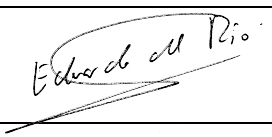
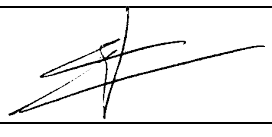
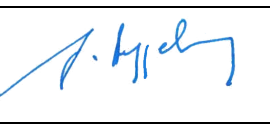


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Clarification note

Temporary measures adopted by the European Union Agency for Railways for delivering authorisations in the framework of the restrictions related to the COVID-19 pandemic

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Document History

<i>Version</i>	<i>Date</i>	<i>Comments</i>
1.0	03/04/2020	Initial version

The purpose of this document is to provide applicants and other external stakeholders of the vehicle authorisation business with information in regards to the specific topic referenced in the title. The clarifications contained in this document may be integrated in the next revision of the guidelines for the practical arrangements for the vehicle authorisation process, without prejudice of the formal process foreseen for updating the guideline.

The present document is a non-legally binding guidance of the European Union Agency for Railways. It is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

1. Description of the issue

The emergency measures adopted in different countries to fight the COVID-19 outbreak, which often include severe travel restrictions, shutdowns of manufacturing facilities and teleworking of the concerned staff, are creating difficulties for some actors involved in the vehicle authorisation process to fulfil their legal duties and obligations. In particular:

- Notified Bodies (NoBos) cannot perform the evaluations, audits, visits and inspections as planned, affecting the issuing and renewal of certificates
- Applicants cannot obtain from suppliers the documentation that they need to build the file accompanying the application for authorisation (in particular, files accompanying the EC declarations of conformity and/or suitability for use for Interoperability Constituents (IC))

This documentation needs to be included in the file accompanying the application for authorisation pursuant to Regulation (EU) 2018/545 in order to consider that an application is complete and to issue an authorisation.

2. Line to take

In view of the exceptional situation created by the COVID-19 outbreak, the Agency has decided, pending the possible adoption of EU temporary measures related to the acts governed by Regulation (EU) 2018/545, to adopt the following temporary measures when assessing applications for vehicle and/or vehicle type authorisation:

- › **When COVID-19 emergency measures are temporarily preventing the NoBos from carrying out planned assessments, visits, inspections, audits or any other on-site activity necessary to issue or renew a certificate.**

On 27 march 2020, the European Commission's directorate general GROW – Free movement of goods – issued a communication on the impact of COVID-19 on the activities of Notified Bodies. This communication provides for flexibility and specific guidance in reaction to the COVID crisis to NoBos when performing their tasks – particularly those activities requiring visits to manufacturers' premises – and at the same time encourages NoBos to continue carrying out their tasks to the extent that is currently possible in respect of the different and varying confinement measures taken at Member States level.

DG GROW's communication also makes reference to an EA communication on Corona virus dated 23 MARCH 2020 (<https://european-accreditation.org/ea-communication-to-the-impact-of-the-covid-19-outbreak/>).

Furthermore, the Mandatory Document IAF MD 4:2018, issued by the International Accreditation Forum (IAF), gives further details on the use of information and communication technologies (ICT) for auditing/assessment purposes. The Informative Document IAF ID 3:2011, issued by IAF as well, provides information on the different steps the NoBos could follow regarding the management of extraordinary events or circumstances¹.

Recommendations are also published in the website of IAF, European Accreditation (EA) and International Laboratory Accreditation Cooperation (ILAC):

<https://iafaq.com/>

<https://european-accreditation.org/information-center/newsroom/news/>

https://ilac.org/latest_ilac_news/

¹ Informative Document IAF ID 3:2011 specifically covers activities related to surveillance audits, but similar principles can be followed for other NoBo activities.

In addition to this, NoBos shall apply as general guidance the recommendations for use (RFUs) and other administrative decisions and documents issued or updated by NB-Rail, including in relation to COVID-19 issues.

