Compliance with the R&TTE Directive
Presented by Alan Binks
Technical Director, BABT
The purpose of this webinar is to introduce:

- An overview of the Radio and Telecommunications Equipment Directive
- The roles and responsibilities of various parties under the RTTED
- The Compliance options available under the RTTE Directive
- The issues that can arise when trying to compile a compliance folder
European RTTE Directive

• Introduced from 8th April 2000 and all new equipment within its scope placed on the European Market must follow one of the RTTE Directive Conformity Assessment Procedures

• The RTTE Directive European Market is all EU members and all EFTA members

• There is also an agreement with Switzerland which gives access to the European Community
EU and EFTA Member Countries

- Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom plus, since 1st May 2004, Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia plus, since January 2007, Romania and Bulgaria.

- So the RTTED now gives a one step access to 30 European Countries
Definitions and Key concepts

- **Placing on the Market:**
  - The initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community. This applies for each individual item of the product and not just the first item of the product type. Placing on the market includes free issue.

- **Putting into Service:**
  - Takes place at the moment of first use within the European Community. This applies for each individual item of the product and not just the first item of the product type, e.g., mobile phones roaming from outside Europe.

- **Notified Body**
  - A body identified to the EU commission by their member government as competent within a defined scope to assess for compliance with a particular directive.

- **Essential Requirements**
  - Lay down the necessary elements for protecting the public interest.
  - Are mandatory and must be applied.

- **Blue Book:**
• **Intended Purpose**
  – Manufacturers are required to state the intended purpose of the equipment in their user instructions.
  – Compliance with the R&TTE Directive is only required when the equipment is used within its Intended purpose.

• **Surveillance Authority**
  – Organisation within a member state appointed to check for the compliance of products supplied into and used within its jurisdiction.

• **Declaration of Conformity**
  – Mandatory formal statement of compliance with the Directive with respect to a product, required prior to affixing CE mark.
Roles and Responsibilities

- **EU Commission**
  - Issue the Directive
  - Establish legal Basis for the Directive and its ongoing effectiveness
  - Publish lists of Harmonised Standards in the Official Journal

- **TCAM (Telecommunications Conformity Assessment & Market Surveillance Committee)**
  - EU wide committee of Administrations, and other relevant parties advising the Commission on the Technical Effectiveness and interpretations of the R&TTE Directive

- **R&TTE CA (The Radio & Telecommunications Terminal Equipment Compliance Association)**
  - Association of Notified Bodies, Test Laboratories, Administrations and Manufacturers established to advise on the implementation of the Directive (Secretary attends TCAM)

- **ADCO (Administrative Co-operation Working Group)**
  - EU wide committee of Administrations, and other relevant parties providing administrative cooperation and consistent application of surveillance.
  - Joint market surveillance campaigns are carried out and information exchanged on irregularities found.

- **Administration**
  - Responsible Department of Government in the member state
Roles and Responsibilities

- **Manufacturer**
  - Design product to meet the Essential Requirements of R&TTE
  - Establish compliance through test (and justification) and compilation of compliance documentation
  - Define the manufacturing process to ensure all individual items of the product comply with the R&TTE Directive
  - Write Declaration of Conformity and apply CE mark

- **Importer to EU**
  - Inspect DoC
  - Hold TCF or have ready access to it [e.g. within 5 days]
  - Where No DoC may assemble TCF, establish compliance, and fix CE mark on their own responsibility
Before the introduction of the European Directives and Harmonised Standards, each Member State had its own rules for approval of Radio and Telecoms products prior to entry into their national Markets. Approvals were national. Separate approvals were required for each country.

The TTE (Telecommunications Terminal Equipment) and the SESE (Satellite Earth Station Equipment) Directive introduced European Approvals and reduced burden for those types of equipment.

These early directives were used for placing telecoms and satellite equipment onto the European Market. Each Directive required different conformity assessment procedures. These procedures were widely accepted as a route to market outside of Europe. Non-networked Radio equipment still required National Approval.
Regulatory Background

• The RTTE Directive (1999/5/EC)

  • replaced the above Directives
  • Included non-networked radio
  • and integrated the safety, EMC and radio requirements for both radio equipment and telecommunications terminal equipment in one Directive resulting in the ability to use one conformity assessment procedure.
BABT’s Role in the RTTE Directive

• BABT is appointed as a Notified Body for all equipment types within the scope of the Directive and for all conformity assessment procedures which involve a Notified Body.

