

Guidance on NB opinion where harmonised standard not applied

Introduction

A key responsibility¹ of a NB is to give an opinion on the compliance of radio equipment with the requirements of the Directive "... where a manufacturer has not applied or has only applied in part the harmonised standards ...". There are, of course, two scenarios: either appropriate harmonised standards do not exist or an existing harmonised standard has not been applied by choice. In either case, the NB must determine whether the requirements of the Directive have been met by applying the notion of "essential requirements" directly.

Guidance to manufacturers

A manufacturer must never presume that the absence of a harmonised standard for a particular product or feature or function of a product is an indication that there are no requirements. The essential requirements apply to all products, all features and all functions within the scope of the Directive. Where no current harmonised standard is applicable, for whatever reason, the manufacturer must seek a formal opinion from a notified body in order to comply with the conformity assessment procedures of the Directive.

Guidance to notified bodies

This guidance applies only to NB under Annex IV of the Directive. The NB should carry out a formal risk assessment taking account of the following points:

i) General

The Directive requires compliance² when equipment is "...properly installed and maintained and used for its intended purpose..." The NB should thoroughly familiarise itself with the equipment and relevant installation and maintenance documentation so that its opinion is formed in the proper context. In so doing, the NB should note any inconsistencies between obvious uses of the equipment and the stated intended purpose so that its opinion may be suitably qualified and not open to misinterpretation.

An aspect relevant to the intended purpose may be the number of items of equipment likely to be taken into use and their overall potential for harmful effects to networks or the radio spectrum.

ii) Harmonised standards & other standards or regulations

Although not mandatory, where a relevant harmonised standard exists, it should generally be applied to the fullest extent possible. Typically, deviations from strict application of the standard would be appropriate where a product design does not permit the application of a particular test in the manner specified but the intention should be to establish a similar level of overall technical compliance. Also, it is possible that there is an error in the published standard or that it unintentionally restricts technologies not commercialised at the time of its publication. However, it is not appropriate to deviate from a harmonised standard simply to secure commercial advantage by omitting product features or relaxing the specified limits.

Candidate harmonised standards published by CENELEC or ETSI and awaiting listing in the Official Journal should be treated as above. Harmonised standards in the course of preparation should be taken into account but wider discretion is possible in which case it would be appropriate to provide explanatory feedback to the responsible technical body.

¹ Annex IV & Article 10.5 of the Directive

² Article 6.1

In the absence of relevant harmonised standardisation, it may be appropriate to reference non-harmonised standards or standards from other regions, countries, professional bodies or organisations. In particular, utmost account should be taken of any relevant ECC Reports and Compatibility Studies. In all such cases, strict adherence to the standard is not appropriate without detailed consideration of the relevance of the standard to the EU in the context of the essential requirements of the Directive and the other points listed here. Similarly, it may be helpful to review equivalent regulatory requirements applied in other countries or regions.

iii) Geographic or other limitations on the location(s) of intended use

Control of spectrum remains essentially a national matter and so it is essential to consider the spectrum plan for the intended location(s) of use and any relevant interface regulations for the member state(s) concerned. In this context “location” implies not only the physical placement but also any relevant environmental factors. In extreme cases, it may be necessary to liaise directly with the spectrum authority for the relevant member state.

iv) Other sources of relevant information

The R&TTE CA liaison with TCAM is an important source of information about issues concerning application of the Directive. Key points are summarised for members after each TCAM meeting and are open for discussion in the R&TTE CA Steering Committee meetings. Individual Member States may also operate national procedures for disseminating relevant information from TCAM. Public TCAM documents are available at:
<http://forum.europa.eu.int/Public/irc/enterprise/tcam/library>.

R&TTE CA liaison with ADCO, ECC and ETSI may also highlight important factors for NB consideration. These are reported in R&TTE CA Steering Committee meetings and, where appropriate, published in R&TTECA Technical Guidance Notes.

v) Records & documentation

The notified body should maintain records which show the rationale, based on the above considerations, used to arrive at a particular opinion. The records should identify any documents referenced in the assessment and the particular limits applied to determine compliance with the essential requirements.

The opinion itself should be documented in accordance with R&TTE CA TGN10 “Guidance on the Minimum Content of a Notified Body Opinion Document”.

vi) Essential Radio Test Suites (ERTS)

The ERTS is produced under Annex III of the Directive which is invoked from Annex IV. It is possible that different NBs will be involved in preparing the ERTS and issuing the opinion. This guidance relates specifically to the opinion but may also be useful in preparing an ERTS where it is not defined in a harmonised standard

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.