

## **Guidance on Technical Documentation**

### **1. Introduction & Legal Basis**

Annex II of the R&TTE Directive requires a manufacturer to establish technical documentation. It must be kept by the manufacturer or his authorised representative in the EU for at least 10 years after the last product has been manufactured and shown on request to the national surveillance authorities in the member states. In the words of the directive, the documentation must cover:

- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where such standards referred to in Article 5 have not been applied or do not exist,
- results of design calculations made, examinations carried out, etc.,
- test reports.

The manufacturer or his authorised representative must also keep a copy of the relevant Declaration of Conformity with the technical documentation. Together, these documents make up a Technical Construction File (TCF) which forms the basis of a notified body opinion under Annex IV of the Directive. This guidance describes the content of a TCF expected by a notified body when an opinion is requested.

### **2 Purpose of Technical Documentation**

The purpose of the technical documentation referenced in Annex II of the directive is to verify the conformity of the product with the essential requirements of the directive. It is not intended to be a comprehensive dossier of design and manufacturing information complete in every detail.

The nature and detail of the documents included will vary from case-to-case. The specific product(s) concerned must always be clearly identified. However, information about design, manufacture and operation is relevant only to the extent that it concerns compliance with the essential requirements: complete documentation concerning conceptual design, manufacturing drawings, subassemblies, and electronic circuits is not expected. This is an overriding consideration in all that follows. For example, where harmonised standards have been applied in full, a detailed product description, user information and test reports clearly referencing the product as described will suffice. Where other solutions are adopted or a range of products is covered by a single set of documentation, more design details and technical explanation will be required.

Although it is not a requirement of the directive, it is recommended that the documentation is organized in a file with sections corresponding to the elements identified in Annex II Item 4 of the directive. This is the basis of the advice which follows. The file should carry a unique reference which can be readily associated with the relevant Declaration of Conformity if the declaration does not itself form part of the file.

International standard EN ISO/IEC 17050—2:2004 “Conformity assessment — Supplier’s declaration of conformity — Part 2: Supporting documentation”, with the exception of clause 5.2a), is generally applicable to establishing and maintaining technical documentation for the purposes of the directive.

### **3. general description of the product [EN ISO/IEC 17050-2 Clause 5.1a)]**

All products covered by the technical documentation must be identified by model / type /brand etc. If more than one model etc is covered, the relationship between them should be explained.

Full user information should be provided describing how the product is intended to be used and any precautions to be observed in installing, using and maintaining it. For complex equipment, only those sections of the user information relevant to compliance are required.

Where software or firmware affects compliance, it should be explicitly referenced and any user configurable options explained.

If not included in the user information, photographs or illustrations showing external features and internal layout should be provided. These should be in sufficient detail to permit reliable visual identification of the equipment concerned.

### **4. conceptual design & manufacturing drawings & schemes of components, sub-assemblies, circuits, etc., [EN ISO/IEC 17050-2 Clause 5.1b)]**

Information is required only for those aspects which directly affect compliance. Typically, this will include circuit diagrams, PCB layouts and parts lists for all network or radio interface circuits, power supplies and ports for connecting other apparatus which communicates via or interacts with those interfaces. Circuit elements need only be shown in sufficient detail for an understanding of compliance issues.

Components that are critical for compliance purposes (eg safety isolation or RF sources) should be specifically identified with alternatives (if any). Similar considerations apply to software and firmware as well as hardware.

Note, this information may also be used to assist in identifying the apparatus covered by the technical documentation particularly in cases where there is doubt arising from post-market surveillance.

### **5. descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product [EN ISO/IEC 17050-2 Clause 5.1b)]**

For simple equipment, a circuit diagram and the user information provided in response to previous sections may be sufficient. For more complex equipment, a block diagram with an outline technical description would be appropriate.

In all cases, the points of connection to communications networks and to antennas (integral or external) must be clear. The network interface(s) and/or radio spectrum usage should be identified.

Ports for connection of other apparatus should also be identified together with any specifications for such other apparatus required to ensure overall compliance with essential requirements.

**6. a list of the standards referred to in Article 5, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where such standards referred to in Article 5 have not been applied or do not exist [EN ISO/IEC 17050-2 Clause 5.2b)]**

The list of standards is specifically those standards harmonised for the purposes of the R&TTE Directive. The particular version of each standard should be identified together with the relevant clauses or parts if it has not been applied in full.

Where harmonised standards are not applied (e.g. because they are not available), other standards may be used provided some explanation of their relevance to essential requirements is given [see also R&TTE CA TGN 11]. “Standards” should be interpreted broadly in this context to include requirements and recommendations issued by any recognised body competent in the field concerned. For example, decisions and recommendations by ECC and ITU-R typically include relevant requirements for spectrum use. A notified body opinion will be required in all such cases but it is the manufacturer’s responsibility, not the notified body’s, for putting together the rationale for compliance.

