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# REVISED PROPOSAL FOR RESOLVING INTERPRETATION ISSUES AND REQUIREMENTS FOR THE TECHNICAL SERVICES IN THE FRAMEWORK OF THE 1958 AGREEMENT (ECE/TRANS/WP.29/2006/72/Rev.1); IN WHICH THE AMENDMENTS TO ECE/TRANS/WP.29/2006/72 ARE HIGHLIGHTED

Submitted by the representative of the European Community (EC)

<u>Note</u>: The text reproduced below was prepared by the representative of the European Community, with a view to assisting WP.29 in its consideration of the questions concerning the interpretation of the Regulations annexed to the 1958 Agreement and the requirements for the Technical Services conducting the tests according to the Regulations. It is based on the text of document TRANS/WP.29/2003/100, and takes into account the comments received from various representatives at previous sessions.

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The credibility of the type approval system and the Regulations annexed to the 1958 Agreement 1/relies upon the transparent application of harmonized standards and the integrity of the Contracting Parties and their Approval Authorities. 2/

Ideally, no interpretation should be necessary in the application of these Regulations and it is proposed that new measures be adopted by the World Forum for Harmonization of Vehicle Regulations (WP.29) to ensure that only high quality and unambiguous texts are adopted in the future. New measures are also needed to address the on-going problem of interpretation with existing Regulations.

It is proposed that WP.29 actively encourages all Contracting Parties, their Technical Services 3/ and the Working Parties subsidiaries to WP.29 to adopt the following guidance in the operation of the type approval system.

It is recognized that dealing with the practical aspects of resolving issues covered in this document will require applicants (manufacturers) to present information for technical review that could be commercially sensitive. In these circumstances, WP.29 expects those involved with managing the review process to observe, wherever possible, the commercial nature of the information and to share only with others what is necessary to help the decision making process, and to agree beforehand with the applicant to whom the information may be provided.

#### A. <u>Interpretation issues</u>

While Approval Authorities bear the ultimate responsibility, Technical Services make daily interpretations of Regulation texts. In most of the cases, those decisions are soundly based and technically robust but, occasionally, some can be poorly judged. Some interpretations require decisions on borderline issues, while others could involve items

<sup>&</sup>lt;u>1</u>/ Agreement concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions (E/ECE/324-E/ECE/TRANS/505/Rev.2).

<sup>2/ &</sup>quot;Approval Authority" means the authority of a Contracting Party with competence for all aspects of the approval of wheeled vehicles, equipment and parts, for the authorisation process, for issuing and, if appropriate, withdrawing approval certificates, for acting as the contact point for the Approval Authorities of other Contracting Parties for designating the Technical Services and for ensuring that the manufacturer meets the obligations regarding the conformity of production.

<sup>3/ &</sup>quot;Technical Service" means an organization or body designated by the Approval Authority of a Contracting Party as a testing laboratory to carry out tests, or as a conformity assessment and other tests or inspections on behalf of the Approval Authority, it being possible for the Approval Authority itself to carry out those functions.

beyond the scope of the specific Regulation, such as new technologies. With the recent rapid development in advanced vehicle systems, the new technology issues could become more significant in the near future. It is recognized, however, that no specific guidance is available to help Approval Authorities reach the robust decisions that are expected.

Resolving interpretation issues is very important not only for governments but also for the industry in order to achieve a consistent vehicle development, compliance assessment and cost reductions. Interpretations should therefore follow a reasonable approach, taking into account the practical/actual situation of the vehicle development as well as of the regulatory background (objectives and spirit of the regulation).

An important first step in overcoming these problems is to encourage Approval Authorities to communicate with each other to ensure that Regulations are applied in a consistent and appropriate manner. Where a difference of opinion exists due to an ambiguous regulatory text, the appropriate subsidiary Working Party shall be contacted. The subsidiary Working Party should consider ways to clarify the regulatory text to allow a single interpretation

## 1. <u>Interpretation prior to approval being granted</u>

When an application for type approval requires the Approval Authority to make a significant interpretation of the Regulation, or if so requested by the applicant for approval, the Approval Authority shall actively inform and seek guidance from other Authorities before making a decision.

The Approval Authority concerned shall notify the other Approval Authorities applying the Regulation of the issue and of their proposed solution, including any supporting information from the manufacturer. As a general rule, this should be done via electronic media. A period of 14 days should be allowed for replies.

