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PROCEDURE FOR DESIGNATION OF CONFORMITY ASSESSMENT BODIES (NOTIFIED BODIES) IN RAIL TRANSPORT

/First Version/

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1. SCOPE AND OBJECTIVES

1.1. This procedure is developed in compliance with:

- Chapter 6 (a) of the Law for Railway Transport
- Ordinance No 57 of June 2004 establishing the conditions and essential requirements for railway infrastructure and rolling stock, in order to achieve interoperability between the national railway system and the Trans European railway system. (introducing Directive 96/48/ЕО; Directive 2001/16/ЕО);
- Art. 13 (a), paragraph 2, item 1 of the Rules of Procedure of the Railway Administration Executive Agency (RAEA);

1.2. The objective of this procedure is to establish a standardized and equal approach to assessment of applicant competency and his ability to fulfill the requirements for execution of conformity assessment procedures related to interoperability constituents and subsystem verification, for which the candidate applies, in accordance with the legislative requirements.

2. RESPONSIBILITIES

In order to carry out the activities covered by this procedure the following units shall take responsibility:

2.1. Minister of Transport shall:

- Make a decision on issuance of conformity assessment permission or justified refusal;
- Issue permission for execution of conformity assessment activities or justified refusal.

2.2. Executive Director of RAEA shall:

- Assign the examination of submitted application and all enclosed documents for issuance of conformity assessment permission for the interoperability constituents and subsystems verification;
- Sign notification letters for submission to the applicant;
- Approve the members of the auditing committee (by written order), whose task is to examine applicant’s documentation.
- Approve the members of the auditing committee (by written order), whose task is to carry out on applicant’s site checks.
- Make a proposal to the Minister of Transport to issue or to refuse the issuance of conformity assessment permission for interoperability constituents and subsystem verification.

*NOTE 1: Same person shall be appointed as lead assessor in both auditing committees.

2.3. Chief Legal Advisor shall:

- Monitor if the procedure is in compliance with the legislative requirements related to the issuance of permission for conformity assessment of interoperability constituents and subsystem verification.
### PROCEDURE

**DESIGNATION OF CONFORMITY ASSESSMENT BODIES (NOTIFIED BODIES) IN RAIL TRANSPORT**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-ordinate the draft of conformity assessment permission or justified refusal which is enclosed in the final report of the lead assessor;</td>
<td>3</td>
</tr>
</tbody>
</table>

#### 2.4. Director of Interoperability Directorate shall:

- Allocate the activities related to the issuance of permission for conformity assessment of interoperability constituents and subsystems verification for each specific application;
- Co-ordinate all notification letters for submission to the applicant.
- Co-ordinate a draft order for submission to the Executive Director of RAEA concerning appointment of the lead assessor and members of the committee, who will examine the application and the enclosed documentation.
- Co-ordinate a draft order for submission to the Executive Director of RAEA concerning appointment of the lead assessor and the members of the committee, which will execute the on site check.
- Review the reports of the lead assessor and the team of assessors, who examine the documentation and execute the on site check.

#### 2.5. Head of Notification and Registration Department shall:

- Draw up a draft order for submission to the Executive Director of RAEA regarding appointment of the lead assessor and the committee members, who will examine the application and the enclosed documentation.
- Draw up a draft order for submission to the Executive Director of RAEA regarding appointment of the lead assessor and committee members, who will execute the on site check.
- Review the reports presented by the lead assessor and the team of assessors related to the examination of applicant’s documentation and the on site check.
- Prepare letters of notification for submission to the European Commission and Member States concerning the notification of conformity assessment bodies through EC NANDO Input system.
- Keep the files and provide access to them.

