Appendix A: Comparative table of roles and competences specified in Annex C to ERA Assessment Scheme (Technical Document 000MRA1044 v. 2.0)

Decision maker	Technical reviewer	Technical lead evaluator	QMS lead auditor	QMS auditor	Inspector	Lead inspector
			Description			
The person(s) assigned to make certification decision as described in 7.6.2.	The person assigned for reviewing all the information and results related to the evaluation as described in point 7.5.1 of EN ISO/IEC 17065.	For each individual project, where inspection and auditing activities are required, a technical lead evaluator shall be appointed. This technical lead evaluator has the overall authority and responsibility to ensure that all project activities of the evaluation phase are correctly prepared, executed and documented in reports and other records as described in point 7.4 of the EN ISO/IEC 17065. Therefore, the technical lead evaluator shall set up a project team according to the requirements of the ERA Assessment Scheme to cover all the evaluation activities.	The QMS lead auditor has the overall authority and responsibility to ensure that all project auditing activities of the evaluation phase are correctly prepared, executed and documented in reports and other records as described in point 7.4 of the EN ISO/IEC 17065. QMS lead auditor supports the technical lead evaluator in the QMS audit activities.	The QMS auditor supports the QMS lead auditor.	The inspector supports the technical lead evaluator in performing the activities related to inspections within the scope of assessment. Where appropriate, the inspector may support the auditor or the lead auditor acting as technical expert. The inspector may also act as mentor to other inspectors.	The lead inspector has the overall authority and responsibility to ensure that all project inspection activities of the evaluation phase are correctly prepared, executed and documented in reports and other records as described in point 7.4 of the EN ISO/IEC 17065.
			Training and experience			
			General			
One or more of the following possibilities shall apply: › MASTER university degree (or equivalent) in a relevant subject						
+ 6 years of proven professional experience preferably relevant for the railways;	+ 3 years of proven professional experience preferably relevant for the railways;	+ 3 years of proven professional experience relevant for the technical scope in which the person is intended to work;	+ 3 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways;	+ 1 year of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways;	+ 3 years of proven professional experience relevant for the technical scope in which the person is intended to work;	
› BACHELOR university degree (or equivalent)						
+ 8 years of proven professional experience preferably relevant for the railways;	+ 5 years of proven professional experience preferably relevant for the railways;	+ 5 years of proven professional experience relevant for the technical scope in which the person is intended to work;	+ 5 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways;	+ 3 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways;	+ 5 years of proven professional experience relevant for the technical scope in which the person is intended to work	
› Relevant technical vocational trainings in the field of the scope of the assessment of at least 2 years						
+ 11 years of proven professional experience preferably relevant for the railways.	+ 8 years of proven professional experience preferably relevant for the railways.	+ 8 years of proven professional experience relevant for the technical scope in which the person is intended to work.	+ 8 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways.	+ 6 years of proven professional experience relevant to quality management systems relating to a technical area, preferably in railways.	+ 8 years of proven professional experience relevant for the technical scope in which the person is intended to work.	
			Specific in addition to General			

Specific in addition to General:

Decision maker	Technical reviewer	Technical lead evaluator	QMS lead auditor	QMS auditor	Inspector	Lead inspector
Sound knowledge and understanding of the relevant requirements for the CAB certification processes based on EN ISO/IEC 17065 and the testing, inspection and auditing processes based respectively on EN ISO/IEC 17025, EN ISO/IEC 17020 and EN ISO/IEC 17021-1.	› Training (internal or external) on the relevant requirements for the CAB inspection processes based on EN ISO/IEC 17020, EN ISO/IEC 17021-1 and EN ISO/IEC 17065;		› Training (internal or external) on the relevant requirements for the CAB inspection processes based on EN ISO/IEC 17020 and EN ISO/IEC 17065;			› Proven experience of at least 1 year as mentoring period according to EN ISO/IEC 17020 point 6.1.6 including minimum participation in more than one project and documented final positive assessment of his/her competences in the relevant technical scope in which the person is intended to work as inspector.

