### **DIGITAL SYSTEM**





Independent assessment in trials with automated vehicles – Drive Sweden Policy Lab Case 6

Cilli Sobiech, Kristina Andersson and Björn Enqvist

RISE Report: 2024:12

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#### **Abstract**

#### Independent assessment in trials with automated vehicles

The purpose of case 6 of the Drive Sweden Policy Lab 2023-25 is to examine the scope of an independent assessment in trials with automated road vehicles. The Swedish Transport Agency's regulations and general advice on permission to conduct trials with automated vehicles have recently been amended by adding a general advice that the applicant's risk assessment should in certain cases be supplemented with a statement from an independent assessor regarding traffic safety (TSFS 2021:4, last amended by TSFS 2022:82). The regulation enables trials with automated vehicles in Sweden since 2017 and clarifies the circumstances under which it is reasonable safe to conduct trials with such vehicles.

In the beginning of 2023, a policy lab was initiated with Swedish, Danish, Norwegian, and Austrian actors, which acts as a platform for collaborative policy development by relevant actors facing a common policy related challenge. Vehicle manufacturers, transport providers and operators, authorities, potential assessors, and applied research examine together the scope of independent assessments for trials with automated vehicles. The policy lab generates guidelines for independent assessments by clarifying and exemplifying the application and scope of such assessments in trials with automated vehicles. The policy lab considers knowledge and previous experiences from other transport sectors, from various countries with independent assessment already in place and from relevant EU and UNECE regulations, such as the requirements of independent assessment for the international market e.g., for a type-approval in the EU (ADS compliance assessment) or the proposed process for audits from the working group Validation Methods for Automated Driving as part of WP29. Drive Sweden Policy Lab case 6 is partly financed by Sweden's innovation agency Vinnova, through its strategic innovation program Drive Sweden, and partly by the project parties.

Key words: independent assessment, trials with automated vehicles, traffic safety, safety case, third-party assessment, audit, policy lab

RISE Research Institutes of Sweden AB

RISE Report: 2024:12 ISBN: 978-91-89896-57-4

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## List of abbreviations

| Abbreviation | Definition                                              |
|--------------|---------------------------------------------------------|
| ADS          | Automated Driving System                                |
| ALKS         | Automated Line Keeping Systems                          |
| DRD          | Danish Road Directorate                                 |
| DRSA         | Danish Road Safety Agency                               |
| EU           | European Union                                          |
| Euro NCAP    | The European New Car Assessment<br>Programme            |
| FAT          | Factory Assessment Test                                 |
| HARA         | Hazard Analysis and Risk Assessment                     |
| НМІ          | Human Machine Interface                                 |
| ISO          | International Organization for Standardization          |
| ODD          | Operational Design Domain                               |
| OEM          | Original Equipment Manufacture                          |
| PLATT        | Policy Lab Autonoma TransportTjänster                   |
| SAE          | Society of Automotive Engineers                         |
| SAT          | Site Assessment Test                                    |
| SIP          | Strategic Innovation Programme                          |
| STA          | Swedish Transport Agency                                |
| TER          | Technical Evaluation Report                             |
| TRC          | Technical Recognition Centres                           |
| UNECE WP 29  | World Forum for Harmonization of<br>Vehicle Regulations |

#### **Preface**

The Swedish government has 17 strategic innovation programs (so-called SIPs). Drive Sweden is one of these. Drive Sweden consists of members from academia, industry, and society. Together, the members work on the challenges associated with next-generation mobility systems for people and goods. The SIPs are financed by Sweden's innovation agency Vinnova, Formas, a research council for sustainable development, and the Energy Agency. Lindholmen Science Park AB hosts Drive Sweden.

This project is partly financed by Vinnova through Drive Sweden, partly by the parties within Drive Sweden Policy Lab case 6. The project started in March 2023 and ended in March 2024. RISE Research Institutes of Sweden AB has been project coordinator. In addition to RISE, the following parties have been included in the project:

- Amobility (Holo)
- Applied Autonomy
- AustriaTech GmbH
- Einride Autonomous Technologies
- Keolis AB
- Scania CV AB
- Swedish Transport Administration

In the reference groups AstaZero, SAFER, SKR, Volvo Cars, Volvo Buses and Combitech AB have been included. The Swedish Transport Agency (STA) participated actively with input to the discussions and workshops.

Many thanks to Björn Enqvist (Combitech AB) and others who participated and contributed with their opinions and knowledge. A special thank you to Olav Madland, Applied Autonomy, for hosting a study trip to Stavanger in the purpose of studying their trial with autonomous buses.

If you want to know more about the project or the report, please contact kristina.andersson@ri.se.

Any views and positions expressed in this report are the authors' own. Other parties or representatives may have a different analysis and come to different conclusions.

Gothenburg in February 2024

The authors

### 1 Introduction

### 1.1 Background

In 2017, the ordinance on trials with automated vehicles was introduced in Sweden (TSFS 2017:92). The ordinance enables trials with automated vehicles and clarifies the circumstances under which it is reasonable to conduct trials with such vehicles.

Our project has its origins in an earlier project called PLATT (Policy Lab Autonoma TransportTjänster). When PLATT started in 2017, the ordinance was new, and no one really knew how it would work. In the PLATT project, different stakeholders gathered to discuss concepts and ways of working when preparing the application for testing autonomous vehicles on public road. The objective was to understand the next step and gaining confidence among different stakeholders.

The Government's ordinance is supplemented by the Swedish Transport Agency's regulation and general guidelines for the permit process (TSFS 2021:4). This regulation has recently been amended by adding a general advice that companies' own risk assessment should in some cases be supplemented with a statement from an independent assessor regarding the road safety of the trial.

The new general advice applies from 1 September 2022 (TSFS 2022:82):

#### General advice

If the application includes trials where technical systems are used to a large extent to ensure traffic safety, the risk assessment should be supplemented with a statement about the trial from someone who is organizationally independent and has expertise in complex and automated systems. It should be stated whether the person who issued the statement considers that the system can ensure traffic safety.

In the beginning, there was no further guidance what exactly such third-party statement should cover. The idea was then born to reuse the knowledge from the earlier PLATT-project to explore what the change entails. There is also a general interest of OEM's and other stakeholders on the assessment and acceptance processes of safety cases. Development of safety assessment methodology of Autonomous Driving System (ADS) also calls for enhanced understanding among stakeholders in Sweden.

During the project, in Octobre 2023, STA published supplementary information<sup>1</sup> as a guidance, which we have considered in the project results.

<sup>&</sup>lt;sup>1</sup> TSG 2023-6693: Supplementary information for trial operation permits with automated vehicles. Guidance for TSFS 2021:4.

https://www.transportstyrelsen.se/globalassets/global/vag/fordon/automatiserade-fordon/supplementary-information-for-trial-operation-permits-with-automated-vehicles-1.ot.pdf

### 1.2 Objectives

The aim of the project is to generate guidelines for independent assessments by clarifying and exemplifying the application and scope of such assessments in trials with automated vehicles. The following questions are for example of interest to the project partners:

- What are the guidelines on independent assessment in other countries?
- What are other relevant guidelines from UNECE and the EU?
- How does it relate to the STA's application process i.e., when is the need for an independent assessor discussed?
- How is the reasonableness of a safety assessment guaranteed to make it easier for the STA to grant permits?
- What type of trial is affected by the change (e.g. which level of autonomy)?
- What is the right level of assessment? Which acceptance criteria should it include?
- Significance of independent assessment for the international market and, for example, type approval within the EU?
- How can it be ensured that the required competence exists to carry out the assessment?
- Is any kind of certification or accreditation of independent assessors required?
- How should the auditor's independence be ensured?

