ISSN 1831-9424

European Commission

Interpretation of EU Regulation 2022/1426 on the Type Approval of Automated Driving Systems

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2024

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JRC136417

EUR 31842 EN

PDF ISBN 978-92-68-12555-7 ISSN 1831-9424 doi:10.2760/86028 KJ-NA-31-842-EN-N

Luxembourg: Publications Office of the European Union, 2024

How to cite this report: European Commission, Joint Research Centre, Ciuffo, B., Dona, R., Galassi, M.C., Giannotti, W., Sollima, C., Terzuoli, F. and Vass, S., *Interpretation of EU Regulation 2022/1426 on the Type Approval of Automated Driving Systems*, Publications Office of the European Union, Luxembourg, 2024, https://data.europa.eu/doi/10.2760/86028, JRC136417.

Contents

Abstract

In 2022, the European Commission adopted the first worldwide legislation concerning the type-approval of the Automated Driving Systems of fully Automated Vehicles, opening the road to their introduction to the European market. The EU, in this way, becomes the first market in the world where this new generation of vehicles can be placed with a complete and unambiguous legislative framework. In order to define the conditions for the type-approval of vehicles operating without the presence of a driver, the EU Regulation 2022/1426 introduces a series of completely innovative elements that both industry and the Approval Authorities of the European Member States have the task to operationalise. In order to support this phase and to ensure the establishment of as harmonized as possible practices across the EU, the European Commission has launched in 2022 the process of drafting a first interpretation of some among the most innovative aspects of the Regulation. The present report is the result of this process. It has been drafted with the active contribution by the experts who compose the Automated and Connected Vehicles sub-group of the Working Group on Motor Vehicles (MVWG-ACV). In its final form the report is composed by two parts. A first part of technical interpretation of the regulatory text and a second part composed by six appendixes providing examples and relevant resources to support the operationalization of different aspects of the legislation.

Acknowledgements

The report is the result of the discussions and the contributions by the experts part of the Working Group on Motor Vehicles (MVWG), established 1970 to assist the European Commission (in particular DG GROW) in the preparation of legislative proposals and policy initiatives related to motor vehicles. In particular the contributors are all part of the sub-group focusing on Automated and Connected Vehicles (ACV)[1]. The role of the Editors has been to moderate the discussions within the sub-group and to consolidate the main conclusions into the present report,

The Editors are grateful to the two JRC colleagues appointed by the JRC Editorial Review Board to review the report, for their fruitful suggestions.

This work has been carried out in the framework of the Administrative Arrangement n. 36380 between DG GROW and JRC

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[1] All documents produced by the MVWG-ACV sub-group are available in the relevant section of the European Commission Communication and Information Resource Centre for Administrations, Businesses and Citizens (Circabc) Library

1 Introduction

1.1. The present document provides information to support the interpretation of the requirements established in the Commission Implementing Regulation (EU) 2022/1426 on 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 ("Regulation" hereinafter). The document also provides information and guidance on possibilities to comply with those requirements, and how to provide evidence of such compliance.

1.2. The target audience are manufacturers submitting systems for type-approval and the Technical Services / Approval Authorities assessing those systems. The purpose is to facilitate a harmonized interpretation and implementation of the Regulation.

1.3. The document strictly provides information to support the interpretation of the Regulation; it does in no form introduce new requirements. Whenever conflicting, the contents of the Regulation are legally binding.

2 Note regarding evidencing the requirements

2.1. This document is intended to provide support for the interpretation of the Regulation, and provides indications on what may constitute "acceptable means of compliance" (AMC) for the Technical Services / Approval Authorities and on the information that manufacturers should supply. It provides information only, it is applicable on a voluntary basis and it is not intended to be exhaustive, i.e., means of compliance other than those illustrated here may be acceptable. The document cannot create additional obligations; moreover, it provides material to assist in understanding what information may be useful in demonstrating compliance and to contribute to uniform implementation. The AMCs are developed with the presumption of compliance with the rules, so that it is recognised that conforming to this AMCs is one acceptable way of complying with the relevant section of the Regulation.

2.2. The standards referenced in the present document that are not referenced in the Regulation are intended as examples only and do not constitute binding requirements at any level. The same holds for the text included in the appendixes to the present document. They can be helpful in implementing the requirements of the Regulation but their use is not mandatory. Depending on the vehicle type defined by the manufacturer, and the practices and procedures they use, alternative and/or equivalent concepts may be used and information may be supplied to comply with the requirements established in the Regulation.

2.3. Alternative and/or equivalent methodologies used to comply with the requirements established in the Regulation, as well as refinements or nuances of the methodologies after the implementation, can be introduced as future amendments to update the present document with aim at contributing to uniform implementation of the Regulation.

3 Guidance on the requirements of Regulation 2022/1426

3.1. In the following, paragraph numbers refer to the same articles of the Regulation.

3.2. In the following, text in "italic" recall the original text from the Regulation.

A ANNEX I - Information document for EU type-approval of fully automated vehicles with regard to their automated driving system

Guidance to support the manufacturers in the preparation of the relevant entries of the Information Document is provided in Appendix 4 "Technical Guidance on Safety Assessment".

B ANNEX II - Performance Requirements

1. DDT under nominal traffic scenarios

No guidance included in this document as regards this paragraph.

2. DDT under critical traffic scenarios (emergency operation)

No guidance included in this document as regards this paragraph.

3. DDT at ODD boundaries

No guidance included in this document as regards this paragraph.

4. DDT under failure scenarios

No guidance included in this document as regards this paragraph.

5. Minimal risk manoeuvre (MRM) and Minimal risk Condition (MRC)

No guidance included in this document as regards this paragraph.

6. Human machine interaction

No guidance included in this document as regards this paragraph.

7. Functional and operational safety

7.1. The manufacturer shall demonstrate that an acceptable degree of consideration has been given to the functional and operational safety for the ADS during its design and development processes. The measures put in place by the manufacturer shall ensure that the fully automated vehicle is free of unreasonable safety risks to vehicle occupants and other road users during the vehicle lifetime when compared with comparable transport services and situations within the operational domain.

7.1.1. The manufacturer shall define the acceptance criteria from which the validation targets of the ADS are derived to evaluate the residual risk for the ODD taking into account, where available, existing accident data(1), data on performances from competently and carefully driven manual vehicles and technology state-of-the-art.

Note [(1)] For instance based on current accident data on buses, coaches, trucks and cars in the EU, an indicative aggregated acceptance criteria of 10-7 fatalities per hour of operation could be considered for market introduction of ADSs for comparable transport services and situations. The manufacturer may use other metrics and method provided it can demonstrate that it leads to an absence of unreasonable safety risk when compared with comparable transport services and situations within the operational domain.

Paragraph 7.1 introduces the obligation for the manufacturer to demonstrate that the ADS is free from unreasonable safety risks when compared to *"comparable transport services and situations within the operational domain".*

Paragraph 7.1.1 introduces the concept of validation targets and, in a footnote, provides an example of how accident data could be used in determining the acceptability of the residual risk. The Regulation does not define specific acceptance criteria, or metric, or approach to comply with. The regulation states that the manufacturer shall define the acceptance criteria, and is allowed to use any metric, both qualitative and quantitative, and approach provided that it takes into account -*"where available"*- current existing accident data, data on performances from competently and carefully driven manual vehicles and technology state-of-the-art, and provided that it allows to demonstrate that its safety level at least compares to comparable services, being run in the same operational domain.

A footnote linked to *"existing accident data"* provides an example of one criterion based on existing EU accident data on buses, coaches, and cars that *"could be considered"*: (10^{-7} fatalities of accident-involved road users per hour of vehicle operation). Such threshold is considered as a possible value suitable for the market introduction of ADS based on similar services and situation as the ones which the aggregated data refers to, i.e. buses, coaches, trucks and cars in the EU. Depending on the use case and the availability of data, similar threshold metrics, like fatalities per mileage (km), fatalities per trip, or involvement in fatal accidents per hour of operation, mileage or trip might be used.

The footnote -which is merely one example of a possible use of accident data in deriving acceptance criteria- specifically provides that: *"The manufacturer may use other metrics and method provided it can demonstrate that it leads to an absence of unreasonable safety risk when compared with comparable transport services and situations within the operational domain"*.

Therefore, a more suitable reference threshold could be specifically derived for each use-case, taking into account the specific operational design domain (ODD) defined for it (including where relevant the country of market introduction), and the available data.

Moreover, the rule text requires taking into account such accident and other data only *"where available"*, and if data on truly comparable services are not available, there is no request to use data that is not truly comparable. In case data are available, the link between data analysis and the safety acceptance criteria remains under the manufacturer's responsibility to justify.

Note that the comparison with similar services implies that the manufacturer is in charge of the identification and selection of similar services the vehicle could be employed for, and of the evaluation of the current level of risk of those services. The acceptability criteria and the related metric have to be defined by the manufacturer so as to allow a comparison with those similar services on the basis of the available data.

The following table shows a conceptual example of *"comparable transport services"*. The selection of similar services shall account for the specific ADS use-case and the related ODD.

Table 1. Example of comparable transport services to specific ADS use-cases

ADS service	**Reference human-driven service**
Shuttle	Buses
Robotaxi	Taxi
Hub to Hub	Trucks
Valet Parking	Parking

Source: JRC

The data for the identification of the acceptable residual risk for similar services in the ADS ODD can be obtained by measured or recorded data. A collection of available data sources and databases is reported in Appendix 3. Accident and traffic data can differ in terminology and definitions, and can be biased due to e.g. different inclusion criteria, different degrees of underreporting, etc. These shortcomings should be considered when using such data. In addition, it is acknowledged that data of sufficient granularity to accurately calculate the acceptable residual risk may not be fully available for the time being. In this case, evaluations or assumptions based on expert judgment, as well as alternative approaches to demonstrate that the ADS is free of unreasonable risks to occupants and other road users can be adopted and proposed to the type-approval authority.

Moreover, the aggregate safety target provided as an example in the footnote is a transportation-system-wide characteristic and, by its nature, does not reflect criteria that might logically be applied to specific use cases, vehicle types, or ODD characteristics. The manufacturer could take into account these shortcomings of aggregate data by defining a more particularised/suitable threshold able to compensate for the lack of sufficient information/data in the accurate definition of the acceptable residual risk.

Also, aggregate accident data do not clearly distinguish the performance of competent and careful human drivers among the broader driver population or the effects of state-of-the-art technology in avoidance of some crashes. The manufacturer could take into account these shortcomings of aggregate data by defining a more ambitious/suitable threshold able to compensate for the uncertainty or the lack of sufficient information/data in the accurate definition of the acceptable residual risk. Special attention shall be given to the situation when dealing with fatal accidents only. Accident data is usually heavily biased for such analysis, as the road users being involved in such kind of accidents (responsible for the accident or not) do not represent the average competent and careful driver. Any analysis provided shall consider this effect and explain how it has been taken into account.

Further guidance for this paragraph is provided in Appendix 3, "Technical Guidance on Safety Targets and Acceptance Criteria" and in Appendix 4 "Technical Guidance on Safety Assessment".

7.2. The manufacturer shall have processes to manage the safety and continued compliance of the ADS over lifetime (wear and tear of components especially for sensors, new traffic scenarios, etc.).

This paragraph requires the manufacturers to manage the safety and continued compliance of the ADS during the ADS lifetime. This includes the compliance with the identified safety threshold, which can be carried out also considering data from ADS real world operations, provided that they are statistically significant.

For vehicles not owned and operated by the manufacturer that are equipped with an ADS made by the manufacturer, this may entail making software updates and replacement ADS equipment available to owners and operators and continued analysis of available data to permit remediation of newly discovered safety risks related to the ADS.

Technical Guidance on the processes to manage the safety and compliance of the ADS over lifetime is also available in Appendix 4 "Technical Guidance on Safety Assessment".

8. Cyber security and software updates

No guidance included in this document as regards this paragraph.

9. ADS data requirements and specific data elements for event data recorder for fully automated vehicles

No guidance included in this document as regards this paragraph.

10. Manual driving mode

No guidance included in this document as regards this paragraph.

11. Operating manual

No guidance included in this document as regards this paragraph.

12. Provisions for periodic roadworthiness tests

No guidance included in this document as regards this paragraph.

C ANNEX III – Compliance assessment

Part 1 Traffic scenarios to consider

1. Minimum set of traffic scenarios

No guidance included in this document as regards this paragraph.

2. Scenarios not covered by point 1

2.1. Scenarios that are not listed in point 1 shall be generated to cover reasonably foreseeable critical situations, including failures and traffic hazards within the operational design domain.

2.2. When ADS capabilities depend on remote capabilities, scenarios shall include failures and traffic hazards stemming from the corresponding remote capabilities.

2.3. The method to generate scenarios that are not listed in Section 1, shall follow the principles set in Appendix 1 to Part 1 of this Annex.

2.4. The method used by the manufacturer to generate scenarios that are not listed in point 1 shall be documented in the documentation package to be provided for the ADS assessment.

No guidance included in this document as regards this paragraph.

Appendix 1 Principles to be followed to derive scenarios relevant for the ODD of the ADS

Guidance for this paragraph is provided in Appendix 2 to the present report: “Technical Guidance on Scenario Generation and Coverage”.

Part 2 Assessment of the ADS safety concept and audit of the manufacturer safety management system

1. General

No guidance included in this document as regards this paragraph.

2. Definitions

No guidance included in this document as regards this paragraph.

3. Documentation on the ADS

No guidance included in this document as regards this paragraph.

4. Verification and tests

No guidance included in this document as regards this paragraph.

5. Safety management system (SMS)

No guidance included in this document as regards this paragraph.

6. Reporting provision

No guidance included in this document as regards this paragraph.

7. Competence of the auditors/assessors

No guidance included in this document as regards this paragraph.

Part 3 Tests

No guidance included in this document as regards this paragraph.

Part 4 Principles for credibility assessment for using virtual toolchain in ADS validation

1. General

No guidance included in this document as regards this paragraph.

2. Definitions

No guidance included in this document as regards this paragraph.

3. Components of the credibility assessment framework and related documentation requirements

Guidance for this paragraph is provided in Appendix 5 “Technical Guidance for the Credibility Assessment of Virtual Testing Toolchain”.

4. Documentation structure

No guidance included in this document as regards this paragraph.

Part 5: In-service reporting

1. Definitions

1.3 ‘Critical Occurrence’ means each occurrence in which the ADS is engaged at the time of a collision event and because of which:

(a) at least one person suffers an injury that requires medical assistance as a result of being in the vehicle or being involved in the event;

(b) the fully automated vehicle, other vehicles or stationary objects sustain a physical damage that exceeds a certain threshold or any vehicle involved in the event experiences an airbag deployment.

2. Notifications and reporting by the manufacturer

2.1. The manufacturer shall notify without delay any safety critical occurrences to the type-approval authorities, market surveillance authorities and the Commission.

The notification should be in clear and plain language and should aim at containing as much of the following information as is readily available without prejudice to the applicable national law, but its dispatch is not supposed to be delayed due to the lack of complete information (notification can be provided in separate phases when the information becomes available):

- Manufacturer, WVTA number, type, variant and version if applicable, production year, Vehicle Identification Number
- ADAS and ADS systems on-board, system active at the time of the occurrence
- Name of fleet operator (if any)
- Description of the critical occurrence
- Number of occupants and other road users fatally or seriously injured;
- The extent of damage to the vehicle as far as it is known
- Date and time (local time or UTC) of the critical occurrence
- GNSS coordinates of critical occurrence

Without delay, the manufacturer should submit to the type approval authorities, the market surveillance authorities and the Commission the details omitted from the initial notification as well as other known relevant information.

See also additional guidance material in Appendix 6.

2.2. The manufacturer shall report within one month any short-term occurrences, as described in Appendix 1, which needs to be remedied by the manufacturer to the type-approval authorities, market surveillance authorities and the Commission.

The short-term reporting of occurrences is required for matters of such safety importance that they may require the manufacturer to take remedial action.

Short-term reporting is due within one month of the manufacturer's knowledge of the matter. It is expected that the manufacturer will be able to identify the root cause of the occurrence and the corrective action (if any) within the one month available for reporting the occurrences.

Short-term reporting is needed to provide awareness of situations in which the ADS may be or is posing an unreasonable risk to safety in-service.

The short-term reporting should be in plain language and contain as much of the information included in the proposed template (see Appendix 6) as is available to the manufacturer without prejudice to the applicable national law.

More detailed guidance on a possible template for the short-term reporting of critical occurrences is provided in Appendix 6 to the present report.

2.3. The manufacturer shall report every year to the type-approval authority that granted the approval on the occurrences listed in Appendix 1. The report shall provide evidence of the ADS performance on safety relevant occurrences in the field. In particular, it shall demonstrate that:

a) no inconsistencies are detected compared to the ADS safety performance assessed prior to market introduction;

b) the ADS respects the performance requirements set by this Regulation;

c) any newly discovered significant ADS safety performance issues have been adequately addressed and how.

The granting type-approval authority shall share this information with type-approval authorities, market surveillance authorities and the Commission.

The periodic reporting of occurrences is required to evaluate ADS fleet operation and to provide a suitable framework for the short-term occurrences normalization with respect to the ADS operation.

Periodic reporting is due yearly. It is expected that the manufacturer will be able to retrieve aggregated data concerning ADS operation such as cumulative distance and operating time.

The periodic reporting should be in plain language and contain as much of the information included in the proposed template (see Appendix 6) as is available to the manufacturer without prejudice to the applicable national law.

More detailed guidance on a possible template for the periodic reporting of critical occurrences is provided in Appendix 6.

2.4. Type-approval authorities, market surveillance authorities and the Commission may request the manufacturer supporting data used to elaborate the information provided into the in-service reporting and notifications.

These data shall be exchanged by means of an agreed data exchange file. Type-approval authorities, market surveillance authorities, and the Commission shall take all necessary steps to secure such data.

No guidance included in this document as regards this paragraph.

2.5. Any pre-processing of data should be notified to the granting type-approval authority in the in-service Data Report.

No guidance included in this document as regards this paragraph.

Appendix 1 - List of occurrences for in-service reporting

The Annex III Part 5 Appendix 1 of the Regulation (EU) 2022/1426 provides the list of occurrences to be reported. This list identifies four occurrence categories with some details of situation types that fall into each category.

Guidance for this paragraph is provided in Appendix 6 - Technical Guidance on In-service Reporting

4 Conclusions

The EU Regulation 2022/1426 has opened the road to the market introduction and deployment of fully automated vehicles in Europe. It defines minimum safety requirements that vehicles needs to fulfil and different validation methods to assess their performances. Being the first regulation developed worldwide for the type-approval of fully automated vehicles, it introduces various elements of completely innovative character. In order to support ADS developers and Approval Authorities in the application of the Regulation and in order to ensure that related practices around the EU may be as harmonized as possible, the European Commission has initiated the process to provide an interpretation to some of the most innovative aspects of the legislation. The work has been carried out by the experts of the ACV sub-group of the Working Group on Motor Vehicles, under the lead of the European Commission. The result of this process is the present report. The parts of the Regulation for which an interpretation and/or examples and references have been provided have been identified by the stakeholders involved in the process. In the future, the work will continue to include additional parts of the Regulation as well as to strengthen and consolidate the parts dealt with in the present report in the light of the evidence that will be gathered by the application of the Regulation.

APPENDIX 1 – Technical Guidance on ODD description

Given a specific ODD, it is crucial for the ADS to ensure that:

- it can operate safely within its ODD under conditions reasonably expected in the ODD
- it will be used only within its ODD
- it can monitor whether it is inside/outside its ODD and respond appropriately, especially regarding ODD boundaries.

The conditions constituting the ODD in which the ADS was designed to operate will help determine which ADS competencies are required. For example, if an ADS has an ODD which comprises of roads with non-signalised junctions, one of the required behaviour competencies for the ADS in that ODD could potentially be "unprotected left or right turn". However, the same behaviour competency may not be required if the ODD of an ADS is limited to motorways or highways with signalised junctions.

As the ODD defines the operating conditions of the ADS, and supports the scenario-generation process for ADS testing, as shown in Figure 1, it is important that an appropriate taxonomy is used. The BSI PAS 1883[2], e.g., contains a standardised set of attributes such as scenery, environmental conditions and dynamic elements. On a similar note, the SAE AVSC00002202004[3] presents a lexicon for the ODD definition, including additional elements such as road surface, roadway infrastructure, operational constraints, road users, roadside objects and connectivity, to mention just a few. Other similar efforts are described in the ASAM OpenODD[4] and ISO34503[5].

Figure 1. Correlation between the ODD description and other pillars

Source: Oldoni and Khastgir (2023)

[2] https://www.bsigroup.com/globalassets/localfiles/en-gb/cav/pas1883.pdf
[3] https://www.sae.org/standards/content/avsc00002202004/
[4] https://www.asam.net/standards/detail/openodd/
[5] https://www.iso.org/standard/78952.html

APPENDIX 2 - Technical Guidance on Scenario Generation and Coverage

The present appendix provides technical guidance to the manufacturer on possible approaches they may use to derive scenarios for the certification of ADS based on the ODD, and for assessing their coverage as prescribed in the Commission Implementing Regulation (EU) 2022/1426, Annex III, Part 1, paragraph 2, and the related Appendix 1.0

It proposes principles of a scenario-based approach, among which the search of sufficient coverage of driving situations in the given ODD.

1. Introduction and global approach of driving scenarios

The interest of driving scenarios is based on three main, complementary logics:

- Coverage: a logic of sufficient coverage, aiming at avoiding that driving scenarios wouldn't have been taken into account in the system's design and validation; in line with the idea of covering the space of possibilities, regardless of the potential severity
- Distribution: a logic that is governed by probabilistic thinking and the evaluation of exposure to operational scenarios that the ADS is likely to encounter and is expected to be characterised and assessed in.
- Classification: aiming to consider scenario categories that were defined as nominal, critical and failure scenarios

Furthermore, the use of scenarios for the safety assessment of automated systems will have to combine approaches focused respectively on the vehicle, and the operational conditions in which the vehicle will be deployed that is to say considering the entire ODD, including ODD boundaries.

This appendix presents a possible approach to derive driving scenarios. The possible approach described here aims to achieve sufficient coverage in the identification of potential risks that an ADS may encounter during deployment. Indeed, some of the steps in the safety demonstration process are likely to use or generate scenarios; the identification and analysis of risks allows the contextualisation of critical situations. Linking the risk analysis to scenarios makes it possible to aim for sufficient coverage and relevance.

Working on scenario generation to assess vehicle safety, and more generally system safety constitutes a basis, from which it is possible to deal with scenarios that:

- cover situations within the use case's ODD limits (also linked with ODD definition, see Appendix 1);
- cover and combine safety demonstration activities (risk analysis and failure mode analysis);
- update based on experience feedback or the addition of other scenario description axes as the use cases mature (e.g. remote intervention, coordinated management of several vehicles, interactions with first responders).

The scenario-based approach makes it possible to generate traffic scenarios from reasonably foreseeable driving situations, involving other road users, objects, system failure, but also to characterise specific interactions as for example with law enforcement officers and priority vehicles; and including potential high severity situations.

2. Scenario generation

2.1. Scenario-based assessment

The main purpose of the contribution to the scenario-based safety demonstration is to verify that an ADS, characterised by a set of specifications resulting from its internal design and validation process, is capable of behaving safely in all reasonably foreseeable driving situations it may encounter in traffic.

