RED Notified Body Accreditation/Notification assessment Guide Document (V1.0c)

Introduction

This is the first issue of the accreditation/notification assessment guide for Notified Bodies under the Radio Equipment Directive (for year 2015).

The Radio Equipment Directive Article 3.1(a) and Article 3.1(b) do not require a manufacturer to involve a Notified Body even where the equipment has not followed the harmonised standards. However they (the manufacturer) are completely free to do so.
A formal question has been asked if a Notified Body can ask for an Article 3.2 assessment only, a formal answer has being received from the TCAM Chairman who emphasised that the NB/CAB should meet Article 34.3 of the RED which clearly mentions the Essential requirements of Article 3.
It is further noted that Article 29.2 which clearly indicates:
The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the radio equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 26.)
The view is that Art 26 only allows module choice and equipment choice, not the essential requirement choice.

Therefore the accreditation/notification should demonstrate meeting the requirements of the Annex, which includes the option to assess all relevant articles under the Directive. There is a presumption of conformity where a product has followed all relevant harmonised standards as listed in the Official Journal of Europe (OJEU) at the time the product is placed on the market.

The manufacturer does not need to ask a NB for an assessment if all relevant HS have been applied for Article 3.2 but MUST require an assessment where harmonised standards for Article 3.2 have not been followed in full, in order to receive an EU Type Examination Certificate from a NB in order to enter the market.

By being listed in NANDO an NB must accept any request from a manufacturer to assess a product even in cases where the Harmonised standards have all been applied by the manufacturer. This requires a certain level of technical knowledge, not just of standards, or those skills of an experienced test engineer. The Radio equipment Directive does not detail the expected technical knowledge. This Guide was produced in co-operation of UKAS (the UK accreditation Body) and the R&TTE CA committee to suggest a baseline skills level assessment to the EU and MRA Accreditation Bodies. This document will be reviewed annually.

The Notified Body has the role of technical evaluation, which can require a skill set with a mix of spectrum knowledge, co-existence studies, system reference document (SRDoc) and ESO (ETSI / CENELEC) standards body activity including some means of access to drafting groups.

These skills are rarely obtained from just testing products, and this document aims to guide the assessors as to a typical skill set expected for a Radio Equipment Directive Notified Body.

The Radio Equipment Directive Notified Body skill set is fairly unique around the world. It is different to some other certification and inspection skills, such as the Telecommunication Certification Body (TCB) for FCC, where the FCC makes the technical rules, and the TCB ensure the FCC technical rules are followed. The TCB cannot interpret areas where rules (standards) have not been followed; they have to ask the FCC for their agreement via the KDB process. A Radio Equipment Directive Notified Body does not have to ask permission from a National Authority before accepting a deviation; however they take on the liability themselves (one of the reasons for the requirement for professional indemnity and public liability insurance). Due to this high level technical decision making, there is a requirement to ensure the general technical competence of the Radio Equipment Directive Notified Bodies is at a sufficient level.

This document is a guide; alternative answers and explanations shall be considered by assessors and recorded as acceptable, or not, in the assessment report. As normal, further evidence may be requested for any area. It is not required for each member of the NB to meet this guidance, but across the NB team (if more than one person), the skills should be met.

Note: for all the "Whereas" statements (recitals) referred to within this document. They (the "Whereas" statements) are typically not directly legal requirements and hence may not be included in the National legislation. However it is considered important that the RED NB understand this "Whereas" information.

Checklist

Knowledge Area / Requirement	Question(s)	Y	N A	N	Expected content within answers
GENERAL REQUIREMENTS					
5.1 LEGAL & CONTRACTUAL					
Article 26.2 A conformity assessment body shall be established under national law of a Member State and have legal personality. (768/2008 Article R17.2 & draft EA2/17 5.1.1)	How does the NB demonstrate legal personality?				An example would be a Companies House listing in the UK.
5.2 IMPARTIALITY					