### 1.3 Methodology

In the beginning of 2023, a policy lab was initiated with Swedish, Danish, Norwegian, and Austrian actors, which acts as a platform for collaborative policy development by relevant actors facing a common policy related challenge. Vehicle manufacturers, transport providers and operators, authorities, potential assessors, and applied research examine together the scope of independent assessments for trials with automated vehicles.

This policy lab considers knowledge and previous experiences from other transport sectors, from various countries with independent assessment in place already and from relevant EU and UNECE regulations.

Policy lab, as an idea, has its origins in the question "Can you work with policy and regulatory development in a better way than today?" Reality is becoming increasingly agile, complex, and difficult to grasp, which means that new tools and methods need to be developed to meet and solve important societal challenges. Changes are also happening faster than traditional regulatory development. Accelerated technology development clashes with an existing system and regulations.

The purpose of the policy lab is to explore how technology and service development relates to the existing policies for future mobility services. How can we take advantage of the rapid technological development in a good way to create a more sustainable world? The policy lab brings together a wide range of actors to solve bottlenecks for projects and innovations that are at the forefront. A collective approach is required where different actors work together to reach a solution. Furthermore, through the policy lab,

participants can increase their knowledge of how existing regulations support and hinder the market introduction of new technology and services.

To answer the research and investigation questions presented in the paragraph above, we have mainly used the following methods, which are normally included in a policy lab.

Literature study: We have conducted literature studies to gather information about today's regulations and legal conditions based on this. The literature review has included sources of law (legislation, preparatory works, case law and doctrine, etc.), but also reports and other publications.

Interviews: During the project we have interviewed authorities, applicants, independent assessors, and organisations dealing with harmonization.

Workshops: We have worked with an agile and iterative process where we have checked results and various solution proposals in several workshops with the project partners.

# 2 Guidelines on independent assessment in other countries

Denmark and Spain have both an approval process for trials with automated vehicles which requires an independent assessment. The third-party assessment is considered for the authorities' decisions on the permission for the trial. The application process and the independent assessment are shortly described in the following.

### 2.1 Approval process in Denmark

Denmark has a time-consuming process for the approval of trials including third party assessment. The process is influenced by ideas from the railway sector. There are three separate applications needed to be approved in Denmark, with certain overlapping and dual processing of the same content/material to be provided by applicants. The long approval process resulted in a very low number of trials in Denmark so far (Holo 2021). The lead time for approval can take approx. one year.

From 2017 onwards the Danish legislative framework allowed autonomous pilot projects. Holo, integrator and operator of autonomous vehicles, was granted approval to operate the first autonomous vehicles on the roads in Aalborg (Folketinget) in 2019. Since the law was enacted a total of four projects has been approved under the current legislation. In 2022, the law is up for review in the Ministry of Transport (Transportministeriet), but so far, no decisions have been taken by the government.

The permit process can be described as follows (Holo 2021):

- Applications and permits are granted by the Danish Road Directorate (DRD)
- Before an application can be submitted to the DRD (Figure 1), an approval of the project must be obtained by both a third-party assessor and the Danish Road Safety Agency (DRSA).

• Depending on the project scope, applicants might need to obtain permits from municipalities (road owners) and permits/dispensations from DRSA to conduct public transportation of passengers (Vejdirektoratet).

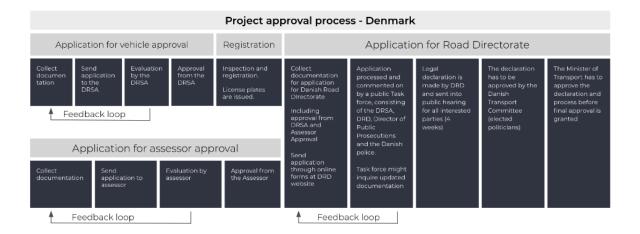


Figure 1: Process for obtaining permits to conduct pilot projects with autonomous vehicles in Denmark including third-party assessment (source: Holo 2021)

Step 1: Approval by the Danish Road Safety Agency (DRSA)

- Applicant provides necessary documentation to obtain vehicle approval to DRSA.
- Only the vehicle approval application, i.e. DRSA is responsible to evaluate and assess the technical application.
- Evaluation based on compliance of the 'Danish regulatory requirements regarding vehicles layout and equipment'. This regulation is largely based on the EU Directive 2007/46/EC.

#### Step 2: Third-party assessment

- The entire project is evaluated by a third-party assessor with traffic safety competencies e.g. a specialized engineering consultancy company.
- The third-party assessor evaluates all aspects of the project in relation to traffic safety.
- If some vehicle technical aspects, or vehicle features, will impact traffic safety in anyway, assessors will have the right to question or demand things changed, even though the vehicle has been approved by the DRSA.
- Outcome: safety assessment, as part of the application for the approval to the DRD

#### Assessors will review:

- General traffic behaviour
- o IT and data (incl. how data is logged)
- o Technical vehicle features /functionalities
- o Infrastructure and road technic

- Organization and resources
- Risk management
- Assessors will have to be approved by DRSA before they can fulfil the role of assessor for the specific project. DRSA evaluates the competencies of the applicant and the structure of the assessment (Retsinformation BEK nr 543 af 24/05/2017).

#### Step 3: Approval of the Danish Road Directorate (DRD)

- Separate application with holistic picture of the project and serve as basis for review (by Vejdirektoratet)
- Contains the third-party assessment, data handling, etc
- Application process is processed by a public task force with members of DRSA, DRD, Danish police, and the director of public prosecutions
- Public task force prepares the legal declaration of the project which is sent to a public hearing (to collect feedback and concerns from the public open for 4 weeks)
- Minister of Transport processes the application and eventually passes the declaration resulting in approval from the DRD.

#### Step 4: Inspection

An inspection of the vehicle is the last step of the approval process (Figure 2).

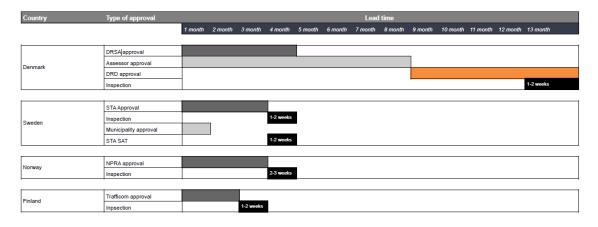


Figure 2: Comparison of lead time for project approvals in the Nordics (source: Holo 2021)

### 2.2 Approval process in Spain

Two different authorities are involved in the process of obtaining a trial permit in Spain. An authority is responsible for road safety issues – how the vehicle is used. Another authority is responsible for type approval.

VEH 2022/07 is an updated version of the Spanish instruction 15/V-113 "Authorization of tests or tests of research carried out with automated<sup>2</sup> vehicles on roads open to general traffic" (2015). It is intended for the regulation of the granting of special authorizations for carrying out tests and research trials with automated vehicles.

