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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).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

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].

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

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[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] 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] REDCATechnical Guidance Note 30, V3.1, May 2022: "Notified Body examination of a manufacturer's risk assessment under Annex III of Directive 2014/53/EU".

[i.7] CENELEC Guide 32, Edition 1, 2014-07: "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 the RED".

[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] Guide for the EMCD (Directive 2014/30/EU), Publication date: 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 (recast) Text with EEA relevance.

[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 (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 (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
DFS	Dynamic Frequency Selection
DoC	Declaration of Conformity
EAU	Electrical Aggregation Unit
EMC	ElectroMagnetic Compatibility

EMCD	ElectroMagnetic Compatibility Directive
EN	European standard
ESOs	European Standardization Organizations
EU/EEA	European Union / European Economic Area
EUA	Equipment Under Assessment
EUT	Equipment Under Test
GPS	Global Positioning System
GSM	General System for Mobile communication
hEN	harmonised European standard (listed in the OJEU)
LBT	Listen Before Talk
LTE	3GPP Long Term Evolution (4G)
MU	Measurement Uncertainty
NB	Notified Body
OJEU	Official Journal of the European Union
OJEU-RED	Official Journal - Directive 2014/53/EU

NOTE: See https://ec.europa.eu/docsroom/documents/51934.

RED	Radio Equipment Directive (Directive 2014/53/EU)
RF	Radio Frequency
TD	Technical Documentation
TX	Transmitter
Wi-Fi®	Wireless Fidelity

4 General

4.1 Legal background

The legal references to a manufacturer's risk assessment are spread across multiple documents, some of which are not easily accessible. Therefore, some of the relevant legal documents related to the risk assessment are listed here, as information to the manufacturer. These documents may be updated at any time and therefore any manufacturer wishing to reference these documents should check for new versions.

The RED Guide [i.3]: Clause 2.6b (Conformity assessment procedures (CAP)):

> *"…Under the Modules mentioned above, an assessment needs to be performed for ensuring that radio equipment complies with the essential requirements set out in Article 3 of the RED (that includes an assessment of the risks and aspects covered by Article 3). Based on the wording of Article 21 and Annex V of the RED, this assessment (whether Module A, B+C or H has been followed) shall be included in the technical documentation…."*

Directive 2014/53/EU (RED) [i.1]: Annex III Module B paragraph 3c (Conformity assessment modules B and C):

> *"…The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the radio equipment…"*

The RED Guide [i.3]: Clause 2.6d (Technical Documentation (TD)):

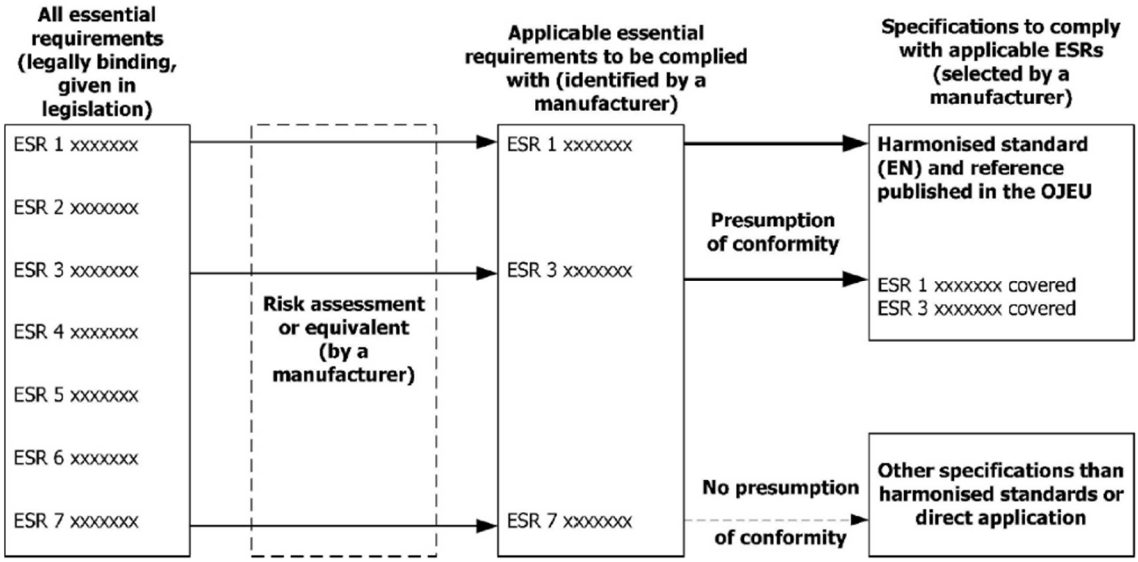
> *"…Annex III of the RED asks to include "an adequate analysis and assessment of the risk(s)" in the TD. Chapter 4.3 of the Blue Guide provides clarification on how such assessment shall be documented…"*

