



Supported by
NB-Rail Association

RECOMMENDATION FOR USE

NB-RAIL COORDINATION GROUP

Administrative Decision according to Interoperability Directive
(EU) 2016/797 art. 30.6



Co-funded by
the European Union

RFU-STR-036

Issue 02

Date 23/06/2020

TITLE

Certified quality management system of manufacturers and/or applicant

ORIGINATOR

CERTIFER / BELGORAIL

SUBJECT RELATED TO

IOD 2008/57 and IOD 2016/797
MODULES WITH QUALITY
ASSESSMENT

AMENDMENT RECORD: ISSUE 02, IOD REFERENCES UPDATE

DESCRIPTION AND BACKGROUND EXPLANATION

In modules related to Quality Management Systems (QMS) assessment, the sentence "When the manufacturer operates a certified quality management system, the notified body shall take this into account in the assessment." deserve an explanation in NBRail for a common understanding.

If the 'certificate' is a quality system approval issued by a NoBo, it must be accepted and no additional assessment is necessary on exactly the same Interoperability Constituent or Subsystem.

If it's an ISO9001 certificate, there are conditions related to the certificate itself, and a method to take it into account.

UNIFE reported in CSG different interpretations of this sentence by different NoBos.

RFU PROPOSAL

CONDITIONS: the Notified Body will take into account a QMS certificate if:

1) This certificate is issued by a QMS certification body under accreditation by a signatory of the "European co-operation for Accreditation (EA) Multilateral Recognition Arrangement (MLA) For Quality Management System" (the updated list of signatories is available on the website: <http://www.european-accreditation.org>).

and

2) The QMS implemented on the Interoperability Constituent (IC) or Subsystem (SS) is really in the scope of this QMS certificate in terms of:

- products included in the certificate,
- phases (design + manufacturing + installation + tests) included,
- geographical units included,
- dates of validity.

METHOD: If the QMS certificate fulfils the above conditions:

The Nobo will make a detailed assessment of QMS specific documents and records (related to the phases required by the TSI) of the concerned IC/SS only (Project Quality Plan, Project Management Plan, design review, ...) and should not completely assess again the Quality Manual and all the general procedures already assessed by the QMS certification body.

THIS RFU WAS AGREED ON



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PLENARY MEETING 059

THIS RFU ENTERS INTO FORCE ON

23/06/2020 (DATE OF PUBLICATION)

FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION.

RFU APPLICATION IS MANDATORY STARTING FROM

23/06/2020

AT THIS DATE ANY PREVIOUS VERSIONS OF THIS RFU WILL BE WITHDRAWN.

RFUs SHALL BE APPLIED BY ALL NOBOS. PLEASE REFER TO RFU-STR-702, CHAPTER 3 OF THE SECTION "DESCRIPTION AND BACKGROUND EXPLANATION", FOR THE LEGAL BASIS SUPPORTING THIS OBLIGATION.

ERA COMMENTS

PLE 059 – 17/06/2020: NO COMMENTS