The instruction VEH 2022/07 defines:

- The procedure for the authorization of research tests/trials.
- Applicable requirements for applicants for authorization.
- The designation procedure for authorized so-called Technical Recognition Centres and the requirements demanded of such organisations.

Designated Technical Recognition Centres (TRC) can carry out an independent assessment for trials with automated vehicles in Spain. To guarantee the maturity, safety and reliability of the automated driving systems, the owner of the vehicle must prove one of the following assumptions:

- 1- That the vehicle has passed in a TRC designated by the General Directorate of Traffic (procedures are included in Annex V of the instruction).
- 2- That the competent authority of another Member State of the European Union has issued, through an equivalent prior checking procedure, authorization to carry out tests on roads open to general vehicle traffic.

Today, IDIADA is an authorized TRC in Spain. Whereas most trials performed in Spain are authorized by another Member State of the European Union to carry out tests.

Annex V in the Spanish instruction describes the standardized procedure for the certification of vehicles for the performance of tests in autonomous mode to guarantee the maximum level of safety for the persons conducting such tests, as well as for the other road users. It also contains the procedure for issuing the Technical Evaluation Report (TER) by the authorized TRC.

The procedure for the TER consists of different phases:

a. Documentation: technical characteristics of the vehicle, safety check and test results.

The documentation requirement refers to the identification of the type of vehicle intended for testing (dimensions, masses, power, etc.), its basic approval/homologation (if applicable), the identification of risks by and according to the criteria of the applicant and the countermeasures applied, the functionalities to be tested and those for which the vehicle is not intended, the emergency stop system and other functionalities of safety (e.g. electromagnetic compatibility).

b. Verification of conformity between the documentation submitted by the applicant and the vehicle to test.

-

<sup>&</sup>lt;sup>2</sup> According to VEH 2022/07, active safety systems or driving assistance systems included as equipment of vehicles that do require necessarily active human control or supervision for their handling or conduction will not be considered as autonomous technology.

The conformity verification process is carried out with the aim of verifying that the vehicle presented for testing on the open road corresponds to the documentation submitted by the applicant.

c. Safety check of the vehicle.

The inspection process is carried out (based on the documentation provided) with the objective of approving or denying tests with prototype vehicles. The inspection always refers to security elements, interior space, condition of the wheels or instrumentation/ballast attachment (if applicable).

d. Dynamic testing/checks: predefined procedures and tests, that may need to be adapted by the TRC.

Dynamic testing is the last step of this procedure and is divided into manual drive test, override systems check (go to manual control) and verification of basic functionalities that have an impact on security for vehicle occupants and other road users. This will make it possible to certify that the vehicle:

- 1) can be driven manually,
- 2) allows manual control to be resumed at the request of the manager/operator, and
- 3) in autonomous driving mode can maintain minimum levels of safety (e.g. braking when a pedestrian crosses).

The procedure described in Annex V has been developed using existing and reference standards for each of the functionalities (e.g. ISO, UNECE standards, and Euro NCAP protocols).

IDIADA estimates that a review takes about two to four weeks to complete.

In earlier versions on the Spanish instruction, a list of standardised tests to be performed was predefined. They were more based on theory than practice. Though this has been changed in the newer version of the instruction and tailormade test plans are created nowadays after a dialog with stakeholders. Focus now is more on hazard analysis and risk assessment (HARA). This was done because the new vehicles to be tested did not fit in to the standardised test based on type-approval requirements.

## 3 Other relevant guidelines from UNECE and EU

The guidelines described in the following section are exemplarily described here as they may be relevant for the safety assessment of automated vehicles. They cover validation methods for automated driving systems as well as the exemption and type-approval procedure for approval of automated vehicles in the EU. They relate to the independent assessment as the specify for example the audit procedures, i.e., how manufacturers will be required to demonstrate the capabilities of an ADS to safety authorities, other relevant regulations to comply with (such as UN Regulation No 155 and UN Regulation No 156) as well as relevant steps for the safety assessment and testing.

## 3.1 New Assessment/Test Method for Automated Driving and Guidelines for Validating Automated Driving System

UNECE WP29 – World forum for harmonization of vehicle regulations - is proposing a multi-pillar approach for testing and validation. Validating Automated Driving System (ADS) safety is a highly complex task which cannot be done comprehensively nor effectively through one validation methodology alone. As a result, it is recommended to adopt a multi-pillar approach for the validation of ADS, composed of a scenarios catalogue and five validation methodologies (pillars).

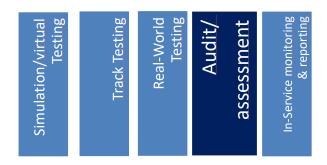


Figure 3: Five validation methodologies (pillars) for the validation of ADS (source: UNECE WP29/2022/58)

The audit/assessment procedures establish how manufacturers will be required to demonstrate the capabilities of an ADS to safety authorities using documentation, their simulation, test-track, and/or real-world testing.

#### The audit will:

- validate that hazards and risks relevant for the system have been identified and that a consistent safety-by-design concept has been put in place.
- verify that robust processes/mechanisms/strategies (i.e., safety management system) are in place to ensure the ADS meets the relevant safety requirements throughout the vehicle lifecycle.

It shall also assess the complementarity between the different pillars of the assessment and the overall scenario coverage.

The purpose of the audit pillar is to assess/demonstrate that the manufacturer has the right processes to ensure operational and functional safety during the vehicle lifecycle and vehicle design is safe by design and that this design is sufficiently validated before market introduction.

It consists of two main components: i) the audit of manufacturer processes through a Safety Management System and ii) the safety assessment of the ADS design. The manufacturer is recommended to demonstrate robust processes for safety throughout the vehicle lifecycle, including monitoring, risk identification, analysis, evaluation, treatment, and validation through testing.

Authorities are supposed to do the assessment, but independent internal audits and external audits can be carried out to ensure that the processes established for the Safety Management System are implemented consistently. The following are examples of processes and activities that should be documented to assure independent design audit and assessment:

- (a) assurance that all practices and procedures applied during the vehicle/system development are followed:
- (b) assurance that there is an independent check of compliance with the applicable requirements and regulations is performed. (i.e., not from a person creating the compliance data):
- (c) process to assure the continuing evaluation of the Safety Management System to ensure that it remains effective.

The purpose of the audit of the safety by design concept of the ADS is to demonstrate that hazards and risks relevant to the ADS have been identified by the manufacturer and a consistent safety-by-design concept has been implemented to mitigate these risks. An auditor/assessor has several tasks like:

- 1. Inspection of the safety approach at the concept (vehicle) level,
- 2. Inspection of the safety approach at the ADS level including a top down (from possible hazard to design) and bottom-up approach (from design to possible hazards).
- 3. Inspection of the documentation that should demonstrate the validation/verification plans and results including appropriate acceptance criteria.
- 4. The auditor/assessor should also perform an assessment of the physical testing (proving ground and/or public road) environment.

# 3.2 Guidelines on the exemption procedure for the EU approval of automated vehicles

As part of the EU strategy on automated and connected mobility ("<u>CAM strategy</u>"), the Commission announced its intention to work with Member States in 2018 on guidelines to ensure a harmonised approach for exemption procedure for the EU approval of automated vehicles.