The Blue Guide [i.2]: Clause 4.1.1 (Definitions of essential requirements):

"Essential requirements must be applied as a function of the hazard inherent to a given product. Therefore, manufacturers have to carry out a risk analysis to ***first identify all possible risks that the product may pose*** *and* ***determine the essential requirements relevant for the product****. This analysis implies that the manufacturer should assess all the different elements of the products and* ***determine which Union harmonisation legislation applies to it****, and which specific essential requirements as set out therein.* ***This analysis has to be documented and included in the technical documentation****. In addition, the manufacturer needs to document the assessment of* ***how the risks identified are addressed to ensure that the product complies with the relevant essential requirements*** *(for example, by applying harmonised standards). If only part of the harmonised standard is applied or it does not cover all relevant essential requirements, then the way relevant essential requirements not covered by it are dealt with, should be documented (179).*

(179) Even where the manufacturer uses a harmonised standard (where its reference is published in the OJEU and which aims to cover certain risks) to satisfy essential requirements, the risk assessment has to be carried out and he must check whether the harmonised standard covers all risks of the product. This is because it cannot be assumed that the harmonised standard covers all requirements of all legislative acts applicable to a given product (or, indeed, all the requirements of the specific act under which it has been developed) or whether the product in question introduces also other risks not considered in the harmonised standard."

The Blue Guide [i.2]: Clause 4.1.2.2 (Role of harmonised standards):



The Blue Guide [i.2]: Clause 4.3 (Technical Documentation):

"…the requirement for an 'adequate analysis and assessment of the risk(s)' requires the manufacturer to first identify all possible risks of the product and determine the essential requirements applicable. This analysis has to be documented and included in the technical documentation. In addition, the manufacturer needs to document the assessment of how he is addressing the risks identified to ensure that the product complies with the applicable essential requirements (for example, by applying harmonised standards). If only part of the harmonised standard is applied or it does not cover all applicable essential requirements, then also the way applicable essential requirements not covered by it are dealt with should be documented in the technical documentation…"

Decision 768/2008/EC [i.5]: Annex II Module A Paragraph 2 (Module A)

"The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s)…"

Decision 768/2008/EC [i.5]: Annex II Module B Paragraph 3 (Module B)

"The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risk(s)…"

4.2 What is risk?

Traditionally, 'risk' means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm, according to article 3 (18) of Regulation (EU) 2019/1020 [i.4]. The determination of the related risk requires then assumptions for the probability of an occurrence of such a harm A, and the degree of severity of the relevant harm B. In theory the related risk is then calculated as A x B. However, this is in practice mostly not a simple multiplication.

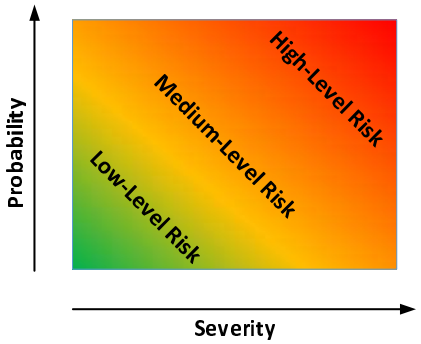


Figure 1: Risk = f (Probability, Severity) in the traditional way

The risk within the scope of the present document is interference/immunity related to the essential requirements in:

- RED article 3.1b (EMC): For example, electromagnetic interference due to the EUT's radiation into the radio spectrum (radiation) and Degradation of performance or loss of functionality of the EUT due to the electromagnetic environment in which the EUT is located (immunity).
- RED article 3.2 (Radio): For example, radio interference due to the EUT's emissions into the radio spectrum and insufficient receiver requirements (e.g. sensitivity, selectivity).

4.3 What is risk assessment?

Risk assessment is the systematic process of determining all potential risks linked with the use of the product as intended. It is followed by the phase of the risk reduction and finally the phase to determine if the residual risk could be acceptable. As a first step, the manufacturer should determine all legislation(s) applicable to his product and extract the applicable essential requirements.

Risk assessment accompanies the whole development process of a new product. Unlike the DoC, which should be established and signed at the end of the development process, the risk assessment should be considered as a 'live' document during the whole lifecycle of the product since the risks/hazards may change over time. The risk assessment should therefore be regularly updated.

