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Annex

Provisions on auditing notified conformity assessment bodies in the framework of Article 34 § 3 of the Agency Regulation¹

1. Introduction

This Annex details the audits performed by the Agency in the framework of the monitoring notified conformity assessment bodies. In this context:

- › Audits concern notified conformity assessment bodies which are recognised (not accredited);
- › The Agency audits the capacity of the notified conformity assessment bodies to meet the requirements laid down in Article 30 of the Interoperability Directive² and in accordance with the criteria provided in clause 4 of this document;
- › Audits are pre-announced.

The provisions for audits take into account:

- › The Agency Regulation, Articles 34 §§ 3-5;
- › ISO 19011:2011 “Guidelines for auditing management system”.

This Annex is aligned with Agency Management Board Decision n° 147 amending the Policy for Visits to Member States.

2. Roles and responsibilities in conducting the audit

The Agency and the notifying authority (or its delegate) perform the audit of the concerned notified conformity assessment bodies as a joint activity³.

This document details on the coordination of the responsibilities between the Agency and the notifying authority (or its delegate) for joint audit activities.

The Agency and the notifying authority will prepare their findings separately, conduct a separate section of the joint audit closing meeting and prepare separate audit reports.

3. Audit objectives

Article 34 § 3 of the Agency Regulation states:

“In the case of notified conformity assessment bodies which are not accredited in accordance with Article 27 of Directive (EU) 2016/797, the Agency may audit their capacity to meet the requirements laid down in Article 30 of Directive (EU) 2016/797”.

¹. Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No. 881/2004 (Text with EEA relevance), OJ L 138, 26.5.2016, p. 1-43.

². Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (Text with EEA relevance), OJ L 138, 26.5.2016, p. 44–101.

³. The joint audit should be understood in line with Note 4 of definition 3.1 of ISO 19011.

4. Audit criteria

The audit criteria are derived from Article 30 of the Interoperability Directive and from the Agency Technical Document “Requirements for conformity assessment bodies seeking notification” – ref. 000MRA1044⁴.

The Agency will perform the audit through document review and on-site visit.

Regarding document review, the Agency may include feedback provided by the notifying authority (or its delegate).

The Agency may reduce the audit criteria if appropriate, after gap analysis between the:

- › procedures for assessment and monitoring provided by the notifying authority to the European Commission (on the basis of Article 29 of the Interoperability Directive) , and
- › The requirements included in the Agency’s Technical Document “Requirements for conformity assessment bodies seeking notification” – ref. 000MRA1044.

5. Audit scope

The audit scope is defined jointly between the Agency and the concerned notifying authority (or its delegate). It defines the extent and boundaries of the audit, such as physical locations, organizational units, activities and processes to be assessed as well as the time period covered by the audit (ref. ISO 19011 point 6.2.2).

The possible scopes are the following: ENE, INF, CCS, RST.

6. Phases of the audit

This section details Agency planning and attending on-site audits.

The following clauses, from 6.1 to 6.6, refer to the corresponding clauses of the ISO 19011:2011 which apply.

a. General

This clause provides description on preparing and conducting audit activities.

b. Initiating the audit

The preparation phase starts with the Agency responsible person contacting the notifying authority (or its delegate) to receive information on:

- › Proposed audit scope.
- › Key activities to be audited, and
- › Samplings (if applicable) to cover a variety of specific services.

The Agency responsible person, in coordination with the joint notifying authority (or its delegate), may agree to observe the concerned notified conformity assessment body carrying out conformity assessment services within its scope of notification⁵.

i. Contact for audit

The Agency responsible person sends the letter of contact addressed:

- › To the concerned notifying authority (or its delegate),
- › Copy:
 - to the Permanent Representation to the European Union of the Member State,
 - to the European Commission – DG MOVE.

The letter of initial contact for audit shall at least include the following information:

- › Legal basis for the:
 - Visit to the concerned notified conformity assessment body.
 - Duty to cooperation by notifying agency and notified conformity assessment body.

⁴. Also known as “NoBo Assessment Scheme”.

⁵. This kind of audit is usually called “witnessing”.

- › The identity and contact details of the proposed Agency staff for the audit
- › Request for:
 - Documentary evidence of the outcome of previous assessments of the concerned notified conformity assessment body,
 - additional documents which may be important to the purpose of the on-site visit (e.g.) notified conformity assessment body's roles and responsibilities, quality manual, list of procedures in force, list of EC certificates issued,
- › Request to support the Agency in granting access to relevant documents, records, information, staff, premises, etc. as relevant within the scope of the on-site assessments.
- › Information regarding the fact that during the audit the Agency may perform interviews, observations and inspect documents, may prepare notes and may request copies (full or partial) of documents or records.
- › Provisions on confidentiality.
- › Provisions on Agency documents' storage space and the used communication channel.
- › Reminder that during the audit the Agency staff uses mainly English language.

The letter shall have in annex the decision of the Executive Director of the Agency for appointment of Agency staff for audits.

The notifying authority (or its delegate) has the opportunity to object to the appointment of any particular Agency staff providing appropriate justifications. In such a case the Agency may propose an alternative person according to the availability of the Agency staff.

ii. Preliminary meeting for audit

The Agency's team leader and the notifying authority's (or its delegate's) contact person may organize a preliminary meeting.

The preliminary meeting is an opportunity for the Agency to:

- › discuss and clarify the planned audit, especially the on-site part,
- › receive information on the document review performed by the notifying authority (or its delegates)
- › discuss, amend and agree the audit plan.