Automated driving can be approved through an EU exemption procedure. Until harmonised EU requirements are adopted, the approval is granted on the basis of a national ad-hoc safety assessment which is mutually recognized by other Member States through a Commission decision. The guidelines on the exemption procedure for the EU approval of automated vehicles aim to harmonize the practice of Member States for the national ad-hoc assessment of automated vehicles and to streamline the mutual recognition of such assessment.

The document does not mention audit. It foresees a procedure between manufacturers and type-approval authorities or the technical services acting on their behalf.

# 3.3 Uniform procedures and technical specifications for the type-approval of the automated driving system (ADS) of fully automated vehicle

Commission Implementing Regulation (EU) 2022/1426 lays down rules for the application of Regulation (EU) 2019/2144 for uniform procedures and technical specifications for the type-approval of the automated driving system of fully automated vehicles regarding small series of vehicles.<sup>3</sup>

The Implementing Regulation applies to the type-approval of fully automated vehicles of category M and N<sup>4</sup>, regarding their automated driving system (ADS), for the following use cases (a) fully automated vehicles on a predefined area, (b) hub-to-hub and (c) automated valet parking<sup>5</sup>.

As the EU regulation aims at type-approval, the required information provision and assessment of the automated driving system is extensive. The regulation describes an adapted approach and describes the requirements for the information provision, for the performance and tests to be performed and documented by the manufacturer. The regulation does not mention independent external audit.<sup>6</sup>

# 3.4 Reflection on independent assessment vs type-approval

In the project we have discussed the difference between third party assessment for trial operations and the type-approval procedure (such as described above). How can third party assessment be a step towards type approval?

<sup>&</sup>lt;sup>3</sup> COMMISSION IMPLEMENTING REGULATION (EU) 2022/1426 of 5 August 2022 laying down rules for the application of Regulation (EU) 2019/2144 of the European Parliament and of the Council as regards uniform procedures and technical specifications for the type-approval of the automated driving system (ADS) of fully automated vehicles.

<sup>&</sup>lt;sup>4</sup> Fully automated M and N category vehicles, i.e., passenger vehicles and goods vehicles, that are designed to accommodate occupants.

<sup>&</sup>lt;sup>5</sup> The implementing legislation for the type-approval of the automated driving system of fully automated vehicles refers in particular to systems listed in points (a), (b), (d) and (f) of Article 11 (1) of Regulation (EU) 2019/2144, i.e. to (a) systems to replace the driver's control of the vehicle, including signalling, steering, accelerating and braking; (b) systems to provide the vehicle with real-time information on the state of the vehicle and the surrounding area; (d) event data recorders for automated vehicles; and (f) systems to provide safety information to other road users. Finally, the approval of the automated driving systems of automated vehicles should not be covered by EU regulation 2022/1426 as it is intended to cover them with a reference to UN Regulation 157 on automated lane keeping systems (2) in Annex I to Regulation (EU) 2019/2144 listing the UN regulations that shall apply on a compulsory basis in the EU. As next stage, the Commission will continue the work to further develop and adopt by July 2024 the necessary requirements for the EU whole vehicle type approval of fully automated vehicles produced in unlimited series.

<sup>&</sup>lt;sup>6</sup> For the whole-vehicle type-approval of fully automated vehicles, the type-approval of their automated driving system under this Regulation should be complemented with the requirements set out in Annex II, Part I, Appendix 1 of Regulation (EU) 2018/858.

In the project, we concluded that the guidelines such as those named above can function as a reference, but the same requirement cannot be used for trials with automated vehicle because the technology is still under development. They are to be kept apart. We can learn from the guidelines what is important to keep in account for the future. We also need to keep apart the expectations between trials and type approvals when discussing the requirements for independent external audit between authorities, OEMs, and assessors.

# 4 The Swedish Transport Agency's approval process for trials with automated vehicles

In this chapter we will describe the Swedish Transport Agency's approval process for trials with automated vehicles and give an introduction to the independent assessment.

# 4.1 The Swedish Transport Agency's approval process for trials with automated vehicles

Ordinance (2017:309) on trials with automated vehicles enables the driving and testing of automated vehicles in road traffic as part of experimental activities in Sweden. The approval is given by the Swedish Transport Agency. The authority has issued additional regulations, such as TSFS 2021:4 (later changed by TSFS 2022:82). These regulations describe, among other things, requirements for

- what an application must at least contain (art 4),
- control of the experimental activities (art 5),
- communication/reporting to the authority (art 6-7) and
- evaluation of the experimental activities (art 8).

The Swedish regulation on trials with automated vehicles mentions that permission may be granted only if the applicant shows that traffic safety can be ensured during the trial operation. This means that the trial operation needs to maintain a safety level in height with current level, i.e., "at least as safe as today" at the intended level for the route/area.

For approval of trials with automated vehicles the Swedish Transport Agency (STA) needs to be provided with the following information by the applicant (TSFS 2021:4):

#### Relevant aspects of the management system and test organisation:

| Responsibility | Describe how responsibilities, tasks and authorities are distributed for the person or persons who will be responsible for the experimental activities. |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| Competence     | Describe how you ensure that those who participate in the experimental activities have suitable competence for the task.                                |

| Responsibility          | Describe how responsibilities, tasks and authorities are distributed for the person or persons who will be responsible for the experimental activities.                                                                                       |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Document                | Describe how you handle and store documents that are important                                                                                                                                                                                |
| management              | to the business.                                                                                                                                                                                                                              |
| Accidents and incidents | Describe how you ensure that accidents, incidents and other deviations are investigated and that preventive measures are taken.                                                                                                               |
| Communication           | Describe how you ensure that information concerning traffic safety is documented and processed within the organization, and how it is communicated to the Swedish Transport Agency, road managers and other external actors who are affected. |

#### Relevant aspects of the test vehicle and test setup:

| Purpose and objectives of the experiment | Explain overall the purpose and goals of the experiment.                                                                                                                                                                                                                                                                                                               |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Automated systems/functions              | Describe automated systems and functions that shall be tested<br>and evaluated in the trial. This includes both a description of<br>the technical system and the system's functionality and<br>limitations (e.g. how the systems follow traffic rules).                                                                                                                |
| Evaluation of the experiment             | Explain in general how you plan to carry out the experiment and how it will be evaluated and why the experiment must take place in real traffic.                                                                                                                                                                                                                       |
| Geographical area                        | Describe the geographical area and on which streets or roads<br>the experiment is to be conducted, as well as who it is<br>responsible for the streets/roads.                                                                                                                                                                                                          |
| Risk assessment                          | Describe which risks you have identified and measures to minimize these to an acceptable level of road safety and how you continuously manage risks during the trial, and that the experiment does not cause any significant disturbance or inconvenience for the surroundings. The risk assessment must consist of a system and trial definition and a risk analysis. |
| Exemption from vehicle ordinance         | Need for exemption according to the vehicle ordinance, when tests are carried out with vehicles that have been modified in one way or another in order to be performed automatically.                                                                                                                                                                                  |

#### Framework for the safety case and risk assessment for test activities:

#### The minimum level of the safety case:

- Safety plan
  - Description of the safety related work, roles, responsibilities, and methodology used to show that the trial operation can be conducted safely.
- System and trial definition
  - Definition of the technical system, its functions, limitations & interfaces (internal/external), and the experimental activities (for functional & operational safety).
  - o The system definition must also describe the intended operating conditions for the experiment (for example, maintenance and environment) and limitations of the technical system.
  - The description of the technical system must be sufficient to be able to identify the risks with the system. It must be clearly stated of which parts the automated functions consist of and the degree of maturity of the respective part.