A risk assessment should, at least, contain the following elements:

- Identification of applicable legislation and associated essential requirements.
- Identification of intended user.
- Identification of intended use including the environmental conditions.
- Identification of all possible risks associated with the essential requirements, taking into account the defined user and intended use.
- Assessment of the identified risks by applying standards (harmonised or non-harmonised, see Annex A) or their own technical specifications to test their radio equipment and ensure that it meets the essential requirements as specified in article 3 of the RED [i.1].
- Measures / Solutions to mitigate the risks that are non-compliant according to the test result.
- Monitor and review the (new) risks.

The final objective of the risk assessment is to ensure that all possible risks posed by radio equipment are identified and mitigated so that the radio equipment complies with the essential requirements.

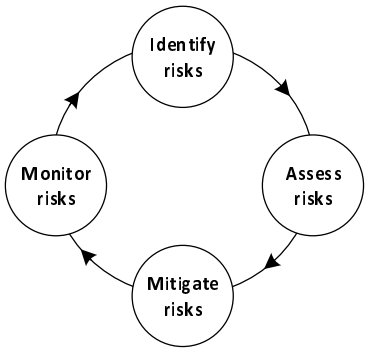


Figure 2: Risk assessment process

Risk assessment also provides an alternative way for the case that some measurements related to the essential requirements cannot practically be carried out. For example, radiated measurements at extreme temperatures cannot normally be performed in anechoic chambers. Risk assessment allows the manufacturer to assess the product on this point in their own manner, e.g. through various tests, calculations, analyses, etc.

4.4 What is the relationship between harmonised standards and risk assessment?

If a harmonised standard cited in the OJEU gives presumption of conformity, why is it necessary to carry out an additional risk assessment? What is the relationship between harmonised standards and risk assessment?

The Blue Guide [i.2] provides a brief explanation in clause 4.1.1:

> *"(179) Even where the manufacturer uses a harmonised standard (where its reference is published in the OJEU and which aims to cover certain risks) to satisfy essential requirements, the risk assessment has to be carried out and he must check whether the harmonised standard covers all risks of the product. This is because it cannot be assumed that the harmonised standard covers all requirements of all legislative acts applicable to a given product (or, indeed, all the requirements of the specific act under which it has been developed) or whether the product in question introduces also other risks not considered in the harmonised standard."*

Harmonised standards cover the "usual" risks of a radio equipment and describe measurement methods accompanied with the according limits to ensure that the residual risk is acceptable so to have presumption of conformity for the related essential requirement of the RED. Radio equipment is becoming increasingly complex, so harmonised standards may not cover all risks that could affect the essential requirements. For example, a "smart" oven with a Wi-Fi interface may pose different risks than a "smart" toothbrush that also has a Wi-Fi interface. In the case of multimode equipment, each operating mode could be tested separately according to a suitable harmonised standard. However, a combination of all these operating modes is not covered by any standard and should be assessed by the manufacturer in a risk assessment.

Risk assessment and harmonised standards are complementary. The risks already identified in harmonised standards, are helping the manufacturer to not start the risk assessment from scratch. The manufacturer can use for example the measurement procedure of a harmonised standard for risks not covered in that standard.

A general challenge is that the manufacturer needs to ensure that the essential requirements are fulfilled under all circumstances according to RED Art 17 (1) (*"The conformity assessment take into account all intended operating conditions …. Where the radio equipment is capable of taking different configurations, the conformity assessment shall confirm whether the radio equipment meets the essential requirements set out in Article 3 in all possible configurations."*), but compliance measurements cannot be done with every possible condition due to time/cost limitations. The harmonised standard provides the state of the art but this does not mean that the application of a hEN would ensure 100 % conformity with the essential requirements over all circumstances of the EUT's intended use.

A risk assessment of the manufacturer should fill the potential gap which the hEN has left, e.g. by providing extended measurements, simulation results, calculations or internal technical analysis, etc.

Table 1 provides examples of how a risk assessment can complement a harmonised standard.