Article 26.3 A conformity assessment body shall be a third-party body independent of the organisation or the radio equipment it assesses. (768/2008 Article R17.3 & draft EA2/17 5.2.1)	How does the NB demonstrate independence? Does the NB identify risks to its impartiality?				[Look for guidance in 17020 / 17065 and ILAC P15?]
Article 26.4 A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the radio equipment which they assess, nor the representative of any of those parties. (768/2008 Article R17.4 & draft EA2/17 5.2.2)	How does the NB demonstrate they meet this requirement? Does their web site etc. suggest they offer consultancy?, how do they ensure their subsidiaries or subcontractors do not offer consultancy"?				This precludes involvement in the generation of any documentation or any justification for the technical construction files.
Article 26.5 Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or	What is "requisite technical competence", how is this interpreted, justified and documented? What are the knowledge, experience and qualification requirements expected for a member of the NB? How does the structure and policy demonstrate that the staff are free from financial inducements?				An example could be an electronic / telecommunications related engineering degree and 3 years relevant experience or 7 years relevant experience. Knowledge of ETSI Standards process; EFIS; SRDocs; sharing studies; co-existence. Professional membership; FEANI, Eur Ing; CEng (UK) Dipl. Ing (Germany), PE and equivalents may indicate a high level of technical knowledge, provided this is in a relevant field. They should also demonstrate their subject

groups of persons with an interest in the results of those activities” (768/2008 Article R17.5 & draft EA2/17 5.2.5)					related Continuing Professional Development (CPD) in topics related to the Radio equipment Directive, (Membership of the R&TTE CA / RED CA counts towards this).
Article 26.8 The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed. The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments. (768/2008 Article R17.5 & draft EA2/17 5.2.5)	How is this demonstrated? ISO 17020 / ISO 17065 – typically via an impartiality committee, the NB must not have a controlling interest in the voting of this committee. Review of contract of employment, including subcontractors as applicable? Do they have a NDA with the external impartiality committee members, including their declaration of competitive interests?				Minimum size for an impartiality committee is expected to be three (for small NB operations) the NB member, a 17020 / 17065 knowledgeable person, and a customer, all with equal voting rights. They should have a NDA signed with each external party, and consider adding a clause for the case where the NB disagrees with the findings, the NB can ask for a review from the Accreditation Body or Member State Authority.
5.3 LIABILITY & FINANCING					
Article 26.9 Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.	The NB shall produce a (time) valid certificate of liability insurance. Record what the value of the insurance is, is this appropriate for the work of the NB if they were to be sued?				NB should be able to provide a justification of the level obtained. They should also be able to demonstrate the insurer understands the NB’s activities. Typically this activity needs Professional Indemnity and Public Liability, appropriate to their and their customer location(s).

(768/2008 Article R17.9 & draft EA2/17 5.2.5)					
5.4 IDENTIFICATION OF NOTIFIED BODY					
Article 20.3 The CE marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Annex IV is applied. The identification number of the notified body shall have the same height as the CE marking. The identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorised representative. (768/2008 Article R12.3 & draft EA2/17 5.4.1)	Ask when NB number is applied to label. What is the size requirement of an NB number on a device? Where is it recorded that this is checked against the requirements of Annex VII, (including the simplified version)?				RED Annex IV is the old R&TTE CA Annex 5, Full quality Assurance. Size of NB number shall be the same size as CE mark.
STRUCTURAL REQUIRMENTS					
6.1 ROLE AS NOTIFIED BODY					
Article 26.6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III and IV in relation to which it has been notified, whether those tasks are carried out by the conformity	Review procedures to see if this requirement is met.				

assessment body itself or on its behalf and under its responsibility: (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities. (768/2008 Article R17.6(b) & draft EA2/17 6.1.1)					
6.2 COOPERATION					
Article 26.11 Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities, the regulatory activities in the area of radio equipment and frequency planning, and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of	Relevant standardisation activities – ETSI (possibly CENELEC as well). CEPT and ECC (frequency planning). NB Co-ordination group R&TTE CA or the successor – must be members as many documents are restricted to members only, members are listed on web site at http://www.rtteca.com/html/notified_bodies.htm.				

