaning of lower IMMUNITY TEST LEVELS for the IEC 61000-4-11 IMMUNITY test. In addition, if for example the national radio regulations specify radiated RF electromagnetic field IMMUNITY over a more narrow frequency range than does this standard, those requirements are not considered to be greater or equal to those determined in accordance with 36.202.1 a) of this standard. For EQUIPMENT and SYSTEMS that include radio equipment, this standard is not intended to substitute for the IMMUNITY requirements of national radio regulations. ⇒