Table 1

Challenge	What a hEN typically is offering	What a risk assessment could offer
A radio equipment has 500 channels over a large bandwidth. Risk is that the RF characteristics as radiated power, unwanted emissions, receiver requirements, etc. would not be the same depending on the channel.	A hEN either leaves this open or specifies how it should be done (e.g. using the lowest and highest channel)	The manufacturer should describe in the risk assessment how he is ensuring that all channels have similar RF characteristics and permitting him to restrict the measurements on the lowest, the highest and the centre frequency instead to measure on each channel.
At which combination of temperature / humidity / voltage should the test be performed?	A hEN either leaves this open or specifies how it should be done (e.g. using the lowest and highest temperature)	Manufacturers should define the worst scenario of temperature / humidity / voltage in a risk assessment, considering the intended use of the product.
Which phenomena (e.g. spurious emissions, radiated power, bandwidth, etc.) have to be tested over temperature profile?	A hEN typically provides conformance measurements at normal temperature and one/two essential requirements (e.g. frequency stability) are measured relatively in a temperature chamber.	Manufacturers should provide additional measurements, simulations etc over the temperature profile if they consider it necessary.
A radio equipment has different configurations: modulation steps, modes, bandwidth, etc.	Old standards usually suggested the worst-case configuration defined by manufacturers, which is no longer allowed. The most current standards leave this open.	Manufacturers should demonstrate their analysis in a risk assessment as to why the configurations were chosen.
Each manufactured unit of a radio equipment to be compliant (e.g. tolerances over series production could be considered)	Compliance measurements with a hEN refer only to one or few samples of a radio equipment.	Manufacturers should describe how they consider this issue.
Measurement uncertainty.	MU is usually an informative part of a harmonised standard	The risk assessment should clearly explain how the measurement results relate with the MU and the limit.

5 Guideline of risk assessment and risk reduction

5.1 Iterative process of risk assessment and risk reduction

The risk assessment should be carried out by the manufacturer from the beginning of the development of its radio equipment under his sole responsibility. The flowchart in Figure 3 provides a possible procedure for a risk assessment.