the work of that group. (768/2008 Article R17.11 & draft EA2/17 6.2.1)					
RESOURCES					
7.1 PERSONNEL					
Demonstrates a general understanding of the RED and associated documents and references.	EU Blue Guide [2014]				Access and knowledge of the guide.
	RE Directive				Knowledge of Directives relevant to NB, shall have a copy of the Directive and explain the general requirements. http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_153_R_0002&from=EN%20 For the RE Directive this should include the "effective and efficient" use of the spectrum.
	Understands and has a working knowledge of the harmonised standards as listed in the OJEU.				They should be able to direct you to the RED OJEU web page: If the RED OJEU is not available at the time of the assessment then ask for the R&TTE OJEU web page which is at: http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/rtte/index_en.htm
	Can correctly explain the date of				After the date of cessation of presumption of

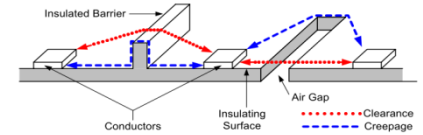
	cessation of presumption of conformity in the OJEU listings, including equipment in serial production?				conformity, all products placed on the market shall meet the requirements of the new standard, and the DoC must be updated (by batch / serial number) to reflect the change.
	Can a product be placed on the market after the date of cessation of presumption of conformity of an applied standard?				No, unless / until a comparison of the “old” superseded and new standards has been performed, and any new / updated requirement in the new standard has been completed. TCF and DoC will also need to be updated.
	Which equipment should fall within the scope of this Directive?				Whereas (6), Article 1.1, Article 2.1(1).
	Which equipment should NOT fall within the scope of this Directive?				The equipment detailed in Article 1.3 and Annex I
	Does Directive 2014/35/EU apply to radio equipment?				Whereas (7).
	Does Directive 2014/30/EU apply to radio equipment?				Whereas (8).
	Is there a requirement to “notify products” under the RED?				No.
	Where do you find individual country frequency allocation tables?				Referred to in Whereas (24) Ask to see the frequency allocation for a specific country of your choice.
	Are domestic animals and / or property included in this directive?				Yes, Whereas (26) and Article 3.1(a).
	What information on intended use needs to be supplied?				“Sufficient” – Whereas 30 has more guidance.

	What requirements can be used to give a presumption of conformity?				OJEU listed harmonised standards, see whereas (38).
	What is the minimum size of the CE mark, what is the “general” guide?				Whereas (44).
	Does CE marking have to appear on the packaging, where is this requirement given?				Whereas (45).
	How did the EU parliament express their concern about the level of performance of RTTE (RED) NBs?				Whereas (49).
	Regulation (EC) No 765/2008				Accreditation whereas (52). Non accredited (53).
	Sub Contract (ISO and RED)				Whereas (54).
	Are public safety (state security) radio included in this directive?				No, Art 1.3.
	Does equipment under the RED also fall under 2014/35/EU?				Only to the level in Article 3.1(a).
	Are antenna included in the Directive?				Article 2.1(1) definition of radio equipment includes antenna.
	Article 2.1(7) harmful interference				2002/21/EC clause 2 (r) Harmful interference' means interference which endangers the functioning of a radio navigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radiocommunications service

					operating in accordance with the applicable international, Community or national regulations.
	Who has responsibility for compliance of radio equipment with this Directive?				Economic operators: manufacturers, importers and distributers.
	What checks do you perform when assessing a Technical construction File?				More than just test reports being presented, there must be checks for consistency in frequency and radiated power etc. between test reports and all the other manufacturer supplied documentation, such as user manual and technical specifications. Correct schematics (minimum of Radio circuitry from baseband to antenna [port] especially reference oscillators, voltage regulatory circuits and any shielding for the RF areas). The TCF must detail how they have dealt with tested and untested variants. TCF content checklist (or actual documentary surveillance of a submitted file) must meet the requirements of Article 21 and Annex V of the RE Directive. If the TCF is updated to show compliance to updated standards, and the product has not been re-tested, has a justification been added to the TCF.
	What checks do you perform when assessing a Technical construction File?				Ask what process they use to ensure the equipment in the report was at the normal operating power and compared with the manufacturers declared power. Was it tested in a “typical” operating mode,