#### 2.6. Lead Assessor shall:

- Be the head of a committee, appointed by an order of the Executive Director of RAEA, for the examination of applications and all enclosed documentation;
- Draw up notification letters for submission to the applicant;
- Draw up a plan for on site checks.
- Co-ordinate on site check plan with the applicant.
- Manage on site check and draw up a report on the results of it.
- Provide applicant with a copy of on site check report, which is accompanied by the lists of established nonconformities;
- Approve the corrective actions and the deadline for their execution proposed by applicant.
- Check the activities undertaken by the applicant in order to rectify the nonconformities;
PROCEDURE
DESIGNATION OF CONFORMITY ASSESSMENT BODIES (NOTIFIED BODIES) IN RAIL TRANSPORT

- Draw up a final report on the results of the work executed by the committee related to documents examination and on site checks.
- Draw up a general report* (based on the final reports) for submission to the Executive Director of RAEA with a copy to the Director of Interoperability Directorate and the Head of Notification and Registration Department on established compliance or noncompliance of application filed and documents enclosed with national legislation requirements.
- Draw up a draft permission for performance of activities related to conformity assessment of the interoperability constituents and subsystem verification;
- Draw up a draft letter which contains a justified refusal for issuance of permission;
- Complete the documentation file of the applicant who was or was not issued a conformity assessment permission, or was refused such;

2.7. Committee for examination of documents and execution of on site checks (assessors and/or technical experts) shall:

- Examine whether the application and the enclosed documents are in full compliance with the legislative requirements, for which each member of the committee shall deliver validated opinion having into account the responsibilities contained in the order of the Executive Director;
- Execute on site checks where every member shall reflect the nonconformities established by him in a validated report for submission to the lead assessor and accompanied by the relevant lists of established nonconformities (Appendix 4);
- Examine the implementation of approved corrective actions.
- Draw up final reports for submission to the Executive Director on the work executed by the committee. These reports shall be signed by each member of the respective committee.

3. STAGES OF THE PROCEDURE

3.1. The verification and assessment procedure of applicants shall include:

3.1.1. Receipt of application (Appendix 1), accompanied by documents referred to in Art. 115 (b) of the Law for Railway Transport and Ordinance No 57 – Chapter 6, section 1 Assessment Bodies”, part I (a) “Issuing of Conformity Assessment Permission”.

3.1.2. Examination of filed application and enclosed documents for establishment of its compliance with legislative requirements;

3.1.3. Execution of on site check;

3.1.4. Delivery of information and data related to the applicant to the European Commission for obtaining identification number of the applicant who has been approved to carry out conformity assessment under the NANDO Input system (Notification of the applicant);

3.1.5. Issuance of conformity assessment permission or justified refusal.
3.2. The procedure shall be open after submission of an application form (Appendix 1) filled in by the applicant and accompanied by a set of documents in compliance with the Law for Railway Transport and Ordinance No 57.

3.2.1. The application form with the accompanying documents shall be filed at RAEA Registry office and shall be given a reference number.

3.2.2. The application with its reference number shall be submitted to the Executive Director of the RAEA who shall assign its implementation to the Director of Interoperability Directorate.

3.3. The applicant’s set of documents shall consist of the following:

3.3.1. Written application form as specified in Appendix N 1, which determines the activities and the subsystems to be assessed, and for which permission is required. Subcontractors can be used, and the following:

- Court order for registration and a certificate for actual commercial registration issued not earlier than one month prior to the application lodging or EIK, issued by National Registry Office.

- Certificate of Liabilities issued by the National Revenue Agency which proves whether the body has no liabilities towards the state and municipal authorities in the context of the Tax Social Security Proceedings Code.

- Reference in tabular form containing information on interoperability constituents and/or subsystems subject to the application, their characteristics, assessment and verification procedures, as well as the names of laboratories where they will be tested, if it is required by the conformity assessment and verification procedure.

