

# Certification methods and automation: benefits, issues, and challenges

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#### **Abstract**

This deliverable reports the state of the art on current certification methods and regulations of airborne systems, aerodromes and ATM systems and explores the suitability of current certification methods and approaches to advanced automation and AI-powered technologies, thus highlighting possible benefits, issues and challenges associated to the introduction of higher levels of automation.

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# **HUCAN**

# HOLISTIC UNIFIED CERTIFICATION APPROACH FOR NOVEL SYSTEMS BASED ON ADVANCED AUTOMATION

# HUCAN

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## 1 Introduction

Certification means any form of recognition, based on an appropriate assessment, that a product, part or appliance, organisation or person complies with the applicable regulatory requirements, through the issuance of a certificate attesting such compliance.<sup>3</sup> This deliverable reports the state of the art on current methods and regulations used in the certification of airborne systems, aerodrome equipment and ATM systems within the European Union legal framework, and explores their suitability for application to advanced automation and AI-powered technologies. The objective is to highlight possible benefits, issues and challenges associated with the introduction of higher levels of automation.

The review focuses on three main applications: 1) **Airborne Systems** (including UAVs), 2) **Aerodrome equipment** and 3) **ATM-related systems**. The review covers elements related to the certification of technology and technical systems (both hardware and software) since these will be adapted to include automation and AI-powered technology. However, the review will also address the certification of organisations, operators and crew since these will have to work with the adapted technology, and their roles and responsibilities may change because of the higher levels of automation.

**Section 2** will map the state of the art of the current regulation on certification in the context of the EU regulatory framework.

**Section 3** will discuss the state-of-the-art methods currently used for certification, i.e. for demonstrating that the systems satisfy the regulations.

**Section 4** will study the suitability of these current methods when applying them to advanced automation and AI by tackling the major ethical and socio-juridical challenges, studying matters of human-machine interaction, trust and predictability, and addressing legal aspects.

This Deliverable 3.1 presents the results of HUCAN **Task 3.1** (Current certification methods and regulations and related issues). It will feed into T3.2 (Certification and automation: benefits, issues, challenges and innovative approaches) and T4.1 (Case studies introduction: level of automation analysis and certification issues).

<sup>&</sup>lt;sup>3</sup> According to Article 3(9) of Regulation n. 2018/1139 "'certification' means any form of recognition in accordance with this Regulation, based on an appropriate assessment, that a legal or natural person, product, part, non-installed equipment, equipment to control unmanned aircraft remotely, aerodrome, safety-related aerodrome equipment, ATM/ANS system, ATM/ANS constituent or flight simulation training device complies with the applicable requirements of this Regulation and of the delegated and implementing acts adopted on the basis thereof, through the issuance of a certificate attesting such compliance"







# 2 State of the art on current regulation in certification

This section has as its main scope to identify and analyse the state of the art of the current legislation and regulation on certification in the context of the EU regulatory framework with specific regards to Airborne systems, Aerodromes and ATM-related technology.

# 2.1 List of relevant regulatory instruments

The most relevant piece of regulation for the governance and certification of civil air transport in the EU is **Regulation (EU) 2018/1139** of the European Parliament and of the Council, the so-called "Basic Regulation" (BR). The Regulation is complemented by a series of additional regulatory instruments which are variously relevant for the purposes of certification and type-approval<sup>4</sup> of specific aviation-related systems and products. Such a list of regulatory instruments is provided in the table below.

Table 1. List of regulatory documents related to certification

Topic	Regulation
Initial Airworthiness	Commission Regulation n. 748/2012
Additional Airworthiness Specification for Operations	Commission Regulation n. 2015/640
Continuing Airworthiness	Commission Regulation n. 1321/2014
Aircrew	Commission Regulation n. 1178/2011
Air operation	Commission Regulation n. 965/2012
Balloons – Air Operations	Commission Regulation n. 2018/395
Sailplanes – Air operation	Commission Implementing Regulation n. 2018/1976
Third-country operations	Commission Regulation n. 452/2014

<sup>&</sup>lt;sup>4</sup> The type approval (or certificate of conformity) is the approval of the design of the aircraft and of all component parts (including propellers, engines, control stations, etc) implying that the design is in compliance with applicable airworthiness, noise, fuel venting, and exhaust emissions standards.



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ATM (ANS provision of services – Air Traffic Management/Air navigation Services	Commission Implementing Regulation n. 373/2017
Interoperability of the European ATM Network	Regulation n. 552/2004 (no longer in force)
Air Traffic Controllers	Commission Regulation n. 2015/340
Airspace usage requirements (ACAS II)	Commission Regulation n. 1332/2011
Airspace usage requirements (PBN)	Commission Implementing Regulation n. 2018/1048
Rules of the Air (SERA)	Commission Implementing Regulation n. 923/2012
Aerodromes	Commission Regulation n. 139/2014
Unmanned Aircraft Systems (UAS) (Rules and procedures for the operation of unmanned aircraft)	Commission Implementing Regulation n. 2019/947
UAS and third-country operators of unmanned aircraft systems	Commission Delegated Regulation n. 2019/945
Regulatory Framework for the U-space	Commission Recommendation n. 2021/554
Information Security	Commission Delegated Regulation n. 2022/1645
Certification of ATM-ANS systems and constituents	Regulation (EU) n. 2023/1768
Requirements and procedures for approval of organisations involved in design or production of ATM-ANS services and systems	Regulation (EU) n. 2023/1769

In addition to these EU regulations, there are relevant **certification standards by EASA** (European Union Aviation Safety Agency) **and ICAO** (International Civil Aviation Organization), that are of relevance to complete the picture, including the ones below:

- EASA Certification Specifications<sup>5</sup> such as
  - o EASA CS-25 (large aeroplanes),



<sup>&</sup>lt;sup>5</sup> https://www.easa.europa.eu/en/document-library/certification-specifications



- EASA CS-22 (sailplanes and powered sailplanes),
- EASA CS-23 (normal, utility, aerobatic and commuter aeroplanes),
- o EASA CS-27 (small rotorcraft),
- o EASA CS-29 (large rotorcraft),
- o EASA CS-26 (additional airworthiness specification for operations)
- ICAO regulatory documents on certification, for example:
  - Annex 8 Airworthiness of aircraft
  - O Annex 11 Air Traffic Services
  - O Annex 14, Vol I Aerodrome Design and Operations
  - Annex 19 Safety Management
  - O Doc 9981 Procedures for Air Navigation Services Aerodromes (PANS-Aerodromes)
  - O Doc 9774 Manual on Certification of Aerodromes
  - O Doc 9760 Airworthiness manual

The overview in the remainder of this chapter will focus on the EU Regulations in Table 1, but will mention the additional ones where appropriate.

# 2.2 Regulation (EU) no. 2018/1139 of the European Parliament and of the Council, "Basic Regulation" (BR)

#### 2.2.1 Context and aim

Regulation (EU) n. 2018/1139<sup>6</sup> (Basic Regulation, BR) entered into force in September 2018 with the aim of updating and consolidating existing aviation safety laws and revising the mandate for the European Union Aviation Safety Agency (EASA).

The Regulation has repealed three previous regulations (Regulations (EC) No 552/2004 on interoperability of EU ATM network, (EC) No 216/2008 common rules in the field of civil aviation and establishing EASA, and Regulation (EEC) No 3922/91 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation). It has amended two directives (Directives 2014/30/EU on reducing interference between electrical and electronic devices and 2014/53/EU on the commercialisation of radio equipment) and four regulations (Regulations (EC) No 2111/2005 on the establishment of a list of banned air carriers and on the identity of the operating carrier, (EC) No 1008/2008 on the operation of air services, (EU) No 996/2010 on civil aviation accidents and incidents and (EU) No 376/2014 on occurrences in civil aviation). Finally, it complements Regulations (EU) No 1321/2014 on airworthiness and (EU) No 748/2012 on environmental certification.

The main objective of the BR is to establish and maintain a **high uniform level of civil aviation safety**, to set out the legal basis for the **establishment of EASA**, to specify EASA's competencies and to establish the scope of common aviation safety requirements.

<sup>&</sup>lt;sup>6</sup> Regulation (EU) n. 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91







The BR has **general application** and is binding in its entirety and **directly applicable** in all Member States. The scope of the BR includes topics such as: airworthiness, aircrew licensing, environmental compatibility related to aircraft operations (including third-country operators), ATM/ANS (including air traffic controllers licensing), aerodromes, ground handling and unmanned aircraft.

The Basic Regulation confers the European Commission the power to adopt **implementing and delegated acts** which may detail how to comply with the essential requirements of the Regulation and possibly regulate subject matters included in its scope.

#### 2.2.2 Principles and definitions

Chapter I (Article 1-4) includes some **general provisions** that should guide aviation safety within the EU.

Article 1 outlines the **objectives and measures** of the BR, aimed at ensuring a high level of safety and efficiency in civil aviation within the EU. It aims to enhance safety standards, promote environmental protection, facilitate free movement of goods and people, and bolster competitiveness in the aviation industry. The BR also seeks to achieve these goals by establishing a framework for cooperation with third countries, promoting cost-efficiency, supporting research and innovation, and ensuring consistent implementation of regulatory measures. Additionally, it emphasises the importance of interoperability, security, and passenger confidence in aviation safety. The regulation outlines various actions, including the establishment of an independent European Union Aviation Safety Agency, to achieve its objectives.

Article 2 defines the **scope and application** of the BR. It covers the design, production, maintenance, and operation of aircraft, as well as aerodromes, aerodrome equipment, and ATM/ANS. Additionally, it specifies regulations regarding personnel and organisations involved in these activities. **Exemptions** from certain provisions are outlined, particularly for activities related to military, low-risk aircraft operations, and smaller aerodromes. Member States have the authority to decide on exemptions and notify relevant authorities accordingly. The regulation aims to ensure safety and interoperability while allowing for flexibility in certain circumstances.

Article 3 lists a series of **definitions**. For the purpose of this deliverable, the following are relevant:

- "ATM/ANS": means air traffic management and air navigation services and covers all of the following: the air traffic management functions and services as defined in point (10) of Article 2 of Regulation (EC) No 549/2004; the air navigation services as defined in point (4) of Article 2 of that Regulation, including the network management functions and services referred to in Article 6 of Regulation (EC) No 551/2004, as well as services which augment signals emitted by satellites of core constellations of GNSS for the purpose of air navigation; flight procedures design; and services consisting in the origination and processing of data and the formatting and delivering of data to general air traffic for the purpose of air navigation;
- "certification" means any form of recognition in accordance with this Regulation, based on an
  appropriate assessment, that a legal or natural person, product, part, non-installed
  equipment, equipment to control unmanned aircraft remotely, aerodrome, safety-related
  aerodrome equipment, ATM/ANS system, ATM/ANS constituent or flight simulation training
  device complies with the applicable requirements of this Regulation and of the delegated and





implementing acts adopted on the basis thereof, through the issuance of a certificate attesting such compliance;

- "aerodrome" means a defined area, on land or on water, on a fixed, fixed offshore or floating structure, including any buildings, installations and equipment thereon, intended to be used either wholly or in part for the arrival, departure and surface movement of aircraft;
- "aircraft" means any machine that can derive support in the atmosphere from the reactions of the air other than reactions of the air against the earth's surface;
- "unmanned aircraft" means any aircraft operating or designed to operate autonomously or to be piloted remotely without a pilot on board;

Article 4 lists some **guiding principles** that measures taken under the regulation must comply with. These principles include:

- 1. Reflecting advancements and best practices in aviation, considering global aviation experiences, and scientific and technical progress.
- 2. Relying on the best available evidence and analysis.
- 3. Allowing for **immediate response** to established causes of accidents, incidents, and security breaches.
- 4. Considering the **interdependencies** between different aviation safety domains and other technical areas like cybersecurity.
- 5. Establishing performance-based requirements and procedures while allowing flexibility in compliance methods.
- 6. Promoting **cooperation and efficient resource utilisation** among Union and Member State authorities.
- 7. Utilising non-binding measures, including safety promotion actions, when feasible.
- 8. Accounting for **international rights and obligations** concerning civil aviation, including those outlined in the Chicago Convention.

Moreover, measures taken under this Regulation must be tailored to the **nature and risk level of specific activities**, considering factors such as the presence of **non-flight crew individuals onboard**, potential risks to third parties or property on the ground, aircraft complexity and performance, flight purpose, airspace usage, operation scale and complexity, the ability of affected individuals to assess and control risks, and past certification and oversight outcomes.

#### 2.2.3 Aviation Safety Management

Chapter II of the Regulation focuses on aviation **safety management** within the European Union. It consists of several articles that outline key programs and responsibilities regarding safety management.

The European Commission is tasked with adopting, publishing, and updating a document known as the **European Aviation Safety Programme** (Article 5). This program encompasses rules, activities, and processes for managing civil aviation safety in the EU, including responsibilities related to state safety management. It also establishes the process for developing, adopting, updating, and implementing the European Plan for Aviation Safety.

The **European Plan for Aviation Safety** is developed and updated by EASA in collaboration with Member States and stakeholders (Article 6). The plan identifies the main safety risks in European





aviation and outlines actions to mitigate these risks. EASA also monitors the implementation of mitigation actions and sets safety performance indicators.

At the national level, each Member State is required to establish and maintain a **State Safety Programme** for managing civil aviation safety within its jurisdiction (Article 7). This program should align with the European Aviation Safety Programme and include elements related to state safety management responsibilities. The State Safety Programme includes or is accompanied by a State Plan for Aviation Safety (Article 8), where Member States, in consultation with stakeholders, identify the main safety risks affecting national aviation safety and outline necessary mitigation actions in this plan.

#### 2.2.4 Substantive Requirements

The core part of the BR (Chapter III, Articles 9-61) focuses on **essential requirements** for safety management in **8 areas**: airworthiness and environmental protection; aircrew; air operations; aerodromes; ATM/ANS; air traffic controls; unmanned aircraft; aircraft used by a third-counter operator into, within or out of the EU.

Specific essential requirements for each type-system are contained in **Annex II to Annex IX**. Depending on the specific area, requirements may refer to:

- Design or performance of the overall product/equipment/infrastructure or any of its part, as
  well as changes to the design of such product/equipment/infrastructure or their parts (e.g.,
  materials and equipment for airworthiness, noise minimisation for environmental
  compatibility in airworthiness, aircraft performance);
- **Procedures** (e.g., air operations or air traffic management);
- Organisational aspects of entities involved in designing, producing, managing, maintaining
  products or infrastructure, as well as those involved in training personnel (e.g., essential
  requirements for qualified entities, responsibility for aerodromes management);
- Physical fitness, knowledge and skills of personnel, including licences and training requirements (e.g. pilots, crews, ATCOs).

Some of the essential requirements are subject to **implementing acts** of the European Commission that have been adopted according to the examination procedure referred to in Article 127(3). Some essential requirements are otherwise left to **delegated powers** of the Commission, which can adopt specific acts in accordance with Article 128.

We specifically review **essential requirements relevant to airborne systems, aerodromes and ATMs** in Sections 2.3, 2.4, 2.5 and 2.6.

#### 2.2.5 Certification, oversight and enforcement system

Article 62 requires the European Commission, EASA and Member States to cooperate within a single European aviation safety system to ensure compliance with the Regulation and with the delegated and implementing acts adopted on its basis.

In particular, EASA and national competent authorities shall:

• receive and assess **applications**, and, where possible, **issue or renew certificates** and **receive declarations**;







- perform oversight of holders of certificates, of natural and legal persons that made declarations, and of products, parts, equipment, ATM/ANS systems and ATM/ANS constituents, flight simulation training devices and aerodromes;
- conduct the necessary investigations, inspections, including ramp inspections, audits and other monitoring activities to identify possible infringements of the requirements set out in the BR;
- take all necessary enforcement measures, including amending, limiting, suspending or revoking certificates issued by them, grounding of aircraft and imposing penalties, in order to terminate identified infringement;
- prohibit, limit or make subject to certain conditions the activities referred to in Chapter III of the BR in the interest of safety;
- ensure an appropriate level of qualification of their staff involved in certification, oversight and enforcement tasks, including by providing adequate training.

Member States shall ensure that their national competent authorities are **independent** when taking technical decisions on certification, oversight and enforcement, and exercise their tasks **impartially** and **transparently** and ensure that such tasks are **organised**, staffed and managed accordingly.

The **allocation of responsibilities** for certification, oversight, and enforcement between EASA and national authorities follows the following criteria:

- **EASA** is responsible when certification, oversight, and enforcement oversight tasks have been attributed to it pursuant to Articles 77 to 82 and Articles 64 and 65. However, Member States may grant **exemptions** under certain conditions, in which case they become responsible for oversight and enforcement for specific aviation providers.
- The **national competent authority** of the Member State where an **aerodrome** is located is responsible for certification, oversight, and enforcement regarding aerodrome certificates and operators, as well as ground handling services or AMS at that aerodrome.
- In the cases not covered by the above, responsibility lies with the national competent authority
  of the Member State where the applicant or declarant has its principal place of business,
  residence, or establishment, unless detailed rules dictate otherwise.
- **Specific responsibilities** are outlined for issuing pilot medical certificates and air traffic controller medical certificates, as well as cabin crew attestations, with certain entities designated for each task as specified in the implementing acts.