The scenario approach, by aiming to inventory the driving situations that the ADS may encounter, is presented as a process whose genesis can be found in the "ODD and OEDR analysis", as described in the EU Regulation, whose underlying idea is to ensure the completeness of the identification of ODD elements/objects and the system's responses through a three-step inventory reasoning:

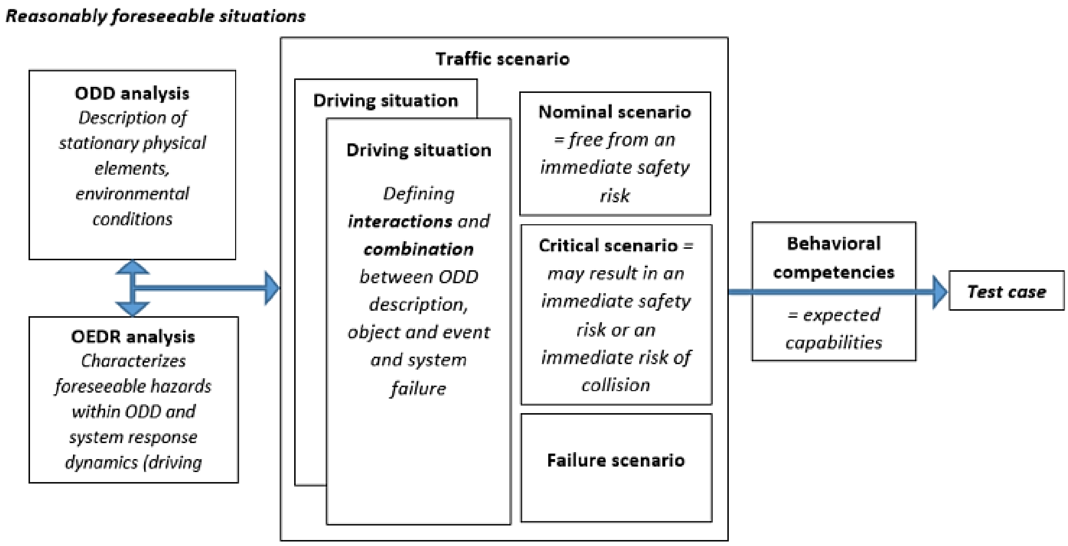
i. traffic hazards ("objects and events");
ii. detection and recognition performance ("detection");

iii. system response performance.

In that sense, behaviours of other road users that are reasonably foreseeable and presence of roadway characteristics in the ODD are explored in more detail by mapping actors with appropriate properties and defining interactions between the objects. Tables 1 and 2, in Appendix I of the EU Regulation (pp.25, 26) give an example of these analysis.

The behaviour of other road users, as long as dynamic events, and the condition of physical static elements within the ODD may fall at any point along a continuum of likelihood called the reasonably foreseeable conditions. The reasonably foreseeable concept should be seen as the notion of conceivability regarding traffic safety: all reasonably foreseeable situations should be taken into account when assessing system safety. It is worth mentioning that considering all reasonably foreseeable situations does not prevent from not considering them for testing according to risk analysis. For example, deceleration by other vehicles may range from what is expected and reasonable in the traffic circumstances, to unreasonable but somewhat likely rapid deceleration, to extremely unlikely (e.g., a sudden cut-in combined with full braking on a clear high-speed road).

Figure 2. Diagram presenting the global scenario-based approach linked with ODD definition and description and OEDR analysis – and the behavioural competencies to form a test case. The scenario-based approach has the virtue to combine all reasonably foreseeable situations applicable



Source: JRC

The concept of reasonably foreseeable, applied to the scenario generation approach, should be distinguished from the scenario-selection process, involving traditional safety analysis and making reference to scenario classification.

Considering an ADS in its ODD refers to a global principle guiding safety demonstration through scenario generation to provide a sufficient coverage of driving situations that might occur.

2.2 Scenario-based approach based on layers

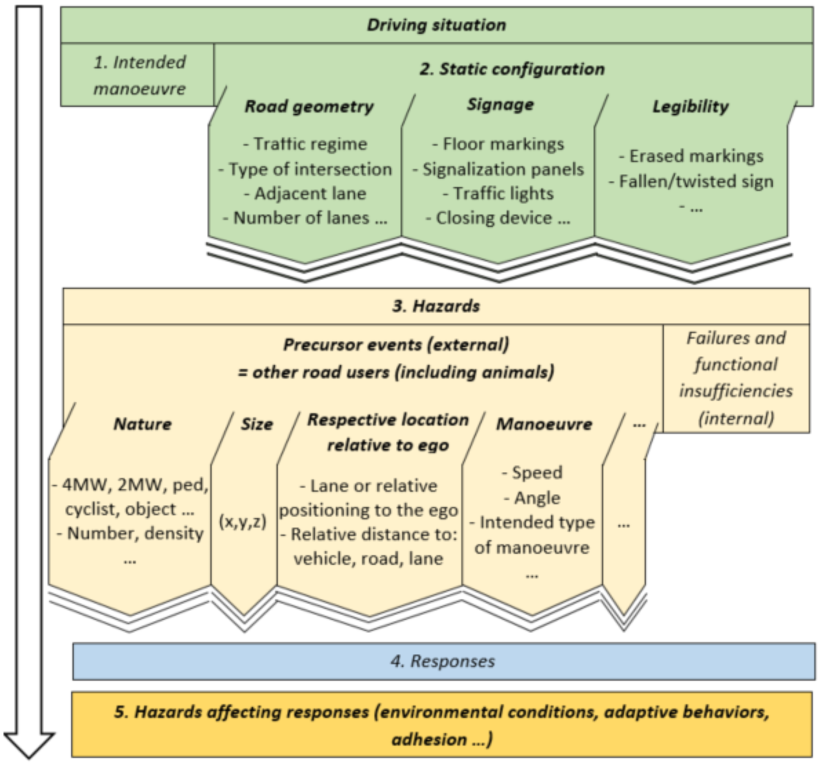
Based on a large literature review on scenario-based approaches that emerged at the international level through projects, the potential use of structural axes of scenario description has emerged.

The introduction of lists of descriptors, aiming to help describing both ODDs and scenarios, and reflecting the concept of sufficient coverage of the scenario-based approach, might lead to consider the maximum exhaustiveness of the descriptors themselves.

It should be noted that the selected approach, that remains at the initiative of the system manufacturer, following the logic of sufficient coverage of driving situations by appropriate coverage of descriptors, tends to contribute to state-of-the-art by combining different inputs from layer generation in international approaches. It appears that the chosen scenario-based approach should represent the global ecosystem vision, without being the only way to consider scenario generation. It is assumed that this paragraph defines the logic under which the scenario-based approach should be built, but does not represent the only possible logical arrangement.

One virtue of the scenario approach based on layers, in practice characterized by descriptors enabling to properly describe all reasonably foreseeable conditions, which apply to an ADS, lead to consider the virtue of combination to assume a good and sufficient coverage of the scenario space of possibilities.

Figure 3. Example of possible arrangement of layers and its decomposition based on the description of its layers (named descriptors). Each layer is composed of an amount of independent descriptors, combined to form scenarios



Source: adapted from French Ministry for Transportation[6]

2.3. Scenario Identification

This part proposes to make the link between different sources of scenarios and the type of scenarios that they can generate preferentially.

It is possible to consider four sources of scenarios, based on either a knowledge-based or data-based identification approach:

- KNOWLEDGE-BASED
  - Scenarios resulting from system design activities, induced by the intended use (operational design domain, OEDR, route, etc.)
  - Scenarios resulting from risk analysis relating to the functional insufficiencies
- DATA-BASED
  - Scenarios resulting from driving (physical or digital), which have
  - Nominal scenarios
  - Critical scenarios
    - Scenarios resulting from accidents, observed in the accidentology representative of the intended use

[6] https://www.ecologie.gouv.fr/sites/default/files/DGITM_Approche-par-scenarios-fevrier-2022-EN.pdf

- Scenarios often called "Edge cases" or notable scenarios (rare, unknown, and dangerous, from area 3 of SOTIF[7])
- Scenarios often called "Corner Cases" by combining at least two constraints which lead to a critical scenario
- "Near accidents" or accidents avoided by interaction between driver and users, likely to become accident scenarios in automated driving.

On that basis, considering scenario sources makes a clear matching between scenarios and descriptors, meaning that descriptors might be induced by:

- Data from driving, both from accident or incidents and from edge cases, leading to consider edge descriptors (new descriptors, larger parameter ranges);
- Axis combination, from possible unknown combination of already known descriptors.

The notion of combination applies to the scenario-based approach as a process contributing to enhance the concept of sufficient coverage of the set of traffic scenarios.

Aligned with the notion of combination of possible descriptors leading to feed the scenarios, it is important to use a scenario approach keeping in mind the two main layers of OEDR approach:

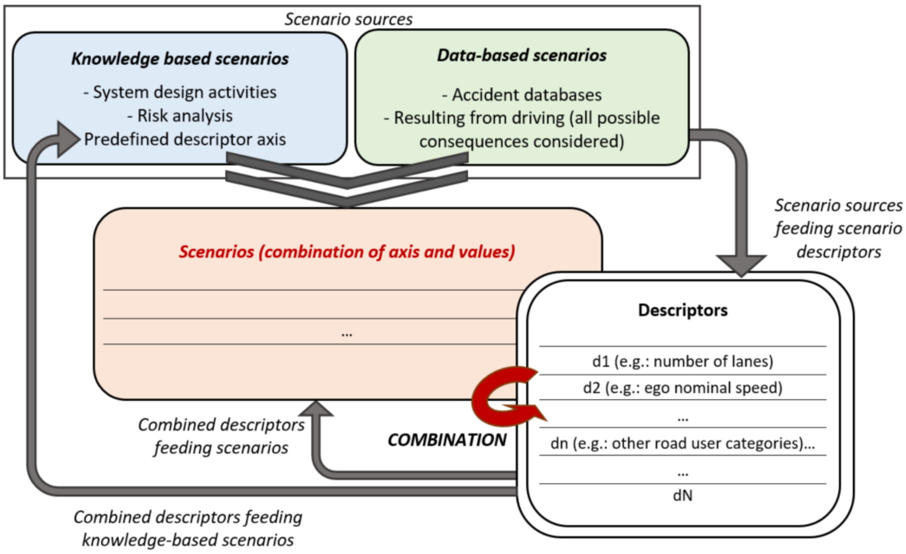
i. OED as the description of hazards that are reasonably foreseeable in the ODD;

ii. R as the possible response of the system (being possibly affected by failures or additional hazards)

It might be appropriate to map scenarios along with the main features of the expected response of the system, in particular in line with behavioural competencies, with the idea of prudential behaviour. For example, driving in front of a school should suggest specific behaviours such as reducing speed, potential pedestrians walking with unpredicted trajectories (in particular regarding children), crossing the street outside of a pedestrian crossing.

Data-based and knowledge-based scenarios are also thought to feed the process of scenario update. That means the scenario-based approach is a living process, where the set of scenarios for a specific system defined to operate in its ODD, is continuously revised. Moreover, as a scenario is defined as the combination of descriptors, which does this living process update continuously too, the set of scenarios is enhanced by the combination of these new descriptors. Descriptors, as being central in the scenario-based approach, are able to feed both knowledge-based scenarios (based from experts) and the list itself by new combinations induced.

Figure 4. Scenario-based approach under angle of two categories of scenario sources and its articulation with the combined-based concept (usable both as a knowledge-based and data-based principle).



Source: Lanaud and Delache (2024)

[7] ISO 21448:2022 - https://www.iso.org/standard/77490.html

In particular, working on scenario generation, especially through the combinatory-based approach does not prevent from dimensioning safety based on proportionate quantitative approaches.

2.4 Scenario enrichment process

The purpose of this paragraph is to present an approach to enrich scenario generation based on the following logic:

- the comparison of scenario descriptors with different sources is likely to reveal:
    - the need for new description attributes: a scenario taken from the sources turns out to be non-describable due to the lack of one or more lines of description
    - values of the description parameters: a scenario taken from the sources modifies the field of "reasonably foreseeable"
- the combination of scenario descriptors, enriched by new attributes, then generates more scenarios, improving coverage

Having said that, the aim of scenario combination, although guided by the principle of sufficient coverage of the scenario space, is not intended to assess an infinite number of scenarios in the testing validation process. The aim of the global scenario-based approach is to be able, based on the combination of appropriate descriptors and attributes, to identify all possible reasonably foreseeable scenarios to include in the testing procedures.

It is worth noting that this document does not provide any indicative methodology to move from scenario generation to a concrete scenario catalogue.

In turn, this enrichment of scenarios makes it possible to improve the mobilization of sources, for example by deepening risk analysis or by collecting traffic or accident data reflecting the new types of scenarios generated by the combination. This enrichment also makes it possible, if necessary, to ensure that nominal scenarios have not been omitted in the design of the system and its ODD.

2.5 Scenarios, ODD and descriptors

Although the aim of this document is not to provide a methodology to move from scenario generation to a concrete scenario catalogue, the link between ODD description and scenario generation is central. As presented in Appendix I, ODD description is crucial when considering safety demonstration activities, among those is scenario generation. Hence, the link between scenario generation and ODD description needs to be clarified. The scenario generation process has been presented as a combinatory-based process based on five layers, those layers enabling to precisely describe the reasonably foreseeable driving situations within the ODD (i.e. conditions under which the system is designed to operate safely). The aim of such an approach is to provide a sufficient coverage of the space of possibilities for a given ADS in a specific ODD, which aims to cover the space of traffic hazards regarding ADS capabilities.

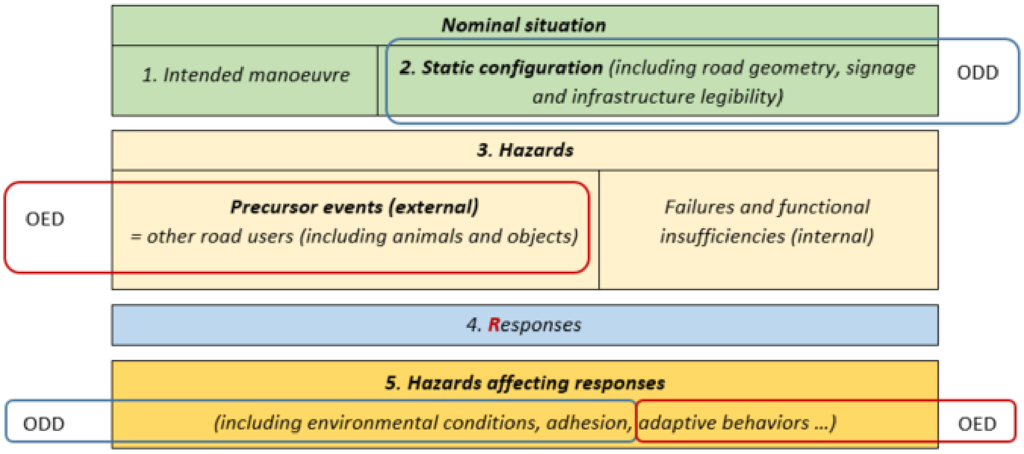
As a result, the link between scenario generation and ODD description becomes obvious. The level of details needed to build a representative and sufficient set of traffic scenarios for a given ADS in a given ODD relies on the representative and relevant level of details of the ODD itself, that is to say describing static elements of the driving environment. In this consideration have not been mentioned dynamic possible elements, which may not be part of specific ODD (named addressable hazards in the previous part 2.1). In that case, it is worth mentioning that ODD consideration through its descriptors has to be linked with OED descriptors (provided in previous graph in 2.2) has they constitute a set of the reasonably foreseeable conditions mentioned in graph in 2.1. As a result, all these considerations place on one hand ODD as a central element when building a scenario generation process, and on another hand put in the middle the concept of descriptors.

This ties in with the idea that sufficient coverage within the scenario-based approach, carried out by the notion of a sufficient list of descriptors is the key to move from inert elements to sets of characteristics intended to build a scenario. It remains under manufacturers' competency to provide a consistent list of both scenarios and ODD descriptors. The list of descriptors will fit the requirements to provide an indicator of the corresponding level of coverage.

This global approach linking scenario generation and ODD description does not seek to describe neither characterize triggering conditions of hazards nor ADS responses.

Hence, making the link between these two important notions is a possible way to move from a theoretical approach named scenario generation to a concrete approach characterized by its intersection with ODD description. The latter process aiming to provide a finite number of concrete scenario for testing procedures.

Figure 5. Illustration of the power of descriptors in the scenario-based approach through the possible arrangement presented in this document, showing the complementarity between ODD descriptors and OED definition (leaving aside failures and functional insufficiencies.



Source: Lanaud and Delache (2024)

3. Articulation between scenario-based approach and other safety demonstration activities

A major challenge of the safety demonstration approach is to ensure the greatest possible and sufficient coverage of safety-relevant scenarios.

This quest for sufficient coverage of scenarios is central to the approach. The requirement of "reasonably foreseeable" applies to it, to which the knowledge-based and data-based approaches presented above contribute. These approaches must combine the search for system malfunctions and external traffic hazards. This search for sufficient coverage of events (malfunctions + traffic hazards) is fed by the combination of deductive approaches on possible causes (hazard -> possible causes) or inductive approaches of failure modes (failure -> hazards). The search for coverage is also fed by the search for traffic hazards specific to the route.

The scenario approach is based on a method of "expert" generation, by combining the axes of description of the scenarios (driving environments * nominal manoeuvres * characteristics of the collision precursor events), which leaves aside any reference to their likelihood and does not specifically rely on data from driving.

The main contribution expected from the scenario approach is thus to avoid the omission of certain types of scenarios from the quantitative approaches used in traditional risk analyses. The generation of scenarios (in particular by combining axes) is therefore a first step, normally completed by a quantification step (frequency / severity). The robustness of the overall approach (scenario generation / quantified risk analysis) should therefore be based on the principle that the scenarios resulting from the generation stage are systematically included in the quantified analyses, even if it means qualifying them as "implausible" or qualifying their consequences as "not serious".

To ensure that the behavioural competencies identified in the previous paragraphs are ready to be assessed through the application of simulations or physical testing, ODD-relevant scenarios must be developed. Scenario creation involves use of assumptions concerning possible actions by road users and their characteristics.

In a logic relative to the consideration of the global approach of vehicle type-approval, in a comparable spirit to that underlying testing, and to avoid multiplying safety demonstrations at different levels (to remove systems that would not maintain a sufficient level of safety), the scenario-based approach should enable to assess separately the overall weighted analysis of scenarios that are (a) common and representative of all deployment environments covered by the ODD; (b) easily characterized ; c) sufficiently critical that a glaring lack or inadequacy of system response could be sufficient to disqualify it; but d) for which the expected system response is not describable in a sufficiently simple and unambiguous way to apply the pass/fail test logic applicable to simple scenarios (such as emergency braking in pedestrian detection, for example).

APPENDIX 3 – Technical Guidance on Safety Targets and Acceptance Criteria

The present appendix provides technical guidance to the manufacturers on the acceptable means of compliance for the definition of the acceptance criteria to evaluate the residual risk of the ADS as prescribed in the Regulation, Annex II, paragraph 7.1.1, and the related footnote.

1. Safety Assessment Approach set in Regulation 2022/1426

The safety assessment approach set out in the Regulation is based on the demonstration of compliance with:

a) Requirements of the safety management system (Annex III, Part 2).

b) General performance requirements (Annex II, except Paragraph 7).

c) Specific performance requirements valid for a minimum set of traffic scenario (Annex III, Part 1).

d) Safety acceptance criteria to demonstrate absence of unreasonable risk (Annex II, Paragraph 7).

Considering that the demonstration of compliance of the safety management system (a) follows its own process and rules, the other three constitute a unique framework that the manufacturer should address organically.

When dealing with the demonstration of compliance, (b) and (c) are, on the one hand, both based on explicit requirements (the former related to the ADS general performance, the latter scenario-specific), and therefore can be grouped as "requirements-based" safety demonstration. In these cases the compliance is demonstrated by means of verification and validation that the ADS meets the defined requirements under the specified as well as real-world conditions.

On the other hand, the demonstration of safety must also consider that unsafe scenarios can still be present without explicit requirements or performance limitations so that the ADS does not meet the defined requirements under certain (unusual) conditions. These cases are potential sources for residual safety risks. The demonstration of compliance with the safety threshold for the acceptability of the residual risk (d) is, by its definition, very different from the others and should be addressed with a dedicated methodology. Establishing compliance with the requirement in Annex II, Paragraph 7, to demonstrate that the manufacturer has given acceptable consideration to functional and operational safety in developing acceptance criteria and validation targets sufficient to ensure that the ADS is free from unreasonable risks, should be addressed with a full explanation of the criteria and targets and the methodologies used to develop them.

The Regulation foresees that, in some cases not covered by requirements (b) and (c), a collision may be unavoidable, and therefore it requires quantifying the residual risk associated to such scenarios, to verify that road users are not exposed to an increased risk.

By combining the residual risks associated with all these scenarios, a global residual risk is obtained, characterizing the use of the considered ADS in the considered ODD. Finally, the global residual risk is compared with a reference threshold value to demonstrate compliance.

Furthermore, the assessment of the residual risk gives also the possibility to the type-approval authority to identify the scenarios associated with a higher residual risk and for which it will be important that proper additional measures are taken into account to mitigate the risk.

The global residual risk can be focused on a specific kind of effect (e.g., deaths, injuries, damages to properties): all the conditions that may lead to the selected effect are concurring to constitute the global residual risk for the selected damage.

The selection of the reference value for the global residual risk comparison can be done by following different approaches. According to paragraph 7.1.1., "*The manufacturer shall define the acceptance criteria from which the validation targets of the ADS are derived to evaluate the residual risk for the ODD taking into account, where available, existing accident data, data on performances from competently and carefully driven manual vehicles and technology state-of-the-art*".

The manufacturer may take into account the particular low societal acceptance of crashes with ADS vehicles compared to conventional vehicles. It may be good practice to increase the acceptance criteria over time.

2. Methodologies for Demonstration of Safety as a Threshold (Acceptable Means of Compliance)

The present section provides guidance on the methodologies suitable to demonstrate compliance with the Regulation in relation to the safety as a threshold approach. It presents a collection of acceptable means of compliance, namely the methodologies that would be acceptable for the type approval authorities. The content of this section is applicable on a voluntary basis and it is not intended to be exhaustive. Depending on the vehicle type defined by the manufacturer, and the practices and procedures they use, alternative and/or equivalent methodologies may be used and consequently, different information may be supplied to comply with the requirements established in the Regulation.

2.1. Probabilistic Approach

The goal of a probabilistic approach is to demonstrate how safety thresholds are met, toward determining acceptability of the residual risk (Annex II, Paragraph 7). Residual risks can arise due to several causes, including, but not limited to:

- Hardware and E/E system failures (ISO 26262)
- Security attacks
- Functional insufficiencies (ISO 21448)

These causes for hazards differ strongly in their nature, thresholds and thus differ in the approaches to demonstrate that an acceptable level of residual risk is met.

The evaluation of residual risks of hardware and E/E system failures is well defined and already established since many years by standards and state-of-the-art approaches. For residual risks stemming from security attacks, there is currently limited experience on how to evaluate these in the context of ADS in the EU. Therefore UN Regulation No. 155 "Uniform provisions concerning the approval of vehicles with regards to cyber security and cyber security management system" needs be interpreted and applied. The approaches outlined in the following address the functional insufficiency category and focus on approaches on how to establish quantitative measures of the residual risk. Due to the limited extent, it is recommended to combine the results with qualitative arguments within a safety argumentation.