- Reference of the technical facilities and equipment of their own laboratories and/or of subcontractors with whom contracts are concluded and completed with identification numbers and numbers of the calibration certificates, in possession of applicant’s own laboratories and/or of laboratories with which the applicant has concluded contracts;

- Written declaration by the applicant certifying that he is in possession of standards required by TSI and national technical requirements needed for performance of conformity assessment activities and verification, and a list consisting of names of applicable standards and national technical requirements according the scope in application form;

- Conformity assessment methods and rules where the conformity assessment is not carried out in compliance with the indicated TSI rules;

- Description of the organizational structure of the applicant (organization chart);

- List of employees, copies of employment or part-time employment contracts, CVs of the employees with their professional and technical experience, certificates of completed education level and certificates of qualification;
• Declaration, which verifies, that the Body meets all criteria, laid down in Art. 115 paragraph 2, item 3 and 4; (b) and 5 of the Law for Railway Transport as well as a personal declaration verifying that every employee meets the same criteria. (declarations about independence and impartibility of NoBo personnel);

• Body insurance contracts concluded for damages, which may occur as a result of conformity assessment activities;

• Document certifying whether the Body has not been declared insolvent and the court and the creditors have not instituted bankruptcy or liquidation proceedings;

• Quality Manual and quality procedures according requirements of BDS EN 45011 and/or BDS EN 45012 and/or BDS EN ISO/IEC 17020 and/or BDS EN ISO/IEC 17025 and working procedures required.

• Quality procedure defining how Subcontractor activities shall be monitored and written declaration stating that the NoBo will maintain actual list of used subcontractors and activities agreed upon;

• Contract with subcontractor on conformity assessment activities, if any;

• Copies of the certificates of accreditation of laboratories (if any);

• Copy of auditor's certificate (certificate for third party auditor) and other documents performing its professional experience as auditor according to BDS EN ISO 19011 requirements, completed education and other additional documents/certificates, if any. 

Above mentioned documents has to be performed in case if the NoBo has in its scope conformity assessment procedure requiring evaluation of producer’s quality system;

• Certificate of paid fees according to Tariff No 5 for the fees collected by the Ministry of Transport;

• Other required documentation according to the Law for Railway Transport and Ordinance No 57;

3.3.2. In order to implement the requested activities the applicant for NoBo may use subcontractors upon satisfaction of the provisions of Art. 56, paragraph 1-4 of the Ordinance No 57;

3.3.3 The Subcontractors should meet the requirements of Art. 115 (b) paragraph 2, item 1-5 and item 8 and 9, paragraph 3 of the Law for Railway Transport;

3.3.4. Where the applicant for NoBo submits copies of accreditation as per Art. 45, paragraph 5, item 6 of the Law for Railway Transport and/or BDS EN 17025, BDS EN 17020, BDS 4501, BDS EN 45012 for performance of the respective interoperability constituents conformity assessment procedures and subsystems of the railway system, declaration under Art 56 “c” paragraph 2, item 6 of Law for Railway Transport, the
Applicant shall not be subject to submission of Declaration as per Art. 56, paragraph 2, item 6 of the Law for Railway Transport.

3.4. The Executive Director of RAEA shall assign to the Director of Interoperability Directorate to process the application filed.

4. EXAMINATION OF APPLICANT DOCUMENTATION

4.1. The examination of applicant documents is carried out by the Committee, appointed by written order of the Executive Director of RAEA. After the examination, the committee shall draw up a report and submit it to the Executive Director on compliance of the contents with the provisions of Art. 115 (b) of the Law of Railway Transport and Ordinance No 57, Chapter 6, Section I “Assessment Bodies”, Section I (a) “Issuing of permissions for conformity assessment”;

4.2. Whereupon the examination of applicant documentation nonconformities are established the applicant shall be notified in writing to weed them out within 30 days. Nonconformities shall be deemed as rectified/corrected after estimation by the committee carried out the examination of the documents.

The deadline as it is defined in Art. 56 (d) paragraph 1 of Ordinance No 57, shall be prolonged in accordance with the time-period needed for elimination of the nonconformities, as per Art. 56 (d) paragraph 2 of Ordinance No 57.