As concerns the renewal (surveillance or re-certification) of a certificate for the quality management system:

- › It can be decided to postpone the audit for a limited period of time (not normally exceeding 6 months beyond the expiry date of the certificate), providing that the certified quality management system (QMS) is considered to be effective enough to ensure that the subsystems and/or Interoperability Constituents (ICs) manufactured during this period are conforming to the approved type and therefore meet the essential requirements.
- › This is under the condition that NoBos produce evidence supporting its confidence about the effectiveness of the QMS for the manufacturing process to ensure that the manufactured subsystems/ICs will conform to the approved type during the extension and explaining the alternative assessment methods and the results of the assessments². This can take the form of a new version of the certificate with extended time validity (including the file accompanying the certificate), a letter, a report, etc.

For the issuing of new certificates:

- › It can be decided to perform the evaluation by means of alternative methods², where possible, if mutually agreed by the parties involved (e.g. manufacturer, applicant, NoBo). This is a decision to be taken by NoBos.
- › NoBos should identify and document the impact of the use of alternative methods on the evaluation activities, in particular the validity, representativeness and objectivity of the evaluations performed remotely.
- › The outcomes of the evaluation activities shall indicate the extent to which the alternative methods have been used and their effectiveness in achieving the assessment objectives
- › NoBos should produce evidence supporting its confidence that the object of assessment (be it a QMS, subsystem or an IC) meets the applicable requirements. This can take the form of a regular certificate (with the relevant supporting documentation), when there are no doubts about the fulfilment of the applicable requirements despite the alternative methods used, or another similar document, etc.

NoBos should act responsibly and assess and balance the risk when providing services in a more flexible manner. In particular, the NoBo should record deviations and not provide such services if the deviations jeopardize the technical validity of that specific activity.

The use of remote assessment should not put at risk the health and safety of products in the EU and the role that NoBos play in conformity assessment. NoBos are requested to inform the relevant authorities of any issues relating to possible non-conformity of products, including where this may be relevant due to the need to postpone specific on-site visits in the context of the conformity assessment activities.

The applicant should include the evidence produced by NoBos in the file accompanying the application (or as a response to an issue created by an assessor), explaining and documenting the deviations as compared to the normal regime, including any risk management undertaken to balance the limitation of the current situation.

² Evidences could be off site reviews of documentation (such as design documents, drawings, calculation notes, technical specifications, test reports, corrective action records, results of internal audits, test/inspection reports, minutes of relevant meetings, register of non-conformities etc.), remote interviews, access to the IT tools supporting the implementation of the QMS, etc

The same principles may be applied, mutatis mutandis, to the evaluations to be performed by Designated Bodies (DeBos) and the evidence that DeBos should produce (e.g. certificate of verification for national rules).

› **When COVID-19 emergency measures are delaying the process of notification of a NoBo for Directive (EU) 2016/797.**

NoBos established in Member States not having transposed Directive (EU) 2016/797 (or the relevant provisions of the Directive, namely Articles 27 to 45 (with the exceptions of Articles 38, 40(1), 40(3), 40(4) and 43) will in principle not be able to carry out activities after 15 June 2020 as their notification under Directive 2008/57/EC will have expired and the MS in question cannot pursue a re-notification under the 4RP due to lack of transposition.

However, NoBos having already obtained the accreditation necessary under Directive (EU) 2016/797, including compliance with the ERA Assessment Scheme for NoBos³, can establish evidence equivalent to the content of an EC certificate (including the accompanying technical documentation). This is subject to all applicable requirements of Directive (EU) 2016/797 and of the ERA Assessment Scheme for NoBos having been fulfilled, and that the evidence is included in the file accompanying the application for authorisation.

› **When COVID-19 emergency measures are temporarily preventing an applicant to gather all the necessary information from a supplier that is needed to build and submit the file accompanying the application for authorisation (e.g. files accompanying the certificates for ICs), or to answer issues raised by the assessors for an on-going application.**

In this case, the applicant should produce evidence describing:

- the reasons for not providing all the required documents (including supporting evidence which should be related to COVID-19), and
- the details of the missing documents with regards to the mandatory content of the file accompanying the application for authorisation pursuant to Annex I of Regulation (EU) 2018/545 (see also the clarification note ERA1209/001).