The functional insufficiency category can be separated in two types:

a) Specification insufficiencies, e.g., unknown scenarios or incorrect specification of safe and rule conform driving behaviour in specific scenarios.

b) Implementation insufficiencies, e.g., limited visibility of the sensors under specific environmental conditions.

For both types of functional insufficiencies, it is expected that cases relevant for residual risk, i.e., not addressed by demonstrating compliance to General performance requirements (Annex II, except Paragraph 7) or to Specific performance requirements valid for a minimum set of traffic scenario (Annex III, Part 1), will in general occur under unusual, rare conditions. A valid approach for demonstrating the acceptability of the residual risk must consider this property. Simply adding residual risks up to evaluate the collective acceptability of the residual risk can lead to wrong conclusions and is not suitable. While UNECE is describing New Assessment/Test Method for Automated Driving[8] as a general approach, in the following, three archetypes of approaches will be described which are by no means exhaustive and may be combined.

2.1.1. Simulation-based Sampling from Nominal and Critical Scenarios and Statistical Models of Performance Limitations

In this approach, all derived nominal and critical scenarios (scenario event sequences, not entire logs of trips) as defined in Commission Implementing Regulation (EU) 2022/1426, Annex III, Part 1, paragraph 2, and the related Appendix 1 are tested in simulation with a structured or statistical sampling of the scenario parameters as well as validated models of performance limitations relevant to the ADS (e.g., leading to increased sensor noise).

To demonstrate that an acceptable level of residual risk is met, the scenarios must be weighted with statistical weights reflecting the occurrence frequency of those scenarios. The statistical weights, the parameter sampling distribution and the statistical models of performance limitations can be obtained from empirical data collection considering the ODD.

[8] (GRVA) New Assessment/Test Method for Automated Driving (NATM) - Master Document | UNECE

Although scenarios from crash data and naturalistic driving data are available, breaking the data down by the conditions that closely reflect those of the intended ODD is not simple. Moreover, because meaningful comparisons can be made only by considering the severity of crash outcomes (e.g., risk-based or outcome-based assessment of severity), variations in how severity is recorded in different crash data sets presents analytical challenges, as does the limited amount of data on the most severe events.

Note that simulation-based testing enables much more extensive testing and thus enables generation of valid performance estimates of collisions and their severity with a fraction of the time and effort as possible in real world testing. However, the validity of the results hinges on the accurate and sufficiently complete characterization of the scenarios as well as the statistical models of performance limitations. More details on scenario parametrization and sampling are described e.g., in ISO 21448:2022 Annex C.5.

2.1.2. Simulation of a certain Software Version and System Configuration against Entire Historical Real-world Logs

This approach is similar to the one described in Section 2.1.1 but differs from it in the sense that entire trip logs of data from real world testing with the ADS are used. This approach measures empirically the ADS's estimated collision rates and severities that would have occurred in that particular software and system configuration, to allow comparison of those rates against human driver benchmarks and other performance criteria. In addition, a filter based on pass criteria for nominal and critical scenarios can be evaluated to find events in which the pass criteria are not yet violated but close to that (so called sub-critical events).

These discovered scenarios are then used to update the scenario-based testing described in Section 2.1.1 and tested in simulation with a statistical sampling of variations of the scenario parameters as well as statistical models of performance limitations relevant to the ADS.

2.1.3. Real-world Testing with Analytical Decomposition of Failure Rates

In contrast to the first two approaches, the third relies on real world testing only, examining observations of outcomes. Instead, to generate statistically valid event rates which can demonstrate the acceptability of the residual risk, the risk acceptance criterion can be decomposed into multiple sub-criteria which can be individually validated. To this end, functional insufficiencies are decomposed into the occurrence of multiple individual insufficiencies. If it can be established according to the system architecture that those individual insufficiencies can occur with a certain degree of statistical independence and a functional insufficiency will only result if all those individual insufficiencies occur at the same time, the risk acceptance criterion can be analytically decomposed. More details on the impact of the ADS system architecture on validation are described e.g., in ISO 21448:2022 Annex C.6.3.

3. Metrics for the Definition of the Safety Threshold

The Regulation does not define a specific metric to be adopted by the manufacturer. The manufacturer is allowed to use any metric (as well as any acceptance criteria and approach) provided that is able to demonstrate that its use does not decrease the safety level in comparison with similar services in the same operational environment, "*taking into account, where available, existing accident data"*.

A list of possible metrics includes (but is not limited to) fatality rate, injury rate, collision rate, energy of impact.

3.1. Fatality Rate

The Regulation uses the concept of validation targets and global safety threshold for the acceptability of the residual risk. The example of acceptance criteria indicated in the footnote of Paragraph 7.1.1 is based on the analysis of current EU road accidents aggregated data and relies on a metric based on the number of fatalities per hour of operation. The threshold is then set to 10^{-7} (fatalities per hour of operation).

Such combined metric and threshold provides an example that could be used for the market introduction of ADS, since they have been extrapolated from available state-of-the-art data. However, such data does not take into account for the *"performances from competently and carefully driven manual vehicles and technology state-of-the-art"*, which the Regulation requires to take into account *"where available"*.

4. Data sources and databases

The manufacturer is in charge of the identification and selection of similar services and situations for the evaluation of the current level of risk of those services in similar ODDs. Such risk can be extrapolated by analysing available data.

Some example of available data and databases is reported in the Table below. National authorities should work to provide additional traffic data from the ODD to manufacturers beyond examples given below, to ensure that data comparisons for acceptance criteria accurately reflect the current level of safety in the ODD in scope.

Table 2. Example of available sources of accident data

Country	Database	Link
European Union	Community Road Accident Database (CARE)	https://road-safety.transport.ec.europa.eu/statistics-and-analysis/methodology-and-research/care-database_en
France	Annual databases of road traffic injuries – 2005 to 2022	https://www.data.gouv.fr/fr/datasets/bases-de-donnees-annuelles-des-accidents-corporels-de-la-circulation-routiere-annees-de-2005-a-2022/

Source: JRC

APPENDIX 4 – Technical Guidance on Safety Assessment

The present appendix provides technical guidance to the manufacturers on the assessment of the ADS safety concept and audit of the safety management system as prescribed in the Regulation, Annex III, Part 2.

1. Introduction

The introductory part of Annex III, Part 2 (Paragraph 1, "General") highlights two relevant aspects concerning the assessment of the ADS safety concept, namely:

1. The type-approval authority (or the technical service acting on its behalf) conducts spot checks and tests to verify "*that the safety argumentation provided by the documentation complies with the requirements of Annex II and that the design and processes described in documentation are actually implemented by the manufacturer*". The targeted spot checks and tests refers in particular to Paragraph 4 "Verification and tests", that states: "*taking into account the results of the analysis of the manufacturer's documentation package, the type-approval authority shall request the tests to be performed or witnessed by the Technical Service to check specific points arising from the assessment*."
2. The acceptance of the ADS by the type-approval authority implies that "*the residual level of safety risk of the type-approved ADS is deemed to be acceptable for the entry into service of the vehicle type*" according to the Regulation. The acceptance is "*based on the provided documentation, audit of the safety management system and the assessment of the ADS safety concept*". It is worth to underline that compliance with safety requirements extends throughout the ADS lifetime and "*remains the responsibility of the manufacturer requesting the type-approval*".

Evidence of the fulfilment of the safety requirements is provided by the manufacturer through the supply of properly prepared and exhaustive documentation. Specific indications of the contents to be included are given in different sections of the Regulation.

In general, the documentation should be effective in showing that:

- the system complies with the requirements laid down by the regulation,
- supplied information and defined procedures/processes correspond to what has actually been done and implemented by the manufacturer.
- the system is free of unreasonable safety risks to vehicle occupants and other road users during the vehicle lifetime,

In the documentation provided by the applicant, the safety concepts and its validation is reported; it includes demonstration that the system takes into account fundamental principles such as redundancy, diversity, capability to operate with reduced functions, possibility of disarming or limiting autonomous driving functions, mitigation of the consequences of possible dangerous conditions. The applicant explicitly states and demonstrates that the system is free from unreasonable risks concerning both the occupants of the vehicle and the other road users.

The type-approval authority performs inspections related to the approach used by the manufacturer to demonstrate the level of safety. This approach shall take into account selected specific hazardous conditions. The type-approval authority assessment can be performed by checking what has been included in the design of the system to deal with possible risks or, vice versa, considering the functions of the system to identify which dangerous conditions the system can cope with.

The type-approval authority checks also the system behaviour by means of physical tests on tracks and roads. The tests check the capability of the system to manage interaction with other road users and possible system failures, the risk mitigation methods, and the ability of the system to manage disturbed situations. Conditions considered to be critical for the behaviour of the ADS can be included. The outcome of the tests should comply with the requirements and with the documentation issued by the manufacturer. Simulations and mathematical models can be used to support and complement physical testing.

The documentation to be provided by the manufacturer requesting the type-approval is a key aspect of the type-approval process, it should report the safety assessment in sufficient level of details to demonstrate the safety, to support the conclusions stated and to provide an adequate input to independent verification and type-approval review. The following section provides support to the manufacturers in the preparation of the relevant entries of the Information Document (ID) as from the Regulation (EU) 2022/1426, Annex I.

In addition, the manufacturer should demonstrate the setting up and application of a safety management system compliant with the requirements; this implies the provisions of methods and procedures for requirements management, requirements implementation, performing tests, identifying gaps and non-compliances, define and applying related remedial actions, and monitor the effects obtained. In addition, the manufacturer shows that it has implemented methods and procedures to manage and to coordinate various aspects related to operational safety, cybersecurity and all other disciplines relevant for the safety of the vehicle, including continuously monitoring the compliance with safety requirements of the ADS during its whole lifetime.

The applicant shall obtain a certification of its safety management system, which is propaedeutic for the type-approval of the ADS which the safety management system is relevant for.

The Regulation establishes that the personnel of the type-approval authority (or any supporting technical organization acting on behalf of it) responsible for inspections and controls must have the necessary skills and competences in technical aspects related to the evaluated system. Demonstration of such a competence is given by appropriate qualifications or specific training.

2. The Information Document

The present section is intended to support the manufacturers in the preparation of the relevant entries of the Information Document (ID) as from the Regulation (EU) 2022/1426, Annex I, which provides a model of the ID for EU type-approval of fully automated vehicles with regard to their automated driving system.

The Regulation (EU) 2022/1426 states that (introduction, point 4) the Information Document *"referred to in 24(1) (a) of Regulation (EU) 2018/858 to be provided by the manufacturer for the type-approval of the automated driving system of fully automated vehicles should be based on the template laid down for the whole vehicle type-approval in Annex II to Commission Implementing Regulation (EU) 2020/683. However, to ensure a consistent approach, it is necessary to extract the entries of the information document that are relevant for type-approval of automated driving system of the fully automated vehicle"*.

Moreover, as pointed out in Article 3 point 1, *"the relevant entries of information document, submitted in accordance with Article 24(1), point (a) of Regulation (EU) 2018/858 with the application for type-approval of the automated driving system of a fully automated vehicle, shall consist of the information relevant for that system as contained in Annex I."*

The provision of the ID by the manufacturer is part of the requirements set out in Annex III, Part 2, Paragraph 3.1, which states that "*the manufacturer shall provide a documentation package which gives access to the basic design of the ADS and the means by which it is linked to other vehicle systems or by which it directly controls output variables as well as off-board hardware/software and remote capabilities. The function(s) of the ADS, including the control strategies, and the safety concept, as laid down by the manufacturer, shall be explained."*

The *"documentation shall be brief, yet provide evidence that the design and development has had the benefit of expertise from all the ADS fields which are involved"*, so as to report the safety assessment in sufficient level of details to demonstrate the safety, to support the conclusions stated and to provide an adequate input to independent verification and type-approval review.

It is worth to remind that, as set out in Annex III, Part 2, Paragraph 3.1.1 (c), "*confidential material… shall be retained by the manufacturer, but made open for inspection"*. Notwithstanding, sensitive information included in the ID and supporting reports, the unauthorised disclosure of which could compromise proprietary and vehicle security, should be identified. Such information should be protected in accordance with guidance on information security in force.

2.1. Format and Content of the Information Document

In the following pages, guidance is provided on the sort of content manufacturers may choose to provide to address relevant sections of the ID, together with references to the relevant sections of the Regulation.

0. GENERAL

No guidance included in this document as regards this section and its sub-sections.

17. AUTOMATED DRIVING SYSTEM (ADS)

This section should include any general information not specifically included in the subsequent sections and sub-sections, but relevant for the type-approval, e.g.:

a) Definitions used for the purposes of the ID.

b) Intended use case of the fully automated vehicle, among the ones allowed by the Regulation, Article 1:

   a. "*Fully automated vehicles, including dual mode vehicles, designed and constructed for the carriage of passengers or carriage of goods on a predefined area.*"

   b. "*'Hub-to-hub': fully automated vehicles, including dual mode vehicles, designed and constructed for the carriage of passengers or carriage of goods on a predefined route with fixed start and end points of a journey/trip.*"

   c. "*'Automated valet parking': dual mode vehicles with a fully automated driving mode for parking applications within predefined parking facilities. The system may use or not external infrastructure (e.g. localization markers, perception sensors, etc.) of the parking facility to perform the dynamic driving task*."

c) Description of the existing approval status.

d) Statement of any similar or identical vehicle that the type-approval authority has already reviewed and approved and a statement of the specific differences and/or improvements that have been made since such approval was granted, if any.

A comprehensive list of regulations, codes and standards which the ID makes reference to should be provided in this section. Every document of the list should also be referenced in the appropriate section when relevant. If the codes and standards have not been prescribed by the Regulation(s), a justification of their appropriateness should be provided.

When allowed by the Regulation, any modification made to or deviation from the requirements should be clearly stated and justified, together with the way in which the modifications/deviations have been addressed in the different sections of the ID.

17.1. General ADS description

The objective of this section is the description of the ADS, its mission, its limits and its overall architecture, including the main sub-systems which the ADS is constituted by, and their relationships. This description constitutes a high-level overview of the ADS, whereas the detailed descriptions of ADS functions, hardware and software are included in §17.2, §17.3 and §17.4 respectively.

This section should include any general description of the ADS as set out in Annex III, Part 2, Paragraph 3.2, but not specifically included in the following sections and sub-sections. In particular, as stated in Paragraph 3.2.1, *"description shall be provided giving a simple explanation of the operational characteristics of the ADS and ADS features"*.

This section should include:

(a) The fields of application and the domain of operation including limitations and restrictions to the use of the ADS.

(b) General description of the ADS in terms of functions, hardware and software.

(c) The *"interaction concept with vehicle occupants, the on board operator (if applicable) and the remote intervention operator (if applicable)"*, as set out in Paragraph 3.2.2.5.

(d) *"The means to activate or deactivate the ADS by the on-board operator (if relevant) or the remote intervention operator (if relevant), vehicle occupants (if relevant) or other road users (if relevant)"*, as set out in Paragraph 3.2.2.6.

(e) The *"operational measures (e.g. on-board operator or remote intervention operator needed) to be met to ensure safety during the fully automated vehicle operation"*, as set out in Paragraph 3.2.2.7.

(f) The *"backend, off-board infrastructure needed to ensure safety during the fully automated vehicle operation"*, as set out in Paragraph 3.2.2.8.

This section should also report the certifications adopted or applied for systems, sub-systems and components included in the vehicles. Those already approved in different vehicles should also be identified.

17.1.1. Operational Design Domain / Boundary Conditions

The description of the ODD and its boundary conditions is required to comply with Annex III, Part 2, Paragraph 3.2.2.1. The description provided should include all the information relevant to its unambiguous definition, namely all the relevant elements must be defined, described and quantified. References for the description of ODD can be found in Appendix 1 and partly in Appendix 2.

Whatever is not reported in the description of the ODD should be considered outside the ODD, and not relevant to its determination. Note that the type-approval authority might request additional information on any element not mentioned or quantified.

17.1.2. Basic Performance

As set out in Annex III, Part 2, Paragraph 3.2.2.2, this section describes the response of the ADS in terms of its behaviour and expected performances in all the possible conditions (e.g. OEDR, planning, etc.) falling within the ODD defined in §17.1.1, for both normal and emergency operation, including the description of the *"interaction with other road users"* (Paragraph 3.2.2.3).

The definition of the main triggering *"conditions for minimal risk manoeuvres"* (Paragraph 3.2.2.4) should be included as well.

This section includes the description of the ADS behaviour in the conditions defined above, including a general description of each element and logic defining the process that determines the ADS performance.

The performance of the ADS when dealing with defined unexpected conditions (i.e., conditions that are unlikely to occur although reasonably foreseeable, but that have been used as "stress-cases" to define ADS performance) should be also included. A list and description of those defined unexpected conditions should be provided. The selection of such conditions can be based on the estimated frequency of occurrence, or on analogous analysis for similar systems, or on engineering expert judgment. In that sense, a link between frequency of exposure and severity may help in the determination and classification of such unexpected conditions. Those unexpected conditions may even fall outside the ODD conditions or beyond the legislative requirements (e.g., recognition of an airplane landing on the highway).

Finally, a categorisation of the logic and related performances can be also included. As an example, they can be subdivided as follows:

1. *Detective*: related to identify the cause or symptoms of an event.
2. *Preventive*: to prevent a negative event from occurring.
3. *Corrective*: when a modification of the response of the ADS is necessary.

It is important to provide an exhaustive description of the performances of the ADS under all reasonably foreseeable conditions. What is explicitly excluded or not described should be considered as beyond the capabilities of the ADS.

17.2. Description of the functions of the ADS

This section should describe the ADS functions and logics adopted, namely, the logical processes connecting conditions (§17.1.1) to performances (§17.1.2). The descriptions are not intended to enter the detail of the hardware adopted, which is the subject of §17.3, while the integration between hardware and logic is the subject of §17.4.

According to Annex III, Part 2, Paragraph 3.3, *"description shall be provided giving an explanation of all the functions including control strategies to ensure the robust and safe operation of the ADS and the methods used to perform the dynamic driving tasks within the ODD, and the boundaries under which the automated driving system is designed to operate, including a description on how this is ensured"*. The provided description shall include *"any enabled or disabled automated driving functions for which the hardware and software are present in the vehicle at the time of production"* and *"the data processing if continuous learning algorithms are implemented"*.

The functions implemented into the ADS must be described on a high level, including how they carry out collection, analysis, synthesis, evaluation and decision making in both normal and emergency operations, as well as all the logical processes covering the acquisition, treatment and interpretation of data, the elaboration process including handling of contradictory information, and the definition of the actions to be performed. The level of details provided should be consistent with the ones required by the following sub-sections. Exchange of data between different functions should also be considered.

The description includes specification of *"all input and sensed variables… and the working range of these defined, along with a description of how each variable affects the ADS behaviour"* (Paragraph 3.3.1), as well as *"all output variables that are controlled by the ADS"*, together with *"an explanation…of whether the control is direct or via another vehicle system. The range over which the ADS is likely to exercise control on each such variable shall be defined"* (Paragraph 3.3.2).

As required by Paragraph 3.3.3, *"limits defining the boundaries of functional operation including ODD-limits shall be stated where appropriate"*.

17.2.1. Main ADS Functions

This section describes the functional architecture and control strategies adopted by each function and by the ADS to handle the different functions and the interfaces among them. Description of functional hierarchy and decomposition of functions can be useful to give a more comprehensible insight.

Some relevant aspects to be addressed are:

(a) Logic for the decision to activate or deactivate functions during ADS operations

(b) Transitions between the various functions of the ADS

(c) Function modes, priorities and limitations, including MRM, EM and intervention request (if applicable).

17.2.1.1. Vehicle-internal functions

Vehicle-internal functions are characterised by being fully on-board of the vehicle, namely input and output data are all generated, collected and treated by on-board features. Those functions are independent from external sources of data or external computational power, and all the necessary processes are performed within the vehicle. However, interfaces with external systems can exist.

These functions are also related to the operational measures to be met (e.g. "on-board operator", see Paragraph 3.2.2.7) to ensure safety during the fully automated vehicle operation.

17.2.1.2. Vehicle-external functions

Vehicle-external functions (e.g., connectivity-related functions, remote intervention functions) are characterised by not being fully on-board the vehicle. These functions usually concern information and/or conditions not directly detectable, measurable or achievable by on-board features, and imply transfer of data to and from external systems.

These functions are related to both infrastructures needed (e.g. "backend, off-board", see Paragraph 3.2.2.8) and operational measures to be met (e.g. "remote intervention operator", see Paragraph 3.2.2.7) to ensure safety during the fully automated vehicle operation.

The interfaces between the vehicle and the external functions should also be described in this section.

17.3. Overview of the major components of the ADS

This section describes the units devoted to ADS technology. In this framework, hardware and software important for driving but not related to the ADS tasks is not included (e.g., gear system, braking system, propulsion system, steering system). These systems, although monitored and actuated by the ADS during the DDT, are not specific features of the ADS. On the other hand, the actuators specifically used by the ADS to perform actions on the above systems are part of the ADS and shall be included in the description.

As required by Paragraph 3.4.1, *"a list shall be provided, collating all the units of the ADS and mentioning the other vehicle systems as well as off-board hardware/software and remote capabilities that are needed to achieve specified performance of the ADS to be approved according to its ODD"*.

Moreover, *"each unit shall be clearly and unambiguously identifiable (e.g. by marking for hardware, and by marking or software output for software content) to provide corresponding hardware and documentation association"*, as stated in Paragraph 3.4.5.1; while Paragraph 3.4.5.3 affirms that "*the identification defines the hardware and software version and, where the latter changes such as to alter the function of the unit as far as this Regulation is concerned, this identification shall also be changed"*.

It is expected that the description can be general for units developed by third-parties, in which case the model and the manufacturer shall be provided. The related specifications and certifications can be indicated and made available to the type approval authority upon request. Whereas, as far as proprietary units are concerned, it is expected that more details are provided and supported by specific documentation.

Whenever redundancy and/or diversity are implemented, they shall be declared; in this sense, indicating the number of the elements involved could ease the clarity of the description.

The descriptions can be distributed in the following sub-sections, as appropriate.

17.3.1. Control units

This section describes the components of the control units, e.g. processors, wiring, memory banks, electronic boards, wireless and net devices, cabling.

17.3.2. Sensors and installation of the sensors on the vehicle

This section describes the sensors, the sensed parameter, the generated signal, the sensor calibration, reliability, working conditions, range of validity and its role in the ADS. Information concerning the possible backup should also be included.

In order to comply with the requirements set out in Paragraph 3.4.6, *"the manufacturer shall provide information on the installation options for the individual components that comprise the sensing system. These options shall include, but are not limited to, the location of the component in/on the vehicle, the material(s) surrounding the component, the dimensioning and geometry of the material surrounding the component, and the surface finish of the materials surrounding the component, once installed in the vehicle. The information shall also include installation specifications that are critical to the ADS's performance, e.g. tolerances on installation angle"*.

17.3.3. Actuators

This section describes the actuators, the functions connected with the actuators, the data/action accepted as input and generated as output, the actuator calibration, reliability, working conditions, range of validity and its role in the ADS. In addition, the information concerning the reliability of the actuators and possible backup should also be included.

17.3.4. Maps and positioning

This section includes descriptions of the system adopted by the ADS to determine its position in terms of standard references and in relation to the surrounding environment, e.g. Global Navigation Satellite System (GNSS) to localise the exact position of the vehicle a place it within predetermined maps to allow proper navigation.

17.3.5. Other hardware

This section includes descriptions of the transmission links used for conveying signals, operating data or energy supply between inter-connected hardware described in the previous sections.