- (a) The Approval Authority having taken account of any comments received, can then issue approvals in accordance with the new interpretation.
- (b) If it is not possible to take a decision according to the comments received, the Approval Authority shall seek further review by the arbitration process in Article 10 of the 1958 Agreement.

### 2. <u>Interpretation anomalies subsequent to approval being granted</u>

In situations where different interpretations exist between Approval Authorities, but subsequent to an approval being issued the following procedures shall be followed.

In the first instance, the Approval Authorities concerned shall seek to resolve the issue by mutual agreement. This will require liaison and for each Contracting Party to review the procedures used to test and approve the vehicle/equipment/part being disputed. The following guidance will be adopted:

- (a) While taking into account the provisions of the 1958 Agreement, and in particular Article 4 thereof, in the event of an error being acknowledged by the Approval Authority, then no further action is needed unless, in the exceptional case of a serious hazard to road safety, vehicle security, or the environment, where the withdrawal of the approval is necessary.
- (b) Where agreement is reached which necessitates a new or different interpretation of existing practice (by either Approval Authority), then this shall be communicated to other Contracting Parties applying the Regulation concerned as a matter of urgency. The other Parties shall have 14 days to comment upon the decision, following which the Approval Authority, having taken account of any comments received, can issue approvals in accordance with the new interpretation.
- (c) Where agreement cannot be reached, then the Approval Authorities concerned shall seek further review by the arbitration process of Article 10 of the 1958 Agreement.
- (d) In any event, the matter shall be brought to the attention of an appropriate subsidiary Working Party. If deemed necessary, the subsidiary Working Party shall submit to WP.29 a suitable regulatory amendment.

#### 3. Arbitration process in accordance with Article 10 of the 1958 Agreement

To resolve issues of interpretation between Approval Authorities, the arbitration process outlined in Article 10 of the 1958 Agreement is to be used.

The primary responsibility remains with the Chairpersons of the subsidiary Working Parties (GRs) to identify issues where this process is necessary, and to put in place measures at the earliest opportunity to resolve the different interpretations. The Chairperson will develop suitable procedures to deal with such issues that might arise, but shall be able to demonstrate to WP.29 that:

- (a) full consideration of the different opinions by the Approval Authorities concerned is undertaken, in addition to the views of other relevant Approval Authorities;
- (b) decisions are based upon appropriate technical advice, taking full account of the subject area;
- (c) wherever possible, an unanimous decision is reached; and
- (d) procedures are transparent and auditable.

If necessary to resolve the issue, the Chairperson shall have the power to add to the next available meeting of the subsidiary Working Party a new agenda item relating to the issue, without the need to obtain prior approval of WP.29. In these circumstances, the Chairperson would be expected to report progress to WP.29 at the earliest opportunity.

#### 4. Procedure to be followed at the end of the arbitration process

At the end of arbitration process, the Chairperson shall provide a report to WP.29.

4.1. Where the issue is resolved within the current regulatory text:

The agreed interpretation of the Regulation shall be implemented and Approval Authorities may issue approvals immediately. The agreed interpretation shall be communicated—The Approval Authorities concerned shall communicate the agreed interpretation to the other Approval Authorities and to the relevant subsidiary Working Party forthwith.

#### 4.2. Where the issue is not resolved:

The Approval Authority shall notify, without delay, to the other Contracting Parties applying the Regulation that the issue has not been resolved. This same notification shall seek their agreement to defer any pending/new approvals until such time as WP.29 approves the new interpretation/amendment or has sought their agreement to process an application through the procedure set out in paragraph section B.

WP.29 shall be informed about the progress. Having considered the facts, WP.29 shall request the relevant subsidiary Working Party to consider the issue as a priority item at its next session. The agenda of the session shall be amended accordingly.

The interpretation that results from the arbitration process shall be transmitted to the subsidiary Working Party in advance of the session. Normal practice for document distribution should be observed but, taking into account the need for a quick resolution of issues, the minimum time for document circulation may be reduced. In these circumstances, however, the Approval Authority involved in the disagreements shall assist the secretariat. Where normal administrative practice has not been followed, the subsidiary Working Party shall take this into account in reaching its decision.

The subsidiary Working Party shall consider any proposal received in respect of the decision. It shall submit formal proposals to WP.29 to amend the Regulation following the normal procedures. WP.29 will consider the issue as a priority item at its next meeting.

