REDCA Technical Guidance Note for a Notified Body examination of a manufacturer's risk assessment under Annex III of Directive 2014/53/EU (The Radio Equipment Directive).

1. Introduction

Under Directive 2014/53/EU, Annex III, Part A, Module B 3(c) (The Radio Equipment Directive), it is required that a notified body shall assess the technical documentation associated with the apparatus to ensure conformity with the applicable requirements 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 alone 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 Radio Equipment Directive (RED). The purpose of this document is intended to provide guidance to notified bodies as to the recommended issues that can be expected to be considered in a risk assessment document and to achieve a consistent approach between various 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. Furthermore, it is not applicable to professional devices covered by Directive 2013/35/EU.

2. Risk analysis and assessment submitted by 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" **Error! Reference source not found.** under clause 4.3 and clause 4.1.2.2.

The risk analysis and assessment should consider and document <u>at least</u> 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.

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 be not 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 giving a presumption of conformity or not 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:

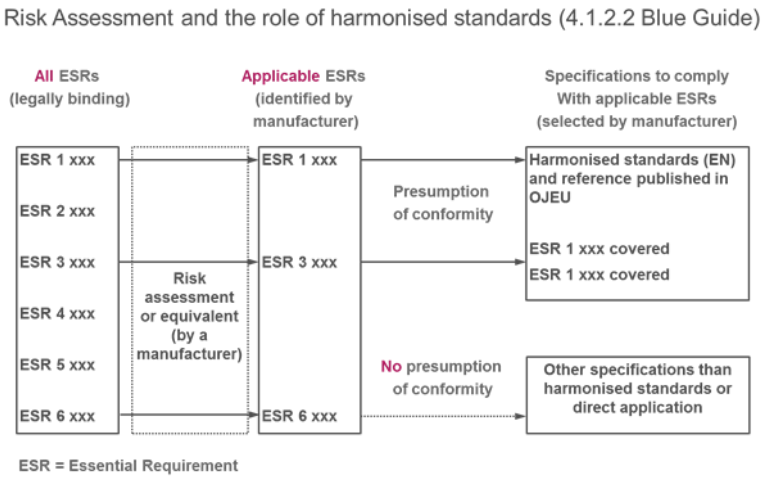

Figure 1 Guidance on how to assess the ESR required taken from Blue Guide clause 4.1.2.2

3. Tasks of the Notified Body

The notified body shall check whether the risk analysis presented is compliant with the minimum requirements in the Blue Guide and take into consideration the content of this guide. The notified body shall take into account for their assessment the information presented in the risk analysis and assessment by the manufacturer. The notified body shall allow any format and structure of the risk analysis and assessment as part of the technical documentation because this can only be entirely determined by the manufacturer. The risk assessment shall however be in a language that can be understood by the notified body.

The notified body shall consider if the manufacturer’s defined user groups and operational conditions are appropriate. Is the product intended to be used by vulnerable people? Is the product intended to be used in conditions outside of the scope of the applied harmonised standards?

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

If the product is covered by more than the RED, such as a radio device incorporated into a device subject to the Medical Equipment Directive, then a more onerous risk assessment may be required by the other directive. The RED NB should take care not to exceed their remit under the RED unless agreed by the manufacturer and they are competent to do so.

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. The type of questions a notified body could ask when asked to review the technical documentation are related mainly to the Essential Requirements of Article 3 of the Radio Equipment Directive they have been asked to assess. These are listed in detail below and in the informative annex.

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. This means that from an LVD point of view voltages within the limits of Safe Extra Low Voltage (SELV) would be considered as "safe." For the purposes of the RED this is not the case and potential heating, energy and other hazards should be included in the risk analysis which might otherwise be neglected.