If no relevant standards exist to address a particular aspect of compliance with essential requirements then an assessment from first principles must be made based on good engineering practice and documented accordingly. Again, this is the manufacturer’s responsibility, not the notified bodies.

This section should deal with strategy only. Results of evaluation in accordance with the strategy identified are covered in subsequent sections.

**7. results of design calculations made, examinations carried out, etc [EN ISO/IEC 17050-2 Clause 5.1c)]**

Where harmonised standards addressing all essential requirements have been applied in full and corresponding test reports are available, no further information is required here.

In all other cases, an explanation of what tests and assessments have been made and how the available technical data and test results have been interpreted in order to determine compliance with the essential requirements should be provided. Typically, this might be the case where formal standards are not available, where

only one model in a range of products has been tested, where reliance is placed on compliance of a sub-assembly for which a third-party holds the detailed compliance documentation, where reliance is placed on calculation rather than testing (for example, certain cases of RF exposure) or where the version manufactured differs in some way from the version to which the test results relate.

It may be helpful to consider this as an exercise in risk analysis seeking to identify potential causes of non-compliance with the essential requirements and the means by which assurance has been gained that such non-compliance does not exist. This might include, for example, documenting how the installation instructions of a sub-assembly supplier have been respected, how “worst case” scenarios for selective tests on a range of models have been determined or why results on a similar but differently named/branded product can be applied.

#### **8. test reports [EN ISO/IEC 17050-2 Clause 5.1c)]**

It is recommended that testing is conducted by laboratories operating in accordance with EN ISO/IEC 17025:2005 “General requirements for the competence of testing and calibration laboratories” and that test reports are drawn up in accordance with clause 5.10 of that standard. However, compliance with this standard is not mandatory and it remains the manufacturer’s responsibility to choose a technically competent laboratory. “In-house” testing is acceptable provided it satisfies these or equivalent criteria.

Test reports must unambiguously identify the apparatus to which they relate so that they can be correctly associated with the corresponding Declaration of Conformity. Where special software or configuration is required for testing this must be clearly stated and the relationship with software for normal use explained.

One test report may cover the whole or part of one or more essential requirements. However, it should be clear whether the report addresses the whole or only part of the essential requirements and, in the latter case, precisely which part(s).

Where harmonised standards do not specify particular test suites or have not been applied in full or other standards or alternative test methods have been used, the test methods should be detailed with justifications for their relevance to the essential requirements.

Opinions and interpretations given in accordance with Clause 5.10.5 of EN ISO/IEC 17025:2000 have no particular status in respect of the R&TTE Directive and must not be confused with a notified body opinion even in cases where a test laboratory and notified body do business with the same trade name.

#### **9. Other items [EN ISO/IEC 17050-2 Clause 5.2b)]**

It is a requirement of the directive that a copy of the Declaration of Conformity must accompany the technical documentation to make up a Technical Construction File when the opinion of a notified body is sought. It is therefore recommended that a copy of the Declaration of Conformity comprises part of the technical documentation in all cases.

International standard EN ISO/IEC 17050-1:2004 Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements provides a suitable model for the Declaration of Conformity.

Where an opinion is obtained from a notified body in accordance with Annex IV of the directive, it is further recommended that a copy of that opinion is added to the technical documentation.

The R&TTE Directive requires records and correspondence relating to the conformity assessment procedures (e.g. technical documentation) to be in an official language of the Member State where the procedure is carried out, or in a language accepted by the notified body involved.

### **Disclaimer**

This guidance document does not replace the text of the R&TTE Directive and is for guidance only. In legal disputes the text of the Directive, or its implementation in National legislation, takes precedence.

30.06.2010 Rev 1: Statement on ADCO / R&TTE CA positions added to Footnote.

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Footnote: An abbreviated version of this guidance is included in the European Commission "Guide to the R&TTE Directive 1999/5/EC" together with other useful information for all parties directly or indirectly affected by the R&TTE Directive and is available for download from the R&TTE CA website:

[http://www.rtteca.com/Guide\\_R\\_TTE\\_DIR\\_1999-5-EC\\_2009-04-20.pdf](http://www.rtteca.com/Guide_R_TTE_DIR_1999-5-EC_2009-04-20.pdf)

**NOTE:** The chairmen of ADCO/R&TTE & R&TTE CA have analysed the differences between the advice in the Commission's RTTE Guide and R&TTE CA TGN15 concerning Technical Documentation and agree that there is no conflict between them. However, in view of the ongoing review of the Directive and the prospect of significant change, it is further agreed that it would not be appropriate to amend the RTTE Guide before there is greater clarity on the way forward. Accordingly, it is agreed by ADCO/R&TTE and R&TTE CA that both guidance documents will continue in parallel in their current form.