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).

Table of Content

This TGN replaces all previously published versions

1.0 Introduction:

Under the Radio Equipment Directive (RED) 2014/53/EU, Annex III, Part A, Module B 3(c), it is required that a notified body shall assess the technical documentation associated with the apparatus to ensure conformity with the essential requirements set out in Article 3 of the Directive and that the technical documentation shall include an adequate analysis and assessment of the risk(s).

The risk assessment is an activity for the manufacturer to perform but the notified body shall take the manufacturer's risk assessment into account as provided in the manufacturer's technical documentation, when performing an EU-Type Examination assessment under Annex III of the RED. The purpose of this document is to provide guidance to notified bodies on the recommended issues that can be expected to be considered in a risk assessment document and to achieve a consistent approach between notified bodies such that manufacturers are not burdened by unnecessary differences and expectations from different notified bodies. This document is not intended to be guidance to manufacturers nor is it intended to influence market surveillance authorities.

2. Risk analysis and assessment submitted by the manufacturer

The risk analysis presented by the manufacturer and assessed by the notified body shall follow the guidance given in "'Blue Guide' on the implementation of EU product rules 2016" under clause 4.3 and clause 4.1.2.2.

The risk analysis and assessment should consider and document at least the following steps:

1. Clearly identifying the intended user groups (e.g. professional, consumer, children etc.) and the operating environment (e.g. Indoor/outdoor, temperature, altitude, etc.) for which the product is intended to be used.

2. Identifying which of the Essential Requirement(s) of the directive are applicable. The Essential requirements of Articles 3.1 and 3.2 apply to all radio equipment, whereas the Essential Requirements of each paragraph of Article 3.3 only apply to the radio equipment within scope of that paragraph.

3. Identifying which harmonized standard(s) or equivalent documentation has been applied to mitigate the risk of non-compliance to the Essential Requirements.

4. Specifically identifying if there are special product characteristics or features which might not be included in the current harmonised standard(s) and how these features are still considered to comply with the Essential Requirements.

5. Specifically explaining how the additional risks in not following the available harmonised standards to provide a presumption of conformity or using alternative compliance methods and standards have been mitigated to demonstrate compliance to the Essential Requirements.

The figure given in 4.1.2.2 of the “Blue Guide” can be used as guidance:

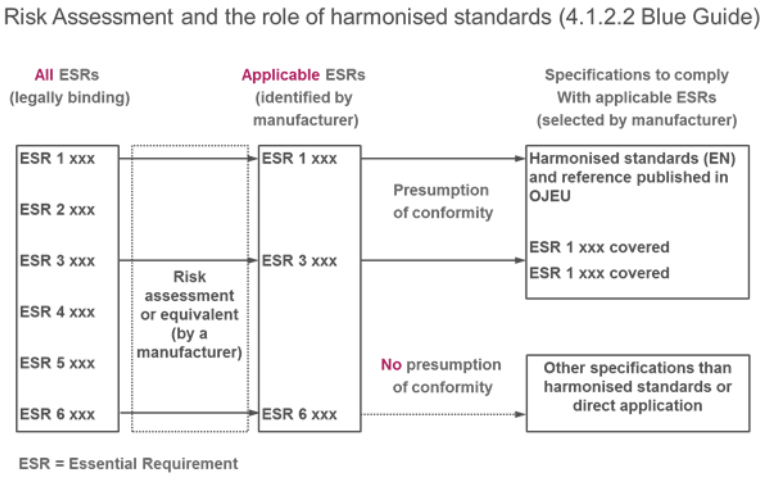

Figure 1: Guidance on how to assess the Essential Requirements (ESR) required taken from Blue Guide clause 4.1.2.2

3. Tasks of the Notified Body

1. The notified body shall check that the manufacturer’s technical documentation for the radio equipment contains a risk assessment analysis.

2. The notified body shall check whether the risk analysis is compliant with the minimum requirements in the Blue Guide and take into consideration the content of this guide.