For the purposes of the RED risk analysis it is only necessary to take into account reasonably foreseen conditions of use. However, there is no reason why a manufacturer should not consider reasonable misuse of the equipment as this takes into account more traditional failure mode analysis techniques and product liability issues. This saves the manufacturer the cost and complexity of having two similar risk analysis documents for different purposes. Therefore, a notified body must 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. This may include:

a. Protection against electrical and mechanical, optical and acoustic hazards. Sharp edges, pointed corners, small part choking hazards. 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. If body-worn, then proximity to the body should be considered to be no greater than 5 mm.
d. If the product is intended to be used by children then their lower body mass for RF exposure should be taken into account. Children must be considered as vulnerable users.
e. If the product is intended to be used in a motor vehicle, consider if vibration, temperature extremes and possible distractions to the driver have been adequately addressed.
f. If the product can be reasonably foreseen to be used at high altitudes (above 2000 meters) then the basic clearance distances of EN60950-1 or EN62368-1 may well be inadequate and additional allowances should be made. Additionally, the other major effect of high altitudes is that the less dense air does not conduct heat as well. To compensate for higher operational altitudes, an NB should ensure the mitigation undertaken by the manufacturer is effective.

Article 3.1(b): Electromagnetic Compatibility

For Electromagnetic Compatibility 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.

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 EM disturbances below the lowest frequency of test on the power cable?
c. If the product has 'other' ports (i.e. other than power), have they been tested? If not, are they likely to cause radiated disturbances due to their length? How has the manufacturer mitigated this?
d. Does the product have telecom cables? Has testing been performed on these ports? If not, why? Is the mitigation reasonable under foreseeable circumstances?
e. Are the technologies within the product likely to cause EM disturbances above the highest frequency of test? Consider the operating frequencies of the product and what communication services should be protected (note many product standards now require testing to 6 GHz due to the multitude of radio services in the 1-6 GHz bands).
f. Are there any other unique factors within the product that should be considered (intentional radiators, but not radio communications, which are not covered by ISM frequency bands for example)?

Immunity:

a. Have all tests required by the applied product standards been done?
b. Are the applied product or generic standards appropriate for the EM 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 Common Mode transients and appropriate RF immunity tests been evaluated?
e. Have Transients and surges been evaluated if use in a vehicular environment is specified?
f. 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.

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 this will be done using radio harmonised standards but for combined equipment a manufacturer may have made use of ETSI guidance documents such as EG 203 367 which provides a guide 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. It also addresses issues to be considered in multi-radio equipment capable of simultaneous transmission. If a manufacturer follows this guidance document, 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 also 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 if 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 any radio dongle removed. Such advice may be practical for professional, trained, operators but not for domestic use).

NB's should also check if the receiver classifications are appropriate and that relevant and appropriate receiver protection tests have been performed. This may need careful consideration if the radio frequencies are not channelized.

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 applied such as Avalanche Beacons and Maritime Services Equipment; NBs must also ensure, in particular, that the relevant Article 3.3 (g) requirements have been satisfied and included in the risk assessment. This will normally be by applying the relevant harmonised standards.

Concern has been raised by the public, media, regulators and manufacturers alike about how radio equipment should be designed and if the measures taken by the manufacturer are adequate to meet the Essential Requirements of Article 3.3 (d), (e), (f) and (i) even though no Delegated Acts or harmonised standards have yet been developed. These specific requirements are currently entirely the manufacturer's own issue. They may choose to include them in their risk assessment and ask the notified body to comment on them but a notified body has no current mandate to reject a risk assessment on the basis of an apparent failure of the manufacturer to adequately support compliance to issues under Article 3.3 (d), (e), (f) and (i).

Conclusion:

It is recommended that NBs 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 have to 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 to cover all requirements of all legislative acts applicable to a given product or whether the product in question introduces also other risks not considered by the RED."

Annex (Informative)

This annex is intended to give some guidance to a notified body if 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 their obligations under Annex III, Part A, Module B, 3 (c) of Directive 2014/53/EU.