Member States may also **jointly assign responsibilities** to their respective national competent authorities for certification, oversight, and enforcement, if:

- 1. such joint responsibility was provided for in an agreement concluded between those Member States before 1 January 1992; and
- 2. if those Member States have ensured that their national competent authorities effectively carry out those tasks in compliance with the BR and with delegated and implementing acts.

In the oversight and enforcement function, **cooperation between EASA** and national authorities must be ensured through, among others, the use of tools and procedures for collecting, exchanging, and analysing safety-related information from ramp inspections. Moreover, EASA will promote understanding and application of regulatory requirements by developing guidance material. Finally, legal or natural persons subject to the regulation can report differences in rule application between





Member States to the Agency, which will cooperate with national competent authorities to address them.

The Commission is empowered to adopt **delegated acts** concerning detailed rules for various aspects such as certification, ramp inspections, safety conditions, and accreditation by the Agency. In addition, the Commission can adopt implementing acts to **ensure uniform implementation and compliance** with detailed provisions concerning certification, oversight, and enforcement tasks of national competent authorities, as well as with detailed provisions regarding gathering, exchange, and dissemination of information, staff qualifications, administration and management systems.

#### 2.2.6 The European Aviation Safety Agency (EASA)

The European Aviation Safety Agency (EASA) holds a major role, acting as the primary decision-maker on certification and type-approval procedures. The Agency is fundamentally involved in specific type-approval and certification processes of Airborne Systems, ATM-related systems and Aerodromes.

EASA acts as one of the main consultative bodies for the EU Commission on aviation, offering both technical and domain-level expertise on the necessary standards to be included in the EU Aviation Safety Programme, also described in the Basic Regulation as the EU Aviation Safety System (Article 5 BR). As a matter of fact, the programme shall include international standards and recommended practices, including those relating to the processes for developing, adopting and updating the plan itself; the consultation with EASA lays the foundation of all of the above, given its powers over the programme once adopted.

EASA coordinates with Member State authorities to receive and assess applications for the certification and type-approval of air transport systems, enacting what is described as a Joint Certification, Oversight and Enforcement System (Article 62 BR). This includes the exchange of relevant information (point 9), conducting inspections (point 7), and implementing continuous and post-market oversight (point 6), among others.

However, EASA ultimately holds the primary role in the certification landscape, as it is not only directly involved in the issuance of approvals for each application but can also be appointed by Member States to "carry out the tasks related to certification, oversight and enforcement referred to in Article 62(2) [...] for which the Member State concerned is responsible under this Regulation and the delegated and implementing acts adopted on the basis thereof" (Article 64 BR), effectively concentrating powers relating to the process in discussion in the hands of EASA.

In conclusion, as EASA administers the EU Aviation Safety Programme, enforces Joint Certification and Oversight alongside Member States with the possibility of being identified as the sole responsible for it, as well as actively take part in specific type-approval procedures, it appears the agency holds the principal role in the certification process for civil aviation.

# 2.3 Airborne Systems: Aircraft and Aircraft Parts

Essential requirements relevant to the certification of manned airborne systems are contained in Annexes II-V of the BR and deal with airworthiness, including environmental compatibility, aircrew, and air operations. Such requirements are then specified in a number of European Commission's implementing regulations (IR), as specified in the following table.





Table 2. Elements of Basic Regulation related to airborne systems

Topic	Basic Regulation	Implementing Regulation
Airworthiness	Annex II – Airworthiness Annex III – Environmental compatibility related to products	IR No. 748/2012 – Initial Airworthiness IR No. 640/2015 – Additional airworthiness specification for operations IR No. 1321/2014 – Continuing airworthiness
Aircrew	Annex IV – Aircrew	IR No. Reg. 1178/2011
Air Operations	Annex V – Air Operations	IR No. Reg 965/2012 – Air operations IR No. Reg. 395/2018 – Air operations (Balloons) IR No. Reg 1976/2018 – Air operations (Sailplanes) IR No. Reg 452/2014 – Third country operators

#### 2.3.1 Airworthiness

**Annex II** covers the following **airworthiness** aspects:

- Product integrity: Ensures structural and material integrity, propulsion system integrity, system, equipment and non-installed equipment functionality, and continuing airworthiness. In particular, systems and equipment required for the assessment of type design, as well as non-installed equipment, must function as intended under any foreseeable operating conditions. Moreover, they must be designed in such a way that any catastrophic failure condition does not result from a single failure not shown to be extremely improbable, and an inverse relationship must exist between the probability of a failure condition and the severity of its effect on the aircraft and its occupants. Furthermore, information that is needed for the safe conduct of the flight and information concerning unsafe conditions must be provided to the crew or maintenance personnel, as appropriate, in a clear, consistent and unambiguous manner. Finally, design precautions must be taken to minimise the hazards to the aircraft and occupants from reasonably probable threats, including information security threats, both inside and external to the aircraft, including protecting against the possibility of a significant failure in, or disruption of, any non-installed equipment.
- Product operations: Addresses safe operation, controllability, smooth transition between flight phases, stability, operational procedures, and protection from hazards during operations. The operating limitations and other information necessary for safe operation must be made available to the crew members. Moreover, product operations must be protected from hazards resulting from adverse external and internal conditions, including environmental conditions. In particular, and as appropriate to the type of operation, no unsafe condition must occur from exposure to phenomena such as, but not limited to, adverse weather, lightning, bird strike, high frequency radiated fields, ozone, etc., reasonably expected to occur during product operation, taking into account the size and configuration of the aircraft.





 Organisations: Specifies conditions for organisation approvals, including having necessary resources, implementing a management system for compliance with airworthiness requirements, establishing arrangements with relevant organisations, and maintaining an occurrence reporting system. Organisations must have all necessary means for their scope of work, including facilities, personnel, equipment, documentation, and access to relevant data.

Annex III covers essential requirements for environmental compatibility of airborne systems-related products. In particular, it addresses the minimisation of noise, of emission and fluid discharge, and trade-offs between such requirements. Systems and equipment designed for environmental protection must function reliably under foreseeable operating conditions. Instructions, procedures, and inspections must be provided to ensure ongoing compliance with environmental requirements.

Airworthiness and environmental-related certifications are further specified in **three implementing regulations** of the European Commission.

#### Implementing Regulation (EU) No 748/2012

The **Implementing Regulation (EU) No 748/2012** lays down rules for the airworthiness and environmental certification of aircraft products, parts and appliances, including conditions for:

- type-certificates;
- certificates of airworthiness, permits to fly and authorised release certificates;
- repair design approvals;
- compliance with environmental protection requirements;
- noise certificates:
- identifying products, parts and appliances;
- certifying certain parts and appliances;
- certifying design and production organisations;
- airworthiness directives.

Regulation No. 748/2012 has been amended multiple times, most recently in March 2023 by Commission Delegated Regulation (EU) 2023/1028.

As a general rule, the certification of products, parts and appliances must follow the content and procedure contained in **Annex I** (so-called "**Part 21**"). Alternatively, certificates may be issued as specified in Annex Ib (so-called "Part 21 Light") for the products that do not exceed certain thresholds (e.g., an aeroplane with a maximum take-off mass (MTOM) of 2,000 kg or less and a maximum operational seating configuration of four persons, a rotorcraft of 1,200 kg MTOM or less and a maximum operational seating configuration of four persons, etc.).

**Section A of Annex I** ("Part 21") establishes general provisions governing the **rights and obligations of the applicant/holder of any certificate** issued or to be issued in accordance with the Regulation. As a general obligation, certificate applicants/holders must, among others:

- establish and maintain a system for collecting, investigating, and analysing occurrence reports to identify adverse trends or deficiencies;
- making information about the reporting system available to operators and others authorised to receive it;





- reporting any failure, malfunction, defect, or occurrence that may result in an unsafe condition to the appropriate authorities;
- reporting deviations from applicable design data and investigating potential unsafe conditions;
- investigating and reporting the reasons for deficiencies in design or production, and proposing corrective actions to the competent authority;
- providing relevant data to the competent authority upon request for correcting deficiencies.

Additional rights and obligations, as well as procedural steps, are specified in relation to particular type-certificates for products (including changes to type certificates and supplemental type-certificates) and for production organisation approval, noise certificates, design organisation, part and appliances, repairs, permit to fly.

**Section B of Annex II** establishes the **procedure for the national competent authority** when exercising its tasks and responsibilities concerned with the issuance, maintenance, amendment, suspension and revocation of certificates, approvals and authorisations.

In general, the competent authority must **establish and maintain a management system** with documented policies, procedures, qualified personnel, adequate facilities, and compliance monitoring mechanisms. It must establish procedures for mutual exchange of information and assistance with other competent authorities, including oversight findings and occurrence reporting.

Also, the authority may delegate tasks related to certification or oversight to **qualified entities**. Ensure these entities comply with regulations, document assessments, and establish written agreements detailing tasks, reports, technical conditions, liability coverage, and information protection. The internal audit and safety risk management processes should cover all tasks performed by qualified entities on behalf of the competent authority.

Details about type-certifications on airworthiness and related certification methods/procedures will be provided in Section 3.2.

Besides specific requirements, the Implementing Regulation (EU) No 748/2012 also includes some rules on the validity of type-certificates, certificates of airworthiness, supplemental type-certificates, airworthiness specifications and approvals for products certified **before the Regulation's implementation**.

Moreover, it specifies conditions for **permits to fly** or other airworthiness certificates issued by Member States for aircraft without certificates of airworthiness.

Finally, it outlines **organisational requirements** for entities responsible for designing products, parts, and appliances, as well as those manufacturing products, parts, and appliances.

## Implementing Regulation No. 640/2015

The Implementing Regulation No. 640/2015 requires additional airworthiness specifications in order to support the continuing airworthiness and safety improvements of (1) aircraft registered in a Member State or (2) aircraft registered in a third country and used by an operator for which a Member State ensures oversight. In such cases, operators must comply with provisions contained in Annex I of the Regulation. The latter mostly refers to requirements for large aeroplanes used in commercial air





transport, covering various aspects such as seats, emergency exits, interior lighting, compartment interiors, and lavatory fire protection.

#### Implementing Regulation (EU) No 1321/2014

The Implementing Regulation (EU) No 1321/2014 rounds off the framework on airworthiness certification by setting out technical rules and procedures for aircraft and components to ensure that aircraft, including any component for installation in or on them, continue to be airworthy. These rules cover aircraft that are:

- registered in a European Union (EU) Member State, unless their safety oversight has been delegated to a non-EU country and they are not used by an EU operator; or
- registered in a non-EU country and used by an EU operator, where their safety oversight has been delegated to a Member State; or
- registered in a non-EU country for which safety oversight has not been delegated to an EU
   Member State and that are dry leased by a licensed air carrier in accordance with Regulation (EC) No 1008/2008

The Regulation requires that the **continuing airworthiness** of an aircraft shall be ensured in accordance with the requirements of **Annex I (Part-M)**. Some exceptions are provided for particular aircraft (such as aeroplanes of 2730 kg maximum take-off mass or less), which must comply with requirements provided in Annex Vb (Part-ML).

Annex I of Regulation No. 1321/2014 on continuing airworthiness establishes (1) the measures to be taken to ensure that airworthiness is maintained, including maintenance, also specifying the conditions to be met by the persons or organisations involved in such continuing airworthiness management; (2) the administrative requirements to be followed by the competent authorities in charge of the application and the enforcement of such measures.

Organisations involved in the continuing airworthiness of aircraft must be approved according to Annex II (Part-145) of the Regulation. Similar to Annex I, Annex II refers both to technical and organisation requirements (e.g. facility requirements, personnel requirements, recruitment and tools, performance of maintenance, etc.), as well as requirements to be followed by the competence authorities during the enforcement.

Finally, the Regulation addresses requirements for **certifying staff and training organisations** involved in aircraft maintenance and continuation. While certifying staff must be qualified according to Annex III (Part-66), with exceptions specified, organisations involved in training personnel must be approved in accordance with Annex IV (Part-147) for conducting various training activities.

#### 2.3.2 Aircrew

**Annex IV of the Basic Regulation** contains essential requirements for **aircrew**. In particular, it specifies requirements for:

 Pilot training, including theoretical knowledge (es., air law, technical matters, flight and human performance, operation procedures etc.), practical skills (es., pre-flight and in-flight activities, collision avoidance precautions and procedures, abnormal and emergency operations etc.), language proficiency, flight simulation, and training course structure. It





emphasises demonstration, continuous assessment and maintenance of competence. Instructors and examiners must also be appropriately qualified.

- **Experience requirements for pilots**, i.e., requirements for acquiring and maintaining sufficient experience.
- **Medical fitness for pilots**, including medical criteria, requirements for aero-medical examiners and centres, and mitigation measures.
- **Cabin crew members**, including training, medical fitness assessment, training course structure, instructor qualifications, and examiner requirements.
- **Training organisations**, including resources, management systems, and arrangements with relevant organisations.

#### Implementing Regulation No. 1178/2011

Aircrew certifications are further detailed in the Implementing Regulation No. 1178/2011 of the European Commission.

The core of the Regulation targets **aircraft pilots** and provides that they must comply with the technical requirements and administrative procedures set out in Annex I and Annex IV of the regulation.

Annex I details general requirements for **pilot licensing** (applications, revalidation, renewals, ratings, validity period, crediting of flight times and theoretical knowledge) and requirements for specific pilot licences (e.g., light aircraft licence, private licence, multi-crew pilot licence, airline transport licence, commercial pilot licence, etc.). Additionally, it contains common and specific requirements for instructors and examiners. Further specifications of these certificates are contained in Section 3.2.

**Annex V** contains requirements related to the qualification of cabin crew involved in commercial air transport operations.

Besides pilot licensing, the Regulation also details technical, organisational or administrative requirements for:

- Pilot training organisation (Annex VII and Annex IV to Regulation (EU) 2018/1139);
- Flight simulation devices (Annexes VI and VII);
- Aero-medical centres (Annexes VI and VII);
- Cabin crew medical fitness and qualifications (Annex IV, V and VI).

#### 2.3.3 Air operations

**Annex V** of the Basic Regulation outlines essential requirements for **air operations**. It covers various aspects such as:

- **General air operations,** ensuring compliance with applicable laws, regulations, and procedures specified in manuals to guarantee flight safety and legality.
- **Flight preparation**, including assessing facilities, ensuring crew and passenger safety, verifying aircraft airworthiness, and evaluating meteorological conditions.
- **Flight operations**, ensuring appropriate crew seating and restraint, adherence to separation and obstacle clearance requirements, and adherence to emergency procedures.
- **Aircraft performance**, including compliance with airworthiness documentation, operational procedures, and limitations expressed in approved manuals.





- **Instruments, data, and equipment requirements**, ensuring aircraft are equipped with necessary navigation, communication, and safety equipment for the intended flight.
- Continuing airworthiness and environmental compatibility, ensuring aircraft are airworthy
  and in environmentally compatible conditions and that maintenance is performed according
  to applicable requirements.
- Crew member requirements, determining crew composition in advance, authority of the pilot in command, and management of fatigue and fitness for duty.
- Additional requirements for commercial air transport operations, including having necessary means for operations, qualified personnel, management systems, security programs, and fatigue management systems.

Air operations requirements are further specified in **four implementing regulations**.

#### Regulation No. 965/2012

The Implementing Regulation No. 965/2012 establishes detailed guidelines for commercial air transport operations involving aeroplanes and helicopters, covering aspects such as aircraft inspections and certification of operators. It also outlines conditions for issuing, maintaining, and revoking certificates for operators engaged in commercial air transport, with a focus on safety.

Article 5 outlines requirements for air operations, specifically for operators engaged in commercial air transport (CAT) operations. It mandates that operators may only conduct CAT operations as specified in **Annexes III and IV**.

Annexes III and IV set out, respectively, organisation requirements for air operations and requirements for commercial air transport operations. Annex III includes:

- general measures on operator responsibility (e.g., ensuring compliance with regulation, maintaining operational control over flights, establishing procedures for safe aircraft operation, ensuring proper training, etc.) and the obligation to establish a management system for responsibility and accountability;
- specific rules on **air operator certification**, leasing agreements between operator and aircraft producer, **flight data monitoring**, operator's personnel requirements;
- the obligation to establish an operation **manual**, the minimum equipment lists, and the journey log;
- measures on **flight crew security** and **compositions**, as well as designation as pilot-in-command, in-flight relief, single pilot operations under IFR or at night, etc;
- measures on **cabin crew composition** and **conditions** for assignments of duties and training.

Annex IV establishes requirements for the following CAT operations aspects, including:

- crew/commander responsibilities during operations, admission to the flight crew compartment, portable electronic devices and carriage of dangerous goods/particular items (weapons, munitions, alcohol etc.); documents, manuals and information to be carried during operations, etc.;
- operating procedures, involving, among others, use of air traffic services (ATS), aerodrome
  operating minima, instrument departure and approach procedures, routes and areas of
  operation, establishment of minimum flight altitude, fuel policy and in-flight fuel
  management, passenger seating and safety, meteorological conditions, etc;





- aircraft performance and operating limitations during the take-off, en-route, and landing phases, following the applicable performance class requirement;
- **Instruments, data, equipment**, such as minimum equipment for flights, operating lights and lighting signs, altitude alerting system, flight interphone system, cockpit voice recorder, flight data recorder, emergency medical kit, survival equipment, etc.