For the Technical reviewer / Technical lead evaluator columns:

- › Proven experience (e.g. 5 completed projects) in any scope of assessment (cf. Annex D), with at least one in the following roles: lead inspector or QMS lead auditor. *(Technical reviewer)*
- › Proven experience (e.g. more than one completed evaluation project) in any the scope of assessment (cf. Annex D) as at least one of the following: (lead) inspector and/or QMS (lead) auditor. *(Technical lead evaluator)*

For the QMS lead auditor / QMS auditor columns:

- › Specific training as auditor (internal or external) based on the EN ISO/IEC 17021-1 lasting at least 5 working days or 40 hours of classroom style training

for lead auditing;	for auditing;

› Participation in QMS audits in the railway domain as follows:

a) For *initial nomination* as

Lead auditor	QMS auditor
Participation in at least:	
3 QMS audits:	2 QMS audits:

- with one of them related to the IOD;
- in a team of at least 2 persons;
- with a duration of at least one day;
- at least at the level of "auditor in training" (reference to 9.2.2.1.4 of EN ISO/IEC 17021-1)

Decision maker	Technical reviewer	Technical lead evaluator	QMS lead auditor	QMS auditor	Inspector	Lead inspector
			- during the last 24 months before nomination as QMS lead auditor.			
			b) For *maintaining the status* as			
			as Lead auditor	QMS auditor		
			Participation in at least 1 QMS audit: - related to the IOD; - in a team of at least 1 person; - with a duration of at least one day; - during the last 36 months;			
			- at the level of "lead auditor".	- at the level of "QMS auditor".		
			c) For *re-nomination* as			
			Lead auditor	QMS auditor		
			(where requirement b) has not been met)			
			Participation in at least 1 QMS audit: - related to the IOD; - in a team of at least 2 persons; - with a duration of at least one day; at least at the level of "auditor in training" (reference to 9.2.2.1.4 of EN ISO/IEC 17021-1) during the last 6 months.			

Legal framework

Decision maker	Technical reviewer	Technical lead evaluator	QMS lead auditor	QMS auditor	Inspector	Lead inspector
Sound knowledge and understanding on the following topics: › IOD 2016: EC conformity assessment, EC suitability of use, EC verification, Article 15 and Annex IV on the role of NoBo in the process of verification; authorisation for the placing in service of fixed installations; vehicle authorisation for placing on the market; role of applicant, NoBo, DeBo, Assessment bodies under the CSM-RA, and where relevant, under PA VA; upgrade/renewal of an existing subsystem; European legal framework and National legal framework. › Railway modules: Decision 2010/713/EU on railway modules, difference between module with QMS and without QMS, applicable modules according to TSIs. › TSIs: Text structure, affected subsystem per TSI, concepts of mandatory standards, harmonised standards, industrial standards, acceptable means of compliance, alternative solutions. › Only for mobile subsystems (rolling stock and on-board control-command and signalling subsystems): PA VA.			› General knowledge and understanding of railway related European legal framework, including vocabulary (e.g. IOD 2016, TSIs and modules, Regulation 2019/250)			
› RSD 2016: Regulation on CSM-RA, legal text and Annex I.			› General application of an QMS and relevant aspects of safety related aspects of a project when applied to the railway technology production process; › Typical operation and maintenance of the product; › Typical design/production defects of this or similar products/ technology and on previous defects of which have materialised in previous applications of this or similar products/ technology – limited to those defects which could interfere with safety, health, the environment or any other essential requirement as defined by IOD 2016.			
› Regulation 2019/250: the templates for 'EC' declarations and certificates for railway interoperability constituents and subsystems, the declaration of conformity to an authorised railway vehicle type and on the 'EC' verification procedures for subsystems.	› Interrelations to the RSD 2016 and to the Regulation on CSM-RA: allocation of roles and responsibilities and risk and safety management. › EN ISO/IEC 17065 and the relevant requirements for the CAB evaluation processes based on EN ISO/IEC 17020, EN ISO/IEC 17021-1 and EN ISO/IEC 17025 in combination with the ERA Assessment Scheme. › ERA documents: technical opinions, technical advices, technical documents, ERA guidance, lines to take, etc. › Documents of the Coordination group of the Notified bodies (Article 44 of IOD 2016): RfU and Q/C.					
	General knowledge and understanding of the following topics: › Modules based on quality assurance: general knowledge and understanding of auditing procedures. › Technical standards: depending on the scope of the assessment: - of the content of the standards quoted in the applicable TSIs, and - ability to understand and evaluate the content of the industrial standards which can be used at designing or manufacturing phases.	› Health and safety requirements: competence of general procedures to manage staff safety for performing on site activities (e.g. tests under energised equipment, with rolling stock in motion, in factories, etc.).				