• Part of TUV Product Service operates with independence accepting work from all valid sources, maintaining confidentiality.

• BABT has been an Independent Approval Body for over 25 Years.

• Appointed under RTTED, LVD and EMC.

• Appointed as a TCB under various European Mutual Recognition Agreements with United States, Canada, Japan and Australia and New Zealand.

• Full UKAS accreditation to EN45011 and ISO17021.
## Scope of a typical R&TTE NB Appointment

<table>
<thead>
<tr>
<th>Aeronautical equipment (not excluded by Annex I.5 of RTTE)</th>
<th>Base Station for Mobile Network</th>
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<tbody>
<tr>
<td>Broadcast</td>
<td>Citizens Band radio</td>
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<tr>
<td>Cordless Telephone</td>
<td>Distress/Position Indicating Beacon</td>
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<tr>
<td>Fixed Link</td>
<td>Fixed Wireless Access</td>
</tr>
<tr>
<td>Industrial, Scientific, and Medical within scope of directive</td>
<td>Maritime (for Non-SOLAS vessels)</td>
</tr>
<tr>
<td>Mobile (Cellular) Telephone Handset</td>
<td>Paging (Radio Messaging)</td>
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<tr>
<td>Private/Professional Mobile Radio</td>
<td>Radar</td>
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<td>Radio Frequency Identification (RFID)</td>
<td>Radio Local Area Network</td>
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<tr>
<td>Satellite Earth station (Fixed / Mobile)</td>
<td>Short Range Device (SRD)</td>
</tr>
<tr>
<td>Telemetry / Telecommand</td>
<td>TTE for fixed (wired) network</td>
</tr>
<tr>
<td>Ultra Wideband</td>
<td>Wireless Microphone</td>
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Scope of R&TTE

- If an NB has a “Full Scope”; see previous slide
- Equipment not covered by the R&TTE Directive:
  - Radios used exclusively by the defence, public security and emergency services. Note: other equipment which is also commercially available to other services does fall under the RTTE Directive
  - Amateur radio equipment if not commercially available
  - Equipment falling within the scope of the Marine Equipment Directive
  - Cable and wiring
  - Radio receivers intended solely for the reception of sound and TV broadcasting services (excludes telecoms equipment such as set-top boxes)
- Please note that certain Air Traffic Management systems are now within the scope of the R&TTE Directive provided they do not affect the safe operation or navigation of an airplane

See Article 1 (5) and Annex I for more details
Features of R&TTE Directive

• Compliant equipment can be sold anywhere in European Union

• Radio equipment (as specified in R&TTE Directive as “Class 2”) - national authorities must be informed four weeks before it is placed on their market. There is a One-Stop Notification service for this purpose at:

   https://webgate.ec.europa.eu/enterprise-portal/

• “Class 2 Equipment” is radio equipment for which the frequencies and permitted usage is not harmonized across Europe

• Some equipment requires National Licensing prior to being brought into use [Products requiring Licensing not same as Class 2 List ]

• Network interface specifications must be made public

• Network operators cannot refuse to connect on technical grounds
Definition of “essential requirements” in Article 3 of the Directive:

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<td><strong>3.1(a)</strong> Health &amp; safety of the user, but no voltage limit applying</td>
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<td><strong>3.1(b)</strong> EMC</td>
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<tr>
<td><strong>3.2</strong> Effective use of spectrum and orbital resources</td>
</tr>
<tr>
<td><strong>3.3</strong> Additional requirements where decided by European Commission: (Rarely used)</td>
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Essential Requirements: Article 3.1a (Safety)

- 3.1(a) - the protection of the health and the safety of the user and any other persons, including the objectives with respect to safety requirements contained in Directive 2006/95/EC but with no voltage limit

- Article 2 of the “new” LVD states “Electrical equipment placed on the market must be constructed using good practice in safety matters such that it does not endanger the safety of persons, domestic animals, or property when correctly installed”
Differences between LVD and R&TTE Directive:

- LVD specifies dangers to Domestic Animals and Property; RTTE does not
- R&TTE Directive specifies “Health and Safety” which currently includes:
  - SAR and RF exposure
  - Acoustic Shock
- R&TTE Directive has no lower or upper voltage limits

- The equipment shall be so designed and manufactured having regard to the state of the art, as to ensure that
  - (a) the electromagnetic disturbance generated does not exceed a level above which radio and Telecommunications equipment and other apparatus cannot operate as intended
  - (b) it has a level of immunity to electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

- There are specific requirements for Fixed Installations
R&TTE Directive Article 3.2 states

- 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
R&TTE Directive Article 3.3 states

- The Commission may decide that certain apparatus shall be constructed such that
  - (a) It interworks via networks
  - (b) It does not harm or misuse network resources
  - (c) It includes safeguards for privacy of data
  - (d) It has features to avoid fraud
  - (e) It supports access to Emergency Services
  - (f) It supports features to help disabled persons

Very Rare: Only about 5 particular decisions:
  - Cospas-Sarsat locator beacons
  - Radio equipment intended to participate in the Automatic Identification System (AIS).
  - Marine radio communication equipment intended to be used on non-SOLAS vessel and to participate in the Global Maritime Distress and Safety System (GMDSS).
  - Avalanche beacons
  - Regional arrangements for radiotelephone service on inland waterways.
“Harmonised Standard”

- Defined in Article 5 of the RTTE Directive
- A standard which has been referenced in the Official Journal of the European Communities:
  - “Where apparatus meets the relevant harmonized standards or parts thereof whose reference numbers have been published in the Official Journal of the European Communities, Member States shall presume compliance with those of the essential requirements referred to in Article 3 as are covered by the said harmonized standards or parts thereof”
- This means that full compliance with appropriate harmonized standard(s) gives an automatic presumption of conformity with the particular essential requirements of the Directive for which it has been listed, providing legal protection for the manufacturer
Harmonised Standards (HS)

- HS contain minimum to address only particular essential requirement
- Sponsored by EU Commission but produced by consensus by European Standards bodies (ETSI, CEN-CENELEC)
- HS are listed in European Official Journal and have effectivity and withdrawal dates
  - Up-issues of HS by ETSI are not harmonised until listed
  - HS cease validity as HS after their Date of Withdrawal
- Conformity to harmonised standards does not guarantee product will work
- Little defence in law if harmonised standards are available and they ignored (i.e. HS are viewed as “State of the Art” Where HS not used entirely Characteristics and limits from appropriate HS must be considered and any deviations from them justified)
Compliance is against Essential Requirements, not standards. However, compliance with appropriate “Harmonised Standards” gives an automatic presumption of conformity with the appropriate Essential Requirements. There does not need to be a “Harmonised Standard” to apply one of the Conformity Assessment Procedures. The Essential Requirements apply even in the absence of harmonised standards.
Access to the R&TTE Directive conformity assessment procedures is via Article 10:

- Telecommunications Terminal equipment, eg wire line modems, and radio receivers can use Annexes II, IV or V
- Where the manufacturer has fully applied Harmonised Standards, Radio Equipment can use Annexes III, IV or V
- Where a manufacturer has not applied, or only applied in part, Harmonised Standards, Radio Equipment can use Annexes IV or V
R&TTE Directive Conformity Assessment Procedures

Non radio Terminal Equipment and receive only radio equipment

Radio transmitting equipment (using harmonised standards)

Radio transmitting equipment (not using or partial use of harmonised standards)

Annex II Internal Production Control

Annex III Internal Production Control plus specific tests

Annex IV Technical Construction File

Annex V Full Quality Assurance
• Member states will notify commission of PTO network interfaces

• Member states shall ensure that PTOs publish technical specifications of network interfaces prior to their use

• Specifications shall be sufficient to enable manufacturers to design and test compatible equipment
• Article 7.1 Member states shall allow the putting into service of apparatus for its intended purpose

• Article 7.2 Member States may restrict the putting into service of radio equipment …)

• States use the following approaches:
  – Defining some equipment licence exempt
  – Issuing Class Licences for equipment meeting additional criteria (above R&TTE requirements)
  – Individual Licences for each Model Design