Current Situation:

Article 3.1(a) Health and Safety

A notified body should consider reasonably foreseeable conditions of use and the environment in which the product could be expected to be used. For example: if the product is a mast-mounted 60 Watt Radio Base Station is it likely that the intended purpose is indoor use below 2000 metres? Does the User Manual or accompanying literature encourage use or behaviour that is obviously inappropriate for the device? The action an NB can take may be limited in some cases but it does indicate if the risk assessment has been appropriately scoped.

The NB may reasonably look to see if the risk assessment addresses any issues that could result in the exposure of sharp or pointed edges and the release of small parts, caps, covers or batteries that could pose a risk to the user. The NB may also consider if the safety standard(s) that have been applied are valid for the time frame that the product will be placed upon The Market. For example the withdrawal dates of certain versions of the applied standards could be relevant to the risk assessment.

For products making use of headphones or certain types of acoustic interface an NB should consider if the mitigation applied by the manufacturer is effective and protects the user from acoustic shock or unnecessary alarm. The most vulnerable, reasonably foreseen, user should be considered as a likely subject for concern.

Similarly, for non-ionizing radiation (SAR) issues under Article 3.1(a) NBs should look for reasonable and foreseeable use of the product being addressed in the risk assessment. In most cases the application of harmonised standards will address this completely. Cases that may need further mitigation could be where the product is intended to be used in intimate contact with the human body, used internally for medical applications, with children or with animals. This does not mean that an animal analogue material needs to be used for the test work but rather a careful justification should be present as to why the test work performed addresses the care of the end user, even if an animal. For products that require the use of a lanyard or holster, an NB should determine if the reasonably foreseen needs of the elderly, disabled or vulnerable have been adequately considered in the risk assessment, for example: Does the lanyard disconnect satisfactorily? Can the product be inadvertently inserted in the holster in a reverse manner? Can the holster be used in an alternate position or orientation which would have an adverse effect on the SAR evaluation that has been performed?

If the product is for professional use, it is reasonable for the NB to consider how the training is provided and how effective it is in minimising the risk to the user(s).

Article 3.1(b) EMC

When a notified body is performing an EU-type examination assessment, the NB should be aware of the current situation for EMC performance below 150 kHz and above 1GHz. 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 EU. Examples are: EN 55014-1, EN 55015 and EN 55011. For the frequency range from 30 kHz to 150 kHz there is a draft presented (77A/980/CDV.IS until 2019-04-30). Based on these compatibility limits for symmetrical signals on wires; 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. So this means the general limits which are valid for all kinds of equipment are not yet readily available.

For EMC performance above 1 GHz, Radio Equipment Directive 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 has decided in its plenary 2017 to start work on establishing general available test methods and limits for products from 6 GHz to 40 GHz.

Additionally, above 1 GHz suitable Immunity limits can be derived from the ETSI EN 301 489 series of standards although these standards are primarily for use with Radio Products under Article 3.1(b) of Directive 2014/53/EU. Useful indications of Immunity limits up to 6 GHz can be obtained especially from EN 301 489-1. This is relevant for all products due to the universal presence of 5 GHz WiFi apparatus being commonly encountered in all operating environments.

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 where Clause 4.3.5.3.2 b) states:

> For carrier frequencies in the range 1 GHz to 20 GHz the frequency of the measuring receiver shall be adjusted over the frequency range 25 MHz to 10 times the carrier frequency, not exceeding 40 GHz. For carrier frequencies above 20 GHz the measuring receiver shall be tuned over the range 25 MHz up to twice the carrier frequency not exceeding 66 GHz. The frequency of each spurious component shall be noted. If the test site is disturbed by radiation coming from outside the site, this qualitative search may be performed in a screened room with reduced distance between the transmitter and the test antenna.

The associated limits are stated in Clause 4.3.5.4:

> The power of any spurious emission shall not exceed 2 nW in the range 25 MHz to 1 GHz and shall not exceed 20 nW on frequencies above 1 GHz.