					who chose it (lab, manufacturer?) does it seem reasonable? Do the Schematics include component values (at least for the baseband to RF chain) or a Bill of materials? How were untested or partiality test variants of the main product assessed. Does the NB have enough technical knowledge to assess if the variants have been realistically assessed as untested or partially tested, and other results being acceptable from the main fully tested product? A comparison of the old and new version of the standards should be included, explaining why no further testing was performed, or why only partial testing was performed: - No further testing if no technical changes and the product has not changed Partial testing where a limit has changed, or a new test or test method is required, but no changes to the hardware.
	What checks do you perform when assessing an EU Declaration of Conformity?				EU Declaration of Conformity [DoC] NB should refer to Annex VI or a detailed checklist based on Annex VI. The DoC with must include the correct standards (including date of standard or version number).
Understands and has a working knowledge of the ETSI standards system.	1. Demonstrate access to the ETSI published standards? 2. How do they access information/standard for new				1. Via http://www.etsi.org/ should be able to check the requirements of the [ETSI] standard against the test reports. 2. Via http://portal.etsi.org/home.aspx and

	equipment and technology? 3. Explain the difference between ETSI Standards, ETSI harmonised standards and the standards listed in the OJEU?				demonstrate their ETSI log on. This access is needed when assessing product(s) that have not followed harmonised “OJEU” standards, such as ETSI draft versions that are still with the drafting group. If access is not possible, ask how they demonstrate access for any draft updates of standards to see if they include new technologies they may be assessing (this can be one of the reasons for a NB to be involved, testing to a draft standard which is not yet public domain). 3. Presumption of conformity comes from OJEU listed standards only. ETSI harmonised standards not listed in the OJEU do not give a presumption of conformity.
Understands and has a working knowledge of the ECO frequency allocation system for EU countries.	Demonstrate access to the EFIS web site, (http://www.efis.dk).				Demonstrate access to the EFIS web site. Chose a frequency and ask then to explain which technology / technologies can use it?
	Understands and has a working knowledge of Class 1 and class 2 requirements? Can go to EU web site, and explain the differences. Review at least on subclass and explain the limitations, can these be exceeded by a NB?				Ensure no alert symbol for RED, however frequency and power to be listed (Article 10 clause 8).
RED Article 3.1(a) Understands and has a working knowledge of RF Exposure requirements	Explain which standards could be applied. Explain SAR, head, body and extremity requirements.				Refer to OJEU listing for Article 3.1(a) – if the RED OJEU listing is not available, use the RTTE one for the assessment – the listing is likely to be the same.

	Explain measured and calculated requirements.				
RED Article 3.1(a) Understands and has a working knowledge of LVD requirements (very basic explanations in this initial document)	Explain the difference to the “standard” LVD requirements. Explain creepage and clearance. Explain creepage and clearance with reference a module integration. Explain creepage and clearance with reference module integration. Explain temperature limitations when incorporating a module into a final host (measured and component ratings). Explain critical components list.				No lower voltage limit. Removes the exclusion from assessment for most low voltage devices, ask if this change is checked and recorded when reviewing LVD test reports.  *Fig. 5. Definitions of Creepage and Clearance.* Although a module can be assessed in itself, it needs a further assessment when integrated into the host as clearance distances may be reduced etc. All components have a maximum temperature rating. Need to review the temperature when the overall equipment is at the maximum and minimum temperature range. A Module installed will probably be affected by heat from other components within the final enclosure. Typical safety critical components are, but not limited to, – Power supplies, transformers, X-caps, Y-Caps, resistors that bridge insulation, optocouplers, surge suppression devices, mains filters, mains switches, mains inlets/ outlets, fuses, thermal cut-outs, safety interlocks, mains lead etc.