3. The notified body shall check whether the risk analysis is adequate for the radio equipment under review, with regard to section 2 of this TGN.

4. The notified body shall consider for their assessment the information presented in the risk analysis and assessment by the manufacturer.

5. The notified body shall allow any format and structure of the risk analysis and assessment as part of the technical documentation because this is entirely determined by the manufacturer. The risk assessment shall however be in a language that can be understood by the notified body.

6. The notified body shall consider whether the manufacturer’s defined user groups and operational conditions are appropriate. For example, if the product is intended to be used

by vulnerable people, or if the product is intended to be used in conditions outside of the scope of the applied harmonised standards, etc.

7. The notified body shall assess whether the harmonised standards, other normative documents, and reference documents applied by the manufacturer entirely cover the essential requirements for which they have been selected.

8. If the product is covered by more than the RED, such as a radio equipment incorporated into a device subject to the Medical Equipment Regulation, then a more onerous risk assessment may be required by the other directive. The RED notified body should take care not to exceed their remit under the RED.

9. The notified body shall take care that any exceptional product characteristics identified are considered in the risk assessment which might not have been dealt with or known at the time the applied harmonised standard(s) had been prepared. It can be expected that this may only occur in very rare, exceptional cases.

10. Annex V d) of the RED requires that where harmonized standards are not applied, a description is required of the solutions adopted to meet the essential requirements of Article 3. This requirement applies to cases where the harmonised standard exists but was not fully applied, or when the appropriate standard is not harmonised in the RED official journal of harmonised standards (OJEU). It applies to all parts of Article 3.1a, 3.1b, 3.2 and 3.3. The description of the required solutions and the manufacturer's decision for choice of solution should be detailed in the risk assessment.

The type of questions a notified body could ask when reviewing the technical documentation are related mainly to the essential requirements of Article 3 of the RED, which they have been asked to assess.

Suggested topics to consider are provided below and in the informative annexes of this TGN.

This TGN and its annexes provide a non-exhaustive list of things to consider.

Please note that the cases provided in this TGN are only examples, and not a definitive checklist of things to consider. This TGN provides some indication on the types of things the manufacturer should include in their risk assessment, and the notified body should review.

Other risks may exist, and the manufacturer should include them in their risk assessment, even if they do not appear in this TGN as one of the given examples.

3.1 Article 3.1(a) health and Safety

The primary consideration under Article 3.1(a) is the protection of health and safety of persons, domestic animals, and the protection of property. For this it is valid to apply the

safety objectives of Directive 2014/35/EU (LVD) but with no voltage limit applying. For the purposes of the RED, all radio equipment requires a safety assessment.

Potential heating, energy and other hazards should be included in the risk analysis which might otherwise be neglected by manufacturers or the safety test standards, which may have been written for the LVD.

For the purposes of the RED risk analysis, it is necessary to consider reasonably foreseen conditions of use. However, there is no reason why a manufacturer should not consider reasonable misuse of the equipment as this includes more traditional failure mode analysis techniques and product liability issues. Therefore, a notified body should not reject a more comprehensive Risk Priority Number or Failure Mode Effects Analysis if it is submitted as part of the technical documentation. There is no constraint on the content and format a manufacturer may use for the risk analysis.

For Article 3.1(a), it is recommended that the notified body should ensure the manufacturer has considered issues affecting the health and safety of the user, and other persons, and domestic animals, in their risk analysis. This may include:

a. Protection against electrical, mechanical, optical, and acoustic hazards. Sharp edges, pointed corners, small part choking hazards, also dust and liquid penetration issues.

b. Other hazards should be considered as relevant for the reasonably foreseen and legal use of the equipment including the operating voltages and temperature of the equipment and the intended working environment. Consider the battery technology used and the potential battery charging hazards.

c. The potential for human and animal exposure to non-ionizing radiation should be considered. RF Exposure should generally be assessed for the most conservative use cases, at worst-case user distances (often the smallest separation distance) and the maximum possible output power based on manufacturing tolerances.