In case other hardware is present in the vehicle in addition to the ones described in the previous sections, it should be described here. E.g.:

a) Hardware necessary for the connection with external infrastructures or external systems (e.g., centralised systems for the automatic parking of the vehicle in dedicated/reserved areas).

b) Special hardware to perform specific functions during maintenance.

17.4. ADS layout and schematics

The systems belonging to the ADS are represented in this section by schemes, namely layouts, flow charts, Process Flow Diagrams, Process and Instrumentation Diagrams.

17.4.1. Schematic system layout

This section should graphically describe the ADS components and their connections; as required by Paragraph 3.4.1, "a*n outline schematic showing these units in combination, shall be provided with both the equipment distribution and the interconnections made clear. This outline shall include:*

a) Perception and objects/events detection including mapping and positioning.

b) Characterisation of Decision-making.

c) *The ADS data elements.*

d) *links and interface with other vehicle systems, off-board hardware/software and remote capabilities."*

Moreover, Paragraph 3.4.2 requires that "*the function of each unit of the ADS shall be outlined and the signals linking it with other units or with other vehicle systems shall be shown. It shall include off-board systems supporting the ADS and other vehicle systems. This may be provided by a labelled block diagram or other schematic, or by a description aided by such a diagram*".

The diagrams presented in this section should clearly describe the main path of the input signals, the elements and components handling and processing the signals as well as the generated output. The elements and components should be identified by the reference ID used in §17.3, and the expected values of the signals should be reported. Redundant and alternative paths of the signals and processes must be included in the description. Both normal and emergency operations should be considered.

However, Paragraph 3.4.5.2 states that "*where functions are combined within a single unit or indeed within a single computer, but shown in multiple blocks in the block diagram for clarity and ease of explanation, only a single hardware identification marking shall be used. The manufacturer shall, by the use of this identification, affirm that the equipment supplied conforms to the corresponding document*".

17.4.2. List and schematic overview of interconnections

The interfaces and connections within the ADS are reported in this section "*by a circuit diagram for the electric transmission links, by a piping diagram for pneumatic or hydraulic transmission equipment and by a simplified diagrammatic layout for mechanical linkages. The transmission links both to and from other systems shall also be shown*" (Paragraph 3.4.3).

The interfaces related to systems external to the vehicle are also included. In addition, this section should also report the compatibility between interfacing systems, e.g. demonstrating that interfaces and interconnections between systems do not interfere each-other and properly work in all the considered normal and emergency operations.

As required by Paragraph 3.4.4, *"there shall be a clear correspondence between transmission links and the signals carried between units. Priorities of signals on multiplexed data paths shall be stated wherever priority may be an issue affecting performance or safety*".

17.5. Specifications

This section describes the responses obtained when the ADS functions are called to operate. The responses must be based on a quantitative description of the behaviour of the ADS vehicle.

This section is focused on the designed behaviour of both the ADS and the vehicle. Therefore, it should include the numerical values resulting from the output of the functions having a direct role in DDT. The numerical values of parameters treated and elaborated in the processes internal to the functions or in functions not directly affecting the final behaviour of the vehicle should be also documented if relevant for more complete and comprehensive description.

The detailed specification descriptions have to be provided in sub-section §17.5.1 for normal operations and in §17.5.2 for emergency operations, whereas §17.5.3 describes the acceptance criteria and §17.5.4 reports the demonstration of compliance.

17.5.1. Specifications in normal operation

This section describes the specifications related to Normal Conditions.

17.5.2. Specifications in emergency operation

This section describes the specifications related to Emergency Conditions.

17.5.3. Acceptance criteria

This section describes the acceptance criteria related to the ADS specifications.

Reference could be made to relevant laws, regulations and norms and to other acceptance criteria, including those established by the manufacturer, if relevant.

17.5.4. Demonstration of compliance

This section should demonstrate the fulfilment of the acceptance criteria mentioned in the previous section.

If no acceptance criteria are defined by law and the acceptance criteria are thus defined by the manufacturer, a demonstration should be provided that the resulting numerical values are reasonable in terms of minimised probability and extent of damage to vehicle (when relevant), passengers and other road users. In that case, the type-approval authority could realize an evaluation of the process itself, which led to the acceptability criteria.

17.6. Safety concept

This section is dedicated to the safety objectives adopted by the manufacturer to ensure safe operation in both normal and emergency operations. They act as the principles guiding the definition of the systems details. The section should describe the approaches adopted to prevent and minimize the possible risks and to handle them so as to minimise the consequences to vehicle occupants and other road users, as well as to assure compliance with traffic rules.

The ADS systems, components and logics are designed to operate in both normal and emergency operations within specific ranges of acceptability. A partial proof of safety is indirectly supported by the fulfilment of defined acceptance criteria; however, the designed behaviour of the ADS vehicle must be actual and verified, i.e., the ADS items and functions affecting safety must not only be designed meeting defined acceptability criteria and included in the ADS, but their effectiveness when called to operate shall be assessed.

The approaches to ensure the designed behaviour of the ADS should be described. As an example, the following general approaches can be used:

1. *Quality*: of components, processes, manufacturing, supply-chain, etc. to ensure low failure rates.
2. *Redundancy*: the most relevant functions/systems/components are provided with backups.
3. *Diversity*: different systems performing the same action based on different physical phenomena.

17.6.1. Manufacturer Statement that the vehicle is free from unreasonable risks

This section should contain the statement that the manufacturer shall provide to comply with Paragraph 3.5.1, namely affirming *"that the ADS is free from unreasonable risks for the vehicle occupants and other road users".*

17.6.2. Outline of the software architecture

According to Paragraph 3.5.2, *"the outline architecture"* of the *"software employed in the ADS" "shall be explained and the design methods and tools used shall be identified"*. This section provides graphical descriptions (e.g. block diagram) of the software architecture, as well as identification of the methods and tools used during the software design and development process.

This section should demonstrate consistency with the approaches defined above (and applicable to software), with the target to prevent and minimize the probability of logic failure and to handle possible logic failures so as to minimise the consequences to vehicle occupants and other road users, as well as to assure compliance with traffic rules.

The identification of logic failure requires the implementation of algorithms performing the verification of inputs and outputs, of the processes, and coherence checks to assure that the logic is working as intended. These algorithms are typically constituted by high-level routines capable to identify and localise abnormal situations, and to implement parallel and independent systems/routines to check and possibly to correct errors. The description of such routines, algorithms and specific systems should be also included in this section.

17.6.3. Means by which the realization of ADS logic is determined

As set out in Paragraph 3.5.2, in this section *"the manufacturer shall show evidence of the means by which they determined the realisation of the ADS logic, during the design and development process".*

17.6.4. General explanation of the main design provisions built into the ADS so as to generate safe operation under fault conditions, under operational disturbances and the occurrence of conditions that would exceed the ODD

As required by Paragraph 3.5.3, *"the manufacturer shall provide the type-approval authority with an explanation of the design provisions built into the ADS so as to ensure functional and operational safety. Possible design provisions in the ADS are for example:*

(a) fall-back to operation using a partial system.

(b) redundancy with a separate system.

(c) diversity of systems performing the same function.

(d) removal or limitation of the automated driving function(s)."

As required by Paragraph 3.5.4, "the manufacturer shall also provide the type-approval authority with an explanation of the operational safety measures to be put in place for the safe operation of the ADS such as an on-board operator or a remote intervention operator, supporting off-board infrastructure, transport and physical infrastructure requirements, maintenance measures, etc.

This section describes also the main design provisions built into the ADS in order to ensure its safe operation and interaction with other road users under fault conditions, under operational disturbances and under the occurrence of planned and unplanned conditions that would lead to exceed the ODD boundaries.

The applicant should also describe the means for recognition of ODD boundaries the strategy implemented to define and handle ADS behaviour when the limits of the ODD are approached.

The means to check the current operational status of the ADS are also part of this section. A set of high-level functions is necessary to check and evaluate the efficiency of the ADS and its systems. These functions continuously perform cross-checks and compare selected indicators of the ADS with reference values. If too large discrepancies are revealed, then corrective actions are taken (e.g., actuation of alternative or back-up systems).

The ADS behaviour should be described under expected and reasonable fault conditions, for which specific design provisions could be implemented into the system.

A list of possible and reasonable fault conditions must be considered and justified, and the behaviour of the ADS/vehicle should be described including the interaction with other road users. The consequence of such conditions should be also evaluated.

17.6.5 General description of failure handling main principles, fall-back level strategy including risk mitigation strategy (minimal risk manoeuvre)

This section should include the description of the failure handling main principles, the fall-back strategy and the risk mitigation strategy, including the minimum risk manoeuvre.

17.6.6. Conditions for triggering a request to the on-board operator or the remote intervention operator

This section should describe how the request to the on-board operator or the remote intervention operator are generated and managed (if applicable), namely:

a) Conditions that lead to generate the request for intervention.

b) How the ADS generates the request to the operator.

c) How the intervention is performed.

d) Functions passing under the control of the operator.

e) Confirmation of the release of the functions under the control of the operator.

f) ADS limitation and intervention on the functions under the operator control.

g) Functions remaining under the control of the ADS after successful intervention.

h) ADS behaviour if the intervention is not succeeded or interrupted.

i) Conditions for the return of functions under the ADS control.

j) Signals given to the operator, occupants and other road users in each of the above phases.

k) Means by which control and checks are executed in each of the above phases.

l) Management and control of time constraints in all the phases above.

The applicant should also describe the methods and measures put in place in order to monitor and correctly evaluate the operator status (if applicable).

17.6.7. Human machine interaction concept with vehicle occupants, on-board operator and remote intervention operator including protection against simple unauthorised activation/operation and Interventions

As set out in Paragraph 3.3.4, this section describes the interface between the vehicle equipped with ADS capabilities and the vehicle occupants (if relevant), on-board operator (if relevant) and remote intervention operator (if relevant), hereinafter referred to as "Human Machine Interface" (HMI). The HMI concept "*when ODD limits are approached and then reached shall be explained. The explanation shall include the list of types of situations in which the ADS will generate a support request to the on board operator/remote intervention operator (if applicable), the way the request is performed, the procedure that handles a failed request and the minimal risk manoeuvre. Signals and information given to the on-board operator/remote intervention operator, vehicle occupants and other road users in each of the above aspects shall also be described*".

The applicant should describe the mechanisms put in place to inform the operator and vehicle occupant (when relevant) about the ADS status and their responsibilities in an understandable and unambiguous way. This section should also report on how the HMI communicates every ADS state, modes of operation, possible limitations, as well as any additional information relevant to the operator and vehicle occupant. At a minimum, the description should address how HMI is capable of informing the operator and vehicle occupant (when relevant) that the ADS:

a) is functioning properly,
b) is currently engaged,
c) is currently unavailable,
d) is experiencing a malfunction,
e) is requesting an intervention request to the operator.

The applicant should describe the methods adopted to design an HMI that is comprehensible, easy, non-distracting, safe to use, and possibly promoting social inclusion. Reference to relevant guidance, best practices, industry standards and well-established design principles is also possible (e.g., ISO 9241 "Ergonomics of human system interaction").

The applicant should also provide descriptions, models, schemes and graphical representations of the information provided to the operator in every mode of operation; namely: Normal operation, intervention request (if applicable), approaching ODD boundaries, emergency operation, emergency manoeuvre, incidental conditions, etc.

This section should also describe the measures adopted to protect against simple unauthorised activation/operation and interventions, and to prevent the attempt to force the ADS to operate in not allowed conditions and modify the manufacturer's conditions.

17.7. Verification and validation by the manufacturer of the performance requirements including the OEDR, the HMI, the respect of traffic rules and the conclusion that the system is designed in such a way that it is free from unreasonable risks for vehicle occupants and other road users

The manufacturer must describe the methodologies used to prove the safety of the ADS vehicle. Both testing, verification and validation techniques are included.

The description of HMI testing (if relevant), verification and validation processes (e.g., empirical studies, simulations, test drives, road testing) should also be included in this section.

The means implemented to protect against simple unauthorised activation/operation and interventions into the ADS should also be verified and validated and described in this section.

The Simulation Handbook has to be provided as annex to the information document.

17.7.1. Description of the adopted approach

This section should describe the approaches adopted by the manufacturer to perform the various steps of the verification and validation activities. The adopted approach is defined by considered objectives, data, variables, measurements, and result expected.

17.7.2. Selection of nominal, critical and failure scenarios

This section should include the list of nominal, critical and failure scenarios, as well as the method used to define such list.

According to the Regulation provisions in Annex III, Part 1, the list shall include the "minimum set of traffic scenarios" defined in Paragraph 1. Such scenarios shall be used if relevant for the specific ODD of the specific ADS. As an example, in case of automated valet parking not every scenario included into the minimum set is applicable.

Each scenario included into the minimum set is characterized by a set of safety requirements and defined parameters. When appropriate, the manufacturer can deviate from the parameters proposed in the Regulation, provided that it can "demonstrate that the fully automated vehicle is free of unreasonable safety risks". "The safety performance metrics and inherent assumptions used by the manufacturer shall be documented" (Paragraph 1.1) and reported in this section. Adopting the same example as above, in case of automated valet parking the parameters may be adapted to take into account specific ODD and ADS conditions such as limited driving speed and lack of visibility.

In addition, the manufacturer shall enrich the list with scenarios "generated to cover reasonably foreseeable critical situations, including failures and traffic hazards within the operational design domain" (Paragraph 2.1); and, if remote intervention/capabilities are envisaged, those scenarios "shall include failures and traffic hazards stemming from the corresponding remote capabilities" (Paragraph 2.2).

The method used to generate those additional scenarios "shall be documented" (Paragraph 2.4) in this section, and "shall follow the principles set in" Annex III, Part 1, Appendix 1 (Paragraph 2.3), that defines principles to be followed to derive scenarios relevant for the specific ODD of the specific ADS. The adopted method should allow to avoid duplication of scenarios, and to define scenarios that possibly envelope entire set of scenarios so as to simplify the following analysis. The method should also allow for the demonstration of completeness of the list of scenarios proposed, to be also documented in this section.

References for the methods to generate, feed and enrich the set of scenario can be found in Appendix 2.

17.7.3. Description of the used methods and tools (software, laboratory, others) and summary of the credibility assessment

In this section the process and tools to perform the safety assessment are described. Validation of the trustworthiness and reliability of information and methods are described. Accuracy assessment of input data is also part of the content of this section.

17.7.4. Description of the results

Different methodologies for safety assessment are generally based on different procedures and data. As a consequence, the output data can be different for different methodologies. In this section the description of the output data is presented. The relative relevance/limitation of the output parameters is indicated. Units and range of the meaning are also reported in this section.

17.7.5. Uncertainty of the results

Any methodology implies some approximation that is reflected in the uncertainty of the results. An estimation of the uncertainty is typically performed. The approach used to estimate uncertainty and the resulting uncertainty values of the output parameters are documented in this section

17.7.6. Interpretation of the results

The meaning and relevance of the result obtained by the application of the chosen methodology need to be considered and evaluated within the wide framework of the assessment process. In this section the relevance between the results and specific objective are described. Interpretation of the results can also include the identification of patterns and trends.

17.7.7. Manufacturer's declaration (same as 17.6.1)

This section should contain the statement that the manufacturer shall provide to comply with Paragraph 3.5.1, namely affirming "that the ADS is free from unreasonable risks for the vehicle occupants and other road users".

17.8. ADS data elements

Learning from in-use data is a central component to the safety potential of ADS: lessons learned from a crash involving a single ADS could lead to safety developments and subsequent corrective actions that can lead to prevention of that crash scenario in other ADS. Also the analysis of crash avoidance data can lead to effective safety improvements of ADS. On the other side, in order to identify legal liability in case of crash or traffic rules infringement, the responsibility for the control of the DDT between the ADS, on-board or remote intervention operator or human driver (where relevant) should be uniquely identified at every moment.

In this section, the applicant should provide evidence of the methods and means used to fulfil the legislative requirements related to the aspects described above, through the implementation of the Event Data Recorder (EDR) and Data Storage System for Automated Driving (DSSAD) on-board the vehicle.

References for this paragraph is provided in Appendix 6 - Technical Guidance on In-service Reporting.

17.8.1. Type of data stored

For each data element recorded, the time-history data and format should be described, including information on the filtering process – if applicable – performed either during the recording phase or during the data downloading phase.

17.8.2. Storage location

The storage location should be described, be it on-board the vehicle or through cloud connectivity to a remote server, including system storage capabilities, capability to record data during a crash event (e.g., providing information on resistance to high decelerations and mechanical stress of a severe impact), data survivability after a crash event, trigger condition to initiate the data storage (if applicable) and means to prevent possible malfunctions.

17.8.3. Recorded occurrences and data elements

The applicant should provide details about all the data elements recorded during the vehicle operation, whether on a mandatory or voluntary basis, together with information on the recording interval time, data sample rate, minimum range, accuracy and resolution. The purpose of the data element collected should also be clarified, be it to satisfy legislative mandatory requirements, voluntary requirements or as source of additional information. Distinction should also be made between EDR and DSSAD data recordings.

17.8.4. Means to ensure data security and data protection

This section should report the means implemented by the manufacturer to ensure that recorded data are appropriately protected from unauthorised access or use, according to the data protection legislation into force, including post end-of-life data management and security. Information on data management by the applicant during the whole vehicle life cycle should also be provided, including the eventuality of discontinued production of the vehicle or of the Company business.

17.8.5. Means to access the data

The applicant should describe the tool that can allow accessing and retrieving the data stored on-board the vehicle and granting data protection and security requirements. In case data recorded are stored in a remote server through cloud connectivity, the means and tools to access the data remotely should also be described.

17.9. Cyber security and software update

This section is dedicated to the description of how cyber security and software update are managed by the applicant. A summary of the evidence provided to comply with the cybersecurity regulation requirements might be presented. Reference to additional relevant codes, regulations and standards might also be included.

The manufacturer should describe in this section the cybersecurity and software update management system put in place to comply with legislative requirements. The following sections will address how the management system processes are implemented and applied to the vehicles on-road.

The following information is mandatory.

17.9.1. Cyber Security type-approval number

Report the cyber security type-approval number.

17.9.2. Number of the certificate of compliance for cyber-security management system

Report the number of the certificate of compliance for Cyber-security Management System.

17.9.3. Software update type-approval number

Report the software update type-approval number.

17.9.4. Number of the certificate of compliance for software-update management system

Report the number of the certificate of compliance for software-update management System.

17.9.5. Software Identification of the ADS

Report the software identification of the ADS, as per the following sub-sections.

17.9.5.1. Information on how to read the RxSWIN or software version(s) in case the RxSWIN is not held on the vehicle

This section should report information on how to read the Software Identification Number (R2022/1426SWIN) or software version(s) in case the R2022/1426SWIN is not held on the vehicle.

The R2022/1426SWIN is a dedicated identifier, defined by the manufacturer, representing information about the type-approval relevant software of the ADS contributing to the type-approval relevant characteristics of the ADS.

17.9.5.2. If applicable, list the relevant parameters that will allow the identification of those vehicles that can be updated with the software represented by the R_xSWIN under item 17.9.5.1.

If applicable, list the relevant parameters and features that allow the identification of the vehicles that can be updated with the software represented by the R2022/1426SWIN under §17.9.5.1.

Note: The reference to 17.9.4.1 within the title is wrong and should be 17.9.5.1.

17.10. Operating manual (to be annexed to the information document)

The applicant should provide descriptions of the rationale behind the selection of information included in the Operating Manual, and the measures put in place in order to clearly present duties, limits, roles and responsibilities to the readers.

The Operating Manual has to be provided as annex to the Information Document.

17.10.1. Functional description of the ADS and expected role of the owner, transport service operator, on board operator, remote intervention operator, etc.

This section describes the information included in the operating manual related to the functional description of the ADS and expected role of the owner, transport service operator, on-board operator, remote intervention operator, etc.

17.10.2. Technical Measures for Safe Operation

This section describes the information included in the operating manual related to the technical measures for safe operation, e.g. description of the necessary backend, off-board infrastructure, timing, frequency and template of maintenance operations.

17.10.3. Operational and environment restrictions

The system is designed to work within specific condition ranges, which shall be clearly identified in the operating manual.

17.10.4. Operational measures

In this section all the operational measures (e.g. on-board operator or remote intervention operator needed) to be met to ensure safety during the fully automated vehicle operation are listed.

17.10.5. Instructions in case of failures and ADS request

This section describes the information included in the operating manual related to the instructions in case of failures and ADS requests, e.g. safety measures by vehicle occupants, transport service operator, on-board operator and remote intervention operator and public authorities to be taken in the event of malfunctioning of the operation.

17.11. Means to enable periodic road worthiness tests

This section includes descriptions related to the periodic road worthiness tests, needed to comply with the requirement set out in Annex III, Part 2, Paragraph 3.1, which states that “the documentation shall describe how the current operational status of the ADS and the functionality and software integrity can be checked.”

List of Figures/Tables

No guidance included in this document as regards this section.

Acronyms

No guidance included in this document as regards this section.

Annex I – Simulation Handbook

The set of simulations performed is provided to demonstrate the comprehensiveness of the performed analysis. For each simulation is at least reported a description of the simulation, the input data, the output data, the interpretation of the results and the conclusions.

Annex II – Operating Manual

No guidance included in this document as regards this section.

APPENDIX 5 – Technical Guidance for the Credibility Assessment of Virtual Testing Toolchain

The present appendix provides technical guidance to the manufacturer for the credibility assessment of the virtual testing toolchain as prescribed in the Commission Implementing Regulation (EU) 2022/1426, Annex III, Part 4, paragraph 3. The technical guidance only focuses on the testing environment credibility regardless of any ADS validation and verification requirements.

The appendix is intended to be used by both manufacturers and type-approval authorities to judge the credibility of the developed M&S. Methods to fulfil the four main pillars of the Simulation Credibility framework (1. M&S Management, 2. M&S Analysis, 3. M&S Verification, and 4. M&S Validation) are investigated based on the best-practices across several industries and research institutions dealing with virtual testing. Eventually, two methodologies are proposed to convey the credibility level achieved by the virtual testing toolchain based on the individual pillars realization.

Definitions

Accuracy: the closeness of a measurement to the true value.

Aleatory Uncertainty: the portion of uncertainty deriving from a random process that cannot be reduced.

Calibration: the process of regulating numerical or modelling parameters in the M&S to match the real-world system output.

Epistemic Uncertainty: the portion of uncertainty deriving from a lack of knowledge about a process that can be reduced via observations.

Precision: the repeatability/reproducibility of a measurement.

Referent: the data, information, knowledge, or theory against which virtual testing results are compared. It may be the Real World System (RWS), a similar or analogous system or a higher-fidelity model.

Subject Matter Expert: a subject who has documented accumulated knowledge within a particular field.

Validation: the process of determining the degree to which an M&S is an accurate representation of the real-world from the perspective of the intended uses of the model.

Verification: the process of determining the extent to which an M&S is compliant with its requirements and specifications.

1. Introduction

This technical document provides guidance to help manufacturers with the implementation of the Simulation Credibility framework for compliance with the Regulation. It has been developed to give sufficient understanding and best practices of the simulation "*credibility*" concept and the development of validation and verification (V&V) methodologies for virtual testing. The V&V methods presented hereafter are not meant to demonstrate any of the ADS requirements. Instead, the focus is only on the (virtual) testing environment regardless of any specific ADS implementation/performance. This document is intended to be a guide and the steps described are not obligatory but highly recommended to be compliant with the ADS regulations.