Additionally, CAT operators must adhere to the relevant provisions of **Annex V**, containing requirements for specific approvals, when conducting various types of operations, including, e.g., those involving performance-based navigation, minimum navigation performance specifications, reduced vertical separation minima, low visibility, transport of dangerous goods, etc. Some derogations are provided for CAT operations starting and ending at the same aerodrome/operating site with performance class B aeroplanes or non-complex helicopters.

As further content, the Regulation addresses the following aspects of air operations:

- the **ramp inspections** for aircraft of operators under the safety oversight of another Member State or a third country, in accordance with Subpart RAMP of Annex II;
- the validity of **conversion of air operator certificates** (AOCs) and **minimum equipment lists** (MELs) issued before the regulation's application, which shall be brought into compliance with the new regulation.

#### Regulation No. 395/2018

The Implementing Regulation n. 395/2018 outlines regulations for balloon air operations. "Balloons" means a "manned lighter-than-air aircraft which is not power-driven and sustains flight through the use of either a lighter-than-air gas or an airborne heater, including gas balloons, hot-air balloons, mixed balloons and, although power-driven, hot-air airships".

According to Article 4, operators of balloons must comply with Subpart BAS of Annex II, except for design or production organisations that comply with certain Commission Regulation (EU) No 748/2012 and operate within their privileges.

Subpart BAS of Annex II establishes:

- **general administrative requirements** regarding the competent authority and demonstration of compliance;
- basic operational requirements, including designation and responsibility of the pilot-incommand, responsibility of crew members, documents, manuals, and information to be carried, dangerous goods and their release over congested areas of cities, towns or settlement;
- **operating procedure requirements**, including fuel supply, passenger briefing, carriage of special categories of passengers, submission of the air traffic service flight plan, flight preparation, take-off and landing conditions, operational limitations at night;
- **performance and operating limitations**, such as weighing of the balloon and operation according performance;
- **instruments and equipment**, minimum instrument for flights, operating lights, flight and navigational instruments, first-aid kit.

Additionally, operators engaged in commercial operations with balloons are exempt from certification requirements but must declare their capacity and means to discharge associated responsibilities to the competent authority. They must also adhere to the requirements set out in **Subpart ADD of Annex II**.





The latter include additional requirements such as occurrence reporting, management system, personnel requirements, and specific airworthiness requirements. However, certain operations involving balloons, such as cost-shared operations, competition flights, introductory flights, and training flights, have specific exemptions outlined in the article.

Regulation No. 395/2018 also includes some requirements for pilots of balloons and training organisations responsible for pilot licences. Pilots must comply with technical requirements and administrative procedures outlined in **Annex III (Part-BFCL)** to the regulation and in Annex IV (Part-MED) to Regulation (EU) No 1178/2011. Training organisations responsible for pilot licences must adhere to the guidelines set forth in Article 10a of Regulation (EU) No 1178/2011.

#### Regulation No. 1976/2018

The Implementing Regulation No. 1976/2018 contains requirements for sailplanes air operations. "Sailplane" means "a heavier-than-air aircraft that is supported in flight by the dynamic reaction of the air against its fixed lifting surfaces, the free flight of which does not depend on an engine".

Sailplane operators must comply with **Annex II** requirements, except for design or production organisations operating within their privileges. Commercial sailplane operators must declare their capability to fulfil responsibilities to the competent authority. However, certain operations, like cost-shared, competition, introductory, and training flights, have exemptions provided their costs are shared or limited, and they adhere to specific conditions outlined in the article.

**Annex II** covers requirements regarding the competent authority, demonstration of compliance, introductory flights, immediate reaction to safety problems, designation and responsibilities of the pilot-in-command, crew responsibilities, compliance with laws and regulations, portable electronic devices, dangerous goods, documents to be carried, journey logs, operating procedures, performance and operating limitations, instruments, data, equipment, and declaration requirements.:

In addition, the Regulation outlines requirements for sailplane pilot licences and training organisations. Pilots must adhere to technical requirements and administrative procedures detailed in Annex III (Part-SFCL) to the regulation and Annex IV (Part-MED) to Regulation (EU) No 1178/2011. Similarly, training organisations for pilot licences must comply with Article 10a of Regulation (EU) No 1178/2011.

#### Regulation No. 2014/452

The Implementing Regulation No 452/2014 establishes that third-country operators shall only engage in commercial air transport operations into, within, or out of the EU territory subject to the provisions of the Treaties if they comply with the requirements of Annex I and hold an authorisation issued by EASA in accordance with Annex II.

In particular, Annex I comprises three sections:

- **General requirements**: Establishes the scope and access provisions for third-country operators.
- **Air operations**: Details general requirements for compliance, operation of aircraft, navigation equipment, documentation, and records.





 Authorisation of third-country operators: Covers application procedures, one-off notification flights, privileges of authorisation holders, changes, continued validity, and handling of findings.

The Annex emphasises compliance with international aviation standards, cooperation with regulatory authorities, and procedures for obtaining and maintaining authorisation for operations within EU territory.

#### Regulation (EU) No. 1645/2022

The Commission Delegated Regulation (EU) No. 1645/2022 sets forth rules and requirements for organisations involved in civil aviation to identify and manage information security risks that could affect aviation safety, particularly concerning information and communication technology systems and data. It emphasises the need to detect, identify, respond to, and recover from information security incidents.

In particular, the Regulation applies to **production organisations**, **design organisations**, **aerodrome operators**, **and apron management service providers** involved in civil aviation. It clarifies exceptions and highlights that the regulation does not override existing information security and cybersecurity requirements laid down in other legislation (e.g., NIS Directives, Cybersecurity Act, etc.)

**Information security** means the preservation of confidentiality, integrity, authenticity and availability of network and information systems. An "**information security event**" is an identified occurrence of a system, service or network state indicating a possible breach of the information security policy or failure of information security controls, or a previously unknown situation that can be relevant for information security.

Article 4 discusses how compliance with **certain security requirements from existing Union legislation** can fulfil the requirements of this Regulation. Specifically, it mentions that compliance with security requirements outlined in Directive (EU) 2016/1148 ("NIS Directive") and in the national civil aviation security programmes of Member States can be considered equivalent to the cybersecurity requirements in this Regulation. The Commission may issue guidelines for assessing this equivalence.

Article 5 specifies the **competent authorities** responsible for certifying and overseeing compliance with the Regulation. For organisations mentioned in Article 2(a), the competent authority designated under Regulation (EU) No 748/2012 is responsible, while for organisations in Article 2(b), the authority designated under Regulation (EU) No 139/2014 takes charge. Member States have the option to designate an independent entity to fulfil these roles, but coordination measures must be in place to ensure effective oversight.

Finally, the Regulation amends previous aviation safety regulation:

- Regulation (EU) No. 748/2012 on airworthiness, establishing that the production organisation shall establish, implement and maintain an information security management system in accordance with Regulation (EU) No. 2022/1645, in order to ensure the proper management of information security risks which may have an impact on aviation safety;
- Regulation (EU) No. 139/2014 on aerodromes, establishing that the aerodrome operator shall establish, implement and maintain an information security management system in accordance with Regulation (EU) No. 2022/1645 in order to ensure the proper management of information





security risks which may have an impact on aviation safety. Also, it requires the **aerodrome operator** to establish a security management system to ensure the security of operational data it receives, defining the procedures relating to a) data security risk assessment and mitigation, b) security monitoring and improvement, c) security reviews and lesson dissemination, d) means designed to detect security breaches and to alert personnel with appropriate security warnings and e) means of controlling the effects of security breaches and of identifying recovery action and f) mitigation procedures to prevent reoccurrence.

# 2.4 Unmanned Aerial Vehicles (UAVs)

A special category of airborne systems is unmanned aerial vehicles (UAVs). Since these aircraft may be at the forefront of including automation and AI-related technologies, they will be addressed separately.

Table 3. Elements of Basic Regulation related to UAV

Topic	Basic Regulation	Implementing/Delegate Regulation
UAVs	Annex IX	Implementing Regulation No. 2019/947 – Unmanned Aircraft Systems (UAS) (Rules and procedures for the operation of unmanned aircraft)  Delegated Regulation No. (EU) 2019/945 – UAS and third-country operators of unmanned aircraft systems)

The substantive requirements referring to unmanned aerial vehicles (UAVs) are contained in **Annex IX** of the Basic Regulation and cover the following aspects:

- Design, Production, Maintenance and Operation: UAVs must be designed with safety as a
  priority, considering factors such as privacy, security, and environmental concerns.
  Manufacturers and distributors are obliged to adhere to standards and provide clear
  information about the aircraft's capabilities and limitations. UAV must minimise
  electromagnetic interference with other radio and telecommunication equipment and must
  themselves be resistant to electromagnetic interference.
- Airworthiness Requirements: UAVs must be robust, controllable, and capable of functioning as intended under foreseeable conditions, including potential system failures. Manufacturing processes and materials must ensure consistent and safe performance.
- Organisational Requirements: Entities involved in the UAV industry must have the necessary
  resources and management systems in place to ensure compliance with safety requirements
  and continuous improvement. They should establish occurrence reporting systems and
  collaborate with other organisations for comprehensive safety compliance.
- Operational and Personnel Requirements: Operators are responsible for ensuring the safe operation of UAVs, complying with all applicable laws, regulations, and procedures. Operations must prioritise the safety of people on the ground and other airspace users, and UAVs must be airworthy with necessary equipment for safe flight.
- Environmental Requirements. Paragraph 3 of Annex IX refers to Annex III with regard to the essential requirements needed for manned aircraft and airborne systems (see Section 2.3.1).





• Registration, Certification and Marking. UAVs requiring design certification must be registered according to specific implementing acts. Operators must register under specific conditions including: (1) UAVs transferring more than 80 Joules of kinetic energy on impact (Annex III, Paragraph 4.2.a); (2) UAVs posing risks to privacy, data, security, or environment (Annex III, Paragraph 4.2.b); (3) UAVs requiring design certification (Annex III, Paragraph 4.2.c), as per Regulation No. 2019/947 (see implementing regulation, section to follow).

#### Regulation No. 2019/947

The Implementing Regulation No. 2019/947 contains provisions for **unmanned aircraft systems** (UASs) operations as well as for personnel, including remote pilots and organisations involved in those operations.

The Regulation establishes three categories of UASs operations:

- **Open**: UAS operations are not subject to any prior authorisation nor to an operational declaration by the UASs operator before the operation takes place.
- Specific: UAS operations require an operational authorisation from the competent authority as per Article 12 or Article 16, or, under the circumstances defined in Article 5 of the Regulation, a declaration to be made by a UAS operator.
- **Certified**: UAS operations require the certification of the UASs pursuant to Delegated Regulation (EU) 2019/945, the certification of the operator and, where applicable, the licensing of the remote pilot.

UASs operations pertain to the **open category** when the following requirements are met:

- The UAS meets certain specifications regarding its class, weight, and safety features, which are set out in Delegated Regulation (EU) 2019/945.
- The remote pilot ensures safe distances from people, maintains a visual line of sight (VLOS)
  except in specific circumstances, and keeps the UAS within a specified distance from the
  ground.
- The UAS does not carry dangerous goods or drop materials during flight.
- Additionally, the "open" category is further divided into three sub-categories based on specific requirements outlined in Part A of the Annex.

If one of the abovementioned requirements is not met, the UAS falls into the **specific category** and must obtain an operational authorisation from the competent authority in the Member State where it is registered. When applying for operational authorisation, the operator must conduct a risk assessment and submit it along with the application, including mitigating measures. The competent authority will issue the operational authorisation if it deems that the operational risks are adequately mitigated. The operational authorisation specifies whether it approves a single operation or a set of operations within a defined time or location, along with the associated mitigating measures, or approves a specific Light UAS Operator Certificate (LUC).

However, operators complying with standard scenarios outlined in Appendix 1 of the Annex can submit a declaration to the competent authority instead of obtaining an operational authorisation. Moreover, certain exemptions from the requirement of operational authorisation or declaration apply to UAS





operators with appropriate privileges under an LUC and operations conducted within model aircraft clubs and associations authorised under Article 16.

Finally, UASs operations shall fall in the **certified category** when:

- the UAS is certified according to specific criteria specified in Article 40 of Delegated Regulation (EU) 2019/945 and;
- the operation involves flying over assemblies of people, transporting people, or carrying dangerous goods with high-risk potential for third parties.

Additionally, UAS operations are classified as "certified" if the competent authority determines, based on the risk assessment outlined in Article 11 of the Regulation No. 2019/947, that the operation's risk cannot be sufficiently mitigated without certifying the UAS and the operator, and possibly licensing the remote pilot.

Article 7 outlines the rules and procedures for the operation of UAS depending on the category:

- Open UAS operations must adhere to the operational limitations specified in Part A of the Annex.
- Specific UAS operations must comply with operational limitations specified in the operational authorisation from Article 12, or the authorisation from Article 16, or a standard scenario defined in Appendix 1 to the Annex, as declared by the UAS operator. This requirement does not apply if the UAS operator holds an LUC with appropriate privileges. UAS operations in the "specific" category must also meet applicable operational requirements outlined in Commission Implementing Regulation (EU) No 923/2012.
- Certified UAS operations must adhere to operational requirements outlined in Implementing Regulation (EU) No 923/2012, Commission Regulation (EU) No 965/2012, and (EU) No 1332/2011.

The Regulation also contains some competency rules applying to remote pilots of UAS:

- Remote pilots in the open category must adhere to competency requirements outlined in Part A of the Annex.
- Remote pilots in the specific category must comply with competency requirements specified in the operational authorisation by the competent authority, or in the standard scenario defined in Appendix 1 to the Annex, or as defined by the LUC. They must possess competencies including applying operational procedures, managing aeronautical communication, controlling flight path and automation, leadership, teamwork, problem-solving, situational awareness, workload management, and coordination or handover.
- Remote pilots operating within model aircraft clubs or associations must meet minimum competency requirements defined in the authorisation granted under Article 16.

Unless privately built or used for operations referred to in Article 16 or meeting the conditions defined in Article 20, UAVs used in operations set out in the Regulation shall comply with the technical requirements and rules and procedures for the airworthiness defined in the delegated acts adopted pursuant to **Article 58** of Regulation (EU) No. 2018/1139.





The Regulation outlines the rules for conducting an operational risk assessment for UAS operations, requiring the following steps:

- 1. **Description of UAS Operation**: Detail the operation's characteristics, propose safety objectives, identify ground and air risks, suggest mitigating measures, and determine the necessary robustness of these measures for safe operation.
- 2. **Description of UAS Operation**: Include the nature of activities, the operational environment, the complexity of operation, technical features of the UAS, and personnel competence.
- 3. **Propose Target Safety Level**: Propose a safety level equivalent to manned aviation, considering UAS-specific characteristics.
- 4. **Identify Risks**: Assess ground and air risks considering factors like visibility, population density, airspace class, impact on air traffic, and other criteria.
- 5. **Identify Mitigation Measures**: Determine measures such as containment, operational limitations, strategic mitigation, coping with adverse conditions, organisational factors, human error risk, and UAS design features.
- 6. **Assess Mitigating Measures**: Evaluate the robustness of proposed measures to ensure they align with safety objectives and adequately mitigate risks throughout the operation.

If the UAS is classified in the "specific" category, the process for authorising operations includes the following key points:

- 1. **Evaluation by Competent Authority**: The competent authority evaluates the risk assessment and mitigating measures proposed by the UAS operator to ensure the safety of the operation.
- 2. **Granting Operational Authorisation**: The authority grants operational authorisation if it determines that the safety objectives consider operation risks, the mitigation measures are adequate, and the operator complies with relevant rules.
- 3. **Refusal of Authorisation**: If the operation is deemed unsafe, the authority informs the applicant with reasons for refusal.
- 4. **Details of Operational Authorisation**: The granted authorisation specifies its scope, specific conditions, technical features of the UAS, operational limitations, and required mitigation measures.
- 5. **Verification of Declaration**: Upon receiving a declaration from the UAS operator, the competent authority verifies its completeness and promptly confirms receipt if all required elements are present, allowing the operator to commence the operation.

Member States must establish and maintain accurate **registration systems** for:

- **UASs whose design is subject to certification**, under the already tackled rules pertaining to categories and risks.
- UASs operators whose operation may present a risk to safety, security, privacy, and protection of personal data or environment.
- UASs operators' registration systems shall provide full name and the date of birth for natural
  persons and the name and their identification number for legal persons, the address of UAVs
  operators, their email address and telephone number, an insurance policy number for UAVs if





required by EU or national law<sup>7</sup> and the operational authorisations and LUCs held and declarations followed by a confirmation in accordance with **Article 12 (b)**.

The registration systems for UAS whose design is subject to certification shall provide the manufacturer's name, the manufacturer's designation of the unmanned aircraft, the unmanned aircraft's serial number and the full name, address, email address and telephone number of the natural or legal person under whose name the unmanned aircraft is registered.