d. Additional requirements may apply for products which are clearly designed or intended to be used by children or specifically attractive to children. In such cases, general safety aspects such as choking hazards of small parts and the ingestion of small batteries and magnets must be considered in a hazard-based assessment. Additionally, for products aimed at children, manufacturers should consider the Toys Directive as their product may be within the scope of that directive.

e. If the radio equipment is intended to be used in a motor vehicle, consider whether vibration, temperature extremes and possible distractions to the driver have been adequately addressed

f. If the radio equipment can be reasonably foreseen to be used at high altitudes (above 2000 meters), the basic clearance distances of EN 62368-1 may be inadequate and additional allowances should be made. Another major effect of high altitudes is that less dense air does not conduct heat as efficiently. Additional assessments may be performed by manufacturers of high-altitude equipment and that would be documented in

the risk assessment. Commercial airline cabin pressure is typically maintained at 2,400 meters, which means this requirement applies to radio equipment intended to be used while on aircraft.

g. Acoustic safety is a consideration for radio equipment that generate audio waves. This should be included in the safety assessment of equipment generating loud sounds and especially equipment with a speaker or headphone socket for audio/music output, such as laptops, tablets, phones, desktop computers, ear buds, portable music players, etc.

h. Regarding temperature extremes and product safety, the risk assessment and the technical assessment should consider all reasonably foreseen use cases. For example, a mobile phone (smartphone/cellphone) is typically used in a comfortable human environment but may also be left on battery charge or as a router in a more extreme environment, such as in a vehicle. Cellular radio modules are based on the same technology and apply the same test standards as phones but may be used in more extreme environmental conditions, such as in a vehicle or IoT solution. Environmental conditions of a cellular module, or equipment containing a cellular module, or a phone may far exceed the minimum requirements in the standard and the manufacturer should consider that. Even when not in use, radio equipment (including the battery) can be left in extreme temperature conditions, which should be evaluated and detailed in the risk assessment by the manufacturer.

3.2 Article 3.1(b) Electromagnetic Compatibility (EMC)

For Electromagnetic Compatibility (EMC), a notified body may wish to consider the following aspects during an assessment of the technical documentation to ensure that the product has been appropriately evaluated for both emissions and immunity characteristics, and these aspects are considered in the manufacturer's risk analysis.

Emissions:

a. What frequency range has the product been tested over? Consider the range of clock frequencies and transmitters used within the product.

b. Are the technologies within the product likely to cause electromagnetic disturbances below the lowest frequency of test?

c. Are the technologies within the product likely to cause disturbances above the highest frequency of test? Consider the operating frequencies of the product and what communication services should be protected.

d. If the product has connection ports in addition to the power port, have they been tested? If not, are they likely to cause radiated disturbances due to their length? How has the manufacturer mitigated this?

e. Does the product have telecom cables? Has testing been performed on these ports? If not, why? Is the mitigation reasonable under foreseeable circumstances?

f. Are there any other unique factors within the product that should be considered? For example, intentional radiators, but not radio communications, which may or not be covered by ISM frequency bands.

Immunity:

a. Have all tests required by the applied product standards been done?

b. Are the applied product or generic standards appropriate for the electromagnetic environment as selected or described by the manufacturer; usually 80 MHz to 6 GHz?

c. Are there ports on the product which are liable to be susceptible and haven't been tested?

d. Have transients and surges been evaluated if use in a vehicular environment is expected? Vehicle transients would apply to equipment intended to be powered through the vehicle 12 V or 24 V connector.

e. Have all the operation modes of the equipment been adequately monitored and evaluated during the tests? All modes and functions must be shown to comply.

f. If EMC tests are deemed 'not applicable' because the equipment is intended to be used only with short cables (less than 3 m), does the product documentation, user manual and intended use support this?

g. The pass or fail criteria applied should be applicable for the normal operation of the product. Manufacturers should not be choosing more relaxed criteria than the user would expect for that type of equipment.

If no harmonised standard has been applied: Check if all relevant phenomena as listed in the generic immunity standard have been considered in the evaluation and in tests done.