1.1. Virtual Testing tool

The importance of virtual testing has been supported by several works given the well-known advantages it delivers:

- *repeatability and reproducibility*: tests can be identically repeated and easily replicated in different facilities (depending on the layout of the toolchain);
- *versatility*: testing possibilities are virtually limitless;
- *safety*: no need to endanger personnel or equipment when performing safety-critical tests;
- *scalability*: tests can be executed at a faster than real-time rate;
- *lower cost*: resulting from the combination of the mentioned points.

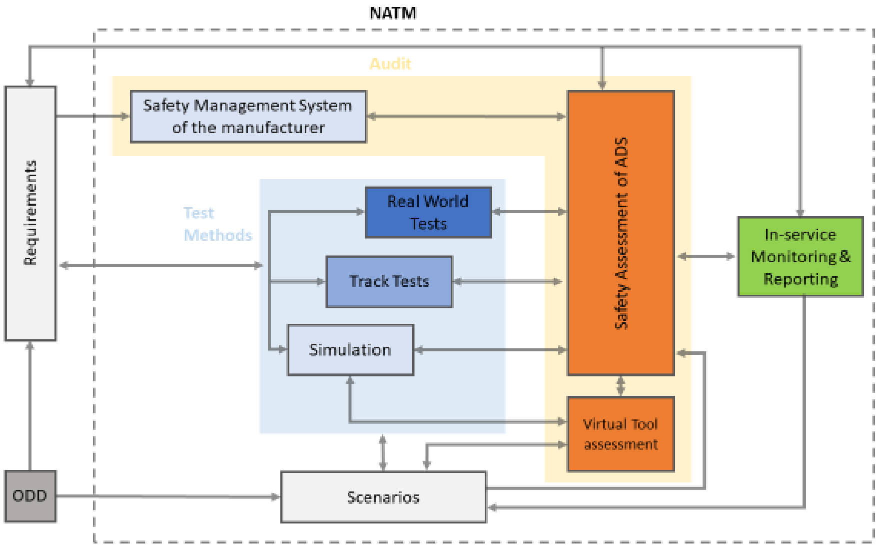
Nonetheless, without sound proof that the simulation-generated evidence is a suitable replacement for the real-world tests for the sake of the ADS type-approval, the virtual tool cannot support the certification phase.

Thus, evidence should be presented by the ADS manufacturer to the type-approval authority concerning the credibility of the virtual tool.

1.2. Regulatory background

The most recent regulatory and guideline approaches for ADS certification leverage virtual testing as a "pillar" that can complement "track test" and "real world test" provided that an assessment of the virtual tool is carried out.

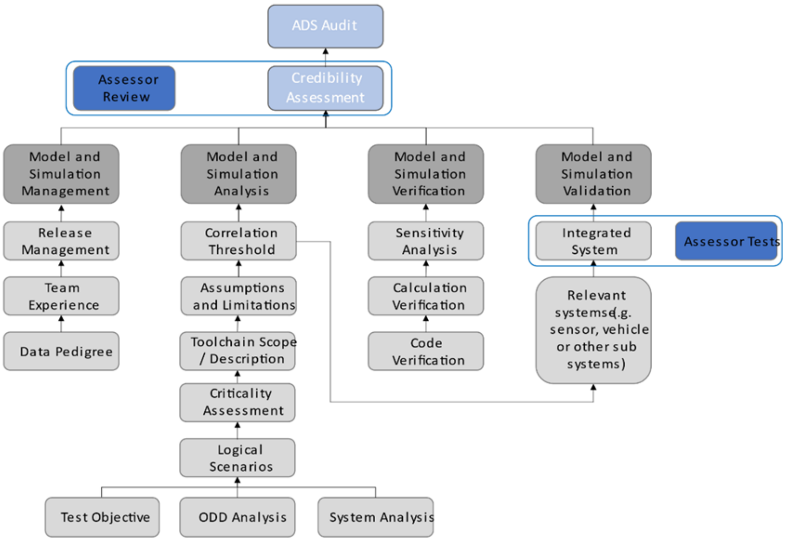
Figure 6. VMAD multi-pillar approach



Source: UNECE (2022b)

In particular, the virtual tool is assessed in terms of its *credibility*. The credibility of a toolchain is a concept that goes beyond the pure validation (i.e., the assessment of the simulation model's fidelity), instead it relies on the set of ingredients.

Figure 7. Simulation credibility framework



Source: EU Commission (2022b)

Validation *per se*, albeit relevant for the credibility assessment, is not deemed a sufficient requirement to recognize simulation-generated evidence as completely trustable for ADS certification. Namely, the limited scope of the validation analysis and the difficulty in retrieving supporting real-world data limit the effectiveness of the validation step. Moreover, given the plethora of possible virtual testing realizations, it is practically impossible to provide meaningful KPIs and acceptance thresholds for all the combinations. Thus, the Regulation foresees the appraisal of the M&S toolchain as a risk-based/informed process grounded on the credibility assessment.

2. M&S Management

This Section illustrates the best practices concerning the management of the M&S toolchain with the aim of fulfilling provisions of the Regulation.

2.1. M&S Management

M&S management procedures shall be established to archive, track, and control the released M&S toolchains and relative artifacts which have been used to support the ADS certification phase. The provisions do not cover M&S releases concerned with the *development* of the ADS or any development/pre-certification phase.

The proper documentation of the steps and modelling decisions undertaken while developing the M&S toolchain constitutes a credibility boosting factor (EASA, 2020). The documentation shall not be limited to the technical details of the M&S toolchain, such as the models/data used, but shall also encompass processes and software/hardware tools that support the M&S.

A non-exhaustive list of those aspects that support the credibility includes (EASA, 2020):

- the required knowledge and expertise for the correct execution of the M&S toolchain;
- best-practices documents including guidance regarding the M&S processes;
- known limitations of the models;
- a method to ensure the traceability of the M&S input data;
- a configuration management (CM) process to keep a record of the software/hardware versions (release, issue, operating system, third-party software tools dependency) associated with each M&S release;
- validation thresholds/methodologies that led to the acceptance of the specific M&S release.

According to the NASA credibility framework (NASA, 2016), a five-level score can be assigned to the M&S management step depending on the degree of fulfilment of the M&S management factor.

Table 3. Template for M&S management credibility level

Level	M&S process/management
0	No/insufficient evidence is given
1	Informal documentation for roles & responsibilities within the M&S context Informal documentation for M&S requirements Informal methods applied for the CM of the M&S
2	Formally approved documentation for roles & responsibilities within the M&S context Formally approved documentation for M&S requirements Formal methods applied for the CM of the M&S
3	Formally established and rigorously controlled processes Measurements of the processes and product compliance documented
4	Measurement including user experience use to improve M&S processes

Source: NASA (2016)

2.2. Release Management

Within each M&S toolchain released for the ADS certification, effort shall be made to identify, manage, process, deliver, control, and archive all M&S-related technical data and products, including the M&S and tools, information, and data used in the development and use of the M&S (NASA, 2019).

According to the existing best practices in fields where simulation and virtual testing are already recognized tools (EASA, 2020; NASA, 2016), each M&S toolchain release shall be accompanied by a document summarizing:

- the intended use for the M&S toolchain;
- the modelling abstractions and assumptions;
- the verification techniques enforced;
- the domain of validation;
- guidance documentation for proper use of the simulation.

The NASA credibility framework (NASA, 2016) provides a five-level credibility score that can be assigned to the release management pillar step depending on the degree of fulfilment of the factor. The scheme delivers high-level guidance on how to assess the differences between consecutive releases for the M&S toolchain. The highest credibility is associated with a release management process where minor changes exist between the M&S software/hardware structure/layout and the usage of two successive versions.

Table 4. Template for release management credibility level.

Level	**M&S structure**	**M&S usage**
0	No/insufficient evidence is given	No/insufficient evidence is given
1	New model/major changes in M&S	Major difference in M&S usage
2	Moderate changes in M&S	Moderate changes in M&S usage
3	Minor changes in M&S	Minor changes in M&S usage
4	Nearly identical M&S	Nearly identical M&S usage

Source: NASA (2016)

2.3. Experience and Expertise (E&E)

The Regulation foresees two layers of E&E assessment: the *organizational level* and the *team level*. The former is mainly concerned with the demonstration of existing processes and procedures within the organization aimed at providing the personnel with suitable M&S skills. The latter deals instead with the individual M&S skills of the team *validating* and *using* the M&S for certification purposes.

The E&E organizational level supports the credibility of the M&S toolchain by means of the fulfilment of the following items:

- the identification of roles and responsibilities within the organization;
- the necessary qualification, competences, and skill levels for staff performing specific tasks within the M&S-related processes;
- the existence of company procedures to document and share lessons learned in the M&S-related processes.

Concerning the second point, practical guidance is provided in EASA (2020). In particular, relevant items to be recorded for the credibility assessment are:

- individuals' qualifications (education, post-graduate courses, ...);

- skills & competences (years of experience on related M&S applications, understanding of processes, roles and responsibilities, …);
- training (initial and recurrent).

Personnel training for M&S development and usage is also covered in general terms by NASA-STD-7009A (NASA, 2016). In particular, it is recommended that the responsible parties shall:

- determine the depth of training or equivalent experience required for M&S developers, operators, and analysts;
- document that the training covered:
- the limit of operation for the M&S;
- the M&S configuration management;
- how to recognise unrealistic results from the simulation;
- sensitivity analysis, uncertainty characterization, and V&V;
- how to report simulation results to decision-makers;
- discipline-specific recommended practices.

An earlier guidance document by NASA (Babula et al., 2009) provided an explicit credibility scheme classification for the "people qualifications" here summarized in the Table below.

Table 5. Template for E&E credibility level

Level	People Qualifications
0	No/insufficient evidence
1	Engineering or science degree
2	Formal M&S training and experience, and recommended practice training
3	Advanced degree or extensive M&S experience, and recommended practice knowledge
4	Extensive experience in and use of recommended practices for this particular M&S

Source: Babula et al. (2009)

Organizational-level and team-level E&E are also accomplished within the ISO 9001:2015(E) Clause 7.2 (International Organization for Standardization, 2015) in the frame of the Quality Management System. The guidance provided by the ISO 9001:2015 standard can also serve as a basis to provide evidence for the simulation credibility assessment.

2.4. Data Pedigree

2.4.1. Input Data Pedigree

The *input data pedigree* element covers the adequacy, coverage, and quality of the input data used to develop and execute the M&S (NASA, 2019). This section aims at providing tools to derive the impact on the M&S credibility of input data.

2.4.2. Traceability

The data used to develop and execute the M&S for ADS certification purposes should be stored. Moreover, a methodology should be established to link the collected data to the corresponding usage (e.g., validation of the M&S or execution of the M&S).

The traceability should cover the specific acquisition equipment that was used to collect the data. In fact, the RWS' knowledge is limited and the data generated is subjected to a degree of uncertainty (i.e., the data acquisition system's accuracy/precision figures). As such, the simulation models' fidelity derived from uncertain data cannot exceed the RWS characterization. If the resultant fidelity is deemed not sufficient for the purpose of the analysis, the input data accuracy/precision should be increased and/or the RWS should be explored in a larger domain. By doing so, better/additional knowledge is generated that permits to craft higher fidelity simulation models.

Applicants shall keep a record of relevant information and data for re-execution while the ADS is supported.

2.4.3. Input data credibility framework

The effect of input data pedigree on the overall credibility of the M&S toolchain can be estimated using the technique suggested in (NASA, 2019) and summarized in the table below. In particular, the higher the number associated with the realization of each field, the more credible the resulting M&S toolchain. The NASA scheme highlights that the less formal sources are not necessarily inferior. Nonetheless, a clear understanding of the data origin is advocated as a major factor contributing to the M&S credibility.

Table 6. Template for the credibility assessment of input data

Field	**Score**
Source of input data	SME Document Test results Operational data
Quality of the source	Notional: uninformed/hypothetical estimation Informed: experienced estimation Specified: deriving from system requirements Derived: calculation from general physical considerations Measured: from direct knowledge
Diversity of data source	Single values (e.g., maximum or minimum) Set of historical values from different sources Single vs. multiple instances
Quantity of source data	A single value A set of values
Form of the data used	Deterministic Deterministic with spread Probability distribution of stochastic data

Source: NASA (2019)

Based on the input data assessment, the following table is proposed in (NASA, 2016) as a template for the input data score assessment:

Table 7. Template for the input data credibility level

Level	**Input Data Pedigree**	**Traceability**	**Uncertainty**
0	No/insufficient evidence	No/insufficient evidence	No/insufficient evidence
1	Some input data known	Informally traceable	No/insufficient evidence

2	Some input data known	Formally traceable	Estimated uncertainties
3	All input data known	Traceable to sufficient referent	Significant data has accuracy and precision provided
4	All input data known	Traceable to RWS	All data has accuracy, precision and uncertainty

Source: NASA (2016)

2.4.4. Uncertainty estimation

Related to the input data quality/adequacy is the characterization of the input uncertainty.

Sources of uncertainty may result from different aspects. A typical characterization is the following:

- **epistemic uncertainty:** lack of knowledge in some of the parameters/processes (can be reduced via increasing knowledge about the RWS)
- **aleatory uncertainty:** inherent variation in the physical system (irreducible);

The maximum credibility for an M&S is obtained when the epistemic uncertainty is reduced. For the sake of the credibility analysis, the way uncertainty has been determined/evaluated has to be reported.

2.5. Output Data Pedigree

2.5.1. Uncertainty estimation

Related to the output data credibility is the characterization of the uncertainty. Maximum credibility is obtained when a quantitative description of the results' uncertainty is provided and methodologies are enforced to mitigate the impact of the resulting uncertainties (NASA, 2019). Vice versa, no contribution to the credibility is provided when no qualitative or quantitative estimation is given. An intermediate credibility contribution is represented by a qualitative description.

The following table proposed in (NASA, 2016) might be used as a template for the uncertainty characterization score assessment:

Table 8. Template for the credibility assessment of output data uncertainty

Level	**Uncertainty Sources**	**Uncertainty Assessment**
0	No/insufficient evidence	No/insufficient evidence
1	Some sources of uncertainty identified	Qualitative assessment
2	Most sources quantitively identified	Propagation of known uncertainties
3	All known sources quantified	Quantitative uncertainty of M&S output
4	All known sources quantified	Statistical analysis of M&S output

Source: NASA (2019)

A common method to provide a quantitative estimation of the uncertainty is Monte Carlo simulation (EASA, 2020). In a Monte Carlo simulation, multiple simulations are executed by randomly sampling within the uncertainty interval the M&S parameters to generate confidence intervals.

2.5.2. Results Assessment and Reporting

The credibility of M&S is supported by a clear explanation of the data processing procedure of the M&S output signals.

3. M&S Analysis and Description

This Section provides guidance on the best practices to define M&S toolchains.

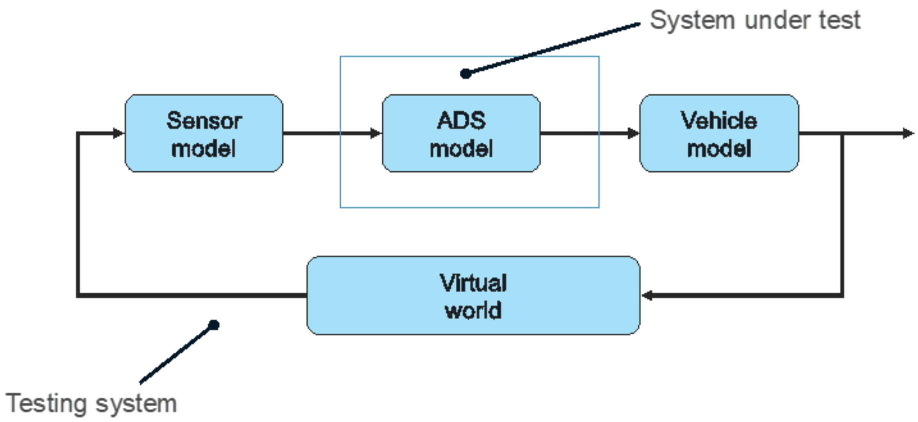
3.1. General Description

No single simulation tool can be used to test all aspects of the ADS software, this is why manufacturers will exploit the attributes of various simulation tools to develop confidence in the safety of the full system (UNECE, 2022c).

Each virtual testing tool will have its own strengths and weakness based on the speed and cost of execution and the level of fidelity achieved. Typically lower fidelity tools are used to cover a vast number of scenarios to obtain a general understanding of the systems performance. Then, it is possible to increase the level of fidelity within a subset of scenarios to validate the performance of the ADS in a statistically relevant number of realistic scenarios.

Moreover, the M&S might consist of "models of models", i.e., simulation models which enclose multiple sub-models to take advantage of the virtual testing's modularity. Whenever such an M&S realization is pursued, the kind of interfaces between models should be documented (e.g., one-way, coupled, etc.). A typical high-level modelling abstraction leveraging on one-way coupling is shown below.

Figure 8. Modelling abstraction with sub-models for ADS virtual testing.



Source: Donà and Ciuffo (2022)

3.1.1. Perception Simulation

Perception simulation can be used to train and validate the perception algorithms of the ADS software with physical accurate sensor models in combination with ground-truth data. This can be done in open-loop since the planning and control algorithms are bypassed.

3.1.2. Full AV Stack simulation (MIL, SIL)

Full AV Stack simulation can accurately render sensor data streams that represent a wide range of environments and scenarios. The ADS software processes the simulated data as if it were coming from the sensors of a vehicle actually driving on the road and sends actuation commands back to the simulator. This allows engineers to test rare conditions, such as rainstorms, snowstorms, or sharp glare at different times of the day and night. Each scenario can be tested repeatedly, adjusting multiple variables such as road surfaces and surroundings, weather conditions, other traffic, and time of day.

HIL can be used to test the entire hardware component or ECU before the real vehicle is available and to test the interactions/ networks of the components within the virtual prototype e.g. conduct E/E failure test of hardware components.

3.1.3. Vehicle in the Loop (VIL) on Test Beds

VIL provides a validation environment for ready-to-drive vehicles in combination with a virtual environment simulation. It allows to execute complex and safety critical scenarios on vehicle level.

VIL on test beds combines this with the advantages of a lab and focuses on flexibility in scenario generation and reproducibility of scenario execution. It allows additionally to test the real sensors and perception in the loop.

VIL on Test bed may consist of the following elements:

- Longitudinal dynamics: The longitudinal dynamics are emulated by the test bed. This can either be a chassis dynamometer or a wheel hub / powertrain test bed. High dynamic dynamometers in combination with a vehicle dynamics simulation allow the execution of various manoeuvres and scenarios including high dynamic manoeuvres at the limits (realistic wheel slip, etc.)
- Lateral dynamics: In case of lateral dynamics, including the steering is required, test beds can be extended by additional devices to allow steering. Ideally steering is not only allowed but also the resulting reaction forces are emulated properly to avoid error states and to ensure a proper operation together with the AV function
- Interface virtual environment simulation: Depending on the use case and the requirements, there are different possibilities: Object list injection (no sensor, no perception in the loop), raw data injection (no sensor but perception in the loop), over-the-air stimulation of the sensor (sensor and perception in the loop). Using the over-the-air stimulation, there are no modification on the vehicle required. Also, a mixed operation is possible.

3.1.4. VIL on proving grounds

VIL on proving grounds focuses more on the interaction between the driver/passenger and the vehicle. In this configuration the real acceleration (longitudinal and lateral) of the vehicle can be experienced by the driver/passenger (difference to Vehicle-in-the-Loop at test beds). A judgment and rating by the real driver are possible.

VIL Test bed may consist of the following elements:

- Longitudinal dynamics: The real longitudinal dynamics are available
- Lateral dynamics: The real lateral dynamics are available
- Interface virtual environment simulation: Typically, the interface between the vehicle and the virtual environment is done via object list injection. Also, raw data injection is possible. Real sensors cannot be considered (with a few exceptions for very simple sensors like ultrasonic).

3.1.5. Driver in the Loop (DIL)

DIL virtual testing can be helpful to support the assessment of this category of functional requirement by analysing the interaction between the driver and the ADS in a safe and controlled environment.

3.1.6. Software Reprocessing (SwR)

SwR involves playing back previously recorded sensor data, rather than synthetic data, to the ADS software to accurately assess the perception performance in an open loop system.

3.1.7. Summary

The table below describes all available test environments. The main difference in these test environments is in the application of virtual and real stimuli and in the items being tested.

Table 9. Summary of ADS virtual testing configurations.

Virtual Testing Tool	**Software**	**Hardware**	**Vehicle**	**Driver**	**Environment**
Perception	Real	Virtual	Virtual	Virtual	Virtual
Full AV Stack (MIL/SIL)	Real	Virtual	Virtual	Virtual	Virtual

Full AV Stack (HIL)	Real	Real	Virtual	Virtual	Virtual
Vehicle in the Loop	Real	Real	Real	Virtual	Virtual
Driver in the Loop	Virtual	Virtual	Virtual	Real	Virtual
Software Reprocessing	Real	Virtual	None	None	Real
Proving Ground	Real	Real	Real	Real	None
Real World Test	Real	Real	Real	Real	Real

Source: JRC

3.2. Scope

The applicant should specify the intended use and application for the M&S. The description may also include the results expected from the M&S.

Practical guidance to state the scope of the M&S toolchain is given in (RoCS, 2022) and here adapted.

Table 10. Template for M&S toolchain scope assessment

Level	**Influence**	**Description**
1	De-risking	The simulation is used to develop/familiarise No certification credit is obtained
2	Critical Point Analysis	Simulation is used to explore the ADS behaviour Simulation is used to perform a selection of critical testing points
3	Partial Credit	Simulation is used to receive certification credit for a portion of the testing domain Supplementary physical tests are necessary for certification
4	Full Credit	Simulation is used to replace certification (physical) testing

Source: Adapted from RoCS (2022)

3.3. Criticality assessment

The criticality assessment procedure aims at establishing the degree to which the M&S influences the ADS certification process and the consequences to the safety of accepting the M&S toolchain. The criticality assessment informs most of the steps of the simulation credibility framework. In fact, the level of detail that the applicant has to deliver is largely influenced by the potential impact the M&S has on the ADS certification process.

Below a list of possible methods which can be enforced to fulfil the criticality assessment pillar are provided. If other methods for the criticality assessment are used, they shall be properly documented.

3.3.1. ISO 26262-8:2018

The supporting software tool's criticality assessment may be carried out in accordance with the ISO 26262-8:2018 standard (International Organization for Standardization, 2018, p. 262). ISO 26262-8:2018 Clause 11 specifies a set of three tool confidence levels known as TCL. The TCL ranges from TCL 1 (lowest confidence) to TCL 3 (highest confidence).

In particular, the TCL depends on the "tool impact" and "tool error detection" levels.

Two possible tool impact are foreseen which are defined as follows:

- **T2:** tool failure or tool failure to detect errors can introduce faults into software output;
- **T1**: other cases.

Conversely, tool error detection the defines the probability of detecting such tool failures as follows:

- **TD1:** high degree of confidence that a tool failure can be prevented and/or detected;
- **TD2**: medium degree of confidence that a tool failure can be prevented and/or detected;
- **TD3**: other cases.

Combining the tool impact with the tool error detection yields the table below.

For TCL1, no particular tool qualification is recommended by ISO 26262. For TCL2 and TCL3, a tool qualification is required which depends on the ASIL level associated with the corresponding software as described by ISO 26262-8 Clause 11, Table 4 – 5.