For the cases described above, the Agency, when acting as an authorising entity, will analyse the alternative evidence provided. When this alternative evidence, together with the rest of required documentation, provides reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities despite the deviations imposed by the current exceptional circumstances, the Agency may include a time limit in the authorisation, pursuant to article 46(6)(a) of Regulation (EU) 2018/545.

The time limit will be decided on a case by case basis, taking into account the information provided by the applicant, and will normally not be longer than 6 months from the date of issuing of the authorisation.

It will be the responsibility of the applicant to provide as soon as possible the missing evidences and request the withdrawal of the time limit to the Agency, through the OSS (the applications in OSS will be kept open for this purpose). If the applicant cannot provide the missing documentation before the expiry of the time limited authorisation, a new timeframe may be agreed. In such case, the applicant should inform the Agency through the OSS.

This clarification note will be subject to any EU measure adopted by the Commission and will be revised or repealed accordingly.

³ Technical Document 000MRA1044 ver. 1.1

3. Legal background

a) Regulation (EU) 2018/545

- › Article 30(1). Application content and completeness
“For the application to be considered complete by the authorising entity and when relevant by the concerned NSAs for the area of use it shall contain the information set out in Annex I.”
- › Article 31(1). The submission of the application through the one-stop shop
“The application for a vehicle type authorisation and/or a vehicle authorisation for placing on the market shall be formally submitted by the applicant through the single entry point of the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796 and shall contain the information set out in Annex I.”
- › Article 46(6). Decision for the authorisation or refusal of the application
“The authorisation decision shall not contain any time limited conditions for use of the vehicle and other restrictions, unless the following conditions are fulfilled:
 - (a) it is required because the conformity to the TSIs and/or national rules cannot be completely proven before the issuing of the authorisation; and/or*
 - (b) the TSIs and/or national rules require that the applicant produces a plausible estimate of compliance.*

The authorisation may then include a condition that real use demonstrates performance in line with the estimate within a specified period of time.”

b) International Accreditation Forum (IAF) Informative document for management of extraordinary events or circumstances affecting Accreditation Bodies (AB), Conformity Assessment Bodies (CAB) and certified organisations (IAF ID 3: 2011 issue 1)

- › 2. Definition. 2.1 Extraordinary event or circumstance
“A circumstance beyond the control of the organization, commonly referred to as “Force Majeure” or “act of God”. Examples are war, strike, riot, political instability, geopolitical tension, terrorism, crime, pandemic, flooding, earthquake, malicious computer hacking, other natural or man-made disasters.”

- › 3. Extraordinary event or circumstance affecting a certified organization
“An extraordinary event affecting a certified organization or CAB may temporarily prevent the CAB from carrying out planned audits on-site. When such a situation occurs, ABs and CABs, operating under recognised standards or regulatory documents need to establish (in consultation with certified organizations) a reasonable planned course of action.

The CAB should assess the risks of continuing certification and establish a documented policy and process, outlining the steps it will take in the event a certified organization is affected by an extraordinary event.

The established policy and process of the CAB should define methods for evaluating the current and expected future situation of the certified organization, and define alternate potential short-term methods of assessing the organization to verify continuing effectiveness of its management systems.

To enable the CAB to assess risk for continuing certification and understand the certified organization’s current and expected future situation, the CAB should gather necessary information

from the certified organization before deciding on an appropriate course of action. The information collected by the CAB should include the following as appropriate:

- *When will the organization be able to function normally?*
- *When will the organization be able to ship products or perform the service defined within the current scope of certification?*
- *Will the organization need to use alternative manufacturing and/or distribution sites? If so, are these currently covered under the current certification or will they need to be evaluated?*
- *Does existing inventory still meet customer specifications or will the certified organization contact its customers regarding possible concessions?*
- *If the certified organization is certified to a management system standard that requires a disaster recovery plan or emergency response plan, has the certified organization implemented the plan and was it effective?*
- *Will some of the processes and/or services performed or products shipped be subcontracted to other organizations? If so, how will the other organizations' activities be controlled by the certified organization?*
- *To what extent has operation of the management system been affected?*
- *Has the Certified organization conducted an impact assessment?*
- *Identification of alternative sampling sites, as appropriate.*