3.3 Article 3.2: Effective and efficient use of the Radio Spectrum

Radio equipment must be designed to make effective and efficient use of the radio spectrum. This includes "combined" as well as "stand-alone" radio equipment. In most cases each radio will have been assessed using harmonised standards; but for combined equipment a manufacturer may have made use of documents such as ETSI EG 203 367, REDCA TGN 01 and REDCA TGN 31 which provide guidance to the application of harmonised standards covering articles 3.1(b) and 3.2 of the Directive 2014/53/EU (RED) to multi-radio and combined radio and non-radio equipment. These documents also address issues to be considered in multi-radio equipment capable of simultaneous transmission. If a manufacturer

follows the guidance documents, they will normally cover all the issues of concern for complex types of radio equipment.

If a device has multiple operation modes, such as radio communication and other features or functions, it is important that the combined effect of all functions have been assessed, and not just each individual operation in isolation. They should also consider whether any mitigation 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.

Notified bodies should also check whether the manufacturer's choice of receiver classification is appropriate, and that relevant and appropriate receiver protection tests have been performed. This may need careful consideration if the radio frequencies are not channelized.

Regarding temperature extremes and radio performance, the risk assessment and the technical assessment should consider all reasonably foreseen use cases. A cellphone may be used as a router in a more extreme environment than the standard specifies, such as in a vehicle. Cellular modules are based on the same technology and test standards as phones but may be used in more extreme environmental conditions. The environmental conditions of a cellular module, or equipment containing a cellular module, or a phone may far exceed the minimum requirements in the standard and the manufacturer should consider that.

The risk assessment should check that the radio does not have the potential to be placed into non-compliant modes by the user, based on unrestricted access to controls or software. If such user or installer control or software flexibility exists, the manufacturer shall explain in their risk assessment how they ensure that the radio cannot be placed into a non-compliant mode of operation.

In cases where radio equipment is installed into other equipment to create a new radio equipment, the risk assessment should document clearly if any results from the original radio are used to justify compliance of the final radio equipment. The technical documentation should show compliance of the final radio equipment. REDCA TGN 01 and TGN 33 may be used for guidance.

Note: The text in this TGN makes reference to other REDCA TGNs, 01, 31, 33. However, these references are for guidance only and this TGN is not reliant on those other REDCA TGNs. If the other TGNs (01, 31, 33) become amended, withdrawn or fail to be formally published, it does not alter the validity or content of this TGN, TGN 30.

3.4 Article 3.3: Certain Radio equipment shall meet particular Essential requirements

When assessing the compliance of certain radio equipment that has additional Article 3.3

requirements within the requested scope of the review, notified bodies must ensure that the relevant essential requirements under Article 3.3 have been satisfied and included in the risk assessment. This will normally be achieved by applying the relevant harmonised standards, where available.

For example, products requiring emergency access, such as mobile phones, avalanche beacons and some maritime services equipment are required to meet Article 3.3(g).

4. Conclusion:

It is recommended that notified bodies assure themselves that the manufacturer's risk assessment does reach a conclusion that the product satisfies the essential requirements as applicable to the product. This may be clarified or illustrated by the manufacturer with statements as to the state-of-the-art knowledge and reasonably foreseen, legal use of the equipment as required by the manufacturer. The conclusion of the risk assessment is separate to the manufacturer's EU Declaration of Conformity.

Disclaimer: Manufacturers must carry out a risk analysis to first identify all possible risks that the product may pose and determine the essential requirements applicable to the product. This TGN is limited to the essential requirements of the Radio Equipment Directive 2014/53/EU (RED). The manufacturer is responsible for covering all requirements of all legislative acts applicable to their product, and determining whether the product in question also introduces other risks not considered by the RED.

5. Annex A – Guidance when Harmonised Standards are not applied

This annex is intended to give some guidance to a notified body when they are reviewing a risk assessment where the manufacturer has not applied harmonised standards or if the product characteristics require an evaluation beyond the scope of the harmonised standards.