Table 11. TCL levels

		Tool detection error		
		TD1	TD2	TD3
Tool impact	TI1	TCL1	TCL1	TCL1
	TI2	TCL1	TCL2	TCL3

Source: Adapted from International Organization for Standardization (2018) p. 262

3.3.2. NASA-STD 7009A

The determination of the criticality assessment for the M&S toolchain can be carried out in accordance with (NASA, 2016). Assessments falling within the red category are the ones strictly demanding following the full credibility assessment described in the present technical guideline. Yellow-labelled entries may or may not require the full credibility assessment depending on the technical authority's discretion whereas the green entries are associated with a low criticality impact.

Figure 9. M&S criticality assessment example

M&S Results Influence						
	5: Controlling	(G)	(Y)	(R)	(R)	(R)
	4: Significant	(G)	(Y)	(Y)	(R)	(R)
	3: Moderate	(G)	(Y)	(Y)	(Y)	(R)
	2: Minor	(G)	(G)	(G)	(Y)	(Y)
	1: Negligible	(G)	(G)	(G)	(G)	(Y)
		I: Negligible	II: Minor	III: Moderate	IV: Significant	V: Catastrophic
		Decision Consequence				

Source: NASA (2016)

Concerning the M&S influence, a guideline is given in (NASA, 2016) here reported (adapted). The influence concept is here intended as the degree to which an M&S impacts the decision-making.

Table 12. M&S influence template for assessment, adapted from

M&S Influence	Real System in Real Environment		Similar System in Similar Environment		Other M&S or Analysis
Controlling	No data are available for the real system in the real environment	&	No data are available for a similar system in similar environments	&	No other M&S or analysis data are available
Significant	No data are available for the real system in the real environment	&	Ample test data for similar systems in similar environments are available		No other M&S or analysis data are available
	or				
	No data are available for the real system in the real environment		No data are available for a similar system in similar environments	&	Credible results from another M&S are available
Moderate	Limited test data for the real system in the real environment are available		Ample test data for similar systems in similar environments are available		No other M&S or analysis data are available
	or				
	No data are available for the real system in the real environment		Ample test data for similar systems in similar environments are available		Credible results from another M&S are available
Minor	Some test data for the real system in the real environment are available		Test data for similar systems in similar environments may or may not be available		No other M&S or analysis data are available
Negligible	Ample test data for the real system in the real environment are available		Test data for similar systems in similar environments may or may not be available		No other M&S or analysis data are available
	or				
	Some flight or test data for the real system in the real environment are available		Test data for similar systems in similar environments may or may not be available		Credible results from another M&S are available

Source: NASA (2016)

Similarly, the potential damage resulting from using the M&S is summarized based on the considerations in (NASA, 2016) for a set of potential targets.

Table 13. M&S decision consequence template for assessment

M&S Impact	Personnel	Operational Status	Goods
Negligible	Inconsequential	No effect	Inconsequential

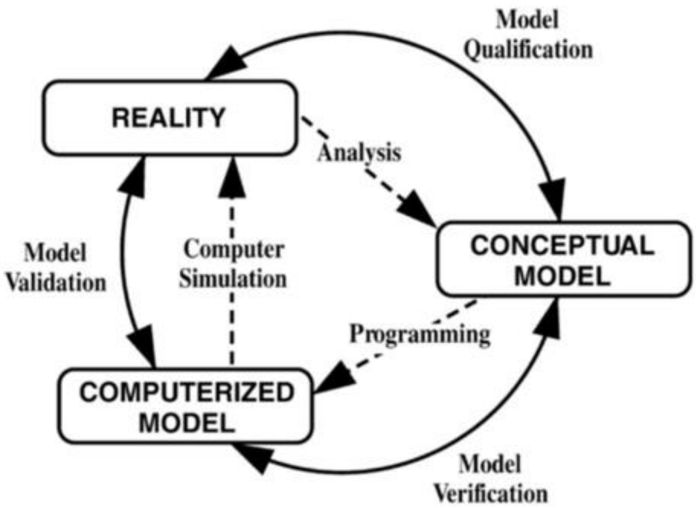
Minor	Minor detriment	Temporary effect	Minor detriment
Moderate	Minor injury or occupational illness	Feature temporary unavailable	Minor detriment with maintenance required
Significant	Severe injury	Significant/permanent degradation	Major damage
Catastrophic	Permanent disability or death	Severe degradation	Destructed

Source: Adapted from NASA (2016)

4. Verification of the Virtual Testing toolchain

There are additional ingredients needed in order to carry out the virtual tests that go beyond the crafting of virtual models. Among them: time-steps definition, solvers, and coupling algorithms. Despite the adoption of validated sub-components, the overall virtual test's outcome might not well represent the RWS due to integration and software implementation issues which shall be addressed using software verification techniques.

Figure 10. Common V&V approach.



Source: adapted from Sargent (2013)

It is thus advised that the M&S toolchain undergoes a *verification* phase. In particular, the verification exercise aims at assessing the correct implementation of the conceptual model. During this phase, the sources of numerical errors should be assigned an upper bound. Three steps are discussed hereafter based on the credibility framework.

According to the NASA credibility framework (NASA, 2016), a five-level score can be assigned to the verification step depending on the degree of fulfilment of the factor.

Table 14. Template for verification credibility level.

Level	**Model Verification Degree**	**Error Bounding**
0	No/insufficient evidence is given	No/insufficient evidence is given
1	Informal practices applied to some of the models/features of the M&S toolchain	Informal practices applied to assess errors
2	Documented practices applied to verify all the M&S features	Most important errors satisfy requirements

3	Formal practices applied to verify end-to-end the M&S toolchain	All important errors satisfy requirements
4	Reliable practices applied to verify end-to-end the M&S toolchain	All model errors satisfy requirements

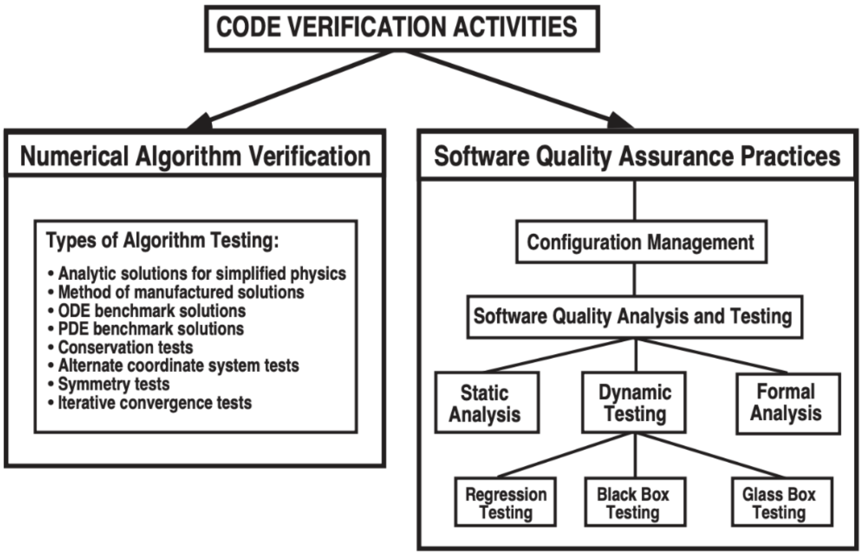
Source: NASA (2016)

4.1. Code Verification

The code verification phase is concerned with the execution of virtual tests demonstrating that no numerical/logical flaws affect the virtual models with respect to the intended purpose of the M&S toolchain and that the numerical algorithms are implemented correctly. Code verification is typically carried out by the simulation software producer as it is not model-specific. Nonetheless, it is up to the applicant to retrieve evidence for code verification procedures being enforced in the software used to develop the M&S toolchain.

An overview of code verification activities is presented in (W. L. Oberkampf et al., 2004) and graphically reported. Code verification is thus divided into the numerical algorithm verification (NAV) component and the software quality assurance (SQA) factor. The NAV component inspects the reliability of the software implementation from the perspective of numerical accuracy and code efficiency (EASA, 2020). The SQA component investigates the reliability of the software implementation from the perspective of the repeatability of results.

Figure 11. Code verification procedures.



Source: Oberkampf et al. (2004)

Where applicable, examples of techniques that might be used to support the code verification argument from the perspective of the SQA are:

- **Unit testing:** execution of a series of low-level tests and comparison of the implemented (coded) model with the conceptual/mathematical models (NASA, 2019);
- **Model (code) coverage:** execution of virtual tests to determine that all logical branches within the model are executed (NASA, 2019);
- **Static testing**: checking of compilation warnings and errors, consistency analysis in the usage of the computer language (EASA, 2020);
- **Dynamic testing**: code execution to investigate memory leaking.

Where applicable, examples of techniques that might be used to support the code verification argument from the perspective of the numerical algorithm verification are:

- **Convergence testing:** execution of tests to demonstrate the convergence to a stationary value while iterating spatial/temporal discretization;
- **Order of accuracy:** execution of tests aiming at assessing whether the solution/discretization error converges with the expected rate;
- **Comparison with a known analytical solution:** whenever a known (analytical) solution is known it should be compared to the corresponding simulation model code realization;
- **Method of Manufactures Solutions:** (MMS) create an analytical solution for the set of equations (ODEs or PDEs) defining the model under analysis without necessarily resorting to a solution backed by physical meaning (W. L. Oberkampf et al., 2004).

The main aim of the code verification phase, from the perspective of the credibility assessment, is to provide evidence of (W. Oberkampf et al., 2007):

- the correctness and fidelity of the numerical algorithms used in the code relative to the mathematical model;
- the correctness of the source code;
- the configuration management, control, and testing of software through SQE practices.

Practical guidance on how to assess the credibility of the code verification phase is given below based on (W. Oberkampf et al., 2007).

Table 15. Template for code verification credibility assessment.

Level	**Code Verification Technique**	**Maturity**
0	Judgment only Minimal testing of any software elements Little or no SQE procedures specified/followed	Low consequence Minimal M&S impact
1	Code is managed by SQE procedures Unit and regression testing conducted Some comparisons made with benchmarks	Moderate consequence Some M&S impact
2	Some algorithms are tested to determine the order of numerical convergence Some features are tested with benchmark solutions Some peer review conducted	High consequence High M&S impact
3	All important algorithms are tested to determine the order of numerical convergence All important features are tested with rigorous benchmark solutions Independent peer review conducted	High consequence Decision-making based on M&S

Source: Oberkampf et al. (2004)

4.2. Calculation/Solution Verification

The calculation/solution verification phase deals with the estimation of numerical errors affecting the M&S toolchain and the characterization of the numerical accuracy. Numerical errors in the M&S might result from, for example, spatial/temporal discretization of the underlying equations and linearization of non-linear systems. Differently from the code verification pillar, the calculation/solution verification step has to be fulfilled by the M&S toolchain creator since it is directly related to the specific realization of the simulation models.

Where applicable, methods to demonstrate the correctness of the M&S include:

- **Float operation:** evaluate the impact of the uncertainty of underflow/overflow and rounding errors (NASA, 2019);
- **Solver tolerances:** evaluate the impact of the uncertainty of different solver tolerances (NASA, 2019). Ideally, the applicant shall perturbate the solution until convergence is achieved;
- **Sampling intervals:** evaluate the impact to uncertainty/accuracy of sampling interval (NASA, 2019). Ideally, the applicant shall perturbate the solution until convergence is achieved.

Notice that the techniques discussed are not meant to substitute the accuracy verification phase which pertains to the validation section discussed in the next section.

From the perspective of the credibility assessment, the calculation/solution verification phase is in charge of (W. Oberkampf et al., 2007):

- assessing the numerical solution errors in the computed results;
- assessing the confidence in the computational results due to human errors.

Practical guidance for the credibility assessment of the calculation/solution verification phase is given in the table below based on (W. Oberkampf et al., 2007).

Table 16. - Template for calculation/solution verification credibility assessment

Level	**Calculation/Solution Verification Technique**	**Maturity**
0	Judgment only Numerical errors have an unknown or large effect of simulation results	Low consequence Minimal M&S impact
1	Numerical effects on relevant SRQs are qualitatively estimated Input/output (I/O) verified only by analysts	Moderate consequence Some M&S impact
2	Numerical effects are quantitatively estimated to be small on some SRQs I/O independently verified Some peer review conducted	High consequence High M&S impact
3	Numerical effects are determined to be small on all important SRQs Important simulations are independently reproduced Independent peer review conducted	High consequence Decision-making based on M&S

Source: Oberkampf et al. (2007)

4.3. Sensitivity Analysis

The sensitivity analysis (SA) deals with the estimation of the sensitivity of the M&S to slight changes in the operating conditions and parametrization. The sensitivity analysis thus aims at providing evidence concerning the M&S robustness. The parameters which demonstrate the larger impact on the results shall have their uncertainty content minimised as much as reasonably possible (EASA, 2020). The parameters' exploration shall not overcome the permissible range of the M&S execution.

According to the NASA credibility framework (NASA, 2016), a five-level score can be assigned to the sensitivity analysis step depending on the degree of fulfilment of the factor.

Table 17. - Template for the sensitivity analysis credibility level.

Level	Sensitivity Knowledge	Key Sensitivity Identification
0	No/insufficient evidence is given	No/insufficient evidence is given
1	Qualitative estimate	No/insufficient evidence is given
2	Sensitivity studied for few parameters	Few key sensitivities identified
3	Sensitivity studied for many parameters	Many key sensitivities identified
4	Sensitivity studied for most parameters	Most key sensitivities identified

Source: NASA (2016)

Additional practical guidance for the sensitivity analysis and uncertainty quantification is also provided in (W. Oberkampf et al., 2007).

Table 18. - Template for SA/UQ analysis credibility assessment

Level	Sensitivity/Uncertainty Analysis Technique	Maturity
0	Judgement only Only deterministic analyses are conducted Uncertainties and sensitivities are not addressed	Low consequence Minimal M&S impact
1	A&E uncertainties propagated but without distinction Informal sensitivity studies conducted Many strung uncertainty/sensitivity assumptions made	Moderate consequence Some M&S impact
2	A&E segregated, propagated and identified in SRQs Quantitative sensitivity analyses conducted for most parameters Numerical propagation errors are estimated and their effect known Some strong assumptions made Some peer review conducted	High consequence High M&S impact
3	A&E uncertainties comprehensively treated and properly interpreted Comprehensive sensitivity analyses conducted for parameters and models Numerical propagation errors are demonstrated to be small No signification assumptions about UQ/SA made Independent peer review conducted	High consequence Decision-making based on M&S

Source: Oberkampf et al. (2007)

5. Validation of the M&S toolchain

The validation of the virtual testing toolchain consists in assessing the discrepancy between the simulation-generated data and the corresponding RWS (Dona & Ciuffo, 2022).

From the perspective of the credibility assessment, the validation procedure aims at establishing (W. Oberkampf et al., 2007):

- the thoroughness and precision of the accuracy assessment of the computational results relative to the experimental measurements;
- the completeness and precision of the characterization of the experimental conditions and measurements;

- the relevancy of the experimental conditions, physical hardware, and measurements in the validation experiments compared to the application of interest.

According to the NASA credibility framework (NASA, 2016), a five-level score can be assigned to the validation step depending on the degree of fulfilment of the factor.

Table 19. - Template for the validation analysis credibility level.

Level	M&S Output Analysed	Referent
0	No/insufficient evidence is given	No/insufficient evidence is given
1	Conceptual model addresses problem statement	Available referent
2	Most key M&S outputs in agreement	Sufficiently similar referent
3	All key M&S outputs in agreement	RWS operating in a representative environment
4	All M&S outputs in agreement	RWS in the full range of operation in real operating environment

Source: NASA (2016)

Practical guidance for the credibility assessment of the validation analysis performed is also provided in (W. Oberkampf et al., 2007) and here adapted.

Table 20. - Template for validation analysis credibility assessment

Level	Validation Technique	Maturity
0	Judgement only Few, if any, comparisons with measurements from similar systems/applications	Low consequence Minimal M&S impact
1	Quantitative assessment of accuracy of SRQs not directly relevant to the application of interest Large or unknown experimental uncertainties	Moderate consequence Some M&S impact
2	Quantitative assessment of predictive accuracy for some key SRQs Experimental uncertainties are well characterized for most SETs but poorly known for IETs Some peer review conducted	High consequence High M&S impact
3	Quantitative assessment of predictive accuracy for all important SRQs from IETs and SETs at conditions directly relevant to the application Experimental uncertainties are well characterized for all IETs and SETs Independent peer review conducted	High consequence Decision-making based on M&S

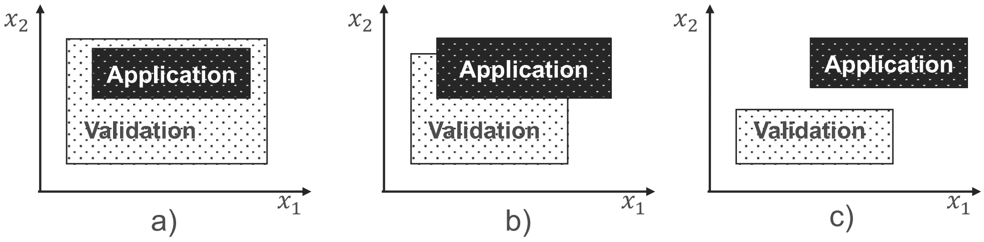
Source: Oberkampf et al. (2007)

5.1. Validation Domain

The validation exercise cannot guarantee the fidelity of the models over an unlimited parameters' space. Instead, the validation domain is bounded by the available RWS. Hence, those bounds shall be clearly stated.

The impact on the credibility of the validation domain assessment is deemed equally as important as the overall validation procedure (EASA, 2020). In particular, the applicant shall state to which extent the validation domain is related to the application domain, i.e., the *degree of extrapolation* foreseen for the modelling approach. Three example scenarios are provided which range from “no extrapolation” (a), to “partial extrapolation” (b), and “full extrapolation” (c).

Figure 12. Validation vs. application/extrapolation domain



Source: Adapted from EASA (2020)

The applicant shall also provide bounds for the parameters’ space where the M&S is deemed credible to avoid extrapolation outside the credibility limits. In this regard, the concept of the domain of *physical reality* suggested in (Lu et al., 2022) can support the credibility argument. The domain of physical reality refers to the domain where the laws of physics underlying the phenomena that are virtually replicated are adequately captured by the simulation model. That is the domain where the modelling assumptions can be corroborated. Maximum credibility is obtained when the M&S application lies entirely within the physical reality domain.

Eventually, the validation scenarios should be different from the scenarios used to calibrate the simulation models in accordance with the V&V best practices.

5.2. Correlation Methodologies

The validation of a virtual testing toolchain shall be based on the quantitative evaluation of a set of KPIs with respect to the real-world data. The assessment returns a measure of correlation which has to be checked against a prescribed correlation threshold.

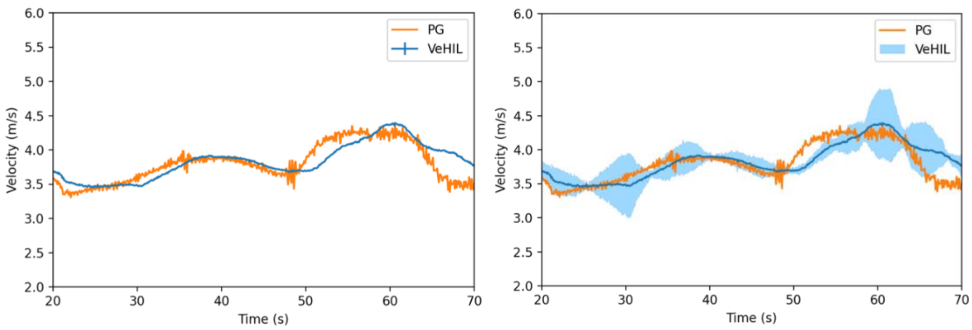
The computation of the correlation is carried out by comparing either time-series or probability distributions depending on the data availability and the virtual testing setup. Deterministic virtual testing environments such as MIL and SIL will originate deterministic results with no possibility of assessing the confidence intervals. Similarly, real-world testing leveraging on a single execution per each test does not allow assessing confidence intervals. Thus, when a MIL testing environment is compared to a single execution for validation purposes, only time-series comparison analysis is possible.

On the other side, a HIL or VIL testing environment is subject to a certain degree of stochasticity, which implies that multiple repetitions will originate a statistical distribution of the results. An analogous result is obtained via the execution of several repetitions for a given proving ground scenario. This way of proceeding allows for carrying out statistical testing on the collected data distributions.

5.2.1. Graphical comparison

Graphical comparisons provide a first validation step which displays the goodness of fit the simulation model. The credibility of the comparison is increased if confidence intervals are provided.

Figure 13. Example of a graphical comparison.



Source: JRC

Nonetheless, the subjectivity inherent to the qualitative nature of the assessment implies that graphical comparisons are only suitable to support the credibility of the developed toolchain. A proper validation methodology shall be based on the quantitative methods described below.

5.2.2. Scalar data comparison

Scalar data comparisons are useful tools to compare significant values of a signal. When only the pick values of a signal is relevant (e.g. the maximum yaw-rate during an emergency obstacle avoidance manoeuvre) for the sake of validation, the Relative Error Criterion (REC) difference amplitude criterion is a suitable metrics

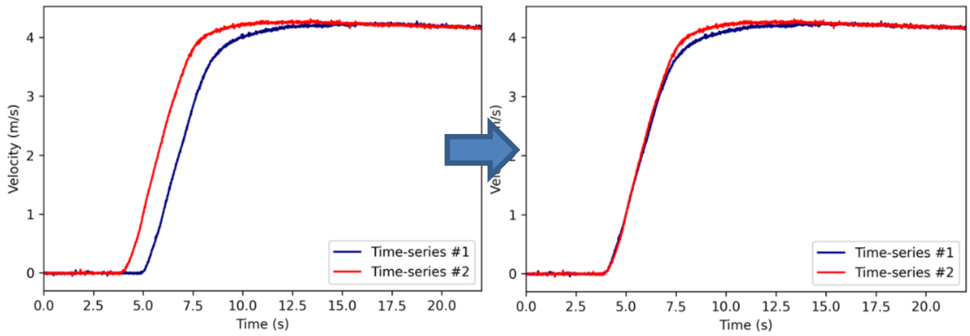
$$\frac{|peak_{real} - peak_{sim}|}{peak_{real}} * 100$$

5.2.3. Time-series comparison

Despite being the first step into the quantitative evaluation, scalar data provide limited information about the agreement of the signals. The study of time-series affords to investigate the correlation of the simulation-generated evidence with the real-world data to a greater extent.

Several tools exist to quantify the distance between time-series. Before any attempt of comparison can be pursued, the time-series have to be synchronized and resampled based on the lowest frequency between real-world and the simulated data. A widespread solution for the synchronization is to adopt the Time-of-Arrival (ToA) criterion. ToA implies the definition of a reference starting time for the signals which is derived from the first time the signal reached a pre-defined amplitude.

Figure 14. Time-of-arrival synchronization example.