Member States have the authority to define **UAS geographical zones** for safety, security, privacy, or environmental reasons, and they may impose various measures such as prohibiting or imposing conditions on UAS operations, setting environmental standards for UAS operations, restricting access to certain classes of UAS or requiring specific technical features like remote identification systems. Member States, based on a risk assessment, can designate geographical zones where UAS operations are exempt from certain requirements of the "open" category. Member States must make information about these UAS geographical zones, including their validity period, publicly available in a common digital format for geo-awareness purposes.

Each Member State must designate one or more entities as the competent authority, which is entrusted with the following tasks:

- enforcing the Regulation;
- managing certificates and licences for UAS operators and remote pilots in the 'certified' category;
- conducting examinations and issuing certificates of competency for remote pilots;
- managing operational authorizations and verifying completeness of declarations for UAS operations in the 'specific' category;
- maintaining records and reports related to UAS operations;
- providing information on UAS geographical zones;
- developing a risk-based oversight system for UAS operators;
- conducting inspections, audits, and incident examinations;
- providing guidance to promote safety in UAS operations;
- establishing and maintaining registration systems for UAS and operators.

Competent authorities and market surveillance authorities cooperate and establish procedures for efficient **safety information exchange**. UAS operators must report safety-related occurrences to the competent authority and exchange information according to Regulation (EU) No 376/2014. EASA and competent authorities collect, analyse, and publish safety information on UAS operations in accordance with the Basic Regulation. Upon receiving safety information, EASA and competent authorities take necessary measures based on evidence and analysis, considering aviation safety interdependencies with cybersecurity and other technical domains. Competent authorities and EASA promptly notify relevant parties and organisations affected by the safety measures in accordance with the BR.

<sup>&</sup>lt;sup>7</sup> The confirmation by legal persons of the following statement: 'All personnel directly involved in the operations are competent to perform their tasks, and the UAS will be operated only by remote pilots with the appropriate level of competency'.





#### Delegated Regulation (EU) No. 2019/945

The **Delegated Regulation (EU) No. 2019/945** was adopted by the Commission on 12 March 2019 and lastly amended on 22 March 2022. It establishes the standards for the **creation and production of unmanned aircraft systems (UAS)**, along with **remote identification add-ons**. It specifies which types of UAS require certification for their design, production, and maintenance under the rules outlined in Implementing Regulation (EU) 2019/947.

The Regulation includes specific rules for:

- UAS designed for operation under regulations governing the "open" or "specific" categories
  of UAS operations as per Regulation (EU) 2019/947, excluding privately built UAS, and bearing
  specific class identification labels indicating their classification. This category also includes
  class C5 accessories kits and remote identification add-ons.
- UAS operated under regulations applicable to the "certified" and "specific" categories of UAS operations according to Implementing Regulation (EU) 2019/947, except when operated under a declaration.

The first category of UAS must conform to the **requirements set out in Parts 1 to 6, 16 and 17 of the Annex**. The latter include requirements for classes C1 to C4 UAS, requirements for a direct remote identification add-on, requirements for a class C5 UAS and C5 accessories, and requirements for a class C6 UAS.

In addition, UAS not classified as toys under Directive 2009/48/EC must comply with **health and safety requirements from Directive 2006/42/EC**, except for risks related to the safety of the unmanned aircraft flight. Updates to software of products already on the market are permissible only if they do not compromise the product's compliance.

The Regulation also imposes a **series of obligations** on **manufacturers**, authorised representatives of manufacturers, **importers**, and **distributors**.

According to Article 12, a product that adheres to **harmonised standards** is assumed to meet the requirements laid out in Parts 1 to 6, 16, and 17 of the Annex to the Regulation. The process for demonstrating conformity is detailed in the same article. The EU declaration of conformity must confirm that the product meets the standards set in Parts 1 to 6, 16, and 17 of the Annex to the Regulation. For UAVs, it should specify the UAV class and follow the model structure outlined in Part 11 of the Annex. Moreover, it should include the elements specified in that Part and be regularly updated. This declaration should also be translated into the language(s) required by the Member State(s) where the product is placed or made available on the market. In cases where a product is subject to multiple EU acts mandating an EU declaration of conformity, a single declaration covering all applicable EU acts must be prepared. This declaration must specify the EU acts involved, along with their publication references. The responsibility for ensuring the product's compliance with the Regulation lies with the manufacturer.

The Regulation sets forth **post-market and product surveillance** procedures. It mandates Member States to organise and conduct surveillance and control in accordance with specific regulations. It also stresses the importance of cooperation between market surveillance authorities and competent authorities designated for safety matters. Additionally, it emphasises the need for communication and coordination mechanisms between these entities, utilising relevant information systems.





Articles 36 to 38 outline the procedures for evaluating and addressing product risks at the national and Union levels, including market surveillance, corrective actions, and the Union safeguard procedure. In particular, if market surveillance authorities find that the product **does not comply with requirements** laid down in the Regulation, they shall require the relevant economic operators to take all appropriate corrective actions:

- to bring the product into compliance with those requirements;
- to withdraw the product from the market;
- to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe. The market surveillance authorities shall inform the relevant notified body accordingly.

Regarding the second type of UAS (i.e., those operating in the "certified" and "specific" categories, unless exempted by a declaration), the Regulation sets forth the following requirements:

- UASs must be certified if they meet certain conditions related to size, purpose, or operational category, including dimensions over 3m, transporting people or dangerous goods, or if operational risk requires certification.
- Certified UASs must adhere to specified regulations.
- UASs in the 'specific' category must meet technical capabilities defined by operational authorisation or Light UAS Operator Certificate (LUC), unless certification is required.
- UASs not subject to registration must have a unique serial number.
- UASs operating below 120 metres in the "specific" category must have a remote identification system allowing for transmission of operator registration number, real-time flight data, and emergency status indication, to prevent tampering.

Finally, the Regulation addresses third-country UAS operators. Such operators must comply with the Implementing Regulation (EU) 2019/947 when operating within the single European sky airspace. The competent authority for such operators will be in the first EU Member State where they intend to operate. However, recognition of remote pilot competency or UAS operator certificates from third countries may be allowed if: i) the third country requests recognition; ii) the certificates are valid in their country of issue; iii) the European Commission, after consulting EASA, confirms that the safety standards of these certificates are equivalent to EU regulations.

#### 2.5 Aerodromes

**Table 4. Elements of Basic Regulation related to Aerodromes** 

Topic	Basic Regulation	Implementing Regulation
Aerodromes	Annex VII	No. 139/2014 – Aerodromes

The substantial requirements referring to Aerodromes are contained in **Annex VII** of the BR and cover the following aspects:

• Infrastructure, Equipment and Data Requirements: focuses on physical characteristics, infrastructure, equipment, and data crucial for safe aircraft operations. Movement areas,





including landing and take-off zones, defined areas, and taxiing/parking areas, must be designed and maintained for safe use by intended aircraft types. Other infrastructure and equipment, such as safety-relevant aerodrome equipment, constructions, storage areas, and security measures, must be reliable and function under various conditions without posing safety risks. Accurate and up-to-date aerodrome data is vital for establishment, maintenance, accuracy, integrity, and accessibility.

- Operational and Management Requirements: Essential guidelines for aerodrome operators
  ensuring safe operations. Operators must possess the necessary resources and continuously
  verify compliance with regulations. Implementation of robust wildlife risk management
  programs and procedures, in order to prevent collisions and handle risks associated with
  adverse weather conditions, are mandatory. Collaboration with various bodies and agencies
  and guaranteeing the correct specification of uncontaminated fuel are imperative. Creation
  and application of a comprehensive aerodrome emergency plan, along with thorough training
  and qualification requirements for personnel, are necessary.
- Use of Management Systems: Mandated implementation for all operators to ensure compliance, manage safety risks, and foster continuous improvement. Operators must establish internal systems to collect and analyse safety incidents involving all relevant parties. Compliance with EU regulations governing such systems is mandatory, along with the necessity of a comprehensive manual detailing instructions, information, and procedures.
- Aerodrome Environment and Surroundings: Implementation of key procedures to safeguard
  aircraft operations are needed. Continuous monitoring and mitigation of hazards, including
  obstacles and issues like development and wildlife attraction, are prescribed. Emergency
  preparedness and planning, including the creation of a local emergency plan, underscore the
  commitment to managing the aerodrome environment effectively.
- Ground-handling Service Requirements: providers must ensure the safe delivery of services
  and compliance with procedures outlined in the aerodrome manual. Development and
  maintenance of a comprehensive manual, alignment with aircraft operators' procedures, and
  employment of adequately trained and qualified personnel are mandated. The establishment
  of a mandatory internal system for collecting and analysing safety incidents is required, with
  reports to be shared with relevant stakeholders.
- Apron Management Services (AMS): strict adherence to operating procedures delineated in the aerodrome manual, establishment of a comprehensive management system, and active involvement in safety programs established by the aerodrome operator are required. Formal agreements with the aerodrome operator and air traffic services provider, along with the implementation of an internal system for the collection and analysis of safety incidents, are crucial requirements.

## Regulation No. 139/2014

The **Implementing Regulation No. 139/2014** lays down certification requirements and administrative procedures related to aerodromes. In particular, the rules include:

- conditions for establishing certification bases, issuing and managing certificates for aerodromes and organisations operating them (Annex II and III);
- conditions for operating an aerodrome (Annex IV);
- defining responsibilities of certificate holders, accepting and converting existing certificates; deciding on exemptions, prohibiting or limiting operations for safety reasons (Annex III);





declaring and overseeing organisations providing apron management services.

Competent authorities, aerodrome operators, and apron management service providers are all required to comply with the specified requirements outlined in different annexes of the Regulation.

**Annex II** content establishes requirements for competent authorities involved in certifying and overseeing aerodromes, operators, and apron management service providers. It includes:

- General requirements, defining the scope and responsibilities of competent authorities, outlining oversight documentation requirements, including legislative acts and technical publications; establishing means of compliance, including Acceptable Means of Compliance (AMC) and alternative means; requires notification to the Agency of significant problems and provision of safety-significant information.
- Management requirements: it mandates the establishment of a management system, including documented policies and procedures. It requires the appointment of personnel responsible for specific tasks and participation in information exchange with other competent authorities.
- Oversight, Certification, and Enforcement requirements, describing oversight activities, including verification of compliance and implementation of safety measures; specifying oversight programmes and planning cycles, including audits and inspections; outlining procedures for initiating certification processes and issuing certificates; establishing requirements for changes to certification basis and issuance of safety directives; detailing declaration requirements for apron management service providers and procedures for addressing findings and observations.

#### **Annex III** includes **organisational requirements for aerodrome operators**. It covers:

- General requirements: It establishes requirements for aerodrome operators and apron management service providers under Regulation (EC) No 216/2008, allowing for alternative means of compliance with prior approval by the Competent Authority designated by the Member State, including notification of any revisions or changes to manuals or procedures.
- Certification: it outlines the certification process for aerodrome operators, detailing obligations, application requirements, demonstration of compliance, terms of certificates, continued validity conditions, management of changes, and termination procedures.
- Additional aerodrome operator responsibilities: it outlines the responsibilities of aerodrome operators, including ensuring safe operation and maintenance of the aerodrome, coordinating air navigation services, providing safety-related information to the Competent Authority, granting access for inspections, responding to safety problems and directives, reporting occurrences, establishing fire prevention measures, and implementing procedures regarding alcohol, psychoactive substances, and medicines for personnel.
- Management: it delineates the management responsibilities of aerodrome operators, encompassing the implementation of a management system integrating safety management, establishment of clear lines of responsibility and accountability, development of safety policies and procedures, coordination of safety training, maintenance of proficiency check programs, provision of adequate facilities, coordination with other organisations, establishment of safety reporting systems, and maintenance of comprehensive record-keeping practices, all tailored to the size and scope of the organisation's activities and in compliance with relevant regulations.





Aerodrome manual and documentation: it outlines the requirements for aerodrome manuals, specifying that the manual must reflect certification basis and relevant regulations, be accessible to personnel, undergo regular review and updates, incorporate safety-related amendments immediately when necessary, be available in an acceptable language, signed by the accountable manager, stored both electronically and in print, and contain specific content including general information, aerodrome management system details, site particulars, reporting requirements, and operating procedures.

**Annex IV** sets forth **operation requirements for aerodromes**. It includes:

- Aerodrome data: Aerodrome operators must maintain and provide relevant data and ensure
  its quality, coordinate with aeronautical information services, report pertinent information
  promptly, and consider time requirements for updates.
- Aerodrome operational services, equipment and installations: Aerodrome operators are responsible for emergency planning, rescue and firefighting, monitoring and inspecting movement areas, reducing wildlife hazards, managing vehicle operations, providing surface guidance systems, and ensuring safe operations in various conditions.
- **Aerodrome maintenance**: Aerodrome operators must establish maintenance programs, inspect and maintain pavements and ground surfaces, drainage systems, and visual aids and electrical systems to comply with essential requirements and ensure safety.

Finally, the Regulation also contains some rules on the **safeguarding of aerodrome surroundings**. It requires Member States to conduct consultations regarding the safety impacts of constructions within and beyond specified limits around aerodromes, including coordination with neighbouring states for aerodromes near national borders. It mandates the monitoring of aerodrome surroundings, involving consultations on various human activities and land use factors such as development, obstacle-induced turbulence, hazardous lights, reflective surfaces, wildlife activity, and interference with aeronautical systems. It addresses wildlife hazard management, requiring Member States to assess wildlife strike hazards through national procedures for recording and reporting strikes, collecting information on wildlife presence, and ongoing evaluation by competent personnel. Additionally, wildlife strike reports must be forwarded to the International Civil Aviation Organization (ICAO) for inclusion in the Bird Strike Information System (IBIS) database.

# 2.6 Air Traffic Management

Table 5. Elements of Basic Regulation related to Air Traffic Management

Topic	Basic Regulation	Implementing/Delegate Regulation
ATM	Annex VIII	IR No. 2017/373 – ATM/ANS provision of services – Air Traffic Management/Air Navigation Services
		IR No. 2015/340 – Air Traffic Controllers
		IR No. 1332/2011 – Airspace usage requirements (ACAS II)
		IR No. 2018/1048 – Airspace usage requirements (PBN)
		IR No. 923/2012 – Single European Rules of the Air (SERA)



IR No. 2023/1770, Interoperability of the European ATM Network

DR No. 2023/1768 – ATM/ANS systems and constituents

IR No. 2023/1769 – ATM/ANS systems and constituents

(organisations)

Pursuant to **Chapter 1**, **Article 3** of the Basic Regulation, ATM/ANS **constituent** refers to tangible objects like hardware and intangible objects like software, which are essential for ensuring the interoperability of the European Air Traffic Management Network (EATMN). ATM/ANS **systems** encompass a combination of airborne and ground-based constituents, along with space-based equipment, that collectively support air navigation services across all phases of flight.

The substantial requirements referring to ATMs and related systems are represented by **Annex VIII** of the Basic Regulation (BR) and cover the following aspects:

- Airspace Usage Requirements: All aircraft, except those engaged in activities specified in Article 2(3) of the Basic Regulation, must adhere to regulations concerning equipment and operation for aviation safety. In addition, equipment used in Air Traffic Management/Air Navigation Service (ATM/ANS) must meet precise standards to ensure interoperability and reliability.
- Aeronautical Information and Data: Data used for generating information must be reliable, accessible, and presented clearly to facilitate informed users' decision-making and operational planning. Also, security and timeliness in information dissemination are crucial for prompt responses to operational needs.
- Meteorological Information: Meteorological data must be of high quality, detailed, and transmitted through reliable channels to enable informed flight decisions. Similarly, timely delivery of meteorological information is essential for flight safety and efficiency.
- Air Traffic Services: ATS must ensure the high quality and accuracy of information for informed decision-making. Details should be meticulously considered to safeguard the safety of all users, including the careful design and maintenance of automated tools. A sufficient separation between aircraft, averting collisions with obstacles, and mitigating other airborne hazards must be ensured. Timely, clear and unambiguous communication among controllers, aircraft, and units is crucial for smooth operations. Robust emergency response mechanisms should be in place to swiftly detect potential crises and execute efficient search and rescue operations.
- Communication, Navigation and Surveillance: Stringent performance criteria are outlined in relation to communication services, navigation services, and surveillance services, aiming to ensure the safety and efficiency of air travel within European airspace. Communication services must ensure availability, integrity, continuity, and timeliness. Navigation services criteria emphasise guidance, positioning, and timing accuracy. Surveillance systems must be designed in such a way as to ensure accuracy, integrity, legitimacy, continuity, and detection probability.
- Air Traffic and Airspace Management: Air Traffic Flow Management (ATFM) should be
  operated so as to optimise available airspace capacity and enhance overall flow management
  processes while prioritising safety, transparency, and efficiency. This includes measures such
  as flight planning, slot allocation, traffic routing options, and airspace access priority rules.