The aim of this TGN is not to set prescriptive limits but rather to indicate to notified bodies where useful information can be obtained which shows the current "state of the art" such that the risk assessment can be consistently evaluated in line with the notified body's obligations under Annex III, Module B, 3 (c) of Directive 2014/53/EU.

If the manufacturer has not applied harmonised standards to demonstrate compliance with the essential requirements of the RED, the manufacturer's risk assessment and the notified body's review will mostly be the same as that described in section 3 of this TGN (above). However, in addition to the review of the risks associated with the radio equipment, the manufacturer is also expected to review the risks associated with use of a non-harmonised

standard. The manufacturer is expected to research the reasons why the standard is not listed on the RED OJEU and compensate for any shortcomings.

For example, if the standard has been rejected by the European Commission (EC) on grounds of inadequate requirements, the manufacturer is expected to compensate in their assessment or testing of their radio equipment, to a level which is acceptable to show compliance with the RED. This may mean testing to greater levels or limits than is required by the non-harmonised standard.

As an alternative example, if the standard has been rejected by the EC on grounds of poor layout or formatting of the standard, the manufacturer is expected to ensure they interpreted the standard correctly and did not do the wrong thing, based on the poor standard layout.

In any case, the manufacturer is expected to document in their risk assessment why they chose a non-harmonised standard, and how the assessment of their equipment can be used to demonstrate compliance with the RED, considering any problems associated with the standard.

6. Annex B – Guidance on typical content ideas (Informative)

The following annex provides some examples of the types of topics the manufacturer should consider in their risk assessment. Creation of the risk assessment is the manufacturer's responsibility and the items in this annex are provided as suggestions only.

The topics covered in this document is a non-exhaustive list.

1. Identification of standards
    a. The risk assessment should identify all the applicable standards to cover the operations, modes, and functions of the radio equipment, including the non-radio operations.

2. The risk assessment should list any harmonized standards applied, which are on the RED OJEU, and ensure that the latest harmonized version has been applied.

3. Correct standards applied
    a. Did you use standards which specifically apply to this product?
    b. Are there other standards which would be more appropriate?
    c. Are there other standards which might also apply?

4. The risk assessment should list any non-harmonized standards applied, and include justification for using those non-harmonized standards

a. It should state why the standard is not listed on the RED OJEU and address any shortcomings or reasons why the EC feels the standard is not sufficient to meet the RED

5. Environment
    a. Have you tested or assessed the product over the correct temperature range for the intended and expected use?
    b. Have you considered additional concerns due to weather and location, such as outdoor use, other hostile locations, high altitude, etc?
    c. Have you considered co-location with other radio equipment in the intended environment or use?

6. Input voltage
    a. Have you assessed the device for use with all possible input supply options?
        i. AC input or AC charger
        ii. DC supply
        iii. Vehicle 12V or 24V
        iv. Battery

7. Cables, ports and accessories
    a. If the product has ports, did you test all the ports which may be used?
    b. Did you test with the cable lengths which could be used with the product?
    c. Did you test with the cable types which could be used with the product?
    d. Did you test with the intended/expected accessories connected?

8. Frequency range of spurious emissions testing
    a. Are there high levels of emissions expected below the minimum frequency tested?
    b. Are there high levels of emissions expected above the maximum frequency tested?

9. Frequency range of RF immunity testing
    a. Are there interference or operation risks below the minimum frequency tested?
    b. Are there interference or operation risks above the maximum frequency tested?

10. Product safety
    a. Are there any safety risks associated with the equipment use which are not covered by the standard?
    b. Will the use of this equipment cause a safety concern, such as use while driving or in hazardous locations?

c. Does the assessment include all reasonably foreseen use and safety risks to people, domestic animals, and property?

11. Acoustic Safety
    a. If the product has loudspeakers, could it exceed safe guidance levels?
    b. If the product has a headset socket or headset attached, could it exceed safe guidance levels?
    c. Does the product produce any other sound or noise which could exceed safe guidance levels?