Source: JRC

Once opportunely synchronized and resampled, the time series can be analysed according to a distance function. Distance estimation is typically carried out by applying some norm function to the vector of residuals. For instance, the L_2 norm (Euclidean distance) reads as:

$$\sqrt{\sum_{i}^{N} (y_{sim,i} - y_{real,i})^2}$$

where N is the total list of samples. The normalization of the L_2 norm over the total number of samples yields the Root Mean Square Error (RMSE):

$$\sqrt{\frac{1}{N}\sum_{i}^{N} (y_{sim,i} - y_{real,i})^2}$$

RMSE can be normalized according to the variance of one of the signals thus originating the Normalized Root Mean Square (NRMSE):

$$\frac{1}{\sigma_{pg}}\sqrt{\frac{1}{N}\sum_{i}^{N} (y_{sim,i} - y_{real,i})^2}$$

Alternative norms can be used to quantify the discrepancies between the time-series, which are susceptible to different features or error signals. For instance, the L_∞ norm returns the maximum absolute value of the error

$$max_i \left(\left|y_{sim,i} - y_{real,i}\right|\right)$$

Recently developed metrics allow separating the contribution of *phase* error (thus the shape of the time-series) to the contribution of the *magnitude* error between the signals, thus providing more insights on possible inconsistencies affecting the model. A recent report published by Sandia (Maupin & Swiler, n.d.) investigates such techniques. In particular, the Sprague-Geers (Sprague & Geers, 2004) metric is presented therein. The same criterion is also adopted to validate virtual models for seats within the field of aviation (*ARP5765B*, n.d.). The metric is based on establishing the integral distance between the signals

$$d_M = \sqrt{\frac{\sum_i^N y_{sim,i}^2}{\sum_i^N y_{real,i}^2}} - 1$$

and the phase difference

$$d_P = \frac{1}{\pi} \cos^{-1} \left(\frac{\sum_i^N y_{sim,i} * y_{pg,i}}{\sqrt{\sum_i^N y_{sim,i}^2 * \sum_i^N y_{real,i}^2}} \right)$$

combined into the total error

$$d_{SG} = \sqrt{d_M^2 + d_P^2}$$

A concept similar to the Sprague-Geers underlies the Dynamic Time Warping (DTW) method (Rabiner & Juang, 1993). Differently from d_{SG} however, in the DTW, the signals are allowed to be rescaled along the time-axis and the corresponding axis deformation part of the metrics assessment.

An alternative analysis that can be carried out is establishing the *correlation* between the signals. Several tools to calculate the correlation have been proposed in the literature. Among them, a commonly adopted tool is the Pearson correlation

$$r_{sim,real} = \frac{\left|\sum_{i=1}^{N} \left(y_{sim,i} - \bar{y}_{sim}\right)\left(y_{real,i} - \bar{y}_{real}\right)\right|}{\sqrt{\sum_{i=1}^{m} \left(y_{sim,i} - \bar{y}_{sim}\right)^2 \sum_{i=1}^{m} \left(y_{real,i} - \bar{y}_{real}\right)^2}}$$

Values of $r_{sim,real}$ close 1 suggest good agreement between the signals, whereas correlation degrades approaching 0.

5.2.4. Statistical testing

Statistical testing is concerned with verifying whether the null hypothesis, *i.e.:* "the model is an accurate representation of the real-world phenomena," cannot be rejected given the evidence generated by the simulation. Statistical testing is particularly useful when dealing with non-deterministic virtual testing environments or multiple repetitions of the same driving scenario on the proving ground.

A common statistical test is the well-known T-test which analyses whether two distributions have a significatively different mean. T-test can be performed on both one-sample or two-sample datasets. A one-sample case study involves determining whether the mean of a population ($\bar{x}$) is statistically different from a given reference mean (μ_0). The "t"-value can be calculated as

$$t = \frac{(\bar{x} - \mu_0)\sqrt{N}}{s}$$

where s is the standard deviation of the sample. One can reject the null-hypothesis is the t value exceeds the critical value resulting from the sample size N and significance level.

A typical example for the one-sample T-test is investigating whether the experimental mean of a quantity differs significatively from the distribution of the same quantity deriving from multiple repetitions on a HIL/VIL setup. Similarly, comparing multiple repetitions on a proving ground with the evidence derived from a deterministic environment originates a one-sample exercise. Conversely, two-sample T-test is found when two distributions are compared. The comparison of more than two distributions can be carried out by exploiting the Analysis of Variance (ANOVA).

While the T-test is mainly concerned with studying the mean of distributions, alternative tests exist which do not make assumptions on input data normality. For instance, the Kolmogorov-Smirnov test evaluates the maximum vertical distance in the Cumulative Distribution Functions (CDFs) of the input distributions.

5.3. Validation Examples

This subsection illustrates the possible approaches that can support the validation of M&S toolchains for ADS. The explanation is mainly divided into "subsystem-based" solutions and "integrated toolchain" approaches. The first is conceived with validating the individual models that make up the toolchain, based on the abstraction framework, by decoupling the corresponding model from the M&S toolchain and evaluating the discrepancy against real-world data. The latter investigates how the overall M&S toolchain is capable to replicate a real-world scenario without analysing the individual contribution of each submodel.

Both approaches are deemed necessary for the maximum credibility. Indeed, the integrated toolchain is the means used to generate the data supporting the certification of the ADS. Nonetheless, since the toolchain will be used in the extrapolation domain, a proper characterization of each submodel encourages the M&S credibility. For all the approaches presented, the corresponding validation domain shall be identified and reported.

5.3.1. Modelling Approach Credibility

State-of-the-art literature provides guidance for M&S validation best practices. In particular, a generic framework to assess the credibility of the modelling approach is given in (W. Oberkampf et al., 2007) which provides support to define:

- the degree to which models are physics-based;
- the degree to which models are calibrated;
- the degree to which models are being extrapolated from the validation and calibration database to the conditions of the application of interest;
- the quality and degree of coupling multiphysics effects that exist in the application of interest.

Based on the considerations above, a framework to assess the maturity level of the M&S toolchain from the perspective of the modelling approach is provided (W. Oberkampf et al., 2007).

The highest maturity level (Level 3) is associated with a M&S toolchain based on fully physical approaches relying on a bidirectional coupling of each simulation model. On the contrary, fully empirical models that only fit experimental data without a reconstruction of the physics behind the phenomena modelled are associated with the lowest grade (Level 0). The lowest maturity, and thus minimal contribution to the credibility, is due to the limited domain of application of those M&S approaches that can be applied only within the range used for calibration with minimal or non-existent extrapolation capabilities.

Table 21. - Template for modelling approach credibility assessment

Level	**Validation Technique**	**Maturity**
0	Judgement only Model forms are either unknown or fully empirical Few, if any, physics-informed models No coupling of models	Low consequence Minimal M&S impact
1	Some models are physics-based and are calibrated using data from related systems Minimal or ad-hoc coupling of models	Moderate consequence Some M&S impact
2	Physics-based models for all important processes Significant calibration needed using SETs and IETs	High consequence High M&S impact

	One-way coupling of models Some peer review conducted	
3	All models are physics-based Minimal need for calibration using SETs and IETs Sound physical basis for extrapolation and coupling of models Full, two-way coupling of models Independent peer review conducted	High consequence Decision-making based on M&S

Source: Oberkampf et al. (2007)

5.3.2. LiDAR/RADAR Model Validation

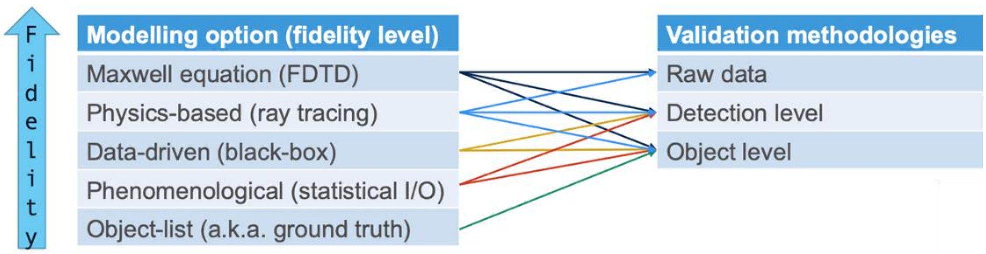
Modelling approaches

The LiDARs/RADARs modelling approaches can informally be divided into fidelity levels depending on the target application for the M&S. In particular, three reference classes (Schlager et al., 2020) can be derived:

- **Low fidelity models**: retrieve the traffic objects' list and status directly from the virtual environment ground-truth. This modelling paradigm does not afford statistical aspects related to the perception, such as false positives/negatives rate. Low fidelity models might however include basic sensor modelling such as accounting for the sensor's Field of View (FoV) and occlusions to filter the whole object list;
- **Medium fidelity model:** similarly to the low fidelity, medium fidelity models retrieve the objects' status from the virtual environment kernel. Nonetheless, medium fidelity sensors introduce detection probability (false positive and false negative), the effect of objects' shape and material on the detection, and environmental effects such as atmospheric degradation;
- **High fidelity model:** take advantage of advanced and computationally expensive rendering techniques to model physical processes happening in the real sensor. High fidelity sensors take as input the simulation rendered 3D environment following ray-tracing/rasterization. These sensor models are then allowed to operate with a similar input with respect to their physical counterparts.

Each fidelity level can be associated with a corresponding validation procedure. For instance, only "high" and "medium"-fidelity levels provide simulated raw-data that can be investigated against the real-world recording. Conversely, "low" fidelity model can only deliver information related to the object/detection level. Hence any validation procedure requiring raw data as an input cannot be embraced.

Figure 15. Modelling options vs. fidelity levels.



Source: JRC

Metrics and KPIs for explicit LiDAR/RADAR Model Validation

The validation of a sensor model is concerned with establishing whether the developed sensor model is a viable solution for the purpose of performing ADS certification via virtual testing. "Explicit" validation techniques directly compare the direct output of the virtual model with respect to the real counterpart for the same set on input when applicable.

The ADS validation shall rely on the highest fidelity modelling approaches in virtual tests where the perception system plays a critical role. Hence, the annex is mainly concerned with the validation of "medium" and "high"-fidelity LiDAR/RADAR models. Such models are typically validated by exploiting the generated "point-clouds" (PC) or at the "occupancy-grid" (OG) level.

OGs are derived from the PCs where a cell (c_i) is assumed to be free ($c_i = 0$) or occupied ($c_i = 1$) if the probability of detecting an obstacle in the cell is greater than 0.5. OGs deriving from simulation tests and real-world tests can be compared exploiting one of the following methods:

- OGs pixel-loss:

$$\sum_{x_c=0}^{weight} \sum_{y_c=0}^{height} | sim_{grid}(x_c, y_c) - real_{grid}(x_c, y_c) |$$

- OGs Pearson correlation:

$$\frac{\left|\sum_{i=1}^{n_c} (c_{i,sim} - \bar{c}_{sim})(c_{i,real} - \bar{c}_{real})\right|}{\sqrt{\sum_{i=1}^{n_c} (c_{i,sim} - \bar{c}_{sim})^2 \sum_{i=1}^{m} (c_{i,real} - \bar{c}_{real})^2}}$$

- OGs ratio:

$$\frac{\sum_{i}^{N\ cell\ sim} c_j}{\sum_{j}^{N\ cell\ real} c_i}$$

As an alternative validation procedure, the virtual and real point clouds (PC) can be characterized taking advantage of a distance function, such as:

- PCs Euclidean distance:

$$D'_{pp} = \frac{1}{M} \sum_{m=1}^{M} \min_{1 \le n \le N} \|p_{sim} - p_{real}\|$$

- PCs Pearson correlation:

$$\frac{\left|\sum_{i=1}^{m} (x_{i,j} - \bar{x}_j)(y_i - \bar{y})\right|}{\sqrt{\sum_{i=1}^{m} (x_{i,j} - \bar{x}_j)^2 \sum_{i=1}^{m} (y_i - \bar{y})^2}}$$

Implicit LiDAR/RADAR Model Validation

The perception system of an ADS is the element which acts as an interface between the simulation environment and the actual ADS. Thus, any information retrieved by the sensors is forwarded to the ADS. The validation of a sensor model shall then not disregard the impact that even small discrepancies between the real and virtual model can have on a complex system such as the ADS.

"Implicit" validation techniques establish the validity of the sensor model by including the perception algorithms (Ngo et al., 2021), in the validation chain. The comparison is then carried out by establishing the difference between the simulation derived and real-world detected/tracked traffic objects.

The evaluation of implicit metrics can be carried out by directly compare the distance between the $(x, y)_{obj,sim}$ and $(x, y)_{obj,\ real}$ coordinates of the tracked obstacles over the duration of the experiment using the techniques highlighted in Annex II. Alternatively, the Intersection-over-Union (IoU) metric, described in the formula below, can be computed in case the detection layer returns bounding-boxes.

$$J(bb_{sim}, bb_{real}) = \frac{|bb_{sim} \cap bb_{real}|}{|bb_{sim} \cup bb_{real}|}$$

5.3.3. Lane Model Validation

Lane model validation is considered to provide a practical example on how the validation is performed as a part of the credibility assessment. Accurate representation of lane models are required for perception algorithm used for most lateral support systems e.g. lane keep assist, lane centring, lane change assist etc. In order to demonstrate that the lane models are fit for purpose processes defined in the credibility assessment can be used. Vehicle dynamics is not considered during this process because the chassis dynamic will have negligible impact on the ability to detect the lane markings. The process consists of the following elements:

- Subsystem – camera model
- Sensor System – camera model with virtual lane markings.
- Integrated System – Lane detection algorithms

Camera Model Validation

Simulation needs to provide accurate image (intrinsic property) from the correct position (extrinsic property) for all cameras for a given scene. Specific intrinsic camera-related phenomena that should be considered during the validation include:

- Lens distortion: optical aberration due to projection;
- Vignette: darkening of the screen border;
- Grain jitter: white noise injection;
- Bloom: presence of fringes around bright areas;
- Auto exposure: image gamma adaption to darker or brighter areas;
- Lens flares: reflection of bright objects on the lens;
- Depth of field: blurring of objects near or very far away of the camera;
- Exposure time: shutter opening duration.

Below is a non-exhaustive list of tools that can be used to support the camera model validation:

- **Macbeth Colour chart Test:** determine camera colour space, noise figures, and exposure characteristics;
- **Opto-Electronic Conversion Function (OECF) chart Tests:** evaluate the relationship between input luminance and output digital level;
- **Special Frequency Response (SFR) chart:** measure sharpness, contrast, and lens effects;
- **Lens Flare characterization:** determine lens sensitivity to flare and ghosting;
- **F-theta calibration:** checkerboard test to determine F-theta polynomial.

Sensor System Validation

The purpose of the sensor system validation is to demonstrate that camera models provide accurate results in the virtual environment which the system under test will be operated in. Pre-defined KPIs can be used to determine performance of the virtual sensor system. For the purpose of lane models the contrast ratio between lane marking and road surface is used to demonstrate the performance of the sensor system in both physical and virtual environments.

A simple framework for dividing sensor performance into several equivalence classes is shown here, as an example. The method relies on efficiently dividing the equivalence classes of the *conditions* that have a significant effect on a sensor performance metric. In this case, the metric is brightness contrast ratio between the lane marking and the road surface. A requirement pattern can be formed that combines performance achievement with certain environmental or scenario-specific conditions.

A generic requirement pattern can be considered, as follows:

The {KPI} shall be {greater than} {KPI Threshold} if {Conditions Exist}

The requirement pattern can be repeated with different conditions, as needed, in order to 1) fully cover all external conditions, including the extreme ends, and 2) define the boundary values at which performance requirements may change depending on the conditions, for example, relaxing the false-positive detection rate of a lane boundary if it is snowing. If this requirement pattern is well-defined across all possible conditions, independently verified, and has commitment from the developers to fulfil the requirements, then the problem of "functional insufficiencies" in sensor performance will likely be reduced or eliminated altogether.

A method of division of the conditional classes follows this simple structure, as an example:

- **Class 1**: Nominal conditions - These are the ideal, best-case conditions.

- **Class 2**: Average conditions - These are the expected, real-world conditions that likely require significant development effort compared to Class 1 conditions, e.g. inner quartile range.

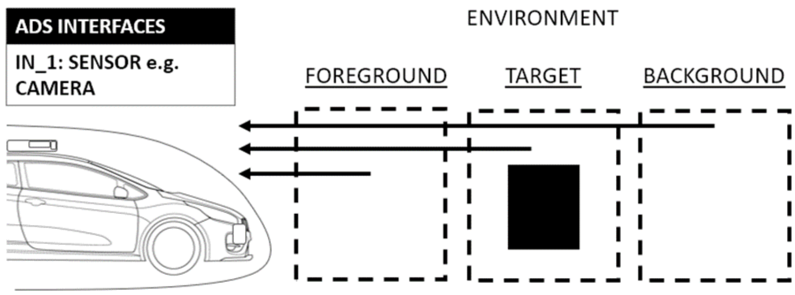
- **Class 3**: Worst-acceptable conditions - These are the worst conditions in which some level of performance will be guaranteed, e.g. 95'th percentile range. These likely require a trade-off between the minimum required performance level and the remaining development effort. Beyond this class, no performance requirements are obligated. (Note, this can be tailored, as needed)

Finally, the conditions themselves may need to be separated into parameters according to the dependence or independence from each other into a minimal parameter set which adequately captures the environmental and scenario-specific conditions. For each sensing modality that has been considered so far, which includes: camera (visible light), radar, LiDAR, ultrasonic, and infrared cameras, the following generic sensor model has shown to be repeatable and useful in analysing all environmental conditions for all sensing modes. It is broken down into three distinct parameters: Foreground, Target, and Background.

In the example of a camera-based system doing lane detection, the "Target" in this case would be the lane, itself. Many attributes may need to be developed to fully capture all the desired attributes of the Target, such as colour, position, curvature, dash type, sharpness (or blurriness), etc. In this case, the attribute of interest is the contrast ratio of the lane with respect to the road surface. The road surface would be the "Background" in the sensing model. The "Foreground" could be anything between the sensor and the Target, such as fog, rain, or clear air, as well as, debris, objects, accumulated snow, etc.

Internal or external classifications of the overall performance capability may (or may not) be useful to consider. For lane models, each parameter and their associated range of variables (Target, Foreground, and Background) should be considered during this phase. The sensor system should be qualified using known KPIs, such as very deterministic static scenarios, at first. This will allow the system to be validated against a measurable KPI. After that it can be extended to varying weather conditions etc. A test matrix can then be established that considers the variation of input parameters. Large variation in real and simulated results provide evidence where there may be limitations in the tool. Any sensor performance limitations should be noted during the assessment to put restrictions on what data can be generated to support the assessment of the ADS.

Figure 16. Camera sensor generic interface



Source: UNECE (2022c)

It is up to the designers to determine what is useful for the overall system goals and the given technical capabilities, but the intent with the sensor system validation approach is to show how the designers and testers may fully specify performance and safety requirements in their development contracts, and show evidence of the fulfilment of their contracts.

<u>Integrated System Validation</u>

Finally the complete integrated system is tested. This includes the sensor system with the integrated perception algorithms. Simulated and real world data are collected from the same environment and synchronized. State changes perception algorithms can then be compared to check if the simulated results match the real world performance. The correlation threshold would determine if lane detection algorithms are used to support: LDW, LKAS or ADS.

After demonstrating that the lane model is accurate enough, the virtual testing tool can be used to support the assessment of lane detection algorithms. Virtual tests can be used to dramatically speed up the validation process and provide enough evidence that the system works as expected across the ODD.

5.3.4. Vehicle System Model Validation

Based on the taxonomy suggested in (Dona & Ciuffo, 2022), vehicle dynamics chassis models can be clustered into three classes:

- **low-fidelity:** point-mass or simple kinematic models that are mainly exploited for trajectory planning, controller synthesis, and microsimulation traffic studies;
- **medium-fidelity:** chassis models such as the "single-track" (or bicycle model) and the "double-track";
- **high-fidelity:** multibody models which replicate the physics of the vehicle dynamics thus including, for instance, dedicated tyres models and suspension characteristics.

In addition to the chassis model, the vehicle system class includes subsystem-specific models like:

- steering model;
- brake model;
- powertrain model;
- ABS/ESP controllers;
- trailer (if any);

The selection of the suitable modelling approach is particularly informed by the ODD analysis (Duser et al., 2021). For instance, if the ADS is expected to operate in urban scenarios only, the target speed range is limited to a speed below 50 km/h. Hence, the validation analysis shall exclude those motorway-like velocities range that might potentially necessitate a higher fidelity modelling.

Regardless of the modelling approach selected, it is advised that both time- and frequency-domain approaches are used to validate the models. The validation domain is recommended to be bounded in terms of longitudinal/lateral acceleration and steering input frequency intervals (Kutluay & Winner, 2014).

Based on (Duser et al., 2021), a set of manoeuvres that can be enforced to generate evidence for the RWS are:

- **longitudinal manoeuvre:**
  - maximum vehicle body pitch angle;
  - braking with various pedal positions;
  - coast-down measurements;
- **lateral manoeuvre:**
  - maximum vehicle body roll angle;
  - slowly increasing steering angle manoeuvre at different speeds;
  - slow weave steering manoeuvre at different speeds;
  - step steer test;
  - sine sweep tests.

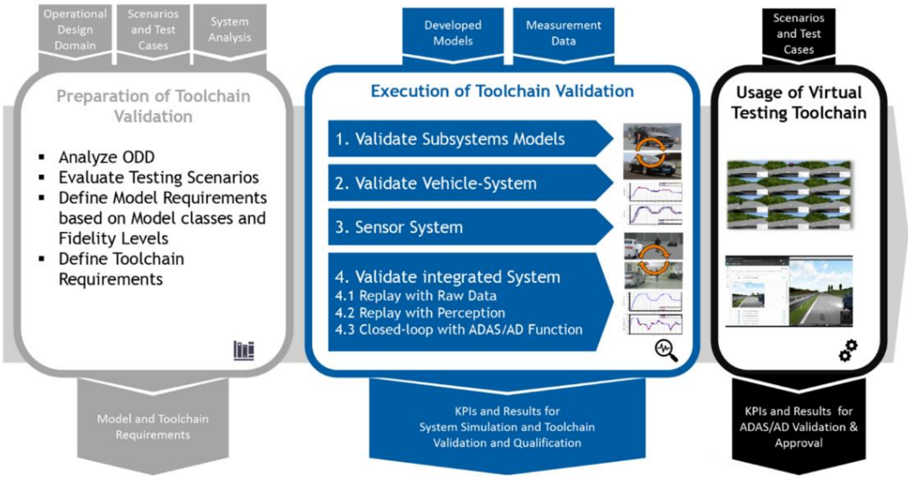
Eventually, relevant ISO standards which support the validation of vehicle dynamics model are:

- **ISO 11010-1:2022**: Passenger Cars - Simulation Model Classification - Part 1 Vehicle Dynamics;
- **ISO 19364:2016**: Passenger cars - Validation of vehicle dynamic simulation - Steady-state circular driving behaviour;
- **ISO 19365:2016**: Passenger cars -Validation of vehicle dynamic simulation - Sine with dwell;
- **ISO 22140:2021:** Passenger cars - Validation of vehicle dynamics simulation - Lateral transient response test methods.

5.3.5. *Integrated Toolchain Validation*

In parallel, or at the of the subsystem-based validation procedures, the whole M&S toolchain shall be validated. This validation step is referred to the "integrated system" validation (Duser et al., 2021).

Figure 17. Subsystems and integrated-level toolchain validation workflow



Source: Duser et al. (2022)

The following steps are suggested when validating the integrated toolchain (Duser et al., 2021):

- **replay with raw data:** determine the correlation between the RWS and the virtual testing-calculated sensor data while the vehicle is not driven by the ADS whereas the trajectory is reconstructed from the experiment;
- **replay with perception:** determine the correlation between the perception of elements in the real-world vs. the virtual world while the vehicle is not driven by the ADS whereas the trajectory is reconstructed from the experiment;
- **closed-loop with ADS function:** determine the overall correlation level using the full simulation pipeline while the ADS is driving the vehicle.