The R&TTE CA have had some recent discussions on safety, and the following documents should be available to the NB "R&TTECA (14)52a German Ad Hoc Working Group on Safety Assessment Result Table 2014-12-08" And "R&TTECA (14)52b Safety Assessment German Notified Bodies RTTE CA Munich 2014-12-08rev01"	The NB should be able to produce these documents (downloaded from the CIRCABC web site or via alternative means) and discuss how they apply the content				
RED Article 3.1(b) Understands and has a working knowledge of EMC requirements	Explain the most common EMC standards for wireless devices. What is an "ancillary device" as stated in EN 301 489-1? Explain performance criteria and how it is monitored for wireless devices. Is this checked for applicability in the reports? Ask what standards need to be applied when a wireless device is added to another product, such as a TV or Fridge.				Must be able to refer to ETSI 301 489-X series Reference: ETSI EN 301 489-1 Annex C
RED Article 3.2 Understands the efficient and effective use requirement	Explain the general requirements for efficient and effective use. Can demonstrate a working knowledge of co-existence issues and considerations when dealing				Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference. RED will require receiver performance assessment as well as the transmit

	with products using new technologies that are not covered by harmonised standards. Can demonstrate technical knowledge to assess product variants (such as RF path) changes. Understands and has a working knowledge of equipment types requiring DFS and the DFS test requirements. Review at least one recent NB Opinion				characteristics. This is one of the changes from the RED compared to the R&TTE Directive. Should know where to find and be able to explain SRDocs, the function of CEPT and the interaction with ETSI and, for extreme cases, SEAMCAT. RF circuit knowledge sufficient to evaluate design and design changes, effects of tracks and component changes in RF path. Standards requiring DFS functionality. What do they expect to see to demonstrate that it cannot be disabled; how to demonstrate new firmware cannot disable DFS or expand frequency range outside the limits for EU. For 2015, a recent TCF should be evaluated. a) Do the recent (2015) R&TTE NB Opinion include an expiry date (latest should be 13th June 2017) b) do they have a process to remind their customers to update their TCFs and associated and NB documents if applicable (not compulsory)
RED Article 3.3.i	Understands and has a working knowledge of the software requirements, in and for, radio equipment?				Requirement to ask what features the manufacturer is expected to have implemented to enforce this statement.
Article 26.6 A conformity assessment body shall	Appropriate experience to perform the conformity				

be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III and IV in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks. (768/2008 Article R17.6(a) & draft EA2/17 7.1.1)	assessment tasks? What technical knowledge do they require of staff to perform the conformity assessment tasks? How does this demonstrate that the required level is sufficient? What do they consider is appropriate experience to perform the conformity assessment tasks? Where are the details of the above recorded for each NB team member?				

Article 26.7 “The personnel responsible for carrying out conformity assessment tasks shall have the following: (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified; (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments; (c) appropriate knowledge and understanding of the essential requirements set out in Article 3, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation; (d) the ability to draw up EU-type examination certificates or quality system approvals, records and reports demonstrating that assessments have been carried out.” (768/2008 Article R17.7 & draft EA2/17 7.1.2)	What do they require as “sound technical and vocational training”? What do they require for staff dealing with the “rubber stamp” jobs (use of harmonised standards only)? What do they require for staff dealing with jobs that involve the assessment where harmonised standards have not been used, or only used on part? What is their requirement to assess a satisfactory level of knowledge? When must a manufacturer use a NB?				A1) Degree + 3 years relevant experience or 7 years relevant experience (what is relevant experience, testing, compliance engineer?) A test engineer or compliance engineer may not have the knowledge of standards development, spectrum sharing studies, or a basic knowledge of RF circuitry in order to evaluate designs, if needed. A2) as A1) + knowledge of RF circuit design [filters, impedance matching, VSWR etc.], ETSI working group activities (via ETSI portal), CEPT and ERO, SRDocs, Co-existence studies and typical ETSI standards requirements including those for receiver parameters. Only if the manufacturer has not used harmonised standards (in full) for article 3.2. A NB opinion is not required for Article 3.1(a) or Article 3.1(b) regards if the manufacturer has used harmonised standards or not. Does the EU Type Examination Certificate cover the details required under the Directive.
7.2 EQUIPMENT					

Article 26.6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III and IV in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner. (768/2008 Article R17.6 & draft EA2/17 7.2.1)	Review to see if this requirement is met?				
7.3 OUTSOURCING					
Article 28 Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 26 and shall inform the notifying authority accordingly. (768/2008 Article R20.1 & draft	Does the NB subcontract any portion of the work for this Directive? Does the NB have a subsidiary that performs any part of the assessment?				If yes to either, how do they ensure the subsidiary / subcontractor meet the requirements set out in article 26 and those under the relevant ISO 17020 / 17065 accreditation. They shall produce the documentary evidence to support this.