• Placing into the Market ≠ Bringing into Service
• Article 11.2 - Each Member State has its own Surveillance Authorities

• The surveillance methods may differ between countries

• Article 9 - Where non-conforming equipment is found Member State may order off its own market and advise other member states
• R&TTE Directive disapplies EMC and LVD Directives except for Wireline Equipment used by Network Operators, or Sub-equipped equipment without regulated interfaces [e.g. Printer Models with/without Bluetooth interface]

• Radio equipment on SOLAS vessels comes under MED and is outside R&TTE Directive (but same equipment in non-SOLAS vessels is under R&TTE Directive)

• Radio Equipment built into vehicles is also subject to Automotive Directive

• Medical Equipment using radio frequencies must meet both Medical and R&TTE Directives

• Radio for Use in hazardous environment must meet both R&TTE and ATEX directive
The European Commission reviews the R&TTE Directive every 3 years.

Commission Legal Services make interpretations.

TCAM make technical interpretations.

R&TTE Compliance Association make Technical Interpretations and provide Testing Advice.

ETSI or CEN/CENELEC revise harmonised standards and submit revisions to the European Commission.
R&TTE Directive
Conformity Assessment
Procedures
• The conformity assessment procedures contained in Annexes II, III, IV and V are invoked through Article 10 of the Directive.
• Access the R&TTE Directive conformity assessment procedures is via Article 10:

– Telecommunications Terminal equipment, eg wire line modems, and radio receivers can use Annexes II, IV or V

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RTTE Directive Conformity Assessment Procedures

- Non radio Terminal Equipment and receive only radio equipment
  - Annex II Internal Production Control

- Radio transmitting equipment (using harmonised standards)
  - Annex III Internal Production Control plus specific tests
  - Annex IV Technical Construction File

- Radio transmitting equipment (not using or partial use of harmonised standards)
  - Annex V Full Quality Assurance
Annex II

- Is used for telecoms terminal equipment and radio receivers

- Invoked by Annexes III and IV

- The manufacturer compiles the technical documentation:
  - description of product
  - conceptual design & manufacturing drawings, schematics, sub-assemblies, circuits, etc.
  - description and understanding of drawings
  - a list of standards, applied in full or part, and descriptions of the solutions adopted to meet essential requirements
  - results of design calculations made, examinations conducted
  - test reports
Annex II

- Manufacturer must
  - take all measures necessary so that the manufacturing process ensures compliance with the technical documentation and the requirements of the RTTE Directive, eg ISO9001
  - Apply the CE marking (provided ALL applicable directives met)

- Manufacturer or his authorised representative draws up a Declaration of Conformity
- **Compliance Risk** if no Notified Body involvement - This is the conformity assessment procedure with the highest compliance risk
Surveillance

• The technical documentation must be available for inspection by surveillance authorities for at least 10 years after the last product has been manufactured.

• Where neither the manufacturer nor his authorised representative is established within the community, the obligation to make the technical documentation available to surveillance authorities is the responsibility of the person who places the product on the community market, e.g. the importer.

• Caution: Periodically ensure the media that the above documentation is held in remains readable. (e.g. If media life = 4 years how do you ensure readability after 10? ) Early versions of Adobe pdfs are not readable by the new versions. Early Word Processing packages may not be readily available so recommendation is that copies of the supporting software packages are maintained as well as the Technical Documentation.
Annex III

- Used for radio transmitting equipment
- Invoked by Annex IV
- Notified Body Involvement
  - identifies the tests to be conducted if the essential radio test suites are not defined in the harmonized standards; or cannot be conducted as defined
- Manufacturer
  - requirements of Annex II apply

Compliance Risk – NB involvement is limited to specifying tests. Risk is similar to Annex II, i.e. compliance risk is high
• Used for all types of equipment within scope of the RTTE Directive

• Manufacturer
  - creates technical construction file, contents as Annex II
  - includes where applicable the Annex III test list
  - submits TCF to Notified Body
  - all other requirements of Annex II apply, eg continuing compliance in production
Annex IV

• Notified Body
  - assesses the TCF
  - give formal “Opinion” within 4 weeks
    - NB opinion usually issued in the form of a certificate confirming compliance with the essential requirements of the Directive – see sample certificate