4.3. The Committee shall accomplish its activities with a final report for submission to the Executive Director of RAEA related to the documents examined and their compliance with the legislative requirements.

4.4. When the report to the Executive Director of RAEA on the examination of the documents is completed with the conclusion that the contents of the application documents correspond to the legislative requirements, the applicant shall be notified in writing that he successfully proceeds to the next stage, as defined in item 5;

4.5. The letters subject to item 4.2 coordinated with the Director of Interoperability Directorate and/or with the Head of Notification and Registration Department shall be signed by the Executive Director and submitted to the applicant.

4.5.1. The letters shall be sent to the applicant by RAEA Registry office by registered post and advice of delivery.

4.6. Where the nonconformities are not rectified within the defined term-period, the committee responsible for the examination of documents shall draw up a justified refusal to the applicant;

4.7 Upon establishment of compliance of the application and enclosed documentation the applicant shall be notified in written form for his successful proceeding to the next stage.

ON SITE CHECK (AUDIT)

5.1. On site check shall be executed by the Committee, appointed by the Executive Director of RAEA. (by written order)
5.1.1. On site check shall be carried out within one month after the submission of the committee report on compliance of the filed application and enclosed documents with the legislative requirements.

5.1.2. After the committee members have been nominated, the lead assessor of the committee shall draw up a plan of on site check. The plan is to be elaborated in accordance with Appendix 2 of this procedure;

5.2. The lead assessor shall coordinate with the applicant the aforesaid plan and shall specify with him the places and the dates for carrying out the check, including the subcontractors.

5.3. In accordance with Item 5.1, the order of the Executive Director shall be entered at the Registry office of RAEA accompanied by the on site check plan, and shall be sent to the applicant by registered post and advice of delivery.

5.4. On site check shall be carried out at the applicant’s and his subcontractors’ sites in order to ascertain their technical competency concerning the conformity assessment of interoperability constituents and subsystem verification, completed in accordance with the specific requirements of the Law for Railway Transport, Ordinance 57 and TSI.

5.5. During the audit the committee shall check the established organization of activities (quality system), technical competency and the ability of the applicant and its subcontractors to carry out the conformity assessment procedures they apply for, depending on the requested scope of assessment.

5.6. In cases, where the applicant and its subcontractors presented accreditation certificate for the respective TSI ‘products’, for which they apply, the assessment shall be carried out in order to establish their capability to perform activities related to the conformity assessment of interoperability constituents and the specific requirements of the Law for Railway Transport, Ordinance 57 and the relevant TSI.

5.7. After completion of on site checks the Head of the Committee (lead assessor) shall draw up on site check report (Appendix 4);

5.7.1. On site check report shall contain the Committee findings and conclusions related to the established organization, technical competency and the capability of the applicant to perform the conformity assessment activities he applied for. The report shall be signed by the applicant, the head of the committee (lead assessor) and the committee members.

5.7.2. Whereas, during the assessment procedure, the Committee establishes nonconformities with the requirements, they have to be a matter of record in lists of nonconformities (Appendix 3) and attached to the report, of which they are an integral part.

5.7.3. A copy of the report and the lists of nonconformities (fulfilled in form according Appendix 3) should be delivered to the applicant within 5 days of the completion of the on site check through RAEA Registry office for undertaking actions in order to rectify shortcomings within the prescribed period;
5.10. The monitoring of implementation of activities for elimination of nonconformities may be checked by documents or through a repeated on site check and/or both.

5.12. The lead assessor shall reflect the results of the checks as per item 5.10. once again in the respective form (Appendix 3)

5.13. After the check has been carried out as described in item 5.10., the lead assessor elaborates a final report for submission to the Executive director of RAEA on on site check, established organization and technical competencies of the applicant, as well as the legal requirements towards NO BOs under the Law for Railway Transport and Ordinance No 57. The report has to be coordinated with the Director of Interoperability Directorate.