WP.29 and the subsidiary Working Parties should opt for the quickest procedure to implementing any necessary amendments, with due consideration of the normal procedures to amend UNECE Regulations (TRANS/WP29/1044). Wherever possible, the necessary amendments should be dealt with by the way of a Corrigendum.

#### B. New technologies development

Developments in vehicle technology can on occasions lead to conflicts with existing regulatory texts and potentially stifle innovation of safer, cleaner, quieter and more secure road vehicles. Contracting Parties recognize that this is to be avoided wherever possible and agree to consider, under exceptional circumstances, special applications to deal with these new technologies.

As a general rule, a Contracting Party may apply for a special amendment to the Regulation that is restricted to a single type of vehicle, equipment or part, when a new technology:

- (a) is not taken into account by an existing Regulation (for example: no appropriate test cycle; substitution of mechanical parts specified in the text by other means; use of a technology which did not exist at the time of the Regulation's drafting); and
- (b) is not sufficiently mature widespread to justify amending the Regulation in a general way.

A Contracting Party may apply for a special amendment to the Regulation that is restricted to a single type of vehicle, equipment or part. An application by one Contracting Party shall not prohibit subsequent applications for the same technology by the same Contracting Party or by other Contracting Parties even if the Regulation is in the process of being amended.

In such a case, the following procedure shall be followed:

The Contracting Party shall submit to the appropriate subsidiary Working Party a file containing the following elements:

- (a) the reasons why the technologies or concept concerned make the vehicle, equipment or part incompatible with the requirements;
- (b) a description of the safety and environmental or other considerations concerned, and the measures taken;
- (c) a description of the tests, including their results, demonstrating that, by comparison with the requirements from which exemption is sought, at least an equivalent level of safety and environmental protection is ensured;
- (d) a document of no more than 1,000 words in its English version suitable for annexing to the Regulation, defining the type of vehicle, equipment or part in question and containing a summary of the points above;
- (e) a statement setting out any impact of the proposed <del>regulatory</del> special amendment on other Regulations.

The subsidiary Working Party shall consider the application as a priority item at its next session following the application. If the Working Party approves the application, then the summary document shall be submitted at the earliest opportunity to WP.29 and AC.1 for adoption as an amendment under the procedures of Article 12 of the Agreement. Where appropriate, the adoption decision shall specify whether the amendment is subject to any other restrictions, such as time limits. In all cases, the validity of the approval shall not be less than thirty-six months. The Approval Authority shall ensure that the manufacturer fully complies with all restrictions placed upon the amendment.

The amendment to the Regulation concerned shall be identified as a supplement to the series of amendments in force at the time, and the Contracting Party and the approval number shall be listed in the "Observations" column of the status document entitled "Status of the Agreement, of the Annexed Regulations and of amendments thereto".

<sup>&</sup>lt;sup>1</sup> "special" is to be translated into French as "spécifique"

If the summary document is adopted as an amendment without time limits, an official amendment to the concerned Regulation has to be prepared and considered by the subsidiary Working Party.

In all cases, the Approval Authority shall observe the requirements of Article 12.2 of the Agreement and grant approvals only in accordance with the stated timescales.

#### C. Worst case selection

The Approval Authority will normally practice "worse casing", i.e. they will establish a variant or version specification from the type specification (which may be a hypothetical variant or version at the request of the manufacturer) that, when tested, represents the type to be approved under worst conditions. The decisions taken along with the justification shall be recorded in the approval documentation.

#### D. Technical Services

#### D.1. Designation of Technical Services

- D.1.1. When a Contracting Party designates a Technical Service, the latter shall comply with the provisions of this document.
- D.1.2. The Technical Services shall carry out themselves, or supervise, the tests required for approval or inspections specified in Regulations, except where alternative procedures are specifically permitted. They may not conduct tests or inspections for which they have not been duly designated.
- D.1.3. The Technical Services shall fall into one or more of the four following categories of activities, depending on their field of competence:
  - (a) category A, Technical Services which carry out in their own facilities the tests referred to in Regulations;
  - (b) category B, Technical Services which supervise the tests referred in the Regulations;
  - (c) category C, Technical Services which assess and monitor on a regular basis the manufacturer's procedures for controlling conformity of production;
  - (d) category D, Technical Services which supervise or perform tests or inspections in the framework of the surveillance of conformity of production.
- D.1.4. Technical Services shall demonstrate appropriate skills, specific technical knowledge and proven experience in the specific fields covered by Regulations.