12. Light or Laser Safety
    a. If the product has a torch or light, could it exceed safe guidance light levels?
    b. If the product has a laser, could it exceed safe levels and are warnings provided?

13. RF Exposure
    a. Has non-ionizing RF exposure been assessed at the appropriate worst-case distance and condition?
    b. Has the non-ionising RF exposure assessment considered the maximum possible average power?

14. EMC
    a. Were all modes and operations fully tested, exercised, and monitored during EMC tests?
    b. Did you monitor all types of operation of the product during the EMC immunity tests?

15. Radio
    a. Was the radio tested at the highest power settings possible?
    b. Were all frequency ranges and bandwidths assessed?
    c. Were all modulation modes assessed?
    d. Was the receiver fully assessed while all possible sources of interference from within the equipment were also active?
    e. Does the user or installer have the possibility to select settings which were not tested?
    f. Does the user or installer have the possibility to set the radio into a mode which was not assessed or could be non-compliant?
    g. Does the user or installer have the possibility to download or install software which could allow non-compliant modes to occur?
    h. Was the radio tested at correct channel occupancy (e.g. pulsed or TDMA)

16. Multi-function equipment

a. Could there be emissions or interference due to multiple transmitters or transceivers, or multiple operations within the product which were not assessed during testing of each function separately?
b. Could there be EMC immunity or functionality problems due to multiple transmitters or multiple operations within the product which were not assessed during testing of each function separately?
c. If transmitters and receivers are co-located within a radio equipment or environment, could the transmitter interfere with the operation of the receiver?

17. Regional regulatory compliance
    a. In an attempt to meet global regulatory demands, could the user or installer select modes or settings which would permit power levels, frequency ranges or other operations which are not permitted in the EU?

18. Software updates
    a. Are any software updates permitted, by the manufacturer or installer, which could alter the performance of the device outside of the modes which were tested?

19. State of the art
    a. Are there any issues associated with this type of product which are known in the media or industry forums to cause problems with EMC, safety, radio, or regulatory compliance?

20. Radio module installation
    a. If accepting any test data from a radio equipment or radio module installed into the equipment, have you ensured that you re-assessed any test cases which could be affected by the installation?
    b. Have you assessed the radiated test cases on installation of a radio module, such as the radiated spurious emissions?
    c. If receiver testing was performed on the module outside of the final equipment, have you assessed that the installation does not adversely affect the receiver performance?
    d. If transmitter testing was performed on the module outside of the final equipment, have you assessed that the installation does not adversely affect the transmitter performance?
    e. Ensure that when accepting test data from a radio module, it is to the latest applicable standard; or re-assess to the correct standard at final equipment level.
    f. Have you got the technical documentation of the radio module available to show to a market surveillance authority, if you are asked to do so?

7. Annex C – Further testing advice notes (Informative)

7.1 Article 3.1(b) EMC

The following section provides guidance for the notified body, manufacturer and test lab in cases where the manufacturer identifies that additional testing is needed but requires guidance on how to approach it.

The manufacturer and notified body should be aware of the current situation for EMC performance below 150 kHz and above 1 GHz. For the protection of the radio spectrum below 150 kHz there are limits for conducted emissions as well as radiated magnetic field emission available from CISPR standards which have been adopted by the EU. Examples are: EN 55014-1, EN 55015 and EN 55011. For the frequency range from 30 kHz to 150 kHz, CISPR has started work to derive limits for the protection of the radio spectrum within this frequency range which then might additionally be used for generic products beside the limits already available in EN 55014-1, EN 55015, EN 55011. Manufacturers may also consider the FCC 15.109 and 15.209 limits, which go down to 9 kHz. Additionally, ERC/REC 74-01 gives limits down to 9 kHz.

For EMC performance above 1 GHz, RED standards can be helpful in deriving useful levels of EMC performance, but it must be remembered that the limits in these standards are for intentional radiators. Standards available under the EMC directive 2014/30/EU do have limits and test levels available above 1 GHz, up to 6 GHz or 18 GHz (e.g. EN 55032, EN 55035, EN 55011, IEC 61000-6-X series). CISPR works on establishing general available test methods and limits for products from 6 GHz to 40 GHz.