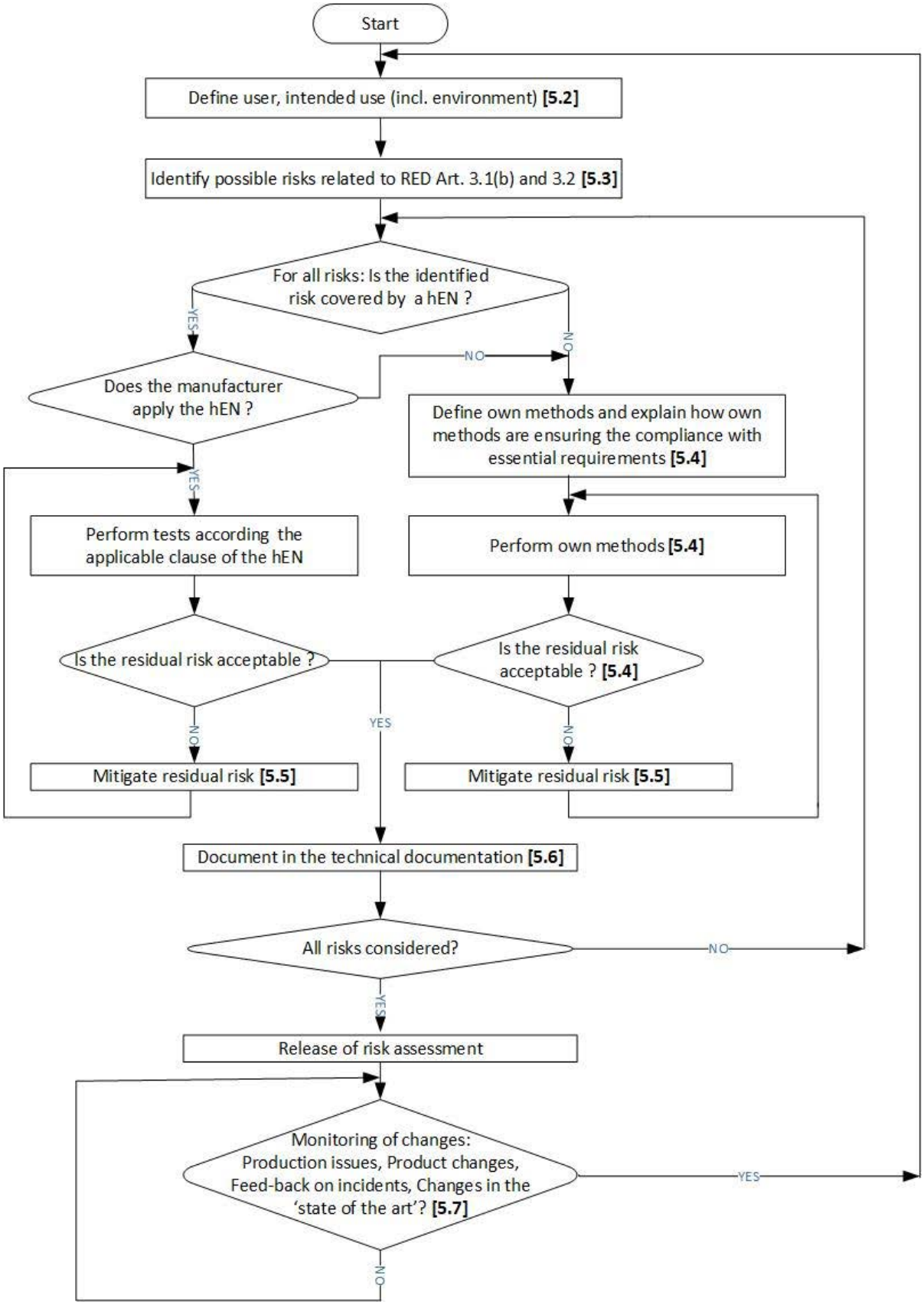


Figure 3: Iterative process of risk assessment

NOTE: Manufacturers need to be aware that the application for article 3.2 of own defined methods instead of applicable harmonised standards published in the OJEU drafted in support of Directive 2014/53/EU requires the involvement of a notified body for the conformity assessment (article 17 of the RED).

5.2 Define user, intended use

For risks associated with EMC (RED article 3.1b) and Radio (RED article 3.2), the intended use should be taken into account, according to RED article 17.1.

Where applicable, the following aspects, among others, should be taken into account:

- The intended use of the radio equipment so as to allow its use in compliance with the essential requirements. Such information may need to include a description of accessories such as antennas and of components such as software, and specifications of the installation process of the radio equipment.
- The intended user groups (e.g. professional, consumer, children, persons with disability, etc.).
- The environmental profile (e.g. medical, automotive, residential, industrial, indoor/outdoor, temperature, altitude, humidity, vibration, dust, input voltage variations, etc.).
- The possibility of coexistence of several technologies (e.g. mobile radio, FM radio, short-range radio, etc.), especially when the frequencies of other technologies are close or similar to the frequency of EUA.
- The possibility to be installed in or nearby another system/equipment (e.g. Elevator, medical device, etc.)
- All specifications as written down in the datasheet or technical document of EUA are considered as intended use and need to be taken into account.

5.3 Identify possible risks related to EMC and Radio

5.3.1 General

Where applicable, the following aspects, among others, should be taken into account:

- All the intended user groups, operating environment and specifications in the datasheet or technical requirement should be taken into account while identifying the possible risks.
- It is recommended that all identified risks are identified by a risk ID defined by the manufacturer so that it is understandable which risk it is. e.g.: 0001, 0002, 0003.
- The risks identified in a hEN can be taken as a reference and should be extended where appropriate. E.g. the EMC test standard normally specifies the EMC frequency range from 150 kHz to 6 GHz. If the manufacturer suspects that his radio equipment may be susceptible to interference outside this range or may cause interference outside this range, the risk assessment would be the place for the manufacturer to identify that risk.
- Pass margins or compliance margins to the limits should be considered in regards of the manufacturing quality process to ensure that all the radio equipment placed on the market will remain compliant with the RED [i.1].
- The user or installer should not be able to modify the radio so that it is no longer compliant, e.g. by changing the settings, updating the software or selecting regions outside the EU. If such user or installer control or software flexibility exists, the manufacturer should explain in their risk assessment how they ensure that the radio cannot be placed into a non-compliant mode of operation.
- Where applicable, all available accessories should be assessed together with the EUA.
- Any software/firmware that has an impact on EMC or radio performance should also be assessed.
- All exceptional product characteristics identified are considered in the risk assessment which might not have been dealt with or known at the time the applied hEN had been prepared. It can be expected that this may only occur in very rare, exceptional cases.

5.3.2 Risks related to EMC (RED article 3.1(b))

Where applicable, the following aspects, among others, should be taken into account:

- Non intentional radiation from the EUA.
- Immunity of the EUA to its intended environment, with the exclusion of radio aspects covered by article 3.2 of the RED [i.1]. It means that exclusion bands around the reception band of the EUA are applied during RF immunity testing (but are covered by the receiver requirements of article 3.2).
- For combined and/or integrated radio and non-radio equipment, the radio and non-radio parts need to be assessed as a single functional unit. ETSI EN 303 446 parts 1 [i.10] and 2 [i.11] are voluntary EN standards defining relevant requirements for EMC for such situation.
- The intended electromagnetic environment of the product is usually defined in 3 main categories: residential; commercial and light-industrial; industrial, which are the ones considered in harmonised standards. In exceptional situation, the electromagnetic environment of the EUA can differ. For such case, IEC TR 61000-2-5 [i.17] provides further description and classification of electromagnetic environments and phenomenon to consider.
- ETSI EG 203 336 [i.16] provides the most important technical parameters for harmonised standards for article 3.1b of the RED [i.1].
- Clauses 4.2 and 4.3, and Annexes 2 and 3 of the Guide for the EMCD [i.13] should be considered.