#### Risk assessment

- The applicant must show that the risks of the test activities have been identified and categorized through risk analysis of the system that is described in the system and trial definition. Risks when interfacing with other systems must also be analysed. At a minimum, the following should emerge from the risk analysis:
  - Description of risk<sup>7</sup>
  - Initial probability (the different levels of probability should be clearly defined and weighted against the experimental activity)
  - Initial consistency (the different levels of consistency should be clearly defined and weighted against the experimental activity)
  - Initial risk classification (based on acceptance criteria<sup>8</sup>/risk matrix)
  - Mitigation (action) with reference to action taken<sup>9</sup>
  - Final probability
  - Final consequence
  - Final risk classification

The participants of the risk analysis and their competence must be stated.

The application process consists of various steps (further described in guideline for TSFS 2021:4). A letter of interest and a following start up meeting initiate the application process and a dialogue between the different parties (Figure 4). The purpose of the dialogue is to ensure a good understanding of the process for all the parties involved and engagement from all the actors involved, such as the STA, the operator, and the

<sup>&</sup>lt;sup>7</sup> Identification of risks is an ongoing process. The risks that identified during the project, for example during risk analyses, can be gathered in a risk source list (hazard log).

<sup>&</sup>lt;sup>8</sup> Acceptance criteria for a sufficient level of safety must be specified by the applicants themselves.

<sup>&</sup>lt;sup>9</sup> The risks identified by the applicant must be reduced to an acceptable level. The acceptance criteria for a sufficient level of must be specified by the applicant, proof for implementation of the risk-reducing measures needs to be shown to the STA (which can be a technical solution, a routine or a driver).

manufacturer (Faxér et al. 2021). Based on this, the application can be sent in and will be assessed by the STA, maybe additional information needs to be provided by the applicant.

Two main tests can be crucial for the decision of the permit: the Factory Assessment Test (FAT) and the Site Assessment Test (SAT). The FAT, if relevant, can for examples concern the inspection or measurement of vehicles or driver environments. According to the provided documentation and the FAT, the STA issues two decisions: (a) decision on exemptions from regulations on requirements for vehicles and (b) decision on temporary permit. This enables the applicant to be able to prepare the activities on the intended route/area prior to the final on-site inspection (validity period of approximately two weeks). Before the final permit is given, the applicant and the authority meet for the SAT, which is normally carried out on the designated site for test activities. If the SAT proves that the vehicle complies with applicable traffic regulations, that the test activities do not cause any significant disturbance or inconvenience to the surroundings as well as that the applicant carries out the trial in accordance with what is described in application, the STA issues the permit for a certain period.

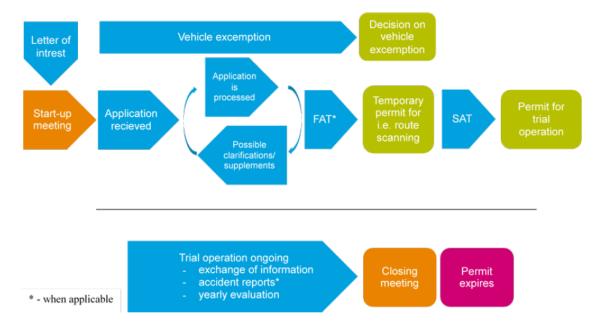


Figure 4: Schematical description of the application process for trials with automated vehicles by the Swedish Transport Agency (source: TSG 2023-6693)

The permit can contain several conditions that the applicant must comply with. Furthermore, the applicant is forced to inform the STA on incidents, accidents and other relevant information that occurred during the test activities.

An evaluation of the trial must be sent to the Swedish Transport Agency annually and at the end of the trial (Guideline for TSFS 2021:4). This is done through a written report that is sent in and the content of the evaluation must be linked to the purpose of the trial and goals.

### 4.2 Independent assessment

In October 2023, STA published a guiding document to help applicants in the application process, while one part is describing the independent assessment (TSG 2023-6693).

If the applicant relies on technical systems to ensure traffic safety, depending on the system's complexity, it may be difficult for the STA to assess the system's safety.

This enables the applicant to hire an independent external assessor themselves.

The purpose of the independent assessment is to review the risk assessment and the evidence of risk management linked to the technical systems (ADS) included in the safety work (other parts of the application are not to be reviewed by the independent assessor but by the STA).

It includes assessment of the implementation of the safety plan as well as assessment of the safety plan including method and its suitability to be used for this system/technology to achieve a trial that can be carried out without affecting traffic safety.

This must be summarized in a report. This report should include at least:

#### • Description of the assessed system

A description that explains the system's function, intended use, interface, limitations and any conditions for using the system.

#### • Description of assessment method

A description that explains how the assessment has been carried out, and what the basis for the assessments that have been conducted are.

#### • References

The report must contain an account of which documents or other sources that form the basis of the assessment and how these have been reviewed. This may also include applied standards or other external requirements documents.

#### • Results

The result of the assessment must be stated, and any deviations or observations shall be accounted for.

#### • Conclusion with statement

A summary of the work carried out as well as a final statement from the independent assessor on whether the system can ensure traffic safety. It must be clearly stated in the conclusion if there are any limitations or conditions for the system.

For the credibility of the assessment, it is important that the person performing the assessment is organizationally independent in relation to the current project and that the assessor has sufficient knowledge of the technology and the process of how these safety-critical systems are developed. If applicants hire an independent assessor, STA wants to see documents that show that he/she has sufficient competence.

To facilitate an efficient permit process, it may be appropriate to have a dialogue with the STA if applicant intend to use an independent assessor. This is primarily to ensure the requirements for the assessor's competence and the plan for his/her work before the assessor begins its assignment.

# 5 General discussion – Independent assessment in a Swedish context

# 5.1 What type of trial is affected by the change?

The general advice refers to the following cases:

If the application includes trials where technical systems are used to a large extent to ensure traffic safety.

In the project we have discussed what this requirement means in detail. According to the partners, we understand that for a trial with automated vehicles of SAE level 4 this would apply. Even in trials with SAE level 3 vehicles this can be the case and is up to discuss with the STA. For example, when SAE level 3 vehicles and ALKS (Automated Line Keeping Systems) is combined an independent assessor might be used, but not regarding a SAE level 3 vehicles combined with a cruise control. To an independent assessor, it should not matter if the vehicle is level 3 or level 4 because the audit will be carried out on the basis of a safe vehicle.

# 5.2 Costs and processing time of an independent assessment

According to the guideline issued by STA, it is difficult to give an approximate for the permit processing time, as the extent and complexity of the experimental activities can vary greatly. So far, without an independent assessment, the processing time is estimated to be between three to six months, i.e., from initial contact to permission being obtained. But, it is not unusual that getting a permit can take more than a year. One reasonably more detailed schedule can be given during the first meeting with the STA. Yet, a prerequisite for efficient permit management is that the application is thoroughly processed and as complete as possible when submitted to the STA.

