

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

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 market⁴ 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 final product that integrates an assessed module.

Under the previous “type approval” regime National Administrations took different approaches, with some requiring only additional EMC testing if the module was installed as per the manufacturer's guidance, whilst others required full EMC and type approval testing on the final product.

This Guidance Note has been constructed to allow a harmonised approach by Notified Bodies across Europe regarding the assessment, documentation and labelling of final products that integrate an assessed module.

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

Conformity Assessment to the Essential Requirements of the Directive

Issue:

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

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 the, person integrating the module becomes the manufacturer of the final product and is therefore responsible for demonstrating compliance of the product with the essential requirements of the R&TTE Directive.

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

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 a 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.

⁴ Note 4 Modules that are not “placed on the market”, for example a custom design module passed directly from one manufacturer to another without being generally available in the market, are not covered by this guidance note. Such modules are not required to meet the requirements of the R&TTE Directive as “relevant components”. The finished product including the module must, of course, fully comply with the Directive.

Guidance:

1. In all cases assessment of the final product 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.

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 73/23/EEC⁵: "However, other electrical components which are intended for being incorporated into other electrical equipment, but for which a safety assessment is feasible, like - for example - some types of 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."

2. Assessed radio modules installed in equipment ***in conformance with the manufacturer's installation instructions*** require no further evaluation under Article 3.2 of the R&TTE Directive and do 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 equipment integrating the radio module must be assessed against Article 3.2 of the R&TTE Directive.

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).

3. 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 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 product manufacturer. Accordingly, the 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

⁵ http://www.europa.eu.int/comm/enterprise/electr_equipment/lv/guides/index.htm

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.

Technical Documentation

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 a compliant module into a final 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.

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.

Notification (Radio modules only)

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 a harmonised standard does not exist for the 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 final integrator is the person responsible for making the notification. If the radio module has already been assessed this implies that the overall product must be re-assessed to allow the notification process to be complete for any product where a harmonised standard does not exist - presently most products.

Guidance:

1. In the case where a Notified Body/Bodies has/have assessed the final equipment 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 equipment the Notification can be made to Spectrum Management Agencies using the Notified Body number(s) on the radio module.

Marking**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.

Guidance:

Where a module is placed on the market in its own right, it will carry the CE marking and, where appropriate, the number of any NB involved.

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 must be shown next to the CE Marking with any additional marking such as the Alert Symbol alongside. The technical documentation will show the role of each NB.

Repetition of the CE symbol itself should be avoided wherever this is practicable.

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.