EA2/17 7.3.1)					
Article 28 Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established. (768/2008 Article R20.2 & draft EA2/17 7.3.2)					
Article 28 Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client. (768/2008 Article R20.3 & draft EA2/17 7.3.3)					
Article 28 Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes III and IV (768/2008 Article R20.4 & draft EA2/17 7.3.4)					
INFORMATION REQUIREMENTS & CONFIDENTIALITY					
8.1 INFORMATION REQUIREMENTS					
Article 36.1	Review process / procedure and				

Notified bodies shall inform the notifying authority of the following: (a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval in accordance with the requirements of Annexes III and IV; (b) any circumstances affecting the scope of or conditions for notification; (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities; (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting. (768/2008 Article R28.1 & draft EA2/17 8.1.1)	Contract as applicable				
Article 36.2 Notified bodies shall, in accordance with the requirements of Annexes III and IV, provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same categories of radio equipment with relevant information on issues relating to negative and, on request, positive conformity assessment	A process is under development of the RTTE CA (RED CA) and will be available to all members. Member of the RTTE CA (RED CA) will provide a presumption of meeting this requirement. Documented alternatives for non-members shall be required. What data is sent for the “request positive conformity assessment results”				Typically technical parameters of the evaluated equipment. (Typically non-commercial information).

results. (768/2008 Article R28.2 & draft EA2/17 8.1.2)	How do they check the request is from another Notified Body?				Refer to NANDO database for email address of NB.
8.2 CONFIDENTIALITY					
Article 26.10 The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes III and IV or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected. (768/2008 Article R17.10 & draft EA2/17 8.2.1)	Is this part of their contract of employment (review contract) or a supplementary contract for the specific role (review)? Do they have a specific contract with the manufacturer stating the requirement to supply documents to the National Authority on reasoned request?				
PROCESS REQUIRMENTS					
9.1 GENERAL					
Acceptance of test data	Is there a mechanism or procedure in place to accept test data from an external testing laboratory? What rules are in place for the acceptance of test data? What is the basis upon which the rules				It should be considered acceptable to perform a reduced level of checking on a 17025 accredited report from a country under ILAC. The reduced level still needs to include checking the product details and the correct test cases have been applied, and noting any parameters which are passes within

	give confidence in the test data? Are these rules applied consistently? Is there a differentiation between ISO 17025 accredited reports and non-accredited reports? If so what is the process?				measurement uncertainty as this may affect the future compliance of the product. The Certificate should comment on parameters within measurement uncertainties. Where the reports are NOT 17025 then a far more detailed review of them should be performed, including checks of the equipment calibration (copies of calibration certificates), estimates of measurement uncertainties (if measurements are close to the limits) and a review of the CV of the person performing the testing (to assess if they are likely to be competent to perform the test).
Article 26.6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III and IV in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;	Review procedures to see if this requirement is met.				

(768/2008 Article R17.6(b) & draft EA2/17 9.1.2)					
Article 26.6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III and IV in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of radio equipment technology in question and the mass or serial nature of the production process. (768/2008 Article R17.6(c) & draft EA2/17 9.1.2)	Review procedures to see if this requirement is met.				
9.2 SCOPE					

9.3 OPERATIONAL OBLIGATIONS					
Article 34.1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes III and IV. (768/2008 Article R17.1 & draft EA2/17 9.3.1)	Request to see procedures and review against Annexes III and/or Annex IV depending on the scope of the NB.				
Article 34.2 Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the radio equipment technology in question and the mass or serial nature of the production process. In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the radio equipment with this Directive." (768/2008 Article R27.2 & draft EA2/17 9.3.2)	Review procedure to ensure additional requirements above those in the Directive (or their country National Legislation) is not being imposed on the customers.				
Article 34.3 Where a notified body finds that the	Review process / procedure and contract as applicable.				Any new product, even from the same series of production, shall be assessed against the newer version of the Standard. This may