5.3.3 Risks related to Radio (RED article 3.2)

The frequency usage conditions, frequency allocations and assignments are mostly harmonised between EU and CEPT member states, although a national sovereignty applies on the use of radio spectrum. EC decisions, ECC recommendations and ECC decisions are the basis for harmonised radio spectrum in Europe. For short range devices for example, ERC Recommendation 70-03 [i.12] summarizes relevant frequency usage conditions of CEPT member states. The risks to be considered are strongly linked with the frequency usage conditions of transmitters. However, also receiver parameters specified in harmonised standards are relevant sources of possible risks. ETSI EG 203 336 [i.16] provides the most important technical parameters for harmonised standards for article 3.2 of the RED.

Where a radio equipment has different interfaces (e.g. Bluetooth®, Wi-Fi, GPS, GSM, LTE, 5G, etc.), each interface should be tested according to the appropriate standard(s). The combinations of more than one interface should also be analysed and/or tested to ensure all the possible combinations also satisfy the essential requirements of RED article 3.2. See also clause 6.1 on multi-radio equipment and combined radio/non radio equipment.

Where applicable, the following elements of risks for radio transmitters in regards of article 3.2 of RED, among others, should be taken into account:

- Frequency band.
- Frequency error.
- Radiated power or fieldstrength.
- Spectral density.
- Duty cycle and other spectrum access mitigation techniques.
- Maximum occupied bandwidth and modulation scheme.
- Unwanted emissions consisting of out of band emissions and spurious emissions, according to Recommendation ITU-R SM.329-12 [i.15].
- Input and/or output intermodulation.
- Adjacent channel rejection.
- Out-of-band gain.

- TX Transient.
- Channel access and occupation rules: time-out time, Listen Before Talk (LBT), Adaptive Frequency Agility (AFA).
- Dynamic Frequency Selection (DFS).
- Variations of above parameters depending on the ambient temperature, EAU's supply voltage or other environmental parameters.
- Impact of above parameters by the antenna characteristics (e.g. gain, single or multiple antennas, beamforming).

Where applicable, the following elements of risks for radio receivers in regards of article 3.2 of RED, among others, should be taken into account:

- Sensitivity.
- Blocking.
- Receiver spurious emissions.
- Impact of above parameters by the antenna characteristics (e.g. gain, single or multiple antennas, beamforming, etc.).

5.4 Define and perform own methods and evaluate the residual risks

A hEN gives a presumption of conformity, which means that if the manufacturer applies a hEN to an identified risk and the limit according to the hEN is met, then the residual risk is considered acceptable and this risk satisfies the associated essential requirements of the RED. However, it is not mandatory to apply a hEN. The manufacturer is free to perform these assessments/tests according to own methods, including his own measurement methods, simulation results, calculations, internal technical analysis or any standards other than hEN etc, as long as he considers these methods appropriate.

When applying own methods, the following aspects, among others, should be taken into account:

- The manufacturer should justify with explanations how the method he is applying is ensuring that the residual risk is acceptable and fulfilling the associated essential requirement of the RED. The manufacturer has freedom to elaborate the explanation in his own way, however, it should be meaningful to prove that the residual risk is acceptable and fulfilling the associated essential requirement of the RED.
- An own method needs not necessarily lead to testing. It can also be simulation results, calculations or internal technical analysis, etc.
- The existing methods developed by the European Standardization Organizations (ESOs) typically define the "state of the art" and can be referenced in their own methods.
- The common test methods and limits from the existing hEN can also be used outside its scope, but this have to be addressed in the risk assessment as well.
- For assessments/tests according to the manufacturer's own methods and if no limit is available, the manufacturer may justify why the risk is acceptable or the associated essential requirement of the RED is met. The justification should be documented either in the risk assessment or in a separate test report.

5.5 Risk reduction

Since the manufacturer has the best knowledge about his own product, they are free to carry out the risk reduction in their own way. Where applicable, the following elements may provide assistance to the manufacturer:

- Identify the cause.

- Find mitigation options.
- Chose mitigation and remedy the cause.
- Measure result after mitigation.
- If residual risk is still unacceptable, try next mitigation and repeat procedure to provide, in the final risk assessment document, the complete solution applied.
- For the residual risks that cannot be reduced to a tolerable range, a restriction should be highlighted in the user manual.
- The manufacturer should also take into account the intended use including the environmental profile (e.g. indoor/outdoor, temperature, altitude, humidity, vibration, dust, etc.) by evaluating whether the residual risk remaining after the measures is acceptable.
- For residual risks that cannot be reduced to a tolerable range under certain conditions, a restriction should be indicated on the packaging and in the user manual in accordance with article 10.10 of the RED. The manufacturer should also take measures, whenever possible, to prevent the end user from unintentionally accessing the restriction. The manufacturer should also justify in the risk assessment how the associated essential requirement of the RED is satisfied with the restriction.
- The manufacturer should also consider if any restriction applied by the manufacturer is practical and sensible and likely to be followed by the end user. For example, a manufacturer stating that the equipment is only intended to be operated with radio dongles removed or disabled. Such advice may be practical for professional, trained, operators but not for domestic home or office use.