Technical topics

Decision maker	Technical reviewer	Technical lead evaluator	QMS lead auditor	QMS auditor	Inspector	Lead inspector
› General knowledge and understanding of all the areas from Annex D. (Normative) List of technical topics per scope of assessment.			› Sound knowledge and understanding of relevant parts of Annex D. necessary to achieve the intended results of the audit they are expected to perform.		› Sound knowledge and understanding of relevant parts of Annex D. › Sound knowledge and understanding of the interfaces with other technical scope related to interoperability and safe integration; › Technical standards: depending on the relevant parts of Annex D: - General broad overview of the content of the standards quoted in the applicable TSIs, and - Ability to understand and evaluate the content of the industrial standards which can be used in the designing or manufacturing phases.	
			› The QMS lead auditor	› The QMS auditor		
			can be accompanied by technical experts as point 9.2.2.2.2 of EN ISO/IEC 17021-1 to fulfil these requirements.			

Non-technical skills

Decision maker	Technical reviewer	Technical lead evaluator	QMS lead auditor	QMS auditor	Inspector	Lead inspector
› Proven ability to apply sound professional judgement;		› Ability to manage on on-going basis the project activities for evaluation; › Ability to form and coordinate a project evaluation team; › Ability to manage subcontracted project evaluation activities; › General knowledge of manufacturer's quality management system methodology i.e. ISO 9001;	› Auditing skills and knowledge: generic and appropriate for specific scope of assessment; › Desired personal behaviour as described in Annex D of EN ISO/IEC 17021-1;		› Ability to prepare and update assessment plans for the projects, including the assessment requirements; › Ability to supervise inspectors under supervision works; › Ability to analyse, judge and make decisions; › Ability for appropriate project and self-organisation; › Effective communication skills; › Writing and editing skills for preparing technical reports; › Good quality of work; › Impartial and non-discriminatory behaviour.	
› Ability to understand and evaluate technical documents that are part of the Evaluation file to allow him/her to make a justified certification decision; › Ability and authority to provide or not provide the certification if the product evaluation project does or does not fulfil the quality requirements.	› Knowledge and understanding of the interfaces with other technical scope related to interoperability and safe integration; › Ability to analyse and verify that the technical documents that are part of the Evaluation file cover all relevant requirements; › Ability to recommend or not recommend the certification if the product evaluation project does or does not fulfil the quality requirements; › Good quality of work; › Impartial and non-discriminatory behaviour.		› Complete list of audit criteria of the complete project; › Form and direct an audit team; › Quality management requirements of relevant railway standards; › Relevant TSIs aspects; › Relevant modules; › Understand interface with common manufacturer certification (e.g. ISO 9001).	› Auditing skills and knowledge: generic and appropriate for specific scope of assessment.		› Proven competence in project management and in the most spread project management IT tools; › Ability to prepare assessment plan, including assessment requirements; › Ability to form and direct project teams; › Ability to coordinate inspectors' works; › Ability to supervise subcontracted activities.
		The technical lead evaluator may be supported by: › (lead) inspectors for inspection activities (ref. Annex G of this document), and; › (lead) auditors for the quality management system approval (ref. Annex H of this document).	If needed, the QMS lead auditor can be supported by QMS auditors.			If a project involves several inspectors or subcontracted activities, one inspector shall be nominated as "lead inspector".