For evaluating Radiated Spurious Emissions above 1 GHz, reference to ERC REC 74-01 is recommended or alternatively reference to EN 300 440 may be useful.

Issues may arise in the foreseeable future due to wireless power transfer (WPT) systems. Anticipated intentional field strengths, out-of-band and radiated spurious emissions that may occur in the vicinity of such systems can be found in ETSI standard EN 303 417. It is recommended that the notified body reviews what measures the manufacturer has taken in their risk assessment to minimise the risk to the product, any likely surrounding equipment and the user and bystanders under conditions of foreseeable use of the equipment.

7.2 Article 3.2 Assessment Guidance (Informative)

When assessing combined radio equipment, or equipment with other functions in addition to the radio operation, manufacturers should ensure that appropriate radio standards have been applied, with or without the other operations of the equipment in effect, depending on the intended and expected use of the equipment

The manufacturer should check that the device can safely function as intended during radio transmission without interference from the radio transmitter and an appropriate evaluation

has been performed to ensure that radio transmit and receive performance is not degraded by the operation of the equipment. The notified body should consider whether any mitigation applied by the manufacturer is practical and sensible and likely to be followed by the end user. Some mitigation solutions may be practical for professional, trained, operators but may not be practical for domestic or office use.

The manufacturer's risk assessment is expected to document how Article 10(2) and 10(10) of the RED are met. It is essential for the notified body to check the Article 10(2) compliance because the notified body cannot issue their EU Type Examination Certificate if the device cannot be placed on the market in at least one EU member state.

8. Annex D – Legal context and definitions

8.1 Legal Context

The requirements for the risk analysis are defined in the RED without specific details or definitions of terminology.

The legal requirements are:

> 2014/53/EU - ARTICLE 5 -2- "… following an evaluation of the risk of non-implementation of the essential requirements."
>
> 2014/53/EU - *ANNEX III - Module B -3- "(c) the technical documentation. 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).****"*

Other information came from non-legal binding documents like:

The Whereas section of 2014/53/EU make several references to risks, some of them are connected to manufacturer tasks including:

- *20) …compliance of radio equipment to be provided by Member States and following an evaluation of the risk of non-implementation of the essential requirements"*
- *60) … Infringing such conditions may create a risk to the essential requirements, particularly a risk of harmful interference.*

The Blue guide 2016 introduces the risk assessment under clause 4.3 and clause 4.1.2.2 but without specific detail.

The Commission documents make use of risk assessments in several fields. A reference is DOC: 2015-IMP-MSG-15; *"EU general risk assessment methodology (Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76)"* where it is stated; *"This EU general risk assessment methodology implements Article 20 of Regulation (EC) No 765/2008 and is intended to assist market surveillance authorities when they assess*

the compliance of products that are subject to Union harmonization legislation". This document contains a common shared definition of risk analysis including definition for Hazards, Risks, Probability.

ISO 31000: 2018; *"Risk management −Guidelines"* provides the '*state of art'* for definition of risk terminology.

Basing on the stated documents, in this TGN the following definition will be used:

8.2 Definitions

Risk Analysis: Is the process to understand the nature of the risk and to determine its magnitude, which results from the combination of consequences and their likelihood.

Risk: Combination of the probability of occurrence of a hazard generating harm in each scenario and the severity of that harm.

Harm: Non-Compliance with an essential requirement.

Probability of occurrence of that harm: The likelihood of the harm occurring.

ESR: Essential Requirement.

Shall: A requirement that is necessary to follow.

Should: Indicates a recommendation.

Note: This terminology is only for this TGN's use and is not mandatory by the manufacturers.

Disclaimer: This REDCA Technical Guidance Note does not replace the text of the RED – 2014/53/EU - and is for guidance only. In legal disputes the text of the RED, or its implementation in National legislation, takes precedence, followed by any information in the RED Guide or Blue Guide.