essential requirements set out in Article 3 or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue an EU-type examination certificate or a quality system approval. (768/2008 Article R27.3 & draft EA2/17 9.3.3)					only need a paperwork exercise to compare the standards if there are no hardware / software changes to the product. There may be a need for partial testing or on some cases full testing. The TCF and DoC must also be updated. If Annex IV, must be reviewed. What about "normal" where NB issues certificate???
Article 34.4 Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality system approval, a notified body finds that radio equipment no longer complies; it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the EU-type examination certificate or the quality system approval if necessary. (768/2008 Article R27.4 & draft EA2/17 9.3.4)	Review process / procedure and Contract as applicable.				What does monitoring mean in practice?
Article 34.5 Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EU-type examination certificates or quality system approvals, as appropriate.					

(768/2008 Article R27.5 & draft EA2/17 9.3.5)					
Article 36.3 Notified bodies shall fulfil information obligations under Annexes III and IV. (768/2008 Article R28.3 & draft EA2/17 9.3.1)	As applicable – not all NB will be Annex IV				
9.4 CONFORMITY ASSESSMENT CRITERIA					
9.5 PREPARATION FOR ASSESSMENT AND CONTRACT REVIEW					
9.6 ASSESSMENT					
Article 10.2 Manufacturers shall ensure that radio equipment shall be so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.	How does the NB plan to check the equipment can be used in at least one country when new technology is in the equipment?				If product complies, in full, with Article 3.2 harmonised standards, with no deviations. Checks on the EFIS database. Possible to contact with at least one National Authority, within the EU, who agree it can be placed on the market on their country.
Article 10.10 In cases of restrictions on putting into service or of requirements for authorisation of use, information available on the packaging shall allow the identification of the Member States or the geographical area within a	The NB shall show where they record these have been (or will be) checked. Where there is a restriction this should be noted on the EU type examination certificate.				

Member State where restrictions on putting into service or requirements for authorisation of use exist. Such information shall be completed in the instructions accompanying the radio equipment…"					
Annex III Module B.1 and B.2 1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3. 2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).	What does the NB actually do when performing an assessment, (the wording infers more than reviewing reports)? How is the NB process described within the management system? Is there a procedure describing the process in sufficient detail to ensure consistency of application?				No requirement to examine a physical sample, review of technical document and supporting evidence.
Annex III Module B.3 The application shall include: (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well; (b) a written declaration that the same application has not been lodged with any other notified body; (c) the technical documentation. The	The NB shall demonstrate how they record that these specific application requirements have been met. How is the assessment of the application recorded? The NB shall demonstrate how they record that these specific application requirements have been met.				Note the reference to Annex V, the requirements to check this should be part of their checklist or procedure.

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 technical documentation shall contain, wherever applicable, the elements set out in Annex V; (d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.					
Annex III Module B.4 The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the radio equipment	What skills do they check to assess adequacy (may refer to earlier items in this guide)?				

Annex III Module B.5 The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations as provided in point 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.	Review NB Procedure(s).				
Annex III Module B.6. Where the type meets the requirements of this Directive that apply to the radio equipment concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. 1. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, 2. the aspects of the essential requirements covered by the examination, 3. the conditions (if any) for its validity and the necessary data for identification of the assessed type. The EU-type examination certificate may have one or more annexes attached. 4. The EU-type examination certificate and its annexes shall contain all relevant information to	The Certificate (or template Certificate) shall be checked for points 1 to 4. Standards by version number				

allow the conformity of manufactured radio equipment with the examined type to be evaluated and to allow for in-service control. Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.	or date In-service control (measurements within uncertainties?). Where is this documented?				
Annex III Module B.7 The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an	Such as OJEU list and notes, R&TTE CA and replacement, CEPT, ECO, ETSI Standards, ETSI WG activities….ADCO (and continuing education records relevant for the role) Where is this in their procedure? This requirement needs to be demonstrated, (Contract?).				