- Airspace Management (AM) is also a crucial aspect to minimise the risk of aircraft separation loss. It involves considering the organisation of military activities while striving for the harmonised implementation of the "flexible use of airspace" concept.
- Requirements for Systems and Constituents: ATM/ANS must ensure integrity, performance, and reliability in all systems and components, regardless of their location (aircraft, ground, or space). Robust information-sharing mechanisms, fostering common understanding among stakeholders, and maintaining consistent processing capabilities should be prioritised. In the design of ATM/ANS systems, safety, security, and the mitigation of single points of failure are primary considerations. Human limitations and capabilities should be factored into system design to ensure usability and effectiveness. Furthermore, systems and data must be safeguarded against both internal and external interference to maintain operational integrity. Clear and unambiguous information is essential throughout the lifecycle of systems, from production and installation to operation and maintenance. This includes the identification of unsafe conditions and the provision of guidance for their mitigation. The safety levels of systems and components must be upheld throughout their service life, including during any modifications or upgrades. This commitment to maintaining a consistent level of service ensures the continued reliability and effectiveness of ATM/ANS systems in facilitating safe and efficient air traffic management.
- Qualifications for Air Traffic Controllers: ATCs must demonstrate adequate educational, physical, and mental maturity to acquire and apply the requisite knowledge and skills, including theoretical concepts relevant to air traffic control, continuously assessed through rigorous training and examinations. Second, ATCs must possess practical skills, relevant under various operational procedures, including managing abnormal situations and considering human factors. ATCs must be proficient in English for effective communication in various situations. Finally, ATCs training courses, as well as instructors/examiners, must ensure adequate theoretical and practical knowledge.
- Service Providers and Training Organizations: Service providers require adequate resources, including systems, facilities, and trained personnel, to effectively deliver services. They must maintain comprehensive manuals, a safety-focused management system, and ongoing training programs to ensure compliance and manage risks. Formal communication channels with stakeholders ensure transparency and accountability. Contingency plans and occurrence reporting systems enhance safety and regulatory compliance. Regular verification of safety requirements ensures a high level of safety. Specifically for air traffic control (ATC) service providers, measures such as roster systems for managing duty and rest periods, education and prevention programs for addressing stress, and procedures to verify cognitive judgement and medical fitness are crucial. Additionally, planning and operations should integrate human factors to ensure safe and efficient performance. Training organisations also require appropriate resources and a safety-focused management system to support effective training, potentially involving collaborations to enhance training quality and regulatory compliance.
- Aero-Medical Requirements. Qualified doctors with specialised training in aviation medicine
  are mandated to serve as aero-medical examiners, ensuring thorough medical assessments for
  air traffic controllers. These examiners must possess practical knowledge of controller working
  conditions to evaluate fitness for duty accurately. Aero-medical centres require proper
  facilities, personnel, equipment, and documentation for conducting comprehensive medical
  examinations. Furthermore, robust management systems are essential to ensure regulatory
  compliance, manage safety risks, and foster continuous improvement in assessment
  processes. Collaboration with other organisations may be necessary to enhance regulatory





compliance and maintain high standards in aviation medicine, potentially involving resource sharing and best practice exchange.

# Regulation (EU) No. 2017/373

The **Implementing Regulation (EU) No. 2017/373** sets forth requirements for ATM/ANS service providers and for the design of airspace structures.

The Regulation includes some provisions directed to Member States. In general, Member States must ensure the provision of appropriate ATM/ANS in a manner that **facilitates general air traffic** while also taking into account **safety considerations**, **traffic requirements**, and **environmental impact**. More specifically, Member States must determine the need for air traffic services, considering factors such as types and density of air traffic, meteorological conditions, and other relevant objectives of air traffic services. Member States must ensure coordination between military units and air traffic service providers, particularly in scenarios where interception might become necessary, as well as the coordination of potentially hazardous air operations over territories and high seas, ensuring timely dissemination of information. Also, Member States are bound to certain requirements for the use of the Single European Sky airspace, including measures to prevent excessive interrogations of secondary surveillance radar transponders and conversion of voice frequency assignments to an 8.33 kHz channel spacing.

**Article 6** of the Regulation outlines the requirements for different ATM service providers to be granted a certificate and exercise the privileges within its scope. In particular, it distinguishes between:

- a. **all service providers**, the requirements laid down in Annex III (Part-ATM/ANS.OR), Subparts A and B, and in Annex XIII (Part-PERS);
- b. **service providers other than providers of air traffic services**, in addition to the requirements of point (a), the requirements laid down in Annex III (Part-ATM/ANS.OR), Subpart C;
- c. providers of ANSs, providers of air traffic flow management and the Network Manager, in addition to the requirements of point (a), the requirements laid down in Annex III (Part-ATM/ANS.OR), Subpart D;
- d. **providers of air traffic services**, in addition to the requirements of points (a) and (c), the requirements laid down in Annex IV (Part-ATS) and the requirements laid down in Regulation (EU) No 923/2012;
- e. **providers of meteorological services**, in addition to the requirements of points (a), (b) and (c), the requirements laid down in Annex V (Part-MET);
- f. **providers of aeronautical information services**, in addition to the requirements of points (a), (b) and (c), the requirements laid down in Annex VI (Part-AIS);
- g. data services providers, in addition to the requirements of points (a) and (b), the requirements laid down in Annex VII (Part-DAT);
- h. **providers of communication, navigation or surveillance services**, in addition to the requirements of points (a), (b) and (c), the requirements laid down in Annex VIII (Part-CNS);
- i. **providers of air traffic flow management**, in addition to the requirements of points (a), (b) and (c), the requirements laid down in Annex IX (Part-ATFM);
- j. **providers of airspace management**, in addition to the requirements of points (a) and (b), the requirements laid down in Annex X (Part-ASM);
- k. **providers of flight procedure design services**, in addition to the requirements of points (a) and (b), the requirements laid down in Annex XI (Part-FPD);





I. **the Network Manager**, in addition to the requirements of points (a), (b) and (c), the requirements laid down in Annex XII (Part-NM).

**Annex III (Part-ATM/ANS.OR)** of the Regulation establishes common requirements for ATM/ANS providers. Besides general requirements, it covers the following aspects:

- Management (Subpart B): it covers technical competence, management systems, change
  procedures, contracted activities oversight, personnel appointments, facilities, recordkeeping, operations manuals, and procedures.
- Specific organisation requirements for service providers other than ATS providers (Subpart C): it focuses on safety assessments and assurance procedures for changes to the functional system, ensuring compliance with regulations and the specified context.
- Specific organisational requirements for ANS and ATFM providers and the network managers (Subpart D): it includes provisions for business, annual, and performance plans, security management, financial strength, liability and insurance cover, reporting requirements, and coordination with competent authorities. The requirements cover aspects such as safety, financial capability, security, and performance evaluation, ensuring compliance with regulations and effective service provision.

# Annex IV (Part-ATS) includes:

- General requirements, including provisions for ownership transparency, prevention of
  conflicts of interest, coordination with aerodrome operators, military units, meteorological
  services providers, and aeronautical information services, as well as the provision of relevant
  traffic information in U-space airspace.<sup>8</sup> It also covers timekeeping, contingency
  arrangements, reporting of system failures, operation of air traffic control services, and
  procedures for the transfer of control responsibilities. These requirements aim to ensure the
  safe, efficient, and transparent provision of air traffic services while facilitating effective
  coordination among relevant stakeholders.
- Safety management: including the establishment of a safety management system (SMS), safety risk management processes, safety assurance mechanisms, and safety promotion initiatives. It mandates safety assessments and assurance for changes to the functional system, specifying safety criteria and acceptability standards. Additionally, it outlines licensing and medical certification requirements for air traffic controllers to ensure compliance with safety standards and regulations.
- Human factors requirements: it includes the prevention and mitigation of risks associated with the problematic use of psychoactive substances, stress, and fatigue among air traffic controllers. The requirements include developing policies, procedures, and management programs to address these issues effectively. Additionally, it mandates the development and monitoring of rostering systems to manage the risks of occupational fatigue, with specific elements to be specified within these systems. Collaboration with air traffic controllers or their representatives is also required to identify and mitigate fatigue-related risks.
- Requirements for communications and information: for communications, it specifies the use of voice or data link communications, frequency allocation, recording facilities, and

<sup>&</sup>lt;sup>8</sup> U-space airspace ATM-related aspects have been included in the Implementing Regulation (EU) 2021/665 of 22 April 2021 amending Implementing Regulation (EU) 2017/373.







communication protocols. It also includes provisions for the use of the VHF emergency frequency, coordination between different air traffic service units, surveillance data usage, automatic recording of surveillance data, retention of recorded information, and background communication recording. Regarding information, it covers the provision of up-to-date meteorological conditions, detailed information on hazardous phenomena near aerodromes, and specific meteorological data for different types of air traffic service units. Additionally, it mandates the supply of information on aerodrome conditions, the operational status of associated facilities, and navigation services. The overall aim is to ensure that air traffic service units have access to accurate and timely information, especially meteorological data, crucial for safe and efficient aircraft operations.

Other relevant annexes for ATM-related services' and organisations' certification are:

- Annex V on specific requirements for providers of meteorological services (Part-MET)
- Annex VI on specific requirements for the providers of aeronautical information services (Part-AIS)
- Annex VII on specific requirements for providers of data services (Part-DAT)
- Annex VIII on specific requirements for providers of communication, navigation, or surveillance services (Part-DAT)
- Annex IX on Specific requirements for providers of air traffic flow management (Part-ATFM)
- Annex X on specific requirements for providers of airspace management (Part-ASM)
- Annex XI on Specific requirements for providers of flight procedure design services (Part-FPD)
- Annex XII on Specific requirements for the network manager (Part-NM)
- Annex XIII on Requirements for service providers concerning personnel training and competence assessment (Part-PERS)

# Regulation No. 2015/340

The Implementing Regulation No. 2015/340 lays down technical requirements and administrative procedures relating to air traffic controllers' licences and certificates, including those relating to authorities tasked with surveillance and oversight of those same processes.

In particular, **Article 2** of the Regulation outlines compliance requirements and procedures for student air traffic controllers, air traffic controllers, and individuals involved in licensing, training, testing, checking, and medical examination of applicants, as follows:

- All mentioned individuals must be qualified and licensed according to Annexes I, III, and IV by the competent authority.
- Organisations involved must meet technical and administrative requirements and be certified by the competent authority.
- Medical certification must adhere to technical requirements and administrative procedures.
- ATCs working in airspace covered by the Treaty but employed by providers outside the territory must hold a licence from a third country and demonstrate equivalent training and examination standards.
- Instructors and assessors from training organisations outside the Member States must hold a licence from a third country, demonstrate equivalent training and examination standards, and have their privileges specified in a certificate. These privileges are limited to instructing and assessing organisations outside the Member State's territory.





**Annex I** includes requirements for the licensing of ATCs:

- General requirements: it outlines procedures for applying for, exchanging, and using air traffic
  controller licences, ensuring compliance and safety, with provisions for revocation or
  suspension if requirements are not met.
- Licences, ratings and endorsements: it delineates the requirements and procedures for obtaining and maintaining student air traffic controller licences, air traffic controller licences, ratings, endorsements, and language proficiency endorsements, encompassing training, assessment, validity periods, and renewal criteria.
- Requirements for instructors and assessors: it outlines the qualifications, privileges, application process, validity, and renewal criteria for instructors and assessors in air traffic control training programs, including theoretical and practical instructors, as well as assessors, with specific requirements for endorsements and temporary authorisations to cover exceptional situations.
- Air traffic controller training: it outlines the comprehensive requirements for air traffic
  controller training, including objectives, types of training (such as initial, unit, and
  continuation), composition of training courses, prerequisites, training plans, performance
  objectives, examinations, assessments, and training for instructors and assessors, all aimed at
  ensuring the acquisition and maintenance of skills necessary to deliver safe and efficient air
  traffic control services.

Annex III contains requirements for air traffic controllers training organisation and aero-medical centres. Regarding the former, the following aspects are considered:

- **General requirements**: it establishes the requirements for air traffic controller training organisations and aero-medical centres to obtain and maintain certification in accordance with Regulation (EC) No 216/2008 and this Regulation.
- Requirements for air traffic controller training organisations: it outlines the application
  process, means of compliance, terms of approval, changes to the organisation, continued
  validity, access to facilities and data, reaction to safety problems, and occurrence reporting for
  air traffic controller training organisations.
- Management of air traffic controller training organisations: it covers the management system, contracted activities, personnel requirements, facilities and equipment, record keeping, funding, and insurance requirements for training organisations.
- Requirements for training courses and training plans: it specifies the requirements for training courses and training plans, including the development of training plans and courses, subjects for rating endorsements, methods of assessments, examination and assessment results, and certificate issuance.

# Regulation No. 923/2012

The **Implementing Regulation No. 923/2012** includes rules of the air and operational provisions regarding services and procedures in air navigation. In particular, those rules are contained.

The Member States must ensure compliance with the common rules and provisions set out in the Annex to the Regulation. The Annex contains rules on:

• **Flight over the high seas**: this shall be governed by the rules outlined in Annex 2 to the Chicago Convention, with provisions from Annex 11 applied consistently for the seamless operation of





- air traffic services. Member States may designate ATS providers for areas of responsibility over the high seas.
- Applicability and compliance: it defines application to airspace users operating within or out
  of the Union, with compliance required for pilots-in-command regarding aircraft operation,
  pre-flight actions, and authority over aircraft disposition while prohibiting the use of
  psychoactive substances by safety-sensitive personnel.
- Collision avoidance: it specifies general rules and collision avoidance procedures for aircraft
  operations, covering aspects such as negligent operation, minimum heights, cruising levels,
  dropping or spraying, towing, parachute descents, aerobatic flights, formation flights,
  unmanned free balloons, prohibited and restricted areas, and signals, emphasising
  responsibilities for collision avoidance manoeuvres and right-of-way protocols.
- Flight plans: it outlines the requirements and procedures related to flight plans, including the submission, contents, completion, changes, and closure of flight plans. It specifies when a flight plan must be submitted, what information it should contain, how changes to the plan should be reported, and the procedures for closing a flight plan after landing.
- Visual meteorological conditions, visual flight rules, special VFR and instrument flight rules:
   it delineates visual meteorological conditions (VMC) and visual flight rules (VFR), including
   visibility and cloud distance minima, VFR flight regulations, special VFR conditions within
   control zones, and rules for transitioning from instrument flight rules (IFR) to VFR
- Airspace classification: it outlines the classification of airspace into different categories (Class A-G), specifying the types of flights permitted, air traffic control services provided, communication requirements, and speed limitations for each class, along with the requirements for communication and transponder use in radio mandatory zones and transponder mandatory zones.
- Air traffic services: it outlines the objectives of air traffic services, which include preventing
  aircraft collisions, facilitating the flow of air traffic, providing advice for safe flight operations,
  and assisting in search and rescue efforts. Additionally, it emphasises the importance of
  coordination between air traffic services units and aircraft operators to ensure the safe and
  efficient conduct of flights, including the provision of relevant information to aircraft operators
  upon request.
- Air traffic control service: it delineates the provision and operation of air traffic control services, stating that they must be provided to IFR flights in certain airspace classes, all VFR flights in specific classes, special VFR flights, and aerodrome traffic at controlled aerodromes, detailing the responsibilities of air traffic control units to prevent collisions, issue clearances, and ensure orderly traffic flow, as well as the requirements for coordination between units and adherence to flight plans, including the reporting of position and termination of control, with a mandate for continuous air-ground communication and guidelines for communication failures.
- Flight information service: it includes the dissemination of various pertinent data such as SIGMETs, weather conditions, collision hazards, and volcanic activity, with pilots retaining final decision-making authority regarding any suggested alterations to flight plans, and air traffic control service taking precedence over flight information service when necessary.
- Altering service: the alerting service shall be provided to all aircraft under air traffic control
  service, those with filed flight plans, or otherwise known to air traffic services, including
  aircraft suspected of unlawful interference, with nearby aircraft promptly informed of
  emergencies, unless the situation involves unlawful interference, in which case discretion is
  exercised to avoid aggravating the situation.





- Interference, emergency contingencies and interception: Aircraft are advised to set transponders to Code 7500, notify ATS of significant circumstances, and attempt to land at the nearest suitable aerodrome, while air traffic services prioritise their safety; in emergencies, including unlawful interference, aircraft receive maximum consideration and assistance, with prompt information exchange and coordination between ATS and relevant authorities, while interception procedures involve compliance with visual and radio instructions to ensure safety and clarification of conflicting instructions.
- Services related to meteorology Aircraft observations and reports by voice communications: Aircraft are required to make special observations and report specific meteorological conditions encountered during flight, such as turbulence, icing, thunderstorms, dust storms, volcanic activity, and other non-routine conditions that may affect safety or operational efficiency; these observations are reported via voice communication as airreports, which are then transmitted promptly to other concerned aircraft, meteorological watch offices, and ATS units for dissemination and operational awareness.

#### Regulation (EU) No. 2023/1770

The Implementing Regulation (EU) 2023/1770 establishes operating rules concerning the utilisation of airspace and lays down requirements for aircraft equipment, essential for safe and standardised operations within the Single European Sky airspace. The Regulation has a narrow yet essential scope, as it is applied to operators of aircraft outlined in Article 2(1), points (b)(i) and (ii), and Article 2(1), point (c), of Regulation (EU) 2018/1139 (Basic Regulation), engaged in general air traffic and operating within, into, or out of the Single European Sky airspace. The Regulation follows the previous implementing regulations on the interoperability for the ATM European network, now no longer in force.

