



Guidance on risk assessment for radio equipment

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Reference

RTR/ERM-RM-639

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OJEU, radio, RED, risk, risk assessment

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Foreword

This Technical Report (TR) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

A technical Report (TR) is an ETSI deliverable, containing only informative elements, approved for publication by a Technical Body (TB), see ETSI Directives [i.18], clause A.3.

Modal verbs terminology

In the present document **"should"**, **"should not"**, **"may"**, **"need not"**, **"will"**, **"will not"**, **"can"** and **"cannot"** are to be interpreted as described in clause 3.2 of the [ETSI Drafting Rules](#) (Verbal forms for the expression of provisions).

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Introduction

The conformity assessment procedure for radio equipment requires manufacturers to adequately analyse and assess the risk(s) related to the essential requirements of the Radio Equipment Directive 2014/53/EU (RED) [i.1], as set out in its article 3, even if a harmonised standard is fully applied.

Several guidance documents related to the essential requirements in general and specifically of RED already exist:

- Both Blue Guide [i.2] and the RED Guide [i.3] provide brief guidance on risk assessment.

- CENELEC has already published the CENELEC Guide 32 on Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment which is applicable to the risk assessment and risk reduction related to article 3(1)a (electrical safety and health) of RED [i.7]. ISO/IEC has published a similar Guide with ISO/IEC Guide 51 [i.8].
- REDCA has published in May 2022 the Technical Guidance Note 30 (TGN30) on Notified Body examination of a manufacturer's risk assessment under Annex III of Directive 2014/53/EU [i.6]. This guidance is intended for notified bodies, but may also be useful for manufacturers.

The present document is intended to assist manufacturers in the collection of relevant information for risk assessment and the subsequent performance of risk assessment and mitigation. This risk assessment should be documented and be part of the technical documentation required by article 21 of Directive 2014/53/EU [i.6].

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1 Scope

The present document is to support manufacturers with a systematic and easy-to-understand guidance on how to carry out a risk assessment.

The present document covers the essential requirements of Directive 2014/53/EU (RED) [i.1], articles 3(1)b and 3(2).

NOTE: The present document provides guidance on risk assessment only for RED [i.1], articles 3(1)b and 3(2), which does not mean that manufacturers need to perform risk assessment only for these two articles. The general approach to risk assessment should apply to all aspects of the essential requirements described in RED [i.1], article 3.

2 References

2.1 Normative references

Normative references are not applicable in the present document.

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long-term validity.

The following referenced documents may be useful in implementing an ETSI deliverable or add to the reader's understanding, but are not required for conformance to the present document.

- [i.1] [Directive 2014/53/EU](#) of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (RED).
- [i.2] Commission Notice: "[The 'Blue Guide' on the implementation of EU product rules 2022](#)".
- [i.3] European Commission: "[Guide to the Radio Equipment Directive 2014/53/EU](#)" ('RED Guide'), Version of 19 December 2018.
- [i.4] [Regulation \(EU\) 2019/1020](#) of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011.
- [i.5] [Decision No 768/2008/EC](#) of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.
- [i.6] [REDCA Technical Guidance Note 30](#): "Notified Body examination of a manufacturer's risk assessment under Annex III of Directive 2014/53/EU (The Radio Equipment Directive)", V3.1, May 2022.
- [i.7] [CENELEC Guide 32](#): "Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment", Edition 1, July 2014.
- [i.8] [ISO/IEC Guide 51:2014](#): "Safety aspects — Guidelines for their inclusion in standards".
- [i.9] ETSI EG 203 367 (V1.1.1): "Guide to the application of harmonised standards covering articles 3.1b and 3.2 of the Directive 2014/53/EU (RED) to multi-radio and combined radio and non-radio equipment".

- [i.10] ETSI EN 303 446-1 (V1.2.1): "ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 1: Requirements for equipment intended to be used in residential, commercial and light industry locations".
- [i.11] ETSI EN 303 446-2 (V1.2.1): "ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 2: Requirements for equipment intended to be used in industrial locations".
- [i.12] [ERC Recommendation 70-03 \(February 2022\)](#): "Relating to the use of Short Range Devices (SRD)".
- [i.13] European Commission: "[Guide for the EMCD \(Directive 2014/30/EU\)](#)", 24/01/2019.
- [i.14] [Directive 2014/30/EU](#) of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.
- [i.15] Recommendation ITU-R SM.329-12 (09/2012): "Unwanted emissions in the spurious domain".
- [i.16] ETSI EG 203 336 (V1.2.1): "Guide for the selection of technical parameters for the production of Harmonised Standards covering article 3.1(b) and article 3.2 of Directive 2014/53/EU".
- [i.17] IEC TR 61000-2-5: 2017: "Electromagnetic compatibility (EMC) - Part 2-5: Environment - Description and classification of electromagnetic environment".
- [i.18] ETSI Directives.

3 Definition of terms, symbols and abbreviations

3.1 Terms

For the purposes of the present document, the following terms apply:

combined equipment: equipment consisting of two or more products where at least one of which is radio communication or radio determination equipment

NOTE: According to ETSI EG 203 367 [i.9], clause 3.1.

essential requirements: For the purposes of the present document, unless otherwise defined, the term refers to the essential requirements set out in articles 3.1(b) and 3.2 of the Radio Equipment Directive 2014/53/EU (RED) [i.1].

harmonised standard listed in the OJEU (hEN): European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation which is cited in the Official Journal for Directive 2014/53/EU

multi-radio equipment: combined equipment consisting of two or more radio products

NOTE: According to ETSI EG 203 367 [i.9], clause 3.1.

3.2 Symbols

Void.

3.3 Abbreviations

For the purposes of the present document, the following abbreviations apply:

AFA	Adaptive Frequency Agility
CAP	Conformity Assessment Procedures
CEPT	European Conference of Postal and Telecommunications Administrations
DFS	Dynamic Frequency Selection