addition to the original EU-type examination certificate.						
Annex III Module B.8 Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued. Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the Official Journal of the European Union have not been applied or not been fully applied. The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted	Procedure? Records? How? (could be a list of NBs with email addresses?) What should be included in the email (Standards and failing parameters only?) Email list of member states? Via ADCO? EU Commission? Contract with customer to state this					

by the manufacturer for 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate.	is a legal requirement?? How does the NB ensure the files will be available for 10 years??					
Annex III Module B.9 The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market.	How has the NB made sure the Manufacturer is aware of the requirement?					
Annex III Module B.10 The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9 [above], provided that they are specified in the mandate.	If applicable, how is this recorded?					
Add in Annex IV module H checks						*ONLY FOR Annex 4, FQA. This will typically require a site visit to a current R&TTE Annex 5 customer for the assessment, or an initial assessment with a new customer for Annex 4 of the Radio equipment Directive.*
1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the requirements of this Directive that apply						

to it					
2. Manufacturing The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.					
3. Quality system 3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the radio equipment concerned. The application shall include: (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well; (b) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation shall contain, wherever applicable, the elements set out in Annex V; (c) the documentation concerning the quality system; and (d) a written declaration that the same application has not been lodged with any other notified body.					
3.2. The quality system shall ensure compliance of the radio equipment with the requirements of this Directive that apply to it. All the elements, requirements and provisions					

adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of: (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality; (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the radio equipment will be met; (c) the design control and design verification techniques, processes and systematic actions that will be used when designing radio equipment pertaining to the radio equipment type covered; (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out; (f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.; (g) the means of monitoring the achievement of the required design and product quality and the effective					

operation of the quality system.					
3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard. In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant radio equipment field and radio equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements. The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.					
3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.					
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any					

intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.					
4. Surveillance under the responsibility of the notified body 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.					
4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular: (a) the quality system documentation; (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.; (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.					
4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and					

applies the quality system and shall provide the manufacturer with an audit report.					
4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out radio equipment tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.					
5. CE marking and EU declaration of conformity 5.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each item of radio equipment that satisfies the applicable requirements set out in Article 3.					
5.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.					
6. The manufacturer shall, for a period ending 10 years after the radio equipment has been placed on the market, keep at the disposal of the national authorities: (a) the technical documentation referred to in point					

3.1; (b) the documentation concerning the quality system referred to in point 3.1; (c) the change referred to in point 3.5, as approved; (d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.					
7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.					
8. Authorised representative The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.					
ANNEX V CONTENTS OF TECHNICAL DOCUMENTATION The technical documentation shall, wherever applicable, contain at least the following elements:					Check procedures , process for the “Annex V checklist” checks.

(a) a general description of the radio equipment including: (i) photographs or illustrations showing external features, marking and internal layout; (ii) versions of software or firmware affecting compliance with essential requirements; (iii) user information and installation instructions;					
(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;					
(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the radio equipment;					
(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;					
(e) copy of the EU declaration of conformity;					
(f) where the conformity assessment module in Annex III has been applied, copy of the EU-type examination certificate and its annexes as delivered by the notified body involved;					
(g) results of design calculations made, examinations carried out, and other relevant similar					

elements;					
(h) test reports;					
(i) an explanation of the compliance with the requirement of Article 10(2) and of the inclusion or not of information on the packaging in accordance with Article 10(10).					
Annex VI EU DECLARATION OF CONFORMITY (No XXX) [DoC}					Check procedures , process for the “DoC ” content checks.
1. Radio equipment (product, type, batch or serial number):					
2. Name and address of the manufacturer or his authorised representative:					
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.					
4. Object of the declaration (identification of the radio equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the radio equipment):					
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: Directive 2014/53/EU Other Union harmonisation legislation where applicable					
6. References to the relevant harmonised standards used or references to the other technical					

specifications in relation to which conformity is declared. References must be listed with their identification number and version and, where applicable, date of issue:					
7. Where applicable, the notified body … (name, number) … performed … (description of intervention) … and issued the EU-type examination certificate: …					
8. Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:					
9. Additional information: Signed for and on behalf of: … (place and date of issue): (name, function) (signature):					
Annex VII checks SIMPLIFIED EU DECLARATION OF CONFORMITY					Check procedures , process for the "Simplified DoC" checks.
The simplified EU declaration of conformity referred to in Article 10(9) shall be provided as follows: Hereby, [Name of manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address:					