In addition, Technical Services shall comply with, but not necessarily be approved/accredited in accordance with, the standards listed in annex 1 which are relevant for the activities they carry out.

- D.1.5. An Approval Authority may act as a Technical Service for one or more of the activities referred to in paragraph D.1.3.
- D.1.6. A manufacturer or its representative acting on his behalf may be designated as a Technical Service for category A activities, with regard to only those Regulations which make express provision for such a designation.
- D.1.7. The entities referred to in paragraphs D.1.5. and D.1.6. shall comply with the provisions of paragraph D.1.
- D.2. Assessment of the skills of the Technical Services
- D.2.1. The skills referred to in paragraph D.1. shall be demonstrated by an assessment report established by a competent authority. This may include a certificate of accreditation issued by an accreditation body.
- D.2.2. The assessment on which the report referred to in paragraph D.2.1. shall be conducted in accordance with the provisions of annex 2.
  - The assessment report shall be reviewed after a maximum period of three years.
- D.2.3. The assessment report shall be communicated to the UNECE secretariat and the Contracting Parties upon request.
- D.2.4. The Approval Authority which acts as a Technical Service shall demonstrate compliance through documentary evidence.
  - This includes an assessment which shall be conducted by auditors independent of the activity being assessed. Such auditors may be from within the same organization provided that they are independent to the personnel undertaking the assessed activity.
- D.2.5. A manufacturer or its representative acting on his behalf, designated as Technical Service, shall comply with the relevant provisions of paragraph D.2.
- D.3. <u>Procedures for notification</u>
- D.3.1. Contracting Parties shall notify to the UNECE secretariat the name, the address including electronic address, the responsible persons and the category of activities with respect to each designated Technical Service. They shall also notify any subsequent modifications thereof.
  - The notification act shall state for which Regulations the Technical Services have been designated.
- D.3.2. A Technical Service may conduct the activities described in paragraph D.1. for the purposes of type-approval only if it has been notified to the UNECE secretariat.

- D.3.3. The same Technical Service may be designated and notified by several Contracting Parties, irrespective of the category of activities which they conduct.
- D.3.4. Where in application of a Regulation, a specific organization or competent body, the activity of which is not included in those covered in paragraph D.1., needs to be designated in application of that regulatory act, the notification shall be done in accordance with the provisions of this paragraph.
- D.3.5. The UNECE secretariat shall publish the list and details regarding the Approval Authorities and Technical Services on its website.

#### E. Documents

The Approval Authority shall ensure that the following is included in the approval documentation:

- (a) A record of the worst-case selection and the justification for that selection. This may include information from the manufacturer;
- (b) A record of any significant technical interpretation made, different test methodology applied, or new technology introduced;
- (c) A test report from the Technical Service;
- (d) Information documents from the manufacturer, properly specifying the type being approved;
- (e) A statement of the conformity of production status, stating the basis of the initial assessment (i.e. assessment by the Approval Authority, ISO 9000 certification, etc.), and the date of the initial and any surveillance assessments;
- (f) The approval certificate.

These documents shall be available to other Approval Authorities on request in accordance with Article 5 of the 1958 Agreement. The issuing Approval Authority shall despatch the requested documents within 14 working days after receiving the request, or explain why it cannot comply with the request in time. By this deadline, it shall announce when, within the next 28 days, it will deliver the requested documents.

#### F. Transmission of information

In order to respond in a realistic timeframe to issues of arbitration and document sharing, it is important to work as efficiently as possible and to exploit new communication technologies. WP.29, the subsidiary Working Party (GR) (through its Chairperson or its Secretary), and all other GRs experts involved shall therefore take all possible opportunities to communicate by electronic media, such as e-mail and a bulletin board.

#### Annex 1

# STANDARDS WITH WHICH THE TECHNICAL SERVICES REFERRED TO IN PARAGRAPHS D.1. to D.3.5. HAVE TO COMPLY

- 1. Activities related to testing for type-approval, to be carried out in accordance with Regulations:
- 1.1. Category A (tests performed in own facilities):

EN ISO/IEC 17025 : 2005 on the general requirements for the competence of testing and calibration laboratories.

A Technical Service designated for category A activities may carry out or supervise the tests according to UNECE Regulations for which it has been designated, in the facilities of the manufacturer or of its representative.

1.2. Category B (supervising of tests performed in the manufacturer's facilities or in the facilities of its representative):

EN ISO/IEC 17020 : 2004 on the general criteria for the operation of various types of bodies performing inspection.

