

Technical Guidance Note on Requirements for a Final Product that Integrates an R&TTE Directive Assessed Module

1. Introduction

Under the R&TTE Directive, the definitions of “telecommunications terminal equipment” and “radio equipment” include the notion of a “relevant component” (Articles 2 (b) & (c)), which must be assessed against the essential requirements of the R&TTE Directive (and other relevant Directives where applicable). Therefore, any terminal equipment¹ module or radio² module³ when placed on the Community market must comply with the essential requirements of the R&TTE Directive 1999/5/EC.

There is an issue under the R&TTE Directive regarding the compliance, documentation and labelling requirements of a product that integrates a R&TTE-D assessed module (hereafter *final product*). In this context, an “assessed” module is one that is CE marked and accompanied by all the information required by Article 6 of the Directive including the Declaration of Conformity and information about its proper installation and intended purpose. Such module is manufactured with the intention of being integrated in a designated type of product(s).

In these cases, there are basically three possible scenarios:

- a. Module not placed in the market but integrated in a product by a different manufacturer who places the final product in the market.
- b. Assessed module placed in the market and installed in a product by the user.
- c. Assessed module placed in the market and integrated in a product by a different manufacturer who places the final product in the market.

This Guidance Note has been constructed to allow a harmonised approach by Notified Bodies across Europe regarding the assessment, documentation and labelling of *scenario c* above. This Guidance Note does not apply to the rest of scenarios, since it is understood that responsible persons and applicable compliance requirements are clear in the R&TTE Directive.

The concerns related to the integration of modules assessed against the requirements of the R&TTE Directive into final products are given below:

2. Conformity Assessment to the Essential Requirements of the Directive

2.1. Issue:

Under the R&TTE directive Article 10, the conformity assessment procedure used is at the choice of the manufacturer.

¹ Note 1. An example of a terminal equipment module is a modem intended for integration by another manufacturer in a finished product.

² Note 2. Examples of radio modules are: Any component (IC, hybrid circuit, plug-in unit, etc), which together with an antenna, constitutes the transmitter RF circuit of a Radio communications device, which has well defined RF parameters and which can clearly be identified. A plug-in unit can be characterised as a radio equipment module intended to be used with or within a host, combined or multi-radio equipment, using their control function and power supply.

³ Note 3. It is the responsibility of the manufacturer to declare if a product is a module.

It is clearly the responsibility of the manufacturer to perform the conformity assessment procedures. In the case where a terminal equipment module or radio module is integrated (*scenario c* in section 1), the person integrating the module becomes the manufacturer of the final product and is therefore responsible for demonstrating compliance of the final product with the essential requirements of the R&TTE Directive.

This approach is logical because integrating modules into products can affect the compliance of the final product with the essential requirements.

2.2. Guidance:

1. In general, the aim should be to avoid repeat assessment of the module in the final product where this can be justified on the basis of technical analysis and information provided by the module manufacturer. However, in many cases, it will not have been practical to perform a meaningful assessment of the requirements on the module alone and so complete assessment is required after integration. This should be made clear in the information provided by the module manufacturer concerning the installation and intended purpose of the module in Accordance with Article 6 of 1999/5/EC.
2. In all cases assessment of the final product (which integrates the R&TTE-D assessed module) must be made against the Essential requirements of the R&TTE Directive Articles 3.1(a) and (b), safety and EMC respectively, and any relevant Article 3.3 requirements. Assessment may include technical analysis, design evaluation and testing.

ETSI Technical Report ETSI TR102 070-1, "Guide to the application of harmonised standards to multi-radio and combined radio and non-radio equipment; Part 1: Electromagnetic Compatibility" gives guidance about final products and modules which may have been separately assessed for EMC compliance before integration. It also gives advice about assessment where the harmonised standard applicable to the finished product is different from that relevant to the integrated module. Although the report is set in the context of harmonised standards the principles may be found of more general applicability in assessment of the final product.

The concept of "primary product" and "primary function" defined in the ETSI report may also be found helpful in assessment of safety. However, note the following extract from the "Guidelines on the application of Directive 2006/95/EC"⁴: "However, other electrical components which are intended to be incorporated into other electrical equipment and for which a risk assessment can be undertaken, such as transformers and electrical motors, are covered as such by the Directive and must be CE marked. ...A further assessment of the safety aspects related to the way in which such components are incorporated is in general also necessary."

3. In the case where the product is already radio equipment, even without the addition of a radio module, then assessment of the final product must also be done against Article 3.2.
4. Except as provided for in 3, a final product integrating an assessed radio module with an integral antenna or supplied with a specific antenna and installed ***in conformance with the radio module manufacturer's installation instructions*** requires no further evaluation under Article 3.2 of the R&TTE Directive and does not require further involvement of an R&TTE Directive Notified Body for the final product. In all other cases, or if the manufacturer of the final product is in doubt then the final product integrating the radio module must be assessed against Article 3.2 of the R&TTE Directive.