**Article 2** opens presenting definitions for ATC units, Data Link Services and Offset Carrier Operations:

- **ATC Unit.** Refers to a general term encompassing various entities such as area control centres, approach control units, or aerodrome control towers.
- Data Link Service. Denotes a collection of interrelated air traffic management transactions
  facilitated by air-ground data link communications, each with a clearly defined operational
  objective and commencing and concluding at an operational event.
- Offset Carrier Operation. Pertains to a scenario where the designated operational coverage cannot be guaranteed by a single ground transmitter. In such cases, signals from two or more ground transmitters are offset from the nominal channel centre frequency to minimise interference issues.

Following, the Annexes to the Regulation implement rules concerning the equipment and operation of aircraft, which aircraft operators must uphold and implement. In particular, the **Annexes (I-II)** govern **Surveillance** and **Communications**:

Data Link Services: it focuses on ensuring aircraft are equipped with the necessary capabilities
for data exchange with Air Traffic Control (ATC) units. Operators are required to ensure their
aircraft possess Data Link Communications Initiation Capability, ATC Communications
Management, ATC Clearances and Information, and ATC Microphone Check capabilities.
Additionally, they must establish communication arrangements to overcome any coverage
limitations and ensure compliance with operational procedures.





- Voice Channel Spacing: the requirements are applicable to general air traffic in specific regions
  of the Single European Sky airspace. Operators must ensure that their voice communication
  equipment supports 8,33 kHz channel spacing capability, with exceptions subject to Member
  States' approval.
- Dependent Cooperative Surveillance: it requires the presence of serviceable secondary surveillance radar transponders with Mode S Elementary Surveillance (ELS) capability in all aircraft. Larger or faster aircraft are further required to have 1090 MHz Extended Squitter (ES) Automatic Dependent Surveillance-Broadcast (ADS-B) Out and Airborne Mode S Enhanced Surveillance (EHS). Exceptions are provided for specific situations and retrofit programs. Operators must document compliant operating procedures and ensure personnel are adequately trained.

#### Regulation (EU) No. 2018/1048

The Implementing Regulation (EU) No. 2018/1048 mandates that providers of Air Traffic Management (ATM) and Air Navigation Services (ANS) comply with the requirements for implementing Performance-Based Navigation (PBN) outlined in Subpart PBN of the Annex to the Regulation.

The requirements include:

- Implementation of approach procedures at instrument runway ends according to required navigation performance ("RNP approach") specification, including various minima like lateral navigation (LNAV), lateral navigation/vertical navigation (LNAV/VNAV), and localizer performance with vertical guidance (LPV), with the addition of radius to fix (RF) legs where necessary.
- Implementation of RNP procedures at instrument runway ends without appropriate satellite-based augmentation systems (SBAS) coverage, with LPV minima to be implemented within 18 months of SBAS availability.
- Implementation of standard instrument departure (SID) route and standard instrument arrival route (STAR) routes according to RNAV 1 specification, with exceptions for higher performance requirements in high traffic density or complex terrain environments, which should adhere to RNP 1 specification with additional navigation functionalities.
- Implementation of ATS routes for en-route operations according to RNAV 5 specification.

#### Regulation (EU) 2023/1768

The **Delegated Regulation (EU) 2023/1768** aims to establish comprehensive rules governing the certification and declaration of **ATM/ANS systems and their components**.

Article 4 outlines the certification requirements for ATM/ANS, stating that equipment supporting controller-pilot communications and enabling aircraft separation or collision prevention in air traffic control services must be issued a certificate by the Agency as set out in Annex II. This certificate is valid indefinitely unless certain conditions, such as non-compliance with regulations or revoked certification, occur. Equipment used in limited airspace outside the ICAO EUR region with low traffic volume may be exempt from certification and instead issued a statement of compliance.

In particular, **Annex II** covers eligibility criteria for applicants, application procedures, demonstration of compliance with certification basis, and means of compliance. Requirements include:





- Design specifications: the design of ATM/ANS equipment must include specifications, manufacturing processes, limitations, and identification to ensure compliance with certification standards.
- Inspection and testing requirements: applicants must ensure that test specimens, equipment, and manufacturing processes adhere to design specifications, provide a statement of verification listing any potential non-conformities, allow the Agency to review data, witness tests, and ensure no changes are made to the verification statement before Agency inspections.
- Record-keeping obligations: the certificate holder must maintain and provide all pertinent
  design documents, drawings, test reports, and inspection records to the Agency to ensure
  ongoing compliance with regulations.
- **Manuals**: the certificate holder must procedure and update master copies of all manuals required by the certification and provide copies when requested to the Agency.
- Maintenance instructions: the holder of an ATM/ANS equipment certificate must provide
  comprehensive maintenance instructions to all users, ensuring availability upon request, with
  any changes also accessible and a program detailing how these updates are disseminated
  submitted to the Agency.
- Changes to certification basis: Changes to the ATM/ANS equipment certification basis require Agency approval after the certificate holder demonstrates compliance, except for changes within the organisation's privileges, managed by the design organisation, with a system to classify changes as minor or major, issuing statements as per regulations.

In addition, Article 5 outlines the requirements for the issuance of declarations of design compliance, which must take place in accordance with Annex III. It specifies that declarations are issued for ground-to-ground communication equipment and navigation or surveillance equipment by approved organisations. Declarations are valid indefinitely unless certain conditions occur, such as non-compliance with specifications, regulatory requirements, or unacceptable performance. It also exempts certain equipment used in limited airspace from requiring a declaration and assigns the issuance of declarations for the European Geostationary Navigation Overlay Service (EGNOS) system to the European Union Agency for the Space Programme (EUSPA). Additionally, it specifies that certain points of Annex III do not apply to EUSPA, but EUSPA must provide access to evidence to ensure compliance with technical specifications.

Annex III further specifies the procedures above, outlining the rights and obligations of organisations authorised to issue declarations. It requires demonstrating capability through an organisation approval issued by the Agency and submitting a declaration containing specific information like a description of the design, compliance statement, reference to evidence, and manuals. Means of compliance and record-keeping requirements are detailed, along with procedures for changes to the equipment design, maintenance instructions, and handling of equipment directives. The Annex also mandates granting the Agency access for inspections and investigations as necessary to ensure compliance.

Finally, Article 6 outlines the issuance of a statement of compliance for certain ATM/ANS equipment that is neither subject to certification nor to a declaration of compliance. The statement confirms compliance with detailed specifications issued by the Agency. It is issued by the ATM/ANS provider integrating the equipment or by an approved organisation involved in its design or production. The statement remains valid indefinitely unless the equipment no longer complies with essential





requirements, the provider loses compliance with regulations, or the provider withdraws the statement or faces enforcement measures.

## Regulation (EU) No. 2023/1769

The Implementing Regulation (EU) No. 2023/1769 focuses on establishing technical requirements and administrative procedures concerning the approval of organisations engaged in the design and production of ATM/ANS systems and components.

In particular, the Regulation states that the organisations involved in the design or production of ATM/ANS equipment must demonstrate their capability according to Annex II, with exemptions for organisations involved in EGNOS equipment, which must comply with Regulation (EU) 2021/696 standards and ensure equivalent safety and interoperability standard.

**Annex II** establishes the following requirements:

- General Requirements: it establishes common requirements for organisations involved in designing or producing ATM/ANS equipment; eligibility criteria for applying for organisation approval; application process for approval and demonstration of capability; requirement to maintain an organisation exposition containing various details about the organisation and its operations; duration, validity, and privileges of organisation approval; requirements for facilitating inspections, corrective actions, and immediate reactions to safety concerns; establishment of a system for recording failures, malfunctions, and defects; non-transferability of organisation approval except in cases of ownership change.
- Management Requirements: It includes the implementation of a management system covering responsibilities, policies, performance verification, change management, personnel training, and communication; the establishment of an information security management system; the approval and management of changes in procedures and facilities; the supervision of contracted activities and personnel requirements; a record-keeping system establishment and maintenance.
- Technical Requirements, including the entitlements and responsibilities of organisations regarding design and production activities; the coordination between design and production activities and support to ATM/ANS providers; the handling of ATM/ANS equipment directives, including proposing corrective actions and providing necessary instructions.





# 3 State of the art on current certification methods

Section 2 of this report has provided an overview of the state-of-the-art of regulations related to the certification of airborne systems, ATM systems and aerodromes, including their operational context. In this section, we discuss the **state-of-the-art methods currently used for certification**, i.e. for demonstrating that the systems satisfy the regulations.

Section 3.1 gives the typical structure of the certification process and explains which actors are involved. Section 3.2 gives an overview of the methods used in the certification of aircraft and aircraft parts; this includes certification of the designers and users of those aircraft. Section 3.3 outlines the methods used for the certification of Unmanned Aerial Vehicles (UAV). Section 3.4 addresses Aerodrome certification. Finally, Section 3.5 addresses the certification of Air Traffic Management (ATM), including ATM-related technology (hardware and software) and the users of that technology (Air Navigation Service Providers and air traffic controllers). The chapter focuses on the certification methods used for current applications. Chapter 4 will address their suitability for application to automation and AI-related technology.

# 3.1 Certification process and actors involved

According to **Regulation EU 2018/1139**, 'certification' means any form of recognition based on an appropriate assessment that a legal or natural person, product, part, non-installed equipment, equipment to control unmanned aircraft remotely, aerodrome, safety-related aerodrome equipment, ATM/ANS system, ATM/ANS constituent or flight simulation training device complies with the applicable requirements. Since the subject of a certification can therefore be a wide range of topics, from persons to organisations or operators to a piece of hardware or software, the certification process uses a variety of methods and tools. However, a general overall process can be distinguished:

- 1. Define the requirements and certification standards.
- 2. Provide detailed documentation that demonstrates that the subject (the person/organisation/operator/hardware/software to be certified) meets the requirements.
- 3. Apply for certification by submitting the documentation to the authorities, and collaborate with them by responding to any questions they may have.
- 4. Obtain certification from the authorities.

In Europe, the requirements and certification standards of the first step are set by EASA. These requirements depend on the subject to be certified, varying from rules on certification of the operator, the licensing of pilots, certification standards for an aircraft to required processes for developing software. An overview of these requirements and standards was given in Chapter 2.

The actors who should provide the demonstration in the second step on behalf of the applicants can be an Aerodrome operator, an Air Navigation Service Provider, a Design organisation, a Manufacturer, a Product organisation, a Maintenance organisation, a Training organisation, Subcontractors, etc. These actors are tasked with reaching the essential and specific requirements, as well as dialoguing with the competent authorities to establish how and when to prove their compliance. Their cooperation throughout the process and afterwards is essential, as oversight continues after the issuance of approval by the authorities. The demonstration step in the certification process is often a very lengthy one. For the certification of a new aircraft design, for example, it can





take years and a significant amount of resources. The resulting documentation may include design descriptions, manuals, models, simulations, descriptions of design processes and decisions, assumptions, calculations, test results, etc.

The authorities in the third and fourth steps are Member States and their national competent authorities. Criteria for organisations to be accredited as a qualified entity are provided in **Annex VI of EU 2018/1139**. They cooperate and coordinate within the normative framework defined by EASA and the European Commission. In some cases, Member States can delegate responsibilities related to certification, oversight and enforcement to EASA, to Qualified Entities, or to other Member States.

EASA coordinates with Member State authorities to receive and assess applications for the certification and type-approval of air transport systems, enacting what is described as a Joint Certification, Oversight and Enforcement System, Article 62 of (EU 2018/1139). This includes the exchange of relevant information, conducting inspections, and implementing continuous and post-market oversight, amongst other things. Following Article 64 of EU 2018/1139, EASA can also be requested by a Member State to carry out the tasks related to certification, oversight and enforcement for which the Member State concerned is responsible. Once the Agency accepts such a request, it shall become the competent authority responsible for the tasks covered by that request, and the requesting Member State shall be relieved of the responsibility for those tasks.

In this chapter, the methods and tools used to conduct any of the steps in the above certification process are referred to as **Certification Methods**. These methods take into account international, national and European technical standards from authoritative organisations and bodies, such as ICAO, formed through consensus and then rationalised, collected and published.

The remainder of this chapter identifies the state-of-the-art approaches and methods being applied for the certification of airborne systems, ATM-related systems, and aerodromes. The methods differ in form and framework, given the specificities of each application; nevertheless, they obey the analysed norms in Chapter 2 and the overall approach presented above.

# 3.2 Aircraft and aircraft parts

Chapter 2 explains that the rules and regulations for certification of aircraft and related products, parts and appliances, and of design and production organisations, are provided in Annex I of (EU 748/2012). This Annex is also referred to as **Part 21**, and it is composed of various subparts (see the figure below). Subparts B, D and E are about type certificates, changes to type certificates, and supplemental type certificates. These can only be applied for by **DOA** (design organisation approval) holders, Subpart J, except for minor changes to type certificates (having no appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, noise, fuel venting, exhaust emission or other characteristics affecting the airworthiness of the product).





A General provisions	I Noise certificates	
B type certificates	J design organization approval	
D changes to type certificates	K parts & appliances	
E supplemental type certificates	M repairs	
F production without production organization approval	O European technical standard order authorisations	
G production organization approval	P Permits to fly	
H airworthiness certificates	Q identification of products parts and appliances	

Figure 1. Subparts in Annex I of (EU 748/2012)

## 3.2.1 Type certification

The approval of aeronautical Products (aircraft, engines, and propellers) in accordance with Part 21 is ratified by the issue of a **Type Certificate (TC)** or a **Restricted TC (RTC)**. In general, there will be a **Type Certificate Data Sheet (TCDS)** associated with each TC or RTC issued.

The TC confirms that the aircraft design or type is according to the airworthiness requirements. In Europe, TCs are issued by EASA. Since 2003, EASA has been responsible for the certification of aircraft in the EU and for some European non-EU Countries. The TCDS records the basis of certification, the designation of each approved variant and general information concerning the design. Once the TC is issued, the design cannot be changed unless at least part of the process for certification is repeated to cover the changes. An RTC is issued for aircraft limited to special purposes identified in the applicable type design.

The 4 steps of the type-certification process are:<sup>9</sup>

- **Technical Familiarisation and Certification Basis**: The aircraft manufacturer presents the design to EASA when it is considered to have reached a sufficient degree of maturity. The EASA certification team and the set of rules that will apply for the certification of this specific aircraft type is being established (Certification Basis).
- Establishment of the Certification Programme: EASA and the manufacturer need to define and agree on the means to demonstrate compliance of the aircraft type with each requirement of the Certification Basis. This goes hand in hand with the identification of EASA's "level of involvement" during the certification process.
- Compliance demonstration: The aircraft manufacturer must demonstrate compliance of its product with regulatory requirements: the structure, engines, control systems, electrical systems and flight performance are analysed against the Certification Basis. This compliance demonstration is done by analysis during ground testing (such as tests on the structure to withstand bird strikes, fatigue tests and tests in simulators) but also by means of tests during flight. EASA experts perform a detailed examination of this compliance demonstration by means of document reviews and by attending some of the compliance demonstrations (test witnessing). This is the longest phase of the type-certification process. In the case of large

<sup>&</sup>lt;sup>9</sup> https://www.easa.europa.eu/en/domains/aircraft-products/aircraft-certification





- aircraft, the period to complete the compliance demonstration is set at five years and may be extended if necessary.
- Technical closure and issue of approval: If technically satisfied with the compliance demonstration by the manufacturer, EASA closes the investigation and issues the certificate. EASA delivers the primary certification for European aircraft models, which are also being validated in parallel by foreign authorities for operation in their airspaces. Conversely, EASA will validate the certification of foreign aircraft models according to applicable Bilateral Aviation Safety Agreements between the EU and the concerned third country.

A TCDS is an EASA document that records the type-certification data of a product (such as control surface movement limits, operating limitations, placards, and weight and balance) that may also be available in the flight manual or maintenance manual. The TCDS provides a formal description of the aircraft, engine or propeller that has received type certification by EASA. The EASA website<sup>10</sup> collects **Type Certificate Data Sheets (TCDS)** for various aircraft types.

An aircraft manufactured according to the design in the TC is not yet allowed to fly. First, it must get an airworthiness certificate, which is issued for an aircraft by the national competent authority in the Member state in which the aircraft is registered. To get this, the manufactured aircraft and each sub-assembly must be approved: The design documents are examined for compliance with the Minimum Operating Performance Standards (MOPS) applicable to that sub-assembly. MOPS are published by expert industry groups such as RTCA Inc., EUROCAE, and SAE. Once the aircraft is registered and approved, the competent authority issues a Certificate of Airworthiness (CoA, or C of A), and the aircraft is ready for safe operation. The CoA is valid, and the aircraft may be operated as long as it is maintained in accordance with the rules issued by the regulatory authority.

**Subpart D in Annex I of (EU 748/2012)** establishes the procedure for the approval of changes to type-certificates and establishes the rights and obligations of the applicants for, and holders of, those approvals. This Subpart also defines standard changes that are not subject to an approval process under this Subpart. It also defines a restricted category special airworthiness certificate, which is issued to operate aircraft that have been type certificated in the restricted category (RTC).