If the risk of continuing certification is low, and based on the collected information the CAB may need to consider alternative short-term methods of assessment to verify continuing system effectiveness for the organization. This may include requesting relevant documentation (for example, management review meeting minutes, corrective action records, results of internal audits, test/inspection reports, etc.) to be reviewed off site by the CAB to determine continuing suitability of the certification (on a short-term basis only). At a minimum, the process should address the following items:

- *Proactive communication between the affected certified organization and the CAB.*
- *Steps the CAB will take to assess the affected organization and how the plan to move forward will be communicated.*
- *Specifying the maximum time an alternative short-term assessment method could be used before suspension or withdrawal of certification*
- *Criteria for renewing normal oversight, including the method and timing of any reinstatement activities and assessments.*
- *Possible amendments to organization's oversight plans on a case-by-case basis and in accordance with CAB procedures.*
- *Ensuring that any deviation from accreditation requirements and CAB procedures is justified and documented, and agreement reached with the AB on plans to address temporary deviations from requirements.*
- *Re-establishment of surveillance/recertification activities according to CAB oversight plans when access to the affected location is re-established.*

If contact with the organization cannot be made, the CAB should follow normal processes and procedures for suspension and withdrawal of certification.

When developing alternate short-term methods of assessment the CAB should take into consideration the following limitations:

a) *First Surveillance Audit*

Normally, the first surveillance audit after initial certification is to be within 12 months of the last day of the initial stage 2 audit (ISO/IEC 17021:2011, 9.3.2.2).

However, providing that sufficient evidence has been collected as above, to provide confidence that the certified management system is effective consideration may be given to postpone the first surveillance for a period not normally exceeding 6 months (18 months from date of initial certification).

Otherwise the certificate has to be suspended or the scope reduced.

b) *Subsequent Surveillance Audits*

There may be specific circumstances by which a CAB can justify adjusting the timing of a subsequent surveillance audit. If an organization has to shut down completely for a limited period of time (less than 6 months), it would be reasonable for a CAB to postpone an audit that had been scheduled to occur during the shutdown until the organization resumes operations. The organization should inform the CAB when operations resume so that the CAB can conduct the audit promptly.

c) *Recertification Audits*

Normally the recertification audit must be completed and the recertification decision made prior to expiration to avoid loss of certification (ISO/IEC 17021:2011, 9.1.1.2). However, providing that sufficient evidence has been collected as above, to provide confidence that the certified management system is effective consideration may be given to extend the certification for a period not normally exceeding 6 month beyond the original expiry date.

The re-certification should be carried out within this permissible extended period. Otherwise, a new initial audit should be performed. The expiration of the renewed certification should be based on the original recertification cycle.

d) *Information to the AB*

All deviations from the established certification program should be justified, documented and made available to ABs upon request."

c) *International Accreditation Forum (IAF) Mandatory document for the use of information and communication technology (ICT) for auditing/assessment purposes (IAF MD 4: 2018 issue 2)*

› 0. Introduction

"0.1 As information and communication technology (ICT) becomes more sophisticated, it is important to be able to use ICT to optimize audit/assessment effectiveness and efficiency, and to support and maintain the integrity of the audit/assessment process.

0.2 ICT is the use of technology for gathering, storing, retrieving, processing, analysing and transmitting information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others. The use of ICT may be appropriate for auditing/assessment both locally and remotely.