6. ISSUE OF PERMISSION FOR CONFORMITY ASSESSMENT OF INTEROPERABILITY CONSTITUENTS AND VERIFICATION OF RAIL SYSTEM SUBSYSTEMS

6.1. Where the submitted application and enclosed documentation correspond to the legal requirements described in the general report of the lead assessor, the Executive Director of Railway Agency orders the delivery of applicant’s data the EC, so the latter can receive an identification number through the NANDO Input system;

6.1.2 RAEA informs the applicant in writing that the latter is nominated for notification to the EC.

6.1.3. After receiving identification number from EC by NANDO System, the Executive Director of RAEA makes an official proposal to the Minister to issue permission for conformity assessment of interoperability constituents and verification of subsystems;

6.1.4. The Designated Body may perform the activities of a Notified Body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

6.2. In case the application is declined due to nonconformity with the legislative requirements described in the general report of the lead assessor, the Executive Director of RAEA makes a proposal to the Minister to refuse the issuance of permission.

7. INTERACTION BETWEEN RAEA AND NOTIFIED BODIES

7.1. RAEA experts periodically check the activities of Notified Body and its subcontractors to assure that the Body continues to fulfill the conditions under which it has been designated.

7.2. Checks, described in item 7.1., shall be executed by the nominated by the Executive Director committee in accordance with “Procedure for surveillance of Designated Bodies (NoBo)”.  

7.3. Notified Bodies are obliged to inform the RAEA within 7 days of any changes in their conditions under which it was certified for the execution of conformity assessment (in accordance with Art. 59 paragraphs 3 of Ordinance No 57);
7.4. Notified Bodies must provide in writing information at RAEA, Interoperability Directorate regarding:

7.4.1. Total number of conformity assessment procedures carried out (deadline is December, 15 for the calendar year);

7.4.2. Annual report on the resources used, including technical equipment and personnel, subcontractors and carried out activities (deadline end of February for the previous year);

7.4.3. A List of issued, refused or withdrawn certificates;

7.4.4. Problems and difficulties encountered during execution of activities;

7.4.5. Lodged complaints, objections, claims and actions undertaken for dispute settlement;

7.4.6. Interaction with other Notified Bodies possessing conformity assessment permissions;

7.4.7. Participation in Technical Standardization Committees, working groups on national level in connection with relevant ordinance(s) etc.

7.5 Interoperability Directorate and Notification and Registration Department shall evaluate and analyze the information received as per item 7.4 with the aim to estimate the Notified Bodies activities and to undertake measures for resolution of problems raised and for improvement of their activities.

8. DOCUMENTATION (FORMS) USED IN DIFFERENT STAGES OF THE PROCEDURE

8.1. Application form (Appendix N 1);
8.2. Assessment plan (on site check) – (Appendix N 2)
8.3. List for nonconformities (Appendix 3)
8.4. On site check report (Appendix 4)
8.5. Permission for performance of interoperability constituent conformity assessment activities and verification of subsystems of the rail system (Appendix 5)
8.6. Order for examination of the application and enclosed documents;
8.7. On site check written order;
8.8. Final reports of the lead assessor for submission to the Executive Director for the work executed by the committee.
8.9. General report of the lead assessor on the conformity or non-conformity of the application and enclosed documents with the legislative requirements;
8.10. Justified refusal.
9. REFERENCES

9.1. Law for Railway Transport (Last amendments SG, issue 22 of 24 March 2009, Chapter 6)
9.3. Procedure for “Surveillance of the possessors of Conformity assessment permission”
9.4. Tariff No 5 of fees collection by the Ministry of Transport, Chapter 6, last amendments SG, issue 79 of 09.09.2008
9.5. BDS*EN 45011&1999 General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996)
9.8. BDS EN ISO 19011 Guidelines for quality and/or environmental management systems auditing (ISO 19011:2002)

*Bulgarian State Standard