Major changes to the Type Certificate beyond the authority of the service bulletins require amendments. For example, increasing (or decreasing) an aircraft's flight performance, range, and load-carrying capacity by altering its systems, fuselage, wings, or engines resulting in a new variant, may require recertification. The basic process of type certifications is repeated for this, including maintenance programs. However, unaltered items from the basic design do not need to be retested. Normally, one or two of the original prototype fleet are remanufactured to the new proposed design. As long as the new design does not deviate too much from the original, static airframes do not need to be re-built. But the resultant new prototypes are again subjected to flight tests. Upon successful completion of the certification program, the original type certificate is amended to include the new variant (normally denoted by a new model number additional to the original type-designation, e.g. B747-800, where 800 is added).

<sup>&</sup>lt;sup>10</sup> https://www.easa.europa.eu/en/document-library/type-certificates







Any additions, omissions, or alterations to the aircraft's certified layout, built-in equipment, airframe, and engines, initiated by any party other than the type certificate holder, need an approved **Supplemental Type Certificate (STC)**. The scope of an STC can vary considerably. It could include minor modifications to passenger cabin items or installed instruments. More substantial modifications for example may involve engine replacement. STCs are applied due to either the type certificate holder's refusal (frequently due to economics) or their inability to meet some owners' requirements. STCs are frequently raised for out-of-production aircraft type conversions to fit new roles. Before STCs are issued, procedures similar to type certificate changes for new variants are followed, likely including thorough flight tests. STCs belong to the STC holder and are generally more restrictive than type certificate changes.

#### 3.2.2 SAE ARP4761

Part of the documentation to demonstrate compliance with regulations is a completed safety assessment. Document **ARP4761** by the Society of Automotive Engineers (SAE), and its EUROCAE counterpart, **ED-135**, describes guidelines and methods of performing the safety assessment for certification of civil aircraft. The ARP4761 is part of an extended family of linked methods and documents. These include:

- ARP4754 (the aircraft development process coupled to ARP4761),
- EASA CS-25.1309 (airworthiness requirements for large aeroplanes),
- RTCA DO-178C/EUROCAE ED-12C (international standard on software considerations in airborne systems (civil aircraft) and equipment certification),
- RTCA DO-278/EUROCAE ED-109 (ditto for non-airborne CNS/ATM systems),
- **ARP5150** (guidelines, methods, and tools used to perform the ongoing safety assessment process for transport aeroplanes in commercial service),
- ARP5151 (ditto for general aviation and rotorcraft).

The objective of ARP4761 is to provide guidance and methods for performing the safety assessment for certification of civil aircraft in compliance with EASA CS-25.1309. It is a companion document of ARP4754A, which addresses the development process of those aircraft systems, taking into account the overall aircraft operating environment and functions. This ARP4754A standard includes development planning; an aircraft and system development process, divided into several phases; several integral processes, among which safety assessment, Development Assurance Level (DAL) assignment, requirements validation, and modification to aircraft systems. Here, Development Assurance is "All those planned and systematic actions used to substantiate, to an adequate level of confidence, that development errors have been identified and corrected such that the system satisfies the applicable certification basis" (SAE ARP4761). Development assurance assumes that a more rigorous process is more likely to identify and remove errors before the product is delivered than a less rigorous process. This is based on the premise that in complex and highly integrated electronic systems with software and/or programmable hardware, it is not feasible to test all combinations of inputs and outputs to assign a probability of failure.

**ARP4761** and **ARP745A** are applicable to the development phases of the aircraft and its systems. For the in-service phases, and for avionics, electronic hardware and software development, other documents are referred to, see the following figure:





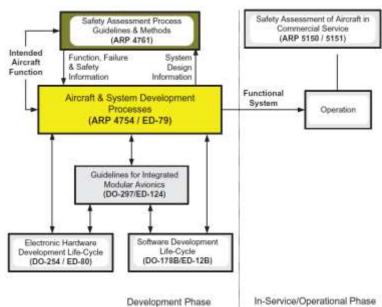


Figure 2. Relationship between ARP4761, ARP4754A and other related documents. Source: (SAE ARP4754A)

**ARP4754A** identifies two phases of system development: function development phase and item development phase. The function development phase includes the development, validation, verification, configuration management, process assurance, and certification coordination for the system. At the lowest level, system requirements are allocated to software or hardware, referred to as items. The software or hardware items have their own development phases. **ARP4754A guidance applies to the system development phase**; DO-178B/C applies to the software development phase; and DO-254 applies to the electronic hardware development phase.

At the function level, an FDAL is assigned based on the system's potential impact on safety. The FDAL determines the amount of rigour required at the system level (e.g., amount of requirement reviews, testing, and independence). The software and electronic hardware are assigned IDALs. The IDAL determines the amount of rigour required for the specific item's development (software or electronic hardware development). Depending on the architecture, the IDAL may be lower than the FDAL.

ARP4761 gives guidance and methods for the safety assessment process, specifically distinguishing the safety assessment process of Functional Hazard Assessment (FHA), Preliminary System Safety Assessment (PSSA) and System Safety Assessment (SSA), and supporting safety analysis methods such as Fault Tree Analysis (FTA), Failure Modes and Effects Analysis (FMEA), Failure Modes and Effects Summary (FMES), and Common Cause Analysis (CCA).





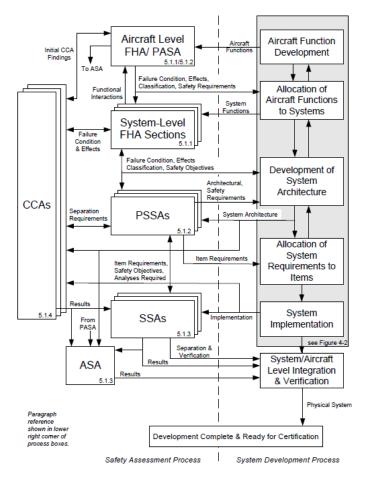


Figure 3. Methods used within ARP4761. Source: (SAE ARP4754)

#### **FHA**

The FHA examines aircraft and system functions (where a system is considered to be a part of an aircraft), in order to identify and classify potential functional failures. FHA is applied at two different levels:

- Aircraft level FHA: This takes as input (from ARP4754A) the Aircraft functions. It identifies
  aircraft functional failures and their effects and classifies them according to the severity of
  each failure condition. The failure condition severity determines the function development
  assurance level (FDAL) allocated to the subsystem, and establishes the safety requirements to
  be considered at the lower level classification, see table below.
- **System level FHA**: Similar to the Aircraft FHA, but at a system level. This takes as input (from ARP4754A) the systems to which the aircraft functions have been allocated, and considers the failures or combination of system or subsystem failures that affect the aircraft-level functions.





Table 6. Failure condition severity as related to probability and function development assurance levels. Derived from (SAE ARP4761)

Failure condition severity	Potential effect	FDAL assigned	Probability
Catastrophic	Failure may cause deaths, usually with loss of the aeroplane	А	Extremely improbable
Hazardous	Failure has a large negative impact on safety or performance, or reduces the ability of the crew to operate the aircraft due to physical distress or a higher workload, or causes serious or fatal injuries among the passengers	В	Extremely remote
Major	Failure significantly reduces the safety margin or significantly increases crew workload. May result in passenger discomfort (or even minor injuries)	С	Remote
Minor	Failure slightly reduces the safety margin or slightly increases crew workload. Examples might include causing passenger inconvenience or a routine flight plan change	D	Reasonably probable
No Effect	Failure has no impact on safety, aircraft operation, or crew workload	Е	Frequent

The probability values are only used for hardware items where reliability is applicable, not for software. Table 1 in (SAE ARP4761) also translates the descriptive probabilities into quantitative maximum probabilities per flight hour following (EASA CS-25.1309), with Extremely improbable being  $< 10^{-9}$ , Extremely remote being  $< 10^{-7}$ , Remote being  $< 10^{-5}$ , Reasonably probable being  $< 10^{-3}$ , and Frequent being < 1 per flight hour.

FHA results are normally shown in table form, with columns identifying function, phase of flight, failure condition, failure effect, and classification. The FHA is developed early in the development process and is updated as new functions or failure conditions are identified.

For each failure condition associated with an Aircraft function, a fault tree is developed, with the failure condition as a top event. The table above provides the associated maximum probability of occurrence of that failure condition. The fault tree is used to derive the lower-level requirements (IDAL) for the system failures at the bottom of the fault tree. These derived requirements may affect the failure condition classification and may include aspects like design constraints, annunciation of failure





conditions, recommended flight crew or maintenance action, etc. They are, in turn, analysed in the System FHA.

#### **PSSA**

The system-level failure conditions are input to the PSSA. The PSSA examines the proposed system architecture. It evaluates the failure conditions identified by the System FHA and safety requirements allocated. Safety requirements for system, subsystem, software and hardware elements are generated. The PSSA establishes specific system and item safety requirements and provides preliminary indications that the anticipated system architecture can meet those safety requirements. The PSSA is updated throughout the system development process. The PSSA usually takes the form of a fault tree analysis and should also include a common cause analysis.

#### SSA

The SSA collects, analyses, and documents verification that the system, as implemented, meets the system safety requirements established by the FHA and the PSSA. It is a systematic, comprehensive evaluation of the implemented system functions to show that relevant safety requirements are met. The SSA is usually based on the PSSA fault tree analysis and uses the quantitative values obtained from the Failure Modes and Effects Summary (FMES). The FMES is a summary of failures identified by a Failure Modes and Effects Analysis (FMEA), in which the failures are grouped together on the basis of their failure effects. The SSA should verify that all significant effects identified in the FMES are considered for inclusion as primary events in the FTA. The SSA must also include applicable common cause analysis results.

Common Cause Analysis (CCA) will identify common failures or common events that eliminate redundancy in a system, operation, or procedure. CCA is used to identify sources of common cause failures and effects of components on their neighbours. It is subdivided into three areas of study: Zonal Analysis, Particular Risks Assessment, and Common Mode Analysis.

Because software and other components of an aircraft may not lend themselves to probabilistic assessment, an "item development assurance level" or IDAL is assigned to each such component, depending on the safety-criticality of the component. This refers to RTCA standards such as DO-178C (Software Considerations In Airborne Systems And Equipment Certification), DO-278 (Guidelines for CNS/ATM Systems Software Integrity Assurance), DO-254 (Design Assurance Guidance for Airborne Electronic Hardware), DO-297 (Integrated Modular Avionics (IMA) Development Guidance and Certification Considerations). For more on this, see the next subsection.

ARP4761 indicates that instead of fault tree analysis, Dependence Diagrams or Markov Analysis can be used. Dependence Diagrams are essentially equivalent to fault trees, and the selection of one over the other is left to the personal preference of the analyst. Markov Analysis techniques are often useful when dealing with deferred maintenance scenarios.

#### 3.2.3 On-board software certification

Certification of software in safety-critical applications requires another approach than the deterministic validation and testing that is done in the certification of hardware. The focus of certification shifts to the process of developing software, including detailing practices of the organisation/manufacturer that constructs it. The most obvious difference between hardware and





software is that software is available in the logical form of bits and bytes and has no physical existence. Because of this, the emphasis of software certification shifts from certification based on failure rates (Mean Time Between Failures) towards the certification of systems based on *how* they are developed (verification).

**RTCA standard DO-178C** (Software Considerations In Airborne Systems And Equipment Certification) defines the processes to follow for certification aspects of on-board software. It is equivalent to **EUROCAE ED-12C**.

On-board software systems require an equivalent level of safety as used for other on-board (hardware) technologies and systems, putting severe demands on the methods and techniques for software engineering. A software engineering standard shall be used that demands rigorous configuration control, extended verification and validation, and quality assurance. Software engineering standards typically pay extensive attention to the fact that documentation and the code needs to be highly structured so as to create possibilities for reviewing.

DO-178C describes the following processes in detail:

- **Software Life Cycle:** concerns the prescribed Software Life Cycle models and marks out the scope of the development path. The phases in the Life Cycle and their coherence are discussed briefly. It also names the prescribed milestones and reviews.
- **Software Planning Process:** describes the project plan or management plan and other plans related to the Software Life Cycle, and the evolution of these planning documents.
- **Verification and Validation:** describes the evaluations, reviews, tests and analyses that are prescribed by the standard and how to deal with them.
- Configuration Management: describes the configuration management of documents and source code. It describes the identification of products, software libraries for configuration control, and releases. It also concerns the procedures for dealing with errors: reporting and status accounting and the implementation of a review board and configuration management board.
- Quality Assurance: describes the audits on how compliance to the standard is achieved.
- **Project Management:** describes the project management of assigning personnel to tasks, budgeting, work breakdown structure, work packages, organising and leading the project.

The start for a certification trajectory is laid in the Development Life Cycle process, starting with the **System Life Cycle**. The main goal of the System Life Cycle is the description of Airworthiness requirements and System Operational requirements to enable the System Safety Assessment Process. The System Safety Assessment Process establishes the failure condition category of the system, defining 5 failure condition levels and Associated Design Assurance Levels (IDALs) ranging from catastrophic (IDAL A) to no-effect (IDAL E), similar to FDAL, see table in the previous paragraph. The most critical systems, such as flight controls and cockpit displays, are labelled IDAL A; whereas less critical systems, such as telemetry and communications, are labelled IDAL C or IDAL D. Each IDAL prescribes distinct levels of rigour in the software development process. There are 71 objectives defined for meeting IDAL A, for example, compared to 26 objectives for IDAL D.

The use of artificial intelligence in the process is not ruled out in advance; its potential effects should be taken into consideration in the **System Safety Assessment Process**.





The **Software Planning Process** produces the software plans and standards that direct all other processes; one plan for each process is set up. Their purpose is to define the means of producing software which will satisfy the system requirements and to provide a level of confidence which is consistent with airworthiness requirements.

The first plan is the **Plan for Software Aspects of Certification (PSAC)**. This is a document used by the certification authority, such as EASA to determine whether an applicant is proposing a software life cycle that is commensurate with the rigour required for the level of software being developed. The PSAC is a primary means of determining whether the software life cycle is appropriate for the level of software being developed. The plans for the other processes are defined in line with the elements defined in the PSAC.

## 3.2.4 Flight testing

A method applied to demonstrate compliance is Testing. Test guidelines are published and followed by each regulator. The testing includes simulations based on aircraft design, testing of the airframe structure, and finally, flight testing in the air. Testing usually involves building several prototype models. This is a lengthy process, and it forms a major part of the cost of development.

Before an aircraft takes to the air, it is subjected to extensive structural tests. Tests include wing loading and deflection, aileron and spoiler functionality during wing loading, fuselage pressure tests, fatigue tests, and flight cycle simulations. These stress the airframe and wings, in most cases significantly exceeding the expected maximum loads that will be experienced in service.

Flight tests are carried out to assess the aircraft's general handling and performance and also to test operations in extreme conditions. This includes operations in extreme heat, cold and altitude. For this, aircraft are often flown to other locations. The various operational tests an aircraft must undergo include:

- Operation of aircraft systems, including autopilots;
- Water ingestion tests, to ensure water won't enter aircraft systems;
- Flutter testing, where vibrations are measured to ensure they won't cause structural damage;
- Low speed take off;
- Rejected take-off (including testing at full aircraft load, with worn brakes);
- Assessment of the aircraft's environmental footprint, including fuel burn.

Pilots often need a special licence to be used as a test pilot. See the paragraphs below for more details.

## 3.2.5 Design organisation

Certification of an **Aircraft Design Organization (ADO)** is a meticulous process aimed at ensuring that the organisation possesses the necessary capabilities, expertise, and procedures to design aircraft that meet stringent safety and performance standards. The typical steps involved are:

1. **Preparation and Documentation**: The ADO compiles comprehensive documentation outlining its organisational structure, design processes, procedures, and quality management system (QMS). This documentation should demonstrate compliance with applicable regulations.





- 2. Organisational Assessment: The regulatory authority conducts an assessment of the ADO's organisational structure, personnel qualifications, and resources to ensure that it has the necessary expertise and capabilities to undertake aircraft design activities. This assessment may include evaluating the qualifications and experience of key personnel, such as design engineers and project managers.
- 3. **Design Process Evaluation**: The regulatory authority reviews the ADO's design processes and procedures to ensure they comply with relevant regulations and industry standards. This includes assessing how the organisation manages design changes, interfaces with suppliers, performs risk assessments, and ensures compliance with airworthiness requirements.
- 4. Quality Management System Audit: An audit of the ADO's quality management system (QMS) is conducted to verify that it meets the requirements of applicable standards, such as ISO 9001:2015 or specific aviation regulations. This audit assesses the effectiveness of the organisation's quality control measures, document control processes, and corrective action procedures.
- 5. **Demonstration of Compliance**: The ADO may be required to demonstrate compliance with specific design standards and regulations applicable to the type of aircraft it intends to design. This may involve submitting design proposals, analyses, and test data to show that the proposed aircraft design meets all relevant airworthiness requirements, including structural integrity, performance characteristics, and system reliability.