Before performing or supervising any test in the facilities of a manufacturer or of its representative, the Technical Service shall check that the test facilities and measurement devices comply with the appropriate requirements of the standard referred to in paragraph 1.1.

- 2. Activities related to Conformity of Production:
- 2.1. Category C (procedure for the initial assessment and surveillance audits of the manufacturer's quality management system):
  - EN 45012:1998 on the general requirements for bodies operating assessment and certification/registration of quality systems.
- 2.2. Category D (inspection or testing of production samples or supervision thereof):

EN ISO/IEC 17020: 2004 on the general criteria for the operation of various types of bodies performing inspection.

#### Annex 2

#### PROCEDURE FOR THE ASSESSMENT OF TECHNICAL SERVICES

- 1. Purpose of this annex
- 1.1. This annex establishes the conditions according to which the assessment procedure of the Technical Services should be conducted by the competent authority referred to in paragraph D.2.
- 1.2. These requirements shall apply mutatis mutandis to all Technical Services, irrespective of their legal status (independent organisation, manufacturer or Approval Authority acting as Technical Service).
- 2. Principles of assessing

Assessing is characterized by reliance on a number of principles:

- (a) independence which is the basis for the impartiality and objectivity of the conclusions,
- (b) an evidence-based approach which guarantees reliable and reproducible conclusions.

Auditors shall show trust and integrity, and shall respect confidentiality and discretion. They shall report truthfully and accurately findings and conclusions.

- 3. Skills required of the auditors
- 3.1. The assessments may only be conducted by auditors having the technical and administrative knowledge necessary for such purposes.
- 3.2. The auditors shall have been trained specifically for assessment activities. In addition, they shall have the specific knowledge of the technical area in which the Technical Service will exercise its activities.
- 3.3. Without prejudice to the provisions of paragraphs 3.1. and 3.2., the assessment referred to in paragraph D.2.5. shall be conducted by auditors independent of the activities for which the assessment is conducted.
- 4. Application for designation
- 4.1. A duly authorized representative of the applicant Technical Service shall make a formal application to the competent authority that includes the following:
  - (a) general features of the Technical Service, including corporate entity, name, addresses, legal status and human and technical resources;
  - (b) general information concerning the Technical Service, such as its activities, its relationship in a larger corporate entity, if any, and addresses of all its physical location(s) to be covered by the scope of designation;

- (c) an agreement to fulfil the requirements for designation and the other obligations of the Technical Service;
- (d) a description of the conformity assessment services that the Technical Service undertakes in the framework of the applicable Regulations and a list of the Regulations for which the Technical Service seeks designation, including limits of capability where applicable;
- (e) a copy of the quality assurance manual of the Technical Service.
- 4.2. The competent authority shall review for adequacy the information supplied by the Technical Service.

#### 5. Resource review

The competent authority shall review its ability to carry out the assessment of the Technical Service, in terms of its own policy, its competence and the availability of suitable auditors and experts.

- 6. Subcontracting the assessment
- 6.1. The competent authority may subcontract parts of the assessment to another designation authority or ask for support from technical experts provided by other competent authorities. The subcontractors and experts have to be accepted by the applicant Technical Service.
- 6.2. The competent authority shall take into account accreditation certificates with adequate scope, in order to complete its global assessment of the Technical Service.
- 7. Preparation for assessment
- 7.1. The competent authority shall formally appoint an assessment team. The former shall ensure that the expertise brought to each assignment is appropriate. In particular, the team as a whole:
  - (a) shall have appropriate knowledge of the specific scope for which designation is sought; and
  - (b) shall have understanding sufficient to make a reliable assessment of the competence of the Technical Service to operate within its scope of designation.
- 7.2. The competent authority shall clearly define the assignment given to the assessment team. The task of the assessment team is to review the documents collected from the applicant Technical Service and to conduct the on-site assessment.
- 7.3. The competent authority shall agree, together with the Technical Service and the assigned assessment team, to the date and schedule for the assessment. However, it remains the responsibility of the competent authority to pursue a date that is in accordance with the surveillance and reassessment plan.

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- 7.4. The competent authority shall ensure that the assessment team is provided with the appropriate criteria documents, previous assessment records, and the relevant documents and records of the Technical Service.
- 8. On-site assessment

The assessment team shall conduct the assessment of the Technical Service at the premises of the Technical Service from which one or more key activities are performed and, where relevant, shall perform witnessing at other selected locations where the Technical Service operates.