A lesson learned from Denmark is that in order for it to be effective, the authority and the assessor should not review the same document. To achieve a separation between the tasks, it is important that the STA is clear about what an independent assessor is to review and what the authority is to review (see chapter 4.2). To limit the applicant's costs for an independent review, it is also important that the STA clearly defines what the assignment should cover.

So far, it is not mandatory for an applicant to hire an independent assessor. It is only a piece of advice. STA has an hourly rate of 1 700 SEK/hour. For an applicant, it may

therefore be interesting to investigate whether it is cheaper to let the work be carried out by STA or whether it is possible to find an independent assessor who has a lower hourly rate. One lesson from Spain is that it is difficult to give an estimate of how much an audit costs because the trials are different (or the cases are not identical). Prices can therefore vary greatly. An applicant also needs to consider whether it is easier to find people with the right skills for the audit than STA can handle. STA may even need to hire a person with the required skills to be able to carry out an assessment of the application, and that takes time too.

# 5.3 How can the independent assessment make the application process easier for the applicant and for the Swedish Transport Agency to grant permits?

The intention to use an independent assessor is discussed between the applicant and the STA primarily to ensure the requirements for the assessor's competence and the plan for his/her work before the assessor begins its assignment. This can be done already during the start-up meeting with the authority (Figure 4).

The intention to include a third-party assessment for the authority is to ensure: "If the application includes trials where technical systems are used to a large extent to ensure traffic safety, i.e. depending on the system's complexity, it may be difficult for the Swedish Transport Agency to assess the system's safety." (TSG 2023-6693).

A third-party assessment should be done in parallel to the application process (based on the risk assessment done by the OEM) and it was discussed as part of the project if it can make the application process easier for applicant and STA, whereas the following can be said:

- Independent assessment is a desktop study with a broad scope, i.e., the assessor needs to look at the complete vehicle system, the ADS, the ODD, the risk management and the configuration management.
- The applicant provides the risk assessment, which is then assessed by the third-party assessor. It is a part of the quality assurance.
- The application will be easier next time as only the site-specific aspects might have to be changed for the application.
- By using an independent assessor, the applicant may get more control and insight in the application process. Applicants from outside Sweden can sometimes be unsure of how the Swedish public access to information and secrecy legislation works. They are concerned that trade secrets may be inadvertently disseminated by the STA. An applicant can therefore have an independent review of material that is sensitive and then not have to submit the material to STA.

#### 5.4 When is a new review needed?

In the project we have discussed for how long an assessment is valid. When will it be redone and who takes the initiative to do a new one? The starting point is that there is a well-defined system configuration and a well-defined ODD. But trials are about testing new things, like software changes. How large must the changes be for the review to no longer apply? There is no clear answer to these questions. The same problem exists with regards to the scope of the permit for trials. How far can an autonomous vehicle evolve during a trial and still be legal? Our conclusion is that it is important for the independent assessor to document what has been included in the review and the scope of the review.

# 6 Discussion - Requirements on an independent assessor

In the guidance provided by the STA, no direct requirements are described on the assessor. But it states that: "For the credibility of the assessment, it is important that the person performing the assessment is organizationally independent in relation to the current project and that the assessor has sufficient knowledge of the technology and the process of how these safety-critical systems are developed. If applicants hire an independent assessor, we want to see documents that show that he/she has sufficient competence" (TSG 2023-6693). So, what can this mean?

# 6.1 Independent according to the Swedish vehicle law

The guidance does not explain the meaning of *organizationally independent*. Is it okay if i.e., a subsidiary is an independent assessor of another subsidiary?

There are however clues as to what might be meant by independent. The Swedish vehicle law (Fordonslagen (2002:574) 4 Chapter. 2h §) describes independence (Swedish: *oberoende*) of the vehicle inspection body as the following:

2 h § The inspection bodies may not conduct or be in a commercial, financial or any other dependent relationship with anyone who conducts:

- 1. trade in, manufacture, import or marketing of vehicles subject to inspection or parts or accessories for such vehicles,
- 2. repair or service of vehicles subject to inspection,
- 3. professional traffic that requires a permit in accordance with Regulation (EC) No. 1071/2009 of the European Parliament and of the Council of 21 October 2009 on common rules regarding the conditions to be met by persons engaged in professional traffic and on the repeal of Council Directive 96/26/EC and the Occupational Traffic Act (2012:210),
- 4. rental activity that requires a permit on car rental, or
- 5. taxi traffic that requires a taxi traffic permit according to the Taxi Traffic Act.

This legislation can be used to help interpret what is meant by independence. According to the Swedish vehicle law it is not okay to use a subsidiary as an independent assessor.

### 6.2 Impartial and independent

In Denmark the requirements on the assessor are further defined. The requirements are taken from the train sector (Retsinformation BEK nr 543 af 24/05/2017). The executive order applies to companies that act as an assessor when assessing the risk of significant changes in railway systems and when there is no requirement for an accredited assessor. According to the legislation an assessor must be *impartial* and *independent*. The regulations refer to the fact that an assessor in this part must comply with the requirements of DS/EN ISO/IEC 17020:2012.

ISO 17020:2012 is a standard that lays down competence requirements for organisations carrying out audits, as well as requirements on how control activities are to be carried out in an impartial and consistent manner.

According to the standard an assessor must be free of impartiality and independence and shall not allow commercial, financial, or other pressure to jeopardise impartiality. Persons employed in an assessor company who are engaged in activities related to assessor activities must also meet the same requirements for impartiality and independence as assessors.

# 6.3 Sufficient knowledge of the technology and process

Evolvement of ADS to more advanced solutions demand new skills of the agency and the assessor. The guideline issued by STA does not list necessary competences.

In Denmark, assessors will have to be approved by the Danish Road Safety Agency (DRSA) before they can fulfil the role of assessor for the specific project. DRSA evaluates the competencies of the applicant and the structure of the assessment (Retsinformation BEK nr 543 af 24/05/2017).

In the Danish executive order (BEK nr 543 af 24/05/2017) referring to railway safety skills, the following competence criteria are named:

#### Competency in railway safety skills:

- Competency within risk management: knowledge of and experience with the usual methods within safety analysis and the relevant standards.
- All relevant competences for assessment of the parts of the railway system affected by the change.
- Competence in the correct application of safety and quality management systems or auditing of such systems.

- Competency within the railway system or parts of the railway system for which significant safety requirements have been laid down including operation and maintenance of the railway system:
  - The assessor must be able to assess the overall coherence in connection with risk management and the safe integration of the assessed system into the overall railway system. This includes the assessor's competence to check the following areas:
    - Organization, i.e., the measures necessary to ensure a coordinated approach to achieving system security through uniform understanding and application of risk management measures to subsystems.
    - Methodology, i.e., the assessment of the methods and resources used by the various stakeholders to support security at the subsystem and system level.
    - The technical aspects necessary to assess whether the risk assessments are relevant and complete, as well as the level of security of the system as a whole.
  - o Assessors can be approved for one, more or all of these competence areas.