Even though these are the Spurious Emission Limits applied to Intentional Radiators, it does give some expectation on the maximum limits that could be relevant for Unintentional Radiators which can be expected to exhibit few issues at these frequencies. However, due to the prevalence of microprocessor clock frequencies being in the GHz region it is recommended that particular attention be paid to minimising emissions in bands used for GPS systems, WiFi and cellular radio services.

For EMC performance below 150 kHz; for Radiated Spurious Emissions limits exist beside EN 55011, EN 55014-1 and EN 55015 also in EN 300 330: Clause 4.3.8.3 Table 5 may be considered useful which gives:

State	Frequency 9 kHz ≤ f < 10 MHz
Operating	27 dBµA/m at 9 kHz descending 3 dB/octave
Standby	5.5 dBµA/m at 9 kHz descending 3 dB/octave

For Emissions EN 55011:2016 + AMD1:2017: “Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement" has no limits from 9 kHz to 150 kHz but limits from 1 GHz to 18 GHz.”

Particular issues may arise in the foreseeable future due to Wireless Power Transfer Systems becoming more prevalent. Anticipated intentional field strengths, out-of-band and radiated spurious emissions that may occur in the vicinity of such systems can be found in draft ETSI standard ETSI EN 303 417 V1.1.1 (2017-09). 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, and legal use of the equipment.

Article 3.2 Effective and Efficient use of the Radio Spectrum

When performing an Annex III assessment NBs must ensure the Radio Equipment has been designed to make effective and efficient use of the Radio Spectrum. This includes “combined” and well as “stand-alone” radio equipment. This will normally be achieved by using radio harmonised standards but for combined equipment a manufacturer will likely have made use of ETSI guidance documents such as EG 203 367 which provides a Guide to the application of harmonised standards covering articles 3.1b and 3.2 of the RED to multi-radio and combined radio and non-radio equipment. It also addresses issues to be considered in multi-radio equipment capable of simultaneous transmission. If an NB checks to see the manufacturer has followed this guidance note (and others, such as TGN 01 and 31) then normally the issues of concern for complex types of radio equipment will have been covered.

When assessing combined radio equipment NBs should ensure that appropriate radio standards have been applied if the radio part can be operated without the device functioning. The NB should also check that if 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. They should also consider if 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 any radio dongle removed. Such advice may be practical for professional, trained, operators but not for domestic use).

NB’s should also check if the receiver classifications are appropriate and that appropriate receiver protection tests have been performed. This may be difficult if the radio frequencies used are not channelized and a pragmatic solution may have to be considered. For example: The harmonised version of EN 300 440 V2.1.1 does not have any Adjacent Channel Selectivity receiver limits for Class 2/3 receivers and no Blocking requirements for Class 3 receivers. Therefore a NB should review the approach the

manufacturer has taken to evaluate the performance of the radio receiver to ensure compliance with the Essential Requirements of the RED has been achieved and ensuring the adequate performance of the receiver.

It is recommended that NBs also check that any relevant Article 10(10) restrictions and labelling has been correctly applied and inform the manufacturer if these are considered inappropriate.

Article 3.3: Certain Radio Equipment shall meet particular Essential Requirements

Currently only Avalanche Beacons and certain Maritime Services Equipment have additional requirements applied under Article 3.3. NBs must also ensure, in particular, that the appropriate Article 3.3(g) requirements have been satisfied and included in the risk assessment. This will usually be achieved by applying the relevant harmonised standards.

There are no Delegated Acts or harmonised standards related to the essential requirements under Article 3.3 (d), (e), (f) and (i). Therefore, it is not within the remit of a notified body to make adverse comment or to reject a risk assessment on the basis these issues unless they are invited by the manufacturer to specifically consider and comment upon these points.

Disclaimer
This guidance document does not replace the text of the Radio Equipment Directive and is for guidance only. In legal disputes the text of the Directive or its implementation in National legislation takes precedence.

***** End of TGN30 *****