An additional example of a complete toolchain validation assessment can be found at https://doi.org/10.1109/ACCESS.2022.3171180 for a VIL setup.

6. Credibility Assessment

The credibility of a M&S realization cannot be directly measured. However, several frameworks exist to support estimating the overall credibility, two of them are summarised below.

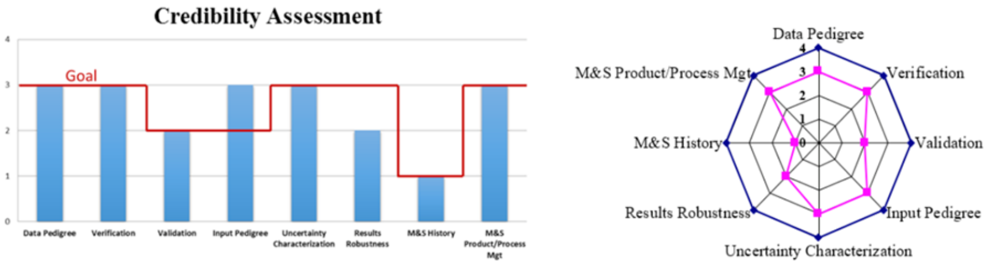
Additionally, it shall be noted that on top of establishing the credibility of each M&S pillar (data pedigree, verification, validation…) it is expected that the ADS manufacturer provides justification for the goal credibility which shall be agreed upon together with the technical authority.

6.1 Credibility Assessment Scale (CAS)

The CAS originates from the credibility framework envisaged at NASA for their M&S approaches following the Space Shuttle Columbia Accident investigation (NASA, 2016). The work has largely contributed to the present document and, in particular, in providing best practices and credibility assessment guidance for each of the factors making up the EU ADS simulation credibility assessment. Nonetheless, the NASA standard provides additional assistance in how to communicate the M&S toolchain overall credibility as resulting from the individual factor qualification effort.

A visual example of the CAS based on (NASA, 2019) is provided.

Figure 18. NASA credibility assessment example



Source: NASA (2019)

The NASA credibility framework (NASA, 2016) foresees eight factors that are in line with the EU ADS credibility scheme:

- Data Pedigree
- Verification
- Validation
- Input Pedigree
- Uncertainty Characterization
- Results Robustness
- M&S History
- M&S Management

divided into three classes:

- M&S Development
- M&S Operations
- M&S Supporting Evidence

Thus best practices following NASA STD7009 can constitute valuable resources to help fulfilling the EU ADS provisions.

Figure 19. NASA STD7009 CAS elements

Development			Operations			Supporting Evidence	
Data Pedigree	Verification	Validation	Input Pedigree	Uncertainty Characterization	Results Robustness	M&S History	M&S Process/Product Mgt

Source: NASA (2019)

6.2 Predictive Capability Maturity Model (PCMM)

As an alternative method to evaluate the level of maturity of M&S toolchain, the PCMM was proposed in (W. Oberkampf et al., 2007). In the PCMM six categories are used for the assessment:

- Representation and Geometric Fidelity
- Physics and Material Model Fidelity
- Code Verification
- Solution Verification
- Model Validation
- Uncertainty Quantification and Sensitivity Analysis

The assessment is evaluated via assigning a score from 0 to 3 to each category.

The PCMM consists of evaluating the maturity level of each category based on the maturity levels defined. Fractional score is foreseen to account for M&S practice that are in between two levels. Once the assessor has assigned a score to each category, the aggregated PCMM score is defined by the [min, mean, max] of the recorded levels.

Albeit the PCMM is a valuable tool to support the credibility handbook formulation, it does not provide guidance for all the pillars foreseen by the credibility framework as of (EU Commission, 2022b). In particular, the document does not include in the discussion practical approaches to quantify the credibility impact of specific data collection procedures and the M&S management. As such, PCMM has to be complemented with third-party methodologies.

Table 22. – M&S maturity levels

Level	Accuracy	Maturity Evidence	Assessment	Application
0	Little No evidence	Little No evidence	Individual Experience	Low-consequence systems Systems with little reliance on M&S Scoping studies Conceptual design
1	Some informal Generalized characterization	Some evidence	Some assessment Internal peer review	Moderate consequence systems Systems with some reliance on M&S Preliminary design support
2	Some formal Detailed characterization	Significant evidence	Some assessment Internal peer review	High-consequence systems Systems with high reliance on M&S Qualification support
3	Formal assessment Precise characterization	Detailed and complete evidence	All assessment Independent peer review	High-consequences systems Decision making based on M&S Certification/Qualification of the system

Source: Oberkampf et al. (2007).

APPENDIX 6 – Technical Guidance on In-service Reporting

The main purpose of in-service reporting is to confirm the safety performance and identify possible improvements for the ADS safety performance, not to attribute blame or liability.

In-Service Reporting addresses the reporting of the in-service ADS occurrences and safety performance by the manufacturer. The Reporting applies to occurrences which endanger or which, if not corrected, would endanger a vehicle, its occupants or any other person, and in more general terms, to all occurrences relevant to the safety performance of the ADS.

In-Service Reporting enables the identification of unreasonable risks related to the use of an ADS on public roads and the evaluation of its safety performance during operation.

In-Service Reporting requires manufacturers to collect and analyse the safety-relevant information related to their in-service ADS' operation and report data on safety-related concerns, occurrences and performance metrics to the relevant authorities, i.e., the type-approval authorities, the market surveillance authorities and the Commission.

In-Service Reporting is a mechanism to provide safety authorities with information about a manufacturer's ADS that complements information that may be gathered from other sources.

In-Service Reporting shall be carried out according to the laws applicable in each contracting party and according to the information available to the reporting actors (manufacturers and/or operators).

1. Objectives

The aim of In-Service Reporting is to contribute to the improvement of road safety by ensuring that relevant information on safety is collected, processed and disseminated.

The In-Service Reporting aims to fulfil three main objectives:

- Identify safety risks related to ADS performance that need to be addressed, including instances of non-compliance with ADS safety requirements;
- Support the development of scenarios through capturing information when the ADS does not perform safely or within a generally acceptable range in unanticipated situations;
- Share information and recommendations to promote continuous improvement of ADS safety performance.

Once there are enough ADS vehicles in-service that have encountered a sufficient range of traffic and environmental conditions then their safety needs to be evaluated. It is therefore essential that a feedback loop, facilitated by In-Service Reporting, is in place. This will provide data to assess and review the ADS manufacturer's safety case and to validate the information that was used to enable market introduction. The operational experience feedback from In-Service Reporting will also allow ex-post evaluation of the regulatory requirements and validation methods, providing an indication of any issues and consequently the need for any modification.

For example, utilising the information on ADS performance under real-world conditions could help to enhance or modify track tests. Furthermore, In-Service Reporting concerning user-interaction metrics could provide information useful for improving an ADS' HMI, its usability, and user education.

In addition, in the early phase of market introduction of ADS vehicles, it is essential that the whole community, i.e. ADS manufacturers, operators, regulators and approval authorities, learns from safety-critical situations involving an ADS. It is important therefore that there is a mechanism that allows information from the In-Service Reporting and recommendations from its analysis to be shared with the ADS community. This will allow others to react and should lead to developments that reduce or prevent that situation from occurring in another ADS.

Collection, processing and dissemination of information related to ADS safety performance from the In-Service Reporting will also help to evaluate the impact of ADS on the safety of the road network.

2. Template for short term reporting

The template provided below is inspired by equivalent practices in automotive and other industries. The proposed formulation has been adapted to cover the foreseen use for an ADS application. The light blue cells are the entries expected to be filled by the reporting actor (ADS operator and/or manufacturer). The text in italic in the light blue cells is representative of an example occurrence reported to the type-approval authority. The text in the right column provides the filling specifications.

The first topic of the reporting form ("WHAT") is a short description of the event aimed at providing a brief summary of the occurrence.

Table 23. – Short term reporting template - WHAT

WHAT		
Entry name	Field to be filled	Type/size
Headline		Text(200)

Source: JRC

Secondly, the occurrence is classified according to a list of possible classes. Currently, the Regulation provides a distinction between critical and non-critical occurrences.

The occurrence category refers to one of the four categories listed in the Annex III Part 5 Appendix 1 of the Regulation while the "occurrence type" refers to a list of sub-categories of occurrences listed in the same appendix.

Table 24. Short term reporting template – OCCURRENCE CLASSIFICATION

OCCURRENCE CLASSIFICATION		
Occurrence class		Text(50)
Occurrence category		Text(50)
Occurrence type		Text(200)

Source: JRC

The reporting form should be filled with weather detail and other information which might help identify the safety relevance of the occurrence (speed, acceleration, and mass). Additionally, if supporting vehicle telematics and/or media (e.g. camera/LiDAR recordings) are provided they should be stated in the following section.

Table 25. Short term reporting template – OCCURRENCE DETAILS

OCCURRENCE DETAILS		
Weather conditions		Text(20)
Lighting conditions		Text(20)
ADS vehicle pre-occurrence speed		Number(3) - [km/h] Time-series – [Km/h, s]
ADS vehicle post-occurrence max deceleration		Number(3) - [m/s^2]
ADS vehicle estimated pre-occurrence total mass (e.g., including passengers and/or payload)		Number(5) – [kg]
ADS vehicle telematics provided		[Y/N]

ADS vehicle EDR data provided		[Y/N]
ADS vehicle DSSAD data provided		[Y/N]
ADS vehicle media provided		[Y/N]
Third-party sources media/telematics provided		[Y/N]
Occurrence reported to the police		[Y/N]
Police report available		[Y/N]
Number of other road users being involved while the occurrence		Number(3) - [-]
Type(s) of other road users being involved while the occurrence		Text (200)
On-board/remote intervention operator available at occurrence		[Y/N]

Source: JRC

The reporting form should be filled with time information, both local and UTC.

Table 26. Short term reporting template - WHEN

WHEN		
UTC date		[YYYY/MM/DD]
UTC time		[HH:mm]
Local date		[YYYY/MM/DD]
Local time		[HH:mm]

Source: JRC

The reporting form should be filled with the complete specification of the occurrence location and a brief description of the local scenery.

Table 27. Short term reporting template - WHERE

WHERE		
Country		Text(50)
State		Text(50)
City		Text(50)
ZIP code		Number(10)
Street		Text(50)
Driving direction		Text(100)

GNSS coordinates		[longitude, latitude]
Scenario within ODD		[Y/N]
Speed limit at location		Number(3) - [km/h]
Roadway type		Text(50)
Roadway surface		Text(50)
Roadway description		Text(100)

Source: JRC

The reporting template should be filled with the levels and details of the damages recorded for both the ADS vehicle and per any other related traffic participant or object. A practical indication of the damage level is found in the aviation practice:

- destroyed: the damage makes it inadvisable to restore the vehicle;
- substantial: the vehicle sustained damage of structural failure requiring major replacement;
- minor: the vehicle can be rendered operational by simple repairs/replacement;
- none: the vehicle sustained no damage;
- unknown: the damage level is unknown.

Table 28. Short term reporting template – DAMAGE

DAMAGE		
Highest damage		Text(20)
ADS vehicle damage level		Text(50)
ADS vehicle damage location		Text(100)
Highest damage to other object		Text(20)
Object damaged (level)		Text(50)
		Text(50)
		Text(50)
		Text(50)

Source: JRC

The reporting form should be filled with details regarding the injury level for both the ADS vehicle occupants and other road users. Examples from the CADaS taxonomy are:

- fatal: death within 30 days of the accident;
- critical: injured (although not killed) in the road accident & injured person in very serious condition, may need surgery or a long hospital stay to survive;
- serious: injured (although not killed) in the road accident and hospitalized at least 24 hours;
- minor: Injured in road accident but no hospitalization required, only first aid;
- none: nobody was injured during the occurrence;

- unknown: injured in the road accident but the injury level is unknown.

The table below is only explanatory but not exhaustive of all injury levels.

Table 29. Short term reporting template – INJURY LEVEL

INJURY		
Maximum injury level		Text(50)
Total fatalities ADS vehicle		Number(3)
Total fatalities other road user		Number(3)
Road user type		Text(50)
Total serious injuries ADS vehicle		Number(3)
Total serious injuries others		Number(3)
Road user type		Text(50)
Total minor injuries ADS vehicle		Number(3)
Total minor injuries others		Number(3)
Road user type		Text(50)
Total non-injured		
Total unknown injuries ADS vehicle		Number(3)
Total unknown injuries others		Number(3)

Source: JRC

The reporting form should be filled with details concerning the ADS vehicle.

Table 30. Short term reporting template – VEHICLE DETAILS

VEHICLE		
Vehicle Identification Number		Text(17)
Type-approval number		Text(50)
License plate		Text(10)
State of registry		Text(50)
Vehicle category		Text(50)
Manufacturer		Text(50)
Model		Text(50)
Model Year		Number(4)
Mileage		Number(9)

ADS version		Text(50)
ADS licensing		Text(50)
Operator (if any)		Text(50)

Source: JRC

The reporting form should be filled with an exhaustive narrative concerning the occurrence. A schematic representation similar to the insurance report might be provided to help with the occurrence understanding. Moreover, this section shall be filled with the post-crash behaviour of the ADS vehicle.

Table 31. Short term reporting template – NARRATIVE

NARRATIVE	
Description of the event	
Post-crash behaviour	

Source: JRC

The report shall include a preliminary root cause analysis, including risk assessment, and the corresponding corrective implementing action (if any) procedure enforced by the reporting authority after the same has become aware of the occurrence.

Table 32. Short term reporting template – ANALYSIS

ANALYSIS	
Root cause analysis	
Corrective implementing action	

Source: JRC

Eventually, the report shall include management details including the reporting entity that provided the report and the reporting status. A few options are provided for the reporting status:

- preliminary: the communication used for the prompt dissemination of data obtained in the early stages of the investigation. More data is expected;
- initial notification: record is based on, or contains information corresponding to the level of information in the initial notification of an accident or incident (ICAO Annex 13, Chapter 4);
- factual: the handling of the occurrence has not yet been completed, but there is sufficient information to analyse and code the occurrence;
- closed on issue: report closed by the reporting organisation on first its issuance;
- closed: no further information is expected.

Table 33. Short term reporting template – MANAGEMENT

REPORT MANAGEMENT		
Reporting entity		Text(100)
Report ID		Text(240)
Report version		Number(10)

Report status		Text(100)
Report date		[YYYY/MM/DD]
Parties informed		Text(100)

Source: JRC

As soon as it is possible to do so, the Member State in which the critical occurrence has taken place should dispatch to the granting type-approval authority and the other recipients the details omitted from the manufacturer report as well as other known relevant information.

Upon sent the notification, the manufacturer should provide to the recipients of the occurrence with any relevant information regarding the ADS involved in the occurrence.

3. Template for periodic reporting

This section provides guidance to help ADS manufacturers and/or ADS operators with the implementation of the periodic reporting scheme.

The following template aims at ensuring that a consistent and comprehensive set of information is delivered to the relevant authority to foster an effective application of the periodic reporting scheme. Further granularity of the information can be considered depending on the ADS use cases.

The first set of entries covers general information about the ADS identification and usage in terms of distance/time travelled. This set of information has the main aim of providing the type-approval authority with the possibility of occurrences normalization with respect to the effective ADS operation.

Table 34. Periodic reporting –VEHICLE IDENTIFICATION

ADS IDENTIFICATION		
Entry name	Field to be filled	Type/size
ADS manufacturer		Text(50)
ADS licensing approval authority		Text(50)
ADS version		Text(50)
Vehicle model		Text(50)
Model year		Text(50)

Source: JRC

Table 35. Periodic reporting – OPERATIONS

ADS OPERATION INFORMATION		
Number of vehicles featuring ADS		Number(10)
Cumulative distance travelled by ADS		Number(10)
Cumulative time travelled by ADS		Number(10)
Average ADS time engagement		Number(10)

Source: JRC

The second list of entries covers the set of occurrences which remained unexplored from short term reporting as of the occurrence table coupled with the safety outcome of such events. Eventually, by combining the ADS operation with the list occurrences, the authority and manufacturer should agree on the Metrics and Safety Performance Indicators to confirm the safety level stated by the ADS manufacturer.

Table 36. Periodic reporting – SAFETY ASSESSMENT OCCURRENCES

OCCURRENCES SAFETY OUTCOME		
Cumulative number of occurrences		Number(10)
Occurrences covered under the short-term reporting provisions		-
Safety critical occurrences known to the ADS manufacturer or OEM		Number(10)
Occurrences related to ADS operation outside its ODD		Number(10)
ADS failure to achieve a minimal risk condition when necessary		Number(10)
Modifications made by the ADS manufacturer or OEM to address an identified and significant ADS safety issue		Number(10)
Occurrences covered under the periodic reporting provisions		-
Communication-related occurrences		Number(10)
Cybersecurity-related occurrences		Number(10)
Interaction with remote operator if applicable		Number(10)
Driver unavailability (where applicable) and other user-related occurrences		Number(10)
Occurrences related to Transfer of Control failure		Number(10)
Prevention of takeover under unsafe conditions		Number(10)
Occurrences related ADS failure		Number(10)
Maintenance and repair problems		Number(10)
Occurrences related to unauthorized modifications		Number(10)
Occurrences related to the identification of new safety-relevant scenarios		Number(10)
Other occurrences		Number(10)

Source: JRC

Thirdly, the safety outcome associated with the occurrences shall be reported together with the (known) aggregate data about other traffic participants involved in the occurrences.

Table 37. Periodic reporting – IMPACT ON (KNOWN) PEOPLE INVOLVED

OCCURRENCES SAFETY OUTCOME		
Fatalities		
ADS vehicle occupants		Number(10)
Other road users		Number(10)
Serious injuries		
ADS vehicle occupants		Number(10)
Other road users		Number(10)
Minor injuries		
ADS vehicle occupants		Number(10)
Other road users		Number(10)
Unknown injuries		
ADS vehicle occupants		Number(10)
Other road users		Number(10)
Accident and serious injuries		Number(10)
Minor incidents		Number(10)

Source: JRC

Table 38. Periodic reporting – (KNOWN) TRAFFIC PARTICIPANTS INVOLVED

OCCURRENCES AGGREGATE DESCRIPTION		
Collision with:		
Passenger car		Number(10)
VAN		Number(10)
Truck		Number(10)
Bus		Number(10)
Other: Vehicle		Number(10)
Motorcycle		Number(10)
Cyclist		Number(10)
Pedestrian		Number(10)

Other: VRU		Number(10)
Animal		Number(10)
Fixed object		Number(10)
Unknown		Number(10)
ADS vehicle damage level		
Destroyed		Number(10)
Substantial		Number(10)
Minor		Number(10)
Unknown		Number(10)
ADS vehicle damaged area		
Front		Number(10)
Front-left		Number(10)
Front-right		Number(10)
Rear		Number(10)
Rear-left		Number(10)
Rear-right		Number(10)
Left		Number(10)
Right		Number(10)
Top		Number(10)
Bottom		Number(10)
Unknown		Number(10)

Source: JRC

The fourth set of entries covers modifications (if any) made to the ADS in case of safety gaps.

Table 39. Periodic reporting – SAFETY GAP

ADS SAFETY GAP		
ADS discovered safety gaps (if any)		Number(10)
Gap #1		Text(500)
Gap #2		Text(500)
ADS addressed safety gaps (if any)		Number(10)

Gap #1		Text(500)
Gap #2		Text(500)

Source: JRC

Eventually, the report shall include management details including the reporting entity that provided the report and the reporting status. A few options are provided for the reporting status:

- **preliminary**: the communication used for the prompt dissemination of data obtained in the early stages of the investigation. More data is expected;
- **initial notification**: record is based on, or contains information corresponding to the level of information in the initial notification of an accident or incident (ICAO Annex 13, Chapter 4);
- **factual**: the handling of the occurrence has not yet been completed, but there is sufficient information to analyse and code the occurrence;
- **closed on issue**: report closed by the reporting organisation on first its issuance;
- **closed**: no further information is expected.

Table 40. Periodic reporting – REPORT MANAGEMENT

REPORT MANAGEMENT		
Reporting entity		Text(100)
Report ID		Text(240)
Report version		Number(10)
Report status		Text(100)
Report data		[YYYY/MM/DD]
Parties informed		Text(100)

Source: JRC

4. Additional Interpretation material

4.1. Role of Type-Approval Authorities

The type-approval authority, where necessary, should verify the information provided during in-service monitoring and reporting, and, if needed, may make recommendations to the ADS manufacturer to remedy any detected conditions constituting an unreasonable risk to safety.

If a serious safety risk is identified, the type-approval authority may recommend temporary safety measures, including immediately restricting or suspending the relevant operations, and require actions to restore an acceptable level of safety.

4.2. Collection and storage of information

It is expected that a reporting system is established at national level by means of a common national database and at European level by means of a Common Central Repository.

Data quality and consistency should be ensured both at national and European level by establishing checking processes.

Short term and periodic reports should be stored within the common national database and made accessible to the type-approval/market surveillance authorities and the Commission as per this Regulation or other applicable national laws.

4.3. Exchange of Information

It is expected that type-approval authorities participate in an exchange of information by making all relevant safety-related information available to the other type-approval authorities, market surveillance authorities and the Commission.

Type-approval authorities, market surveillance authorities, and the Commission should participate regularly in the exchange and analysis of information contained in the Common Central Repository.

It is expected that the Commission promotes and facilitates a broader exchange of information and the dissemination of occurrences to the type-approval authorities, market surveillance authorities with the aim of improving safety.

The dissemination of information should be limited to what is strictly required for the purpose of its users, in order to ensure appropriate confidentiality of that information.

4.4. Protection of information

Given the sensitive nature of safety-related information, the protection of its source and the confidence and trust of the reporters should be guaranteed. To protect the sensitivity of the information, it is expected that it is only used for safety related activities and not for any other purpose.

Security measures need to be in place to protect the confidentiality of information that is shared. For example, the security measures and protocols should ensure that no personal details are ever recorded in the databases either at national or international level and that relevant protections for trade secrets and confidential business information be observed.

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List of abbreviations

ABS Anti-lock Braking System

ADS Automated Driving System

A&E Aleatory and Epistemic

ALKS Automated Lane Keeping System

ANOVA Analysis of Variance

ASIL Automotive Safety Integrity Level

AV Automated Vehicle

CAS Credibility Assessment Scale

CM Configuration Management

E/E Electrical/Electronic

ESP Electronic Stability Program

FoV Field of View

GNSS Global Navigation Satellite System

HIL Hardware-in-the-Loop

IET Integral Effect Test

ISO International Organization for Standardization

KPI Key Performance Indicator

LDW Lane Departure Warning

LIDAR Light Detection And Ranging

LKAS Lane Keeping Assistance System

MIL Model-in-the-Loop

M&S Modelling and Simulation

MMS Method of Manufactured Solutions

NAV Numerical Algorithm Verification

ODE Ordinary Differential Equation

OECF Opto-Electronic Conversion Function

OEM Original Equipment Manufacturer

PCMM Predictive Capability Maturity Model

PDE Partial Derivative Equation

RADAR Radio Detection And Ranging

RWS Real-World System

SA Sensitivity Analysis

SET Separate Effect Test

SIL Software-in-the-Loop

SME Subject Matter Expert

SRQ System Response Quantity

SQA Software Quality Assurance

SQE Software Quality Engineering

ToA	Time of Arrival
UQ	Uncertainty Quantification
V&V	Verification and Validation
VIL	Vehicle-in-the-Loop
XIL	X-in-the-Loop

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