⁴ Note 4. Guidelines on the Application of Directive 2006/95/EC
http://ec.europa.eu/enterprise/sectors/electrical/files/lvdgen_en.pdf

ETSI Technical Report ETSI TR102 070-2, "Guide to the application of harmonised standards to multi-radio and combined radio and non-radio equipment; Part 2: Effective use of the radio frequency spectrum" illustrates the application of the above guidance in different scenarios for various product combinations. It also includes advice on other scenarios (eg where the modules have not been assessed), embedded radio equipment and multi-radio equipment where the above guidance will not normally apply. The report is drafted in the particular context of harmonised standards but the circumstances demanding (or not) further assessment apply equally in the case where harmonised standards do not exist or are not applied in full (ie notified body assessment as the basis of an opinion).

5. In the case where integration of a module requires assessment involving the submission of a TCF to a Notified Body and the module manufacturer has not made his technical documentation available to the final product manufacturer, the module manufacturer will be asked to make the module documentation available directly to the Notified Body. Not having the module documentation may prevent the Notified Body from delivering an opinion on the TCF to the final product manufacturer. Accordingly, the final product manufacturer must ensure that their module manufacturer is aware of this need and is willing to provide the relevant documentation direct to the Notified Body. It is not required that the final product manufacturer's TCF include the module manufacturer's proprietary documentation.

In any event the final product manufacturer should ensure that the build status of the module integrated is known. This could take the form of a model and issue number, or a list of drawing numbers with issue numbers and date.

Note: Assessment means following all the conformity assessment procedures of the R&TTE Directive but with a view to avoiding repetition of the assessment of the integrated module in so far as this can be justified on the basis of technical analysis.

3. Technical Documentation

3.1. *Issue:*

Under the R&TTE directive Annex II, 2 *"The manufacturer must establish the technical documentation described in point 4 and he or his authorised representative established within the Community must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities of any Member State for inspection purposes."*

In the case of a manufacturer integrating an assessed module into a product, they may not have all the information required to enable them to hold all the documentation on the module as required under Annex 2(4). All the technical documentation for the module would reside with the module manufacturer or his authorised representative.

However, it is the responsibility of the final equipment's manufacturer, his authorised representative or person first placing the product on the community market to declare that the final product meets with the essential requirements of the R&TTE Directive. It is also their responsibility to provide all relevant technical documentation to the relevant national authorities of any Member States for inspection purposes.

3.2. **Guidance:**

The final product manufacturer, his authorised representative or person first placing the final product on the community market, must ensure that the module manufacturer is aware that all documentation pertaining to the module must be supplied, on demand, either directly or via the final product manufacturer themselves, to the relevant national authority of any Member States as required by the R&TTE Directive.

4. Notification (Radio modules only)

4.1. **Issue:**

In the case of radio equipment, under the R&TTE directive Article 6 (4) "Notification shall be given no less than four weeks in advance of the start of placing on the market and shall provide information about the radio characteristics of the equipment (in particular frequency bands, channel spacing, type of modulation and RF-power) and the identification number of the notified body referred to in Annex IV or V."

Therefore the Notified Body/Bodies number must be included in a Notification if the Notified Body/Bodies has/have been involved in the assessment procedure of the final product.

"In the case of radio equipment using frequency bands whose use is not harmonised throughout the Community, the manufacturer or his authorised representative established within the Community or the person responsible for placing the equipment on the market shall notify the national authority responsible in the relevant Member State for spectrum management of the intention to place such equipment on its national market."

From the above statement, the manufacturer of the final product is the person responsible for making the notification.

4.2. **Guidance:**

1. In the case where a Notified Body/Bodies has/have assessed the final product this will be the Notified Body number(s) given on the notification to the Spectrum Management Agencies.
2. In the case where a Notified Body has not assessed the final product but just the radio module, the Notification can be made to Spectrum Management Agencies using the Notified Body number(s) on the radio module.

5. Marking

5.1. **Issue:**

Under the R&TTE directive Article 12 (1) "Apparatus complying with all relevant essential requirements shall bear the EC conformity marking referred to in Annex VII. It shall be affixed under the responsibility of the manufacturer, his authorized representative within the Community or the person responsible for placing the apparatus on the market."

Where the procedures identified in Annex III, IV or V are used, the marking shall be accompanied by the identification number of the notified body referred to in Article 11(1). Radio equipment shall in addition be accompanied by the equipment class identifier where such identifier has been assigned. Any other marking may be affixed to the equipment provided that the visibility and legibility of the EC marking is not thereby reduced."

Therefore the question arises as to which Notified Body/Bodies number(s) must be included in the CE marking of the final product.

5.2. Guidance:

The final product must carry CE marking to show compliance with all the directives that are applicable to it. The numbers of all the NBs involved in every aspect of the conformity assessment (including any involved in the assessment of the module) must be shown next to the CE Marking with any additional marking such as the Alert Symbol alongside. The technical documentation of the final product will show the role of each NB.

6. 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.

Rev 4: LVD references updated

Rev 5: Clarification that: assessment does not necessarily mean testing; aim to avoid repeat assessment of module; modules intended for end user installation excluded; consequential editorial amendments and clarifications.