Compliance Risk – Product compliance is assessed by NB. Therefore the compliance risk is less than Annex III or Annex II. However, there is no requirement for 3rd Party continuing compliance assessment. This is the manufacturers responsibility and usually involves an ISO9001

Note: most good NBs will request a copy of the manufacturer’s ISO9001 certificate or will make a check to see if one is in place (view the website) for due diligence but they cannot withhold an Opinion if there isn’t an ISO9001 in place. Some NBs will make a positive statement on their Opinion if there is a current ISO9001 in place
Annex V - Full Quality Assurance (FQA) Approval

- Used for all types of equipment within scope of the Directive

- FQA Approval is a quality management system approval which permits the application of the CE mark of the RTTE Directive

- Quality systems based upon ISO9000 and test facilities operating to ISO17025 inherently meet many but not necessarily all of the requirements for FQA Approval under the Directive

- Uniquely useful for manufacturers making a wide range of products within one product type such as mobile phones or netbooks
Annex V - Full Quality Assurance (FQA) Approval

• Manufacturer

- must operate an approved quality system for design, manufacture and final testing
- lodge an application for the assessment of his quality system with a Notified Body, the application must include
  - all relevant information for products envisaged
  - the quality system documentation
- the quality system must ensure compliance of the products
Manufacturer

- Where the manufacturer sub-contracts activities, eg design, testing, manufacture, it must be demonstrated that he retains control of the sub-contracted processes. Note: It is not permitted to delegate decision-making processes, eg the compliance decision.

- must allow the Notified Body access to audit design, manufacture, inspection, test and storage areas and provide it with necessary information
  - quality system documentation
  - quality records related to design
  - manufacturing quality records

- retain records for 10 years after the last product is manufactured
Notified Body

- Carries out audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and provide a report to the manufacturer
- Maintain a register of equipment placed on the European Market under the FQA Approval
- Does not carry out product compliance assessments, only quality system assessments

Compliance Risk – all quality procedures are regularly assessed by the NB, hence this is the route which minimizes the compliance risk
Conformity Assessment Procedures

Annex II: Internal Production Control

Annex III: Annex II + Specific tests

Annex IV: Annex III + TCF Assessment

Annex V: Full Quality Assurance Approval
CE Marking

Where there is no Notified Body involvement, the CE marking only is required

- This applies for Annex II (and Annex III where the harmonized standards include a full test suite and a Notified Body has not been formally involved in identification of the tests)
- Product shall be identified by type, batch, and/or serial number and by the name of the manufacturer or person responsible for placing the product on the market
This applies for Annex III, IV and V where a Notified Body has been involved in the conformity assessment procedure

- Where one or more Notified Bodies have been involved, the CE marking and the identification number of each of the notified bodies is required
- The CE mark indicates compliance with all relevant European CE Marking Directives (not just the RTTE Directive)
Class 2 radio equipment must carry the equipment class identifier mark

- Class 2 equipment is classified as such because:
  - the frequency used is restricted within certain national boundaries
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<tr>
<td>• self declaration</td>
<td>• includes requirements of Annex II</td>
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<td>• save time and cost over Annex IV</td>
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<tr>
<td>• compilation of technical</td>
<td>• can mean BABT involvement – specifies test suites</td>
<td>• submission of your Technical Construction File (TCF) to BABT</td>
<td>• fast market entry</td>
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<td>documentation required</td>
<td>• IF BABT used, BABT’s NB marking on product</td>
<td>• benefit from BABT opinion</td>
<td>• your compliance endorsed by BABT</td>
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<td>• full liability, including liability for continuing compliance for manufacturing process</td>
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<td>• flexible, allows for sub-contracted design and manufacturing to match your company’s needs</td>
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Summary

- Introduction and overview of the RTTE Directive and the way it interacts with other directives especially the LVD and EMC directives

- Detailed the compliance options available to the manufacturer under the various Annexes of the Directive

- The risks associated with each compliance option

- Ways in which you can minimize your compliance risk

- The ways in which a good Notified Body can help a manufacturer limit their risks
Understanding the pitfalls of the R&TTE Directive 1999/05/EC

An overview of the Directive including Safety, EMC and EuP considerations

25th March 2010
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