According to the Spanish instruction VEH 2022/07, authorized Technological Recognition Centres should fulfil requirements on sufficient technical competence. ENAC, the Spanish National Accreditation Body can guarantee technical competence of the TRC by accreditation. Competence for obtaining accreditation according to the ISO 17025:2017 standard by ENAC needs to be proved for the tests in the following regulations:

- UNECE R13 y R13H (brake systems for light and heavy vehicles),
- UNECE R79.03 (steering system),
- UNECE R131 AEBS (heavy vehicle), R152 AEBS (light vehicle),
- UNECE R157 ALKS (lane keeping),
- UNECE R155 (cybersecurity)
- Implementing EU Regulation 2021/646 (Emergency Lane Keeping System (ELKS))

We have in the project further discussed competence of an assessor. An audit shall only be conducted by assessors with the technical and administrative knowledge necessary for such purpose. This means that an assessor also should have knowledge about ISO 26262-2018 (Functional Safety – Road Vehicles), and ISO/PAS 21448 (Safety of the Intended Functionality of road vehicles); and shall be able to make the necessary link with cybersecurity aspects in accordance with UN R155 and ISO 21434:2021 (Road vehicles — Cybersecurity engineering). An assessor should also have knowledge about Human Machine Interface) to be able to audit the relationship between vehicle - human driver. This competence shall be demonstrated by appropriate qualifications or other equivalent training records.

# 6.4 Approval process and/or accreditation of assessors

In Sweden STA wants to see documents that show that the assessor has sufficient competence. It is unclear what will happen thereafter. For example, should STA approve/reject the intended assessor in a decision. Based on what knowledge?

We think it is important to mention that it is not an ordinary employee who signs the review. It is done by an authorized signatory of the company. It is therefore the company that shall show that it has sufficient knowledges to do the job.

According to the Danish executive order (BEK nr 543 af 24/05/2017), the Danish Civil Aviation and Railway Authority approves assessors and assessor companies for a specific change and for generic approval. Assessors and assessor companies must fulfil the named requirements on assessors (see sufficient knowledge above) to be approved and they should have drawn up and maintained procedures meeting the requirements for control system management bodies according to ISO 17020:2012 for documents and registrations, procedures for quality assurance of the safety assessment report.

In Denmark, the executive order BEK nr 543 af 24/05/2017 applies to companies or parts of companies that must act as assessors for risk assessment where there is no requirement for an accredited assessor.

Furthermore, the assessor company must meet special resource requirements accordingly to ISO 1720:2012. The assessment company must ensure that the person appointed to assess specific changes does not have a connection to changes that could affect the independent assessment of the change. The same applies for subcontractors.

The application for approval by an assessor for a specific change must be attached by:

- 1) a preliminary system definition, and
- 2) documentation that the assessor has qualifications within the area or areas for which approval is sought.
- 3) statement from the assessor that the assessor meets and complies with the requirements of the executive order
- 4) statement from the assessor that the preliminary system definition is sufficient to start assessment

Duration of recognition: The approval to be able to act as an assessor is granted with validity for up to 4 years in Denmark.

The authority supervises that the approved assessor complies with the requirements during the validity of the approval period. The authority can revoke an approval if an assessor, assessor company or expert no longer meets the requirements.

According to the Spanish instruction (VEH 2022/07), Technological Recognition Centres (TRC) can act as independent assessors for trials. To apply for the designation of a TRC the following requirements must be met:

- Being a legal person
- Have been designated as a Technical Service by the competent authority (Spanish Ministry of industry, trade and tourism - MINCOTUR) for the homologation of vehicles according to the regulations in Annex II. In case of suspension or withdrawal of this designation, the centre is not authorized to continue this activity.
- Have, before requesting the designation, demonstrable technical competence in carrying out the activities for which it requests to be designated as Technological Recognition Centre.
- The applicant must provide all the documentation provided for the General Vehicle Regulation, in the present instruction and in subsequent regulations that may be applicable.

Said designation will be valid for a maximum period of 5 years and may be extended successively for periods of 2 years, upon request for extension. An update in compliance with new requirements due to development may be needed. The reports and resolutions of the Technological Recognition Centers will have national validity.

### 6.5 Liability

The guidelines from STA does not mention liability. In Denmark an independent assessor must have valid liability insurance which covers his civil liability according to the Danish executive order (BEK nr 543 af 24/05/2017).

### 6.6 Confidentiality

The guidelines from STA does not mention confidentiality. In the Danish executive order (BEK nr 543 af 24/05/2017), confidentiality should be ensured as follows:

The assessor, employees of the assessor company and associated subcontractors have a duty of confidentiality regarding everything they become aware of during the exercise of their business in accordance with this order. The duty of confidentiality does not apply to the competent administrative authorities in Denmark.

### 6.7 Document handling and management

The guideline issued by STA does not mention document handling. In the Danish executive order (BEK nr 543 af 24/05/2017) document handling and management are described as follows:

The assessor must always be able to document his work to the authority. The documentation must contain at least:

- 1) the information basis for the assessor's work,
- 2) description of the assessor's method, and
- 3) assessor's assessment.

The assessor must keep the documentation for at least 5 years.

# 7 Discussion - What is the right level of assessment by a third party?

Chapter 2 describes the application process in Denmark and Spain. Both countries use independent assessors, but in very different ways. How and what an independent assessor is expected to do is quite different in the two countries. The guideline from STA does not mention what the right level of assessment is by a third party. This can lead to uncertainty about what constitutes a good enough review. We have discussed in the project what the right level of assessment by a third party can be in Sweden. The two main questions are: What is the product to be audited? What is the product/outcome from an audit? It is important that all involved parties agree on this.

First, a major challenge is - do we all agree on what is safe enough? Is safe enough the same level as an attentive human driver or do we demand a higher level of safety regarding autonomous vehicles? The guiding document by STA for example does not include instructions on methods to be chosen or risk acceptance criteria:

It states that the applicant must choose "methods and risk acceptance criteria..." to demonstrate how road safety can be determined during the trial.

Furthermore, it is written that "the trial needs to maintain a level of safety at the level of the current level, i.e. "at least as safe as today" on the intended route/area." It is not clear what one should understand of a current level of road safety today (a driver that has full attention)?

The road safety problems that for example the Swedish Transport Administration is currently working on are at an excessively higher level, especially with regard to the goal of Vision Zero<sup>10</sup>. Does this mean that one should have the ambition from both the supervisory authority (the Swedish Transport Agency) and from the performing parties (industry and others) that the level of road safety for trials with autonomous vehicles should be "significantly safer than today", i.e., we cannot accept any serious accidents?

Secondly, according to the guideline "The purpose of the independent assessor is to review the risk assessment and the evidence of risk management linked to the technical

<sup>&</sup>lt;sup>10</sup> Vision Zero is the goal that no one should die or be seriously injured in traffic.

systems included in the safety work, other parts of the application are not to be reviewed by the independent assessor but by the Swedish Transport Agency."

It includes (according to the STA's supporting supplementary information document):

- assessment of the implementation of the safety plan and
- assessment of the safety plan including method and its suitability to be used for this system/technology in order to achieve a trial that can be carried out without affecting traffic safety.