5.6 Documentation (Checklist)

Where applicable, the following aspects, among others, should be included in a risk assessment document:

- Description of EUA.
- The intended user groups.
- The intended use including the environmental profile.
- Identification of applicable legislation and associated essential requirements.
- The identified possible risks overview with related documents (e.g. test reports, simulation results, calculations or internal technical analysis, etc). These documents may be provided separately, but links to them should be visible in the risk assessment.
- Explanations on how the applied method is ensuring that the residual risk is acceptable and fulfilling the associated essential requirement of the RED, if the manufacturer applies his own methods, including his own measurement methods, simulation results, calculations, internal technical analysis or any standards other than hEN, etc.
- Description of the measures taken to prevent the user or installer be able to modify the product so that it is no longer compliant, e.g. by changing the settings, updating the software or selecting regions outside the EU.
- Risk mitigation methods (harmonised standards, standards, additional assessments/testing, analyses, etc.).
- Identified residual risks after mitigation.
- Monitor production and product returns as well as any industry 'state of the art' changes.
- A conclusion that the product satisfies the essential requirements as applicable to the radio, which is separate to the manufacturer's EU Declaration of Conformity.
- Versioning.

5.7 Monitor production and product returns as well as any industry 'state of the art' changes

Where applicable, the following aspects, among others, should be taken into account:

- The compliance of the radio equipment is not affected after updating a software/firmware. Manufacturers may consider including a confirmation in each release note of software/firmware versions that the essential requirement of the RED is not affected.
- Check if the applied hEN or the clauses therein have changed.
- Check if the version of the applied hEN is superseded.
- Check if the Notified Body EU Type Examination Certificate expires.
- Check if the components used in the radio equipment have changed.
- Check if the rules or regulations applicable to the radio equipment have changed.
- Check feedback associated with compliance issues from users, market surveillance, or any other relevant sources, about the operation of the radio equipment.
- Check if the way people are using the product do not match the defined intended use.

6 Special cases

6.1 Case 1: Multi-radio equipment and combined radio/non radio equipment

- ETSI EG 203 367 [i.9] is a guidance for multi-radio and combined radio and non-radio equipment and:
  - provides guidance for the conformity assessment of this type of equipment;
  - provides guidance on how to make use of assessment(s) already performed on each constituent product of the multi-radio or combined equipment and to, whenever possible, identify the additional assessment necessary (Δ) to complete the Conformity Assessment Procedure (CAP) of this type of equipment;
  - provides guidance upon the selection of the appropriate limits and/or test conditions where different limits and/or test conditions exist in the standards applicable to each constituent product of the multi-radio or combined equipment;
  - helps to avoid duplication of testing wherever possible.
- For radio equipment with multimode and at least one mode is not intended to be used in the EU/EEA/EFTA:
  - The conformity assessment under the RED is limited to the modes that are intended to be used in the EU/EEA/EFTA. In other words, the manufacturer does not have the obligation to assess modes intended to be used in third countries. (non-permitted modes, hereinafter).
  - A risk assessment has to be carried out by the manufacturer in order to determine the impact of the non-permitted modes on the assets that the RED aims at protecting, such as the efficient use of the radio spectrum (RED article 3.2) or EMC (RED article 3.1b), among others.
  - The elements that the manufacturer has to take into account for this activity include: the easiness of activating a non-permitted mode, according to the design of the product or to the potential user profile; and the impact of an illegal mode on the assets protected by the RED. Note that this list is not exhaustive.
- Any radio equipment should comply with the RED and maintain this after incorporation into another device/system intended to be used.

- The manufacturer should evaluate all risks in the risk assessment, including those that could be caused by the combination, to ensure that the essential requirements are not degraded. For the assessment of combined risks, a worst-case approach should be applied.
- For radio equipment with multiple transmitters, the risk presented by the combination of these transmitters should also be assessed, and not just each individual operation in isolation.

Annex A:
Guidance on the use of harmonised and non-harmonised standards

This annex is intended to help the manufacturer to find out whether a standard is a harmonised standard listed in the OJEU and what additional measures are to be taken if the manufacturer does not fully apply a harmonised standard.

