NIST TEL MRA Program

NB Assessment Checklist

Radio Equipment Directive (2014/53/EU) – RED Article 3.3g (mobile phones/Galileo)

Version 1.0 (January 30, 2023)

Introduction

- Radio Equipment Directive (RED) Article 3.3g on access to emergency services was expanded to include mobile phones. The requirements for essential requirement RED Article 3.3g (mobile phones/Galileo) have been applicable since March 17, 2022. See <u>Delegated Regulation 2019/320</u>.
- 2. There are no harmonized standard (hENs) references cited in the Official Journal of the European Union (OJEU) to address RED Article 3.3g (mobile phones/Galileo). Therefore, manufacturers placing mobile phones on the market in the EU are **required** to use the services of an RED Notified Body. The European Commission (EC) has published the following EC Guidelines for the notified bodies and manufacturers: <u>EC Guidelines for Compliance with Delegated Regulation 2019/30</u>

The aim of these EC Guidelines is to harmonize the approach/technical solutions. Other approaches/solutions are allowed with technical justification.

- 3. RED NBs that evaluate mobile phones for the RED may add RED Article 3.3g (mobile phones/Galileo) to their ISO/IEC 17065 Scope of Accreditation. Beginning in 2023, NIST requires inclusion of the applicable essential requirements (ERs) on the NB Scope of Accreditation. The ERs will be provided to the EC (via NIST NANDO notification). The ERs will be listed in NANDO (for public viewing). NBs will only be able to offer NB services for those ERs that are listed in NANDO.
- 4. This assessment checklist shall be used by the US accreditation bodies to document the competency assessment for RED NBs that are adding RED Article 3.3 g (mobile phones/Galileo) to their ISO/IEC 17065 Scope of accreditation.
- 5. It is acceptable for the assessment to add RED Article 3.3 g (mobile phones/Galileo) to be conducted remotely (if the accreditation body allows this).

TO BE COMPLET	ED BY THE ASSESSOR
Name of NB	
NB Number	
Accreditation Body Name	
Date(s) of Assessment	
Type of Assessment	
Assessor Name	
Assessor Signature	

Topics <i>References</i>	Requirement	NB Document Reference identified by NB or Other	Compliance (Y/N/NA)	Assessor Comments or Additional Assessor Instructions
1. Scope of Accreditation				
Reference: NIST	The NB's ISO/IEC 17065			
Requirements & Application	Scope of Accreditation			
for U.S. Conformity	includes mobile phones (a)			
Assessment Bodies Seeking EU	either directly, or (b) by			
Radio Equipment Directive	inclusion of all products			
(RED) 2014/53/EU Notified	covered under the RED on the			
Body Status, Section 4 (f) –	NB's Scope			
latest version				
2. EU Scheme Documents				
RED Article 26.6 (b)	The NB has access to the			
	Delegated Regulation			
	2019/320 <u>and</u> has			
	incorporated/referenced this			
	document in the NB's quality			
	management system.			
	The NB has access to the EC			
	Guidelines for Compliance			
	with Delegated Regulation			
	2019/320 <u>and</u> has			
	incorporated this document			
	into the NB's quality			
	management system.			
	The NB's certification			
	procedures address the			
	evaluation process for RED			
	Article 3.3g (mobile			
	phones/Galileo).			
	The NB's client application			
	addresses RED Article 3.3 g			
	(mobile phones/Galileo).			

3. Training Records				
RED Article 26.7 (a)	The NB maintains records of personnel training for RED Article 3.3g (mobile phones/Galileo).			Assessor: Please list names of trained personnel here:
4. EU TEC and Associated Evaluation Report				
	The NB has issued EU TECs that cover RED Article 3.3g (mobile phones/Galileo).	NB: Please add number issued here:	Assessor: Circle one: Y N/A	Assessor: Please list the number of EU TECs issued for RED Article 3.3g (as of date of assessment):
RED Annex III, Module B, 3 (c) & 4	The NB records demonstrate that the NB is receiving <u>and</u> reviewing the manufacturer's <u>analysis and assessment of</u> <u>risk</u> for RED 3.3g (mobile phones/Galileo).			
RED Annex III, Module B, 5	The NB's evaluation report/record documents the objective evidence provided by the applicants to address RED 3.3.g (mobile phones/Galileo).			
RED Annex III, Module B, 6	The NB's EU TEC correctly addresses RED Article 3.3 g (mobile phones/Galileo).			
EG RE (06) Q&A, Item 21, last paragraph	The NB is aware of the EC's interpretation that (a) the RED essential requirements are considered separate "aspects",			

	(b) that a manufacturer may use a different NB for each "aspect" or essential requirements and (c) may identify more than one RED NB on its DoC.		
5. Technical Competency*			
RED Article 26.7 (a-d) EC Guidelines for Compliance with Delegated Regulation 2019/320	The NB personnel correctly explain the content of the EC Guidelines for Compliance with Delegated Regulation 2019/320 and understand the		*Assessors: Please refer to the technical guidance document provided to NB ABs to formulate appropriate technical questions.
	approaches to be taken.		