0.3 Examples of the use of ICT during audits/assessments may include but are not limited to:

- Meetings; by means of teleconference facilities, including audio, video and data sharing*
- Audit/assessment of documents and records by means of remote access, either synchronously (in real time) or asynchronously (when applicable)*
- Recording of information and evidence by means of still video, video or audio recordings*

- *Providing visual/audio access to remote or potentially hazardous locations*

0.4 The objectives for the effective application of ICT for audit/assessment purposes are:

- To provide a methodology for the use of ICT that is sufficiently flexible and non-prescriptive in nature to optimize the conventional audit/assessment process*
- To ensure that adequate controls are in place to avoid abuses that could compromise the integrity of the audit/assessment process*
- To support the principles of safety and sustainability*

Measures shall also be taken to ensure that security and confidentiality is maintained throughout audit/assessment activities.

0.5 Other schemes, normative documents and conformity assessment standards may impose limitations on the use of ICT for audit/assessment and may take precedence over this document. ”

› 4. Requirements. 4.1 Security and Confidentiality

“4.1.1 The security and confidentiality of electronic or electronically-transmitted information is particularly important when using ICT for audit/assessment purposes.

4.1.2 The use of ICT for audit/assessment purposes shall be mutually agreed upon by the body being audited/assessed and the body performing the audit/assessment in accordance with information security and data protection measures and regulations before ICT is used for audit/assessment purposes.

4.1.3 In the case of non-fulfilment of these measures or non-agreement of information security and data protection measures, the body performing the audit/assessment activities shall use other methods to conduct the audit/assessment.

4.1.4 When no agreement is reached for the use of ICT for audit/assessment, other methods shall be used to fulfil audit/assessment objectives.”

› 4. Requirements. 4.2 Process Requirements

4.2.1 The body shall identify and document the risks and opportunities that may impact audit/assessment effectiveness for each use of ICT under the same conditions, including the selection of the technologies, and how they are managed.

4.2.2 When ICT is proposed for the audit/assessment activities, the application review shall include a check that the client and the audit/assessment body have the necessary infrastructure to support the use of the ICT proposed.

4.2.3 Considering the risks and opportunities identified in 4.2.1, the audit/assessment plan shall identify how ICT will be utilized and the extent to which ICT will be used for audit/assessment purposes to optimize audit/assessment effectiveness and efficiency while maintaining the integrity of the audit/assessment process.

4.2.4 When using ICT, auditors/assessors and other involved persons (e.g. drone pilots, technical experts) shall have the competency and ability to understand and utilize the information and communication technologies employed to achieve the desired results of audit(s)/assessment(s). The auditor/assessor shall also be aware of the risks and opportunities of the information and communication technologies used and the impacts that they may have on the validity and objectivity of the information gathered.

4.2.5 If ICT is used for audit/assessment purposes, it contributes to the total audit/assessment time as additional planning may be necessary which may impact audit/assessment duration

4.2.6 Audit/assessment reports and related records shall indicate the extent to which ICT has been used in carrying out audit/assessment and the effectiveness of ICT in achieving the audit/assessment objectives.

4.2.7 If virtual sites are included within the scope, the certification/accreditation documentation shall note that virtual sites are included and the activities performed at the virtual sites shall be identified.

d) European Accreditation (EA) communication to EA members and accredited conformity assessment bodies regarding the outbreak of COVID-19, 23.03.2020

“[...]

Under these circumstances although not all the applicable standards foresee the use of remote assessment techniques, including document reviews, and recognizing that these assessment techniques may not always enable exactly the same objective to be achieved as on-site assessments, EA suggests the use of these techniques whenever needed to substitute or complement on-site assessments.

Nevertheless EA recognises that, in certain circumstances, accredited CABs and NABs will have to take difficult decisions that could include stopping the provision of certain services or temporarily deviating, in order to be able to provide the services, from certain requirements included in the standards or in the accreditation rules.

When facing these situations, both EA members and accredited CABs are required to act responsibly, to analyse the risk of providing services with deviations from the requirements and not to provide them if such deviations jeopardize the technical validity of that specific activity. EA also expects EA NABs and accredited CABs to act with full transparency, informing affected clients of any change in the procedures and keeping records justifying the decisions taken.

[...]”