What is a harmonised standard that provides presumption of conformity to the RED?

A harmonised standard, that provides presumption of conformity to the Directive 2014/53 (RED) [i.1] article 16, refers **ONLY** to the standard, which is cited in the *Official Journal – Directive 2014/53/EU* (Hereinafter OJEU-RED). In this document, the term "Harmonised standard" (Hereinafter hEN), unless otherwise defined, refers only to the standard, which is cited in the OJEU-RED. The following cases are examples that are **not** hEN.

- Many EN standards state "Harmonised European Standard" on the cover page. However, these standards are hEN and provide presumption of conformity to the RED only if they are cited in the OJEU-RED.
- Standards cited in the OJEU of another directive but not in the OJEU-RED are not hEN for radio equipment. For example, an EMC standard cited in the *Official Journal of Directive 2014/30/EU [i.14]* (https://ec.europa.eu/docsroom/documents/51314) (EMC Directive) but not in the OJEU-RED is not a hEN for radio equipment. The EMC standards in the OJEU RED are hEN and give presumption of conformity to the RED for radio equipment.

It is not mandatory for manufacturers to apply a hEN. They can also apply any standards or use their own methods. However, they should justify with explanations how the applied method is ensuring that the residual risk is acceptable and fulfilling the associated essential requirement. This is also applicable when the manufacturer decides to not apply a hEN or only apply a part of a hEN. Therefore, manufacturers are encouraged to use the hEN because it provides a presumption of conformity. This means that manufacturers who use a hEN to test their radio equipment and meet all the requirements in the standard can consider their radio equipment to be compliant.

The following scenarios can be chosen by the manufacturer:

- **Scenario 1**: A hEN is fully applied.
- **Scenario 2**: A hEN is only partly applied, which means not all parameters of the hEN have been tested. In this case, an additional explanation, how the radio equipment complies with the essential requirements of RED, is required in the technical documentation. A Notified Body (NB) needs to be involved.
- **Scenario 3**: No hEN is available in the OJEU-RED. In this case, the manufacturer may apply another standard or his own specifications. Besides, an additional explanation, how the radio equipment complies with the essential requirements of RED, is required in the technical documentation. A Notified Body (NB) needs to be involved.
- **Scenario 4**: A hEN is available, but the manufacturer prefers to choose another standard or his own specifications. In this case, an additional explanation, how the radio equipment complies with the essential requirements of RED, is required in the technical documentation. A Notified Body (NB) needs to be involved.

The different conformity assessment modules of the RED are shown in the RED Guide [i.3], Figure 1.

For scenario 1, the manufacturer can choose any module for his conformity assessment procedure. This means that the RED does not require manufacturer to involve a Notified Body (NB) by applying module A.

For scenarios 2 to 4, when the relevant hEN related to radio (article 3.2) is not or only partially applied, the RED requires manufacturer to apply module B+C or module H, in both cases involving a NB. About EMC (article 3.1b), the RED leaves the choice to the manufacturer for applying Module A, B+C or H.

Annex B:
An example on how a risk assessment could look like.

Below is an example of a risk assessment for a certain radio equipment which is expected according to this guide. In this example, only a structure with few descriptions is shown. More details are provided in clause 5.

Clause 1: Description of EUA

Clause 2: Intended user group and intended use

Clause 3: Identification of applicable legislation and associated essential requirements

Clause 4: The identified possible risks with control measures and conclusion (overview) as in the following Table.

Risk ID	**Description of the identified risk**	**Risk control measures** A: by applying hEN (see note 1) B: by performing own method	**Related document (see note 2)**	**Conclusion**
RED Article 3.1(b) – EMC				
E001				
E002				
E003				
E004				
…				
RED Article 3.2 – Radio				
R001	Spurious emissions of Band 700 (see note 3)	by applying EN xyz v1.1.1	"Test report xx EN xyz v1.1.1"	OK
R002	Spurious emissions of Band 800 (see note 3)	by applying EN xyz v1.1.1	"Test report xx EN xyz v1.1.1"	OK
R003	Spurious emissions of Band 900 (see note 3)	by applying xyz v1.1.1	"Test report xx EN xyz v1.1.1"	OK
R004	Spurious emissions as all bands are enabled at the same time (see note 3)	by performing own method	"Test report xx spurious emission all bands"	OK
…				

NOTE 1: It is not mandatory for manufacturers to choose a hEN. See annex A for more details.
NOTE 2: The related documents, e.g. the test report, should be included in the technical documentation to prove that the identified risks have been eliminated and verified.
NOTE 3: A multiband repeater with 700, 800 and 900 Bands is taken as an example.

History

Document history		
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