## 3.2.6 Aircraft operators

Airlines need to be certified in order to operate commercial air transportation services. The certification process typically involves several steps, including:

- Air Operator Certificate (AOC): Airlines must obtain an AOC from the relevant aviation authority before they can operate commercial flights. This certificate confirms that the airline has met all regulatory requirements related to safety, maintenance, operations, and management.
- 2. **Safety Management System (SMS)**: Airlines are required to implement a Safety Management System, which is a systematic approach to managing safety risks within the organisation. This includes identifying hazards, assessing risks, implementing mitigations, and continuously monitoring and improving safety performance.
- 3. **Operational Approvals**: Airlines must obtain operational approvals for specific activities or routes, such as Extended Range Twin Operations (ETOPS) for long-distance flights over water, Low Visibility Operations (LVO) for landing in low visibility conditions, or Category II/III Instrument Landing System (ILS) operations.
- 4. **Maintenance Programs**: Airlines must have approved maintenance programs in place to ensure the airworthiness of their aircraft. This includes regular inspections, maintenance checks, and compliance with manufacturer's recommendations and regulatory requirements.
- 5. **Training Programs**: Airlines are responsible for ensuring that their flight crew, maintenance personnel, and other employees receive appropriate training to perform their duties safely and effectively. Training programs must be approved by the aviation authority.
- 6. **Security Measures**: Airlines must implement security measures to protect passengers, crew, and aircraft from acts of unlawful interference, such as hijacking or sabotage. This includes screening procedures, access controls, and training for security personnel.





# 3.2.7 Flight crew

Pilots need to be certified to operate aircraft in commercial aviation. The specific type of certification required depends on the type of flying they will be doing and the jurisdiction in which they will be operating. The main types of pilot certifications are:

- Private Pilot License (PPL): A PPL allows individuals to fly aircraft for personal or recreational
  purposes. This licence typically requires a minimum number of flight hours, completion of
  specific training requirements, and passing written and practical examinations. Private pilots
  are not permitted to receive compensation for flying.
- Commercial Pilot License (CPL): A CPL allows pilots to fly aircraft for compensation or hire.
  This licence requires a higher level of training and experience compared to a PPL. Commercial
  pilots can work as flight instructors, conduct aerial tours, or perform other commercial flying
  activities.
- 3. Airline Transport Pilot License (ATPL): An ATPL is the highest level of pilot certification and is required for pilots who want to act as captains or first officers on commercial airline flights. ATPL holders are authorised to operate large commercial aircraft and are subject to more stringent training and experience requirements than CPL holders.
- 4. **Instrument Rating**: Pilots who wish to fly under instrument flight rules (IFR), which allow flying in adverse weather conditions or through controlled airspace, must obtain an instrument rating in addition to their pilot licence. This rating requires additional training and testing in instrument flying techniques.
- 5. **Type Ratings**: Pilots must also obtain specific type ratings for the aircraft they will be operating. Type ratings are endorsements added to a pilot's licence after completing training and proficiency checks on a particular aircraft type. For example, a pilot trained to fly a Boeing 737 would need a type rating specific to that aircraft model.

In addition to these certifications, pilots must also undergo periodic medical examinations to ensure they meet the medical standards set by aviation authorities. These medical certificates are required to exercise the privileges of their pilot licence.

Specific rules exist for flight test pilots: In many jurisdictions, flight test pilots must hold a CPL or an ATPL. For flight testing of experimental or prototype aircraft, some organisations may additionally require pilots to hold an **Experimental Test Pilot License (ETPL)**. This licence is specific to flight testing and may have additional training and experience requirements beyond those of a CPL or ATPL. In addition, flight test pilots often undergo specialised training programs in flight test techniques, procedures, and safety.

# 3.3 Unmanned Aerial Systems (UAS) and U-space

# 3.3.1 UAS equipment, operator and remote pilot

Future drones with passengers on board, such as air taxi, but also cargo drones or urban package delivery, will need to be certified. In order to allow operations in the certified category, almost all the





aviation regulations will need to be amended. EASA decided<sup>11</sup> to conduct this activity in multiple phases, starting with International flights of certified cargo drones conducted under instrument flight rules (IFR) in airspace classes A-C and taking off and landing at aerodromes under EASA's scope. After that, they will address drone operations in urban or rural environments using predefined routes in airspaces where U-space services are provided, such as air taxi or package delivery services.

Once these regulations are in place, remote pilots will probably be required to pass a knowledge test covering airspace regulations, aviation weather, UAS flight operations, emergency procedures, and safety protocols. UAS operators will need endorsements for conducting flights **beyond visual line of sight (BVLOS)**, flights over people, or unmanned operations in controlled airspace, restricted airspace, night operations, or operations near airports, etc.

According to EASA, the approach used to ensure the safety of these flights will be very similar to the one used for manned aviation. For this reason, these aircraft will need a **type certificate (TC)** and a **certificate of airworthiness (CoA)**, the UAS operator will need an air operator approval issued by the competent authority and the (remote) pilot is required to hold a pilot licence. For the corresponding processes to obtain these certificates, refer to the previous sections on manned aircraft.

# 3.3.2 U-space certification

A regulatory framework for U-space is laid down in the Commission Implementing Regulation 2021/664. This regulation builds on the EC regulations 2019/945 and 2019/947 as described in section 2.4.

The implementation of U-space airspace requires the U-space service provider and the single common information service provider to be certified.

Certification of the U-space service provider is on the basis of the specific services it offers. For a specific airspace that is designated as U-space airspace, a number of mandatory and a number of optional U-space services will need to be provided. The ongoing discussion is on whether these services need to be provided by one software supplier or that several suppliers may provide systems as the backbone for the service provider. However, it is clear that not the software but the service provider needs a certificate.

The certification of a **Common Information Service (CIS)** follows the same rules.

The process for obtaining a certificate is described in EC regulation 2021/664. The EC member state of the principal place of business is considered the authority to provide the certificate or, for service providers established outside the EU, it is the European Union Aviation Safety Agency (EASA) that will perform the certification process.

A certificate can be granted if the U-space service provider or the CIS service provider demonstrates:

- That the services are provided in a safe, secure, efficient, continuous and sustainable manner;
- That the systems and equipment guarantee the quality, latency and protection of the services;

<sup>&</sup>lt;sup>11</sup> https://www.easa.europa.eu/en/domains/civil-drones-rpas/certified-category-civil-drones







- That the service provider has appropriate net capital to commensurate with the costs and risks associated with the services:
- That the service provider is able to report occurrences;
- That the service provider maintains a management system;
- That the service provider maintains a security management system;
- That information can be retained for a period of at least 30 days;
- That the service provider has a robust business plan to ensure they can meet their contractual obligations for at least 12 months after start of the operation;
- That arrangements are in place to cover liabilities;
- That a liability arrangement is in place is they avail themselves of services of another service provider;
- That a contingency plan is in place.

## 3.4 Aerodromes

## 3.4.1 Aerodrome operators

The certification for aerodromes involves a process to ensure that these facilities meet regulatory standards and safety requirements for aircraft operations:

- 1. **Application Process**: Aerodrome operators submit an application for certification to the relevant regulatory authority. This application includes detailed information about the aerodrome's infrastructure, facilities, operational procedures, and management structure.
- 2. **Pre-Certification Assessment**: Before granting certification, regulatory authorities conduct a comprehensive assessment of the aerodrome to verify compliance with regulatory requirements. This assessment may include inspections, audits, and reviews of documentation related to aerodrome design, construction, maintenance, and operations.
  - The aerodrome's infrastructure and facilities are evaluated to ensure they meet safety, security, and operational standards. This includes runways, taxiways, aprons, terminal buildings, hangars, navigation aids, lighting systems, fire protection equipment, and other essential facilities.
  - Aerodrome operators must have documented operational procedures in place to ensure safe and efficient aircraft movements and ground operations. These procedures are reviewed to ensure they address key aspects such as runway incursion prevention, wildlife management, emergency response, air traffic control coordination, and noise abatement.
  - Many regulatory authorities require aerodromes to implement a Safety Management System (SMS) to manage safety risks and hazards proactively. Aerodrome operators develop and implement an SMS that includes processes for hazard identification, risk assessment, safety reporting, safety training, and continuous improvement.
  - Aerodrome operators develop emergency plans and procedures to address various emergency scenarios, such as aircraft accidents, medical emergencies, fires, hazardous material spills, and security threats. Regulatory authorities review these plans to ensure they are comprehensive, well-coordinated, and effective in mitigating risks and protecting personnel, passengers, and property.
- 3. **Certification Issuance**: If the aerodrome meets all regulatory requirements and passes the assessment process, the regulatory authority issues a certification or approval allowing the





- aerodrome to operate. This certification may specify the scope of operations, any conditions or limitations, and requirements for ongoing compliance.
- 4. **Ongoing Compliance Monitoring**: Certified aerodromes are subject to ongoing monitoring and oversight by regulatory authorities to ensure continued compliance with certification requirements. This may include regular inspections, audits, safety assessments, and reporting obligations to identify and address any deficiencies or safety concerns.

# 3.4.2 Aerodrome equipment and equipment manufacturer

Certification of aerodrome-related equipment and of the aerodrome equipment manufacturer typically involves several steps to ensure that the equipment and the manufacturer meet all the necessary standards and regulations for producing equipment used in aviation facilities such as airports.

The method is largely similar to that of ATM-related technology (see next section).

# 3.5 Air Traffic Management

# 3.5.1 ATM-related technology

The certification method for air traffic management (ATM) related technology involves the steps below. For more details, see the EASA document (EASA, 2023c).

- 1. **Safety Assessment**: Manufacturers conduct safety assessments to identify and mitigate potential hazards and risks associated with their systems. This includes analysing system architecture, software design, failure modes, and fault tolerance to ensure safe and reliable operation.
- 2. **System Development**: ATM technology undergoes rigorous development processes that adhere to established standards, which outline procedures for requirements management, design, verification, and validation to ensure compliance with safety and performance objectives.
- 3. **Verification and Validation**: This aims to demonstrate that the ATM technology meets regulatory requirements and performs as intended. It includes testing the system in simulated and operational environments to validate functionality, performance, and interoperability with existing ATM infrastructure.
- 4. **Certification Application**: Manufacturers submit a certification application to the relevant regulatory authority, along with documentation detailing the design, development, testing, and safety assessment. Regulatory authorities review the material to assess compliance with safety, performance, and operational requirements. This may involve a thorough examination of the system architecture, software design, testing results, and safety analyses.
- 5. **Certification Approval**: If the ATM technology meets all regulatory requirements and passes the review process, the regulatory authority issues a certification or approval allowing the technology to be used in air traffic control operations. This certification typically specifies the scope of use, operational limitations, and any conditions or requirements for continued compliance.
- 6. **Ongoing Monitoring and Compliance**: Once certified, ATM technology is subject to ongoing monitoring and compliance activities to ensure that it continues to meet regulatory standards





and operates safely and effectively in the air traffic control environment. This may include regular audits, inspections, and reporting requirements.

Commonly used methods for conducting safety assessments and identifying potential hazards and risks associated with the systems are:

- Hazard Analysis: This involves systematically identifying and assessing potential hazards that
  could arise from the operation of the ATM system. This includes analysing system architecture,
  operational procedures, human factors, environmental factors, and external threats to identify
  potential sources of risk.
- 2. Failure Mode and Effects Analysis (FMEA): FMEA is a systematic method for identifying and analysing potential failure modes within the ATM system, along with their effects on system performance and safety. Each component and subsystem of the system is analysed to identify failure modes, their causes, and the potential consequences on system operation.
- 3. **Fault Tree Analysis (FTA)**: FTA is a method for analysing the causes of system failures and their propagation through the system. It is used to identify potential combinations of component failures or external events that could lead to system failures or hazards. This helps in understanding the dependencies and interactions between different system components and identifying critical failure scenarios.
- 4. **Software Safety Analysis:** This is conducted to identify potential software-related hazards and risks within the ATM system. It includes analysing software architecture, algorithms, data processing, input/output interfaces, and error-handling mechanisms to identify potential sources of software failures or anomalies that could compromise system safety.
- 5. **Fault Tolerance Analysis**: This involves assessing the system's ability to continue operating safely in the presence of component failures or other adverse conditions. Fault-tolerant mechanisms are designed, such as redundancy, error detection, and error recovery to mitigate the effects of failures and ensure continuous system operation.
- 6. **Safety Requirements Allocation**: Safety requirements are allocated to different system components and subsystems based on the results of hazard analysis and safety assessment. This ensures that safety considerations are integrated into the design, development, and testing of the ATM system from the early stages of the lifecycle.
- 7. **Safety Assurance Case**: This documents the safety arguments, evidence, and reasoning behind the safety claims made for the ATM system. It includes summarising the results of safety analyses, testing, and verification activities to demonstrate compliance with safety requirements and standards.

# 3.5.2 Failure Mode and Effects Analysis (FMEA)

The EASA document (EASA, 2023c) is aimed at providing "Detailed Specifications and Acceptable Means of Compliance & Guidance Material for certification or declaration of design compliance of ATM/ANS ground equipment". The document explains that **FMEA** should be used in the certification process of ATM/ANS equipment; therefore, it is described here.

FMEA is an inductive (bottom-up) analysis method that aims to analyse the reliability of a system, item, function, or a piece-part (individual component) by identifying its failure modes; determining the effects on the next higher level of the design; determining, if any, the detection method for each failure mode (not always included); and determining a failure rate for each failure mode (only if the analysis





is performed quantitatively). FMEA can be used to support the safety assessment process by providing or verifying failure rates to quantify basic events (e.g., a Fault Tree Analysis (FTA)).

FMEA considers failures rather than hazards and hence does not usually consider operating procedures, human factors, and transient conditions. A FMEA is performed at a given level and can either consider functions (functional FMEA), or actual pieces of equipment (piece-part FMEA). A piece-part FMEA may be conducted if the more conservative values of a functional FMEA do not allow the system or item to meet a determined failure probability budget. But it is also conducted if a system relies on redundancy (redundancy cannot be addressed well in a functional FMEA) or if a system includes mechanical items and assemblies.

The major steps in FMEA include preparation, analysis, and documentation.

First, preparation of the FMEA includes determining the customer requirements, obtaining current documentation, and understanding the operation of the function. Requirements for an FMEA usually follow from a Preliminary System Safety Assessment (PSSA) activity, as the analyst needs to know the analysis level, safety-related effects, and operational modes of interest. Further information to be obtained includes specifications, current drawings on schematics, parts lists, functional block diagrams, explanatory material regarding the theory of operation, FMEA on a previous or similar function, et cetera.

Secondly, the *analysis* phase of the FMEA includes the following activities:

- Gaining knowledge of the functions and the design being analysed. This includes reviewing and understanding the information collected during the preparation phase.
- Identification of failure modes. Components and functions that make up the given level are considered on how they may fail.
- Determination of the effect of the failure mode. Consider the effect at the given level and on higher levels. This activity includes the definition of 'failure effect categories', corresponding to a unique higher-level effect. Use is made of worksheets (see also documentation step below).
- Determination of how to detect the failure modes. Usually, but not always included. Detection means are also included in the FMEA worksheet.
- Assignment of a failure rate per failure mode (only in case of a quantitative FMEA). Whenever possible, this is determined from failure data of similar systems already in use.

Thirdly, documentation of the FMEA is done in an FMEA report and includes describing the objectives, all inputs and all activities and results. Usually, an FMEA worksheet is used for documentation of the various activities, consisting of a table with column headings such as item, potential failure mode, potential effects of the failure mode, severity of the failure, potential causes of the failure, and likelihood that a potential cause will occur. Checklists exist that are of help in conducting an FMEA.

FMECA is an extension of FMEA that also includes criticality analysis (Failure Modes, Effects and Criticality Analysis), which allows charting the probability of failure modes against the severity. This allows for identifying those failure modes that might need special attention and control measures during design or operation. It is, therefore, more commonly used than FMEA and is more suited than FMEA for hazard control. The main activities to be performed are FMECA largely in line with the





description of the *analysis* step of FMEA above. The main difference is that after the identification of the detection means, the following activity is added: Determining criticality. This is usually expressed in a criticality index, which is a mathematical combination of the severity of the effect and the probability of occurrence of the failure mode.

AMC1 GE.GEN.007 in (EASA, 2023c) states that an FMEA should be performed to evaluate the failure conditions for ATM/ANS equipment. The FMEA should be performed at different levels (e.g. system, subsystem, constituent, etc.) by postulating the ways the chosen level's specific implementation may fail. The effect of each failure condition should be determined at the given level and the next higher level, if applicable, for each operating mode. Specific operating scenarios should be considered when performing such analysis. It should account for all safety-/service-related effects. In cases where it is not possible to identify the specific nature of a failure mode, the worst credible effect should be assumed. The following major FMEA steps should be taken: preparation; analysis; and documentation.

The same reference also provides guidance material on how to conduct the FMEA, which deviates in some cases from the classical description above. It can be noted that elements of other methods, such as HAZOP (Hazard and Operability study), are mixed in. The material also states that FMEA is used to address the effect of software errors that can also be analysed qualitatively. In the literature, related methods such as SFMEA (Software Failure Modes and Effects Analysis) are used for that. Unlike Hardware FMEA, which analyses both the severity and likelihood of the failure, an SFMEA usually analyses only the severity of the failure mode.

#### 3.5.3 ATM software certification

**DO-278A** is the software certification standard applicable to Communication, Navigation, Surveillance/Air Traffic Management (CNS/ATM) systems. The document can be regarded as the "ground"-equivalent to **DO-178C**, though the first thing to notice is that its title does not contain the term "certification". Instead, it focuses on software integrity assurance. Therefore, the authority responsible for "certification" in DO-178C is substituted by the "approval" authority in DO-278A and the document known as the "Plan for Software Aspects of *Certification* (PSAC)" in DO-178C is denoted as