The project partners discussed the requirements and concluded:

- The assignment is quite broad, i.e., the assessor needs to look at the complete vehicle system (ADS), the ODD, the risk management and the document handling of the applicant.
- Focus of assessment should be on the processes in place (e.g., change management or risk monitoring of the OEM/applicant) and competence (in e.g., basic safety functionality & risk handling), not too focused on the result itself.
- The independent assessor does not need to carry out his/her own test. Instead, the applicant is supposed to use technical service and the assessor then reads the report from the technical service.

The following figure illustrates the different tasks in an audit according to the project group:

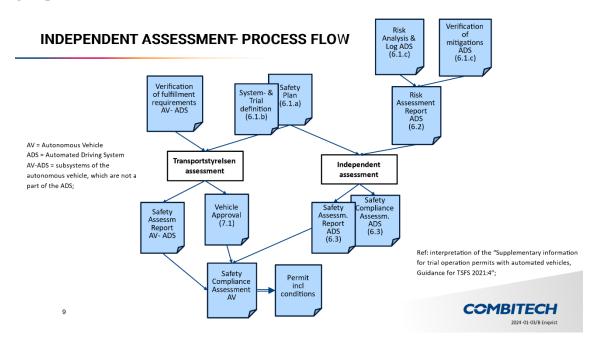


Figure 5: Interpretation of the "Supplementary information for trial operation permits with automated vehicles, Guidance for TSFS 2021:4" (source: Björn Enqvist)

# 8 Discussion - Challenges from the assessor's view

Using an independent reviewer does not mean that applicants do not have to do their homework. On the contrary, an independent reviewer may be tougher in its assessment than an authority. We have in the project investigated what an independent assessor daily challenges would look like. Regarding them as check points for an independent assessor:

- Late incoming deliverables can delay work and influence deadlines.
- Incorrect incoming deliverables such as
  - Missing data
  - o Incorrect/misunderstood data

may affect the quality of the work.

- Unclear acceptance criteria (what is safe enough?) can lead to different result when assessing applicants.
- Too short time available for assessment activities may affect the quality of work.
- Assessment work is split into several batches => penetration of the same material needed for several occasions which is less cost efficient.
- Communication of the assessment result to the sender of the deliverable to make him/her understand of the reasoning behind the assessment decision (if "Fail").
- Keeping yourself as an assessor updated with the details of the specific requirement and its acceptance criteria.

### 9 Conclusions

#### 9.1 Lessons learned

The use of an independent assessor to review applications to conduct trials with automated vehicles is not common practice in the EU. Two countries have used independent assessors on a national level since they introduced the possibility to do trials with autonomous vehicles. Denmark, which does not have its own automotive industry, chose to be inspired by the regulatory framework for independent assessors in the train industry. Spain, which has an automotive industry, chose instead to rely on lessons learned from vehicle type-approval. Resulting in the fact that the who, what, how, etc. of an independent assessment looks different between the two countries. Thus, there is no single conception of what an independent assessment is.

A general lesson is that an independent assessor can drive innovation forward. An independent assessor is probably tougher in its assessment than an authority. Making demands drives development forward. At the same time, the requirements must be achievable for the applicant. Trials and type-approval expectations should be kept separate.

Another question is whether independent assessors are a dead end or a way forward. When autonomous vehicles have come so far in the technology development that they are ready for a market introduction, the regulatory framework for type approval will apply. At the same time, there will always be a need for experimentation and thus a need for independent assessors.

So far, no applicant has used an independent assessor in an application to STA in Sweden. It is therefore unclear what an independent assessment is in the Swedish context. Will it become more like those in Spain or Denmark, or find its own way?

One of the most important questions that needs to be answered is what an independent assessor should do in Sweden. In our project, different views have been expressed. Basically, it has to do with the assessor's degree of freedom. In STA's general advice, an independent assessor currently has a large degree of freedom, as in Denmark.

The advantage of giving an assessor a large degree of freedom is that each pilot is unique and needs to be reviewed based on their circumstances. Initially, Spain tried to control quite strictly how a review should be carried out but had to let go of it as it did not work. The important thing is functionality to ensure safety.

The disadvantage of giving an independent assessor a large degree of freedom to choose what to review and how is to be reviewed is that it risks being very extensive and thus expensive and time-consuming for applicants. There are millions of possible boundary cases to investigate when it comes to autonomous vehicles, e.g., how will the vehicle handle a burning tire/sofa/garbage bag/car on the road. In Denmark, an audit can take more than a year. Another disadvantage is that no audit is identical. It will be necessary to develop new review procedures for each application, which takes time and will be expensive for applicants. An important reason why technology development is progressing and is possible to scale up, is the development of standards. The conclusion is that STA will need to work more on this in the future and clearly explain to an applicant how they view the assignment to an independent assessor and what he/she should do. When exactly is a statement needed and which criteria should the statement cover? A lesson from Denmark is that the STA should avoid making this a parallel assessment that has a life of its own, e.g., some form of approval of an assessor on the part of the STA, as there is a risk that it will take a long time. Such guidance needs to be carried out in harmony with the rest of the application.

Another suggestion for the future is to re-use the trial evaluation reports that must be sent into STA annually. Can independent assessment be improved incrementally by including insights from the trial evaluation reports?

The guiding document from the STA published in October 2023 (TSG 2023-6693), explaining independent assessment, helped the project partners to better understand how an independent assessment should be accomplished, but it also left room for interpretation. Further aspects that were raised on behalf of the project group:

• Good to have additional information on independent assessment and the application in general.

- Independent assessment is understood as a desktop study with a broad scope, i.e., the assessor needs to look at the whole vehicle system, the ODD, the risk management and the document handling of the applicant
- Example questions included in the supplementary information are especially welcomed e.g., is the independent assessor insured? Are the risks in the risk management plan that are managed via one or more organizational routines?
- The supplementary information document still leaves room for interpretation, and it would be helpful if the guideline is annually updated.

### 9.2 Further cooperation and collaboration

It is not clear from the documents what skills are required of an independent assessor in Sweden (such as only systems engineering, traffic engineering or with specific expertise in road safety, etc.). But following the discussions from the project, the assessor needs as a minimum requirement knowledge of road safety.

In the project we had made a list of potential assessors in Sweden and in neighboring countries, in alphabetical order:

- ATKINS
- Combitech
- Comentor (Safety audit & assessment, ISO 26262 assessment)
- COWI (DK)
- Ramboll (DK)
- RISE
- TUV Sud

Our conclusion is that it is possible to find independent assessors.

#### 9.3 Next step

When we wrote the application for this project, we hoped that someone would apply for a trial during the project period where it was relevant to hire an independent assessor. However, this was not the case. We believe that is important that the lessons we have learned in the project need to be put into practice and that is the next step – to learn from experience.

During the conversation with actors that are for example involved in SAE level 4 demonstrations in Norway, the importance of close cooperation to succeed with the pilot was emphasized. The local parties focus on constant improvements by testing and learning gradually about limitations and by mistake, of course in a traffic safe way.

In comparison to Norway which has currently trials with SAE level 4 vehicles ongoing, the conditions in Sweden are different in terms of the regulatory framework for experiments and start-up funding of research projects. Companies in Sweden are

concerned about Sweden falling behind if there was no opportunity to test such things in Sweden. There is a common view that the key to this is to do it together through pilots and to learn from each other to move forward towards sustainable and more efficient public transport.

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RISE Report : 2024:12 ISBN: 978-91-89896-57-4