The preliminary meeting may take place as several forms, such as full day physical meeting, video conference or phone call.

c. Preparing audit activities

i. Performing document review in preparation for the audit

Immediately after the preliminary meeting, the Agency starts with the review of the documents requested for audit.

In particular circumstances and if duly documented, the Agency may rely on the document review performed by the notifying authority (or its delegate).

ii. Preparing the audit plan

The audit plan shall include at the least the following items:

- › Opening audit meeting
- › Performing the audit
- › Closing audit meeting

d. Conducting the audit activities

The Agency and the notifying authority (or its delegate) take part to the on-site assessment activities.

i. Opening audit meeting

The assessment begins with an opening meeting, led by the Lead Assessor chosen between the audit teams (i.e. the notifying authority, or its delegate, and the Agency).

During the opening meeting, the Agency audit team clarifies:

- › Agency's role in the audit and the related legal basis;
- › objectives, scope and criteria of the audit;
- › the adopted monitoring system for notified conformity assessment bodies within the Agency;
- › the expected benefits of its observation;
- › provisions on Agency storage space and the used communication channel;
- › the confidentiality arrangements in place.

The Agency audit team shall present some first preliminary findings based on the previous analysis of available information and documentation.

ii. Performing the audit

Visit of the concerned notified assessment bodies premises in which the identified key activities under assessment are performed.

Following the opening meeting, the audit continues in accordance with the audit plan.

The Agency audit team collects information pertinent to the on-site visit using standard techniques such as interview, observation of activities and review of documents.

During the on-site visit the Agency audit team announces the findings as soon as they appear.

Observers and guides⁶ may accompany the Agency audit team but are not part of it; they should not interfere nor influence with the conduct of the assessment.

Before the closing meeting, prior to leave the site, the audit teams (i.e. the notifying author, or its delegate, and the Agency) shall hold a private meeting in which representatives of the concerned notified conformity assessment bodies are not entitled to participate.

In this private meeting the audit teams:

- › prepare the closing audit meeting,
- › reviews their findings from the assessment and any other relevant information collected
- › draws conclusions

During the private meeting the members of the assessment teams shall share their evaluations including their findings.

With this information the assessment team shall identify and classify all deviations to be submitted to the organization at the closing audit meeting.

iii. Closing audit meeting

At the end of the on-site visit the Agency in coordination with the notifying authority (or its delegate) perform the closing audit meeting.

In this meeting the audit teams produces a joint audit written report on the findings obtained during the assessment.

The Agency shall ensure that the concerned notified conformity assessment body and the notifying authority (or its delegate) have understood and acknowledged the findings.

⁶. Observers and guides are defined in ISO 19011 point 3.11 and 3.12.

An opportunity is provided to the concerned notified conformity assessment body and to the notifying authority (or its delegate) to ask questions about the findings and their basis.

In case of disagreement on a finding, the Agency shall note this as an unresolved issue and present both positions in its reporting.

e. Preparing and distributing the audit report

Within 5 working days after the closing audit meeting, the Agency team leader shall provide a written draft report with the observations of the audit, based on the report presented in the closing audit meeting.

The draft report is addressed to:

- › the concerned notified conformity assessment body,
- › the notifying authority (or its delegate).

This draft report shall include in particular:

- › a list of deficiencies identified,
- › audit conclusions, and
- › recommendations for improvements.

In drafting the draft report, the Agency team leader should take into consideration the list of the suitable elements of assessment report provided in ISO 19011 point 6.5.1 from a) to i).

The concerned conformity assessment body and the notifying authority (or its delegate) shall review the draft report for any misunderstandings or unclear issues and provide feedback within 10 working days.

The Agency may take into account such feedback in preparing the final report; the final report shall be addressed within 10 working days, to:

- › the concerned notified conformity assessment body,
- › the notifying authority (or its delegate), and
- › the European Commission.

i. Grouping the identified deficiencies

The Agency final report shall group the identified deficiencies into two categories:

- › **MAJOR**: deficiencies which prevent the notified conformity assessment body concerned from effectively performing its tasks in relation to railway interoperability, OR
- › **MINOR**: deficiencies which do not prevent the notified conformity assessment body concerned from effectively performing its tasks in relation to railway interoperability.

Concerning the deficiencies categorised as MAJOR, the Agency shall issue a recommendation requesting the Member State in which the concerned notified conformity assessment body is established to take appropriate steps, within a mutually agreed time limit, which is taking into account the significance of the deficiency for the activity of the notified conformity assessment body.

The Agency keeps track of those deficiencies categorized as MAJOR; this information may be shared, respecting the protection of sensitive information, amongst Agency different processes.

The Agency shall request the European Commission to follow up the recommendation in each of the following cases:

- › Member State disagrees with the above mentioned Agency's recommendation,
- › Member State does not take the appropriate steps to solve the identified **MAJOR** deficiencies
- › The concerned notified conformity assessment body does not provide any answer to the Agency within 3 months of receipt of the Agency recommendation.

NOTE 3: Article 34 § 5 of the Agency Regulation provides description of the following European Commission's actions towards the Member State.

f. Completing the audit

The audit is completed when the Agency has:

- › carried out all activities described in the audit plan, and
- › sent out the final audit report.

In case of deficiencies categorised as MAJOR, in addition to the above, the assessment is completed when the Agency has:

- › issued the recommendation, and
- › requested European Commission to follow up the recommendation.