- 9. Analysis of findings and assessment report
- 9.1. The assessment team shall analyse all relevant information and evidence gathered during the document and record review and the on-site assessment. This analysis shall be sufficient to allow the team to determine the extent of competence and conformity of the Technical Service with the requirements for designation.
- 9.2. The competent authority's reporting procedures shall ensure that the following requirements are fulfilled.
- 9.2.1. A meeting shall take place between the assessment team and the Technical Service prior to leaving the site. At this meeting, the assessment team shall provide a written and/or oral report on its findings obtained from the analysis. An opportunity shall be provided for the Technical Service to ask questions about the findings, including non-conformities, if any, and their basis.
- 9.2.2. A written report on the outcome of the assessment shall be promptly brought to the attention of the Technical Service. This assessment report shall contain comments on competence and conformity, and shall identify non-conformities, if any, to be resolved in order to conform to all of the requirements for designation.
- 9.2.3. A written report on the outcome of the assessment shall be promptly brought to the attention of the Technical Service. This assessment report shall contain comments on competence and conformity, and shall identify non-conformities, if any, to be resolved in order to conform to all of the requirements for designation.
- 9.2.43. The Technical Service shall be invited to respond to the assessment report and to describe the specific actions taken or planned to be taken, within a defined time, to resolve any identified non-conformities.
- 9.3. The competent authority shall ensure that the responses of the Technical Service to resolve non-conformities are reviewed to see if the actions appear to be sufficient and effective. If the Technical Service responses are found not to be sufficient, further information shall be requested. Additionally, evidence of effective implementation of actions taken may be requested, or a follow-up assessment may be carried out to verify effective implementation of corrective actions.

- 9.4. The assessment report shall include, as a minimum:
  - (a) unique identification of the Technical Service;
  - (b) date(s) of the on-site assessment;
  - (c) name(s) of the auditors(s) and/or experts involved in the assessment;
  - (d) unique identification of all premises assessed;
  - (e) proposed scope of designation that was assessed;
  - (f) a statement on the adequacy of the internal organization and procedures adopted by the Technical Service to give confidence in its competence, as determined through its fulfilment of the requirements for designation;
  - (g) information on the resolution of all non-conformities;
  - (h) a recommendation of whether the applicant should be designated or confirmed as Technical Service and, if so, the scope of designation.
- 10. Granting/confirming a designation
- 10.1. The competent authority shall, without undue delay, make the decision on whether to grant, confirm or extend designation on the basis of the report(s) and any other relevant information.
- 10.2. The competent authority shall provide a certificate to the Technical Service. This certificate shall identify the following:
  - (a) the identity and logo of the competent authority;
  - (b) the unique identity of the designated Technical Service;
  - (c) the effective date of granting of designation and the expiry date;
  - (d) a brief indication of, or a reference to, the scope of designation (applicable Regulations or part of them);
  - (e) a statement of conformity and a reference to the present document.
- 11. Reassessment and surveillance
- 11.1. Reassessment is similar to an initial assessment except that experience gained during previous assessments shall be taken into account. Surveillance on-site assessments are less extensive than reassessments.
- 11.2. The competent authority shall design its plan for reassessment and surveillance of each designated Technical Service, so that representative samples of the scope of designation are assessed on a regular basis.

The interval between on-site assessments, whether reassessment or surveillance, depends on the proven stability that the Technical Service has reached.

11.3. When, during surveillance or reassessments, non-conformities are identified, the competent authority shall define strict time limits for corrective actions to be implemented.

- 11.4. When the corrective or improvement actions have not been taken within the agreed timeframe, or are not deemed to be sufficient, the competent authority shall adopt appropriate measures such as, conducting a further assessment, suspending/withdrawing the designation for one or more of the activities for which the Technical Service has been designated.
- 11.5. When the competent authority decides to suspend or withdraw the designation of a Technical Service, it shall inform the latter by registered mail. In any case, the competent authority shall adopt all the necessary measures to ensure the continuity of the activities already undertaken by the Technical Service.
- 12. Records on designated Technical Services
- 12.1. The competent authority shall maintain records on Technical Services to demonstrate that requirements for designation, including competence, have been effectively fulfilled.
- 12.2. The competent authority shall keep the records on Technical Services secure to ensure confidentiality.
- 12.3. Records on Technical Services shall include at least:
  - (a) relevant correspondence;
  - (b) assessment records and reports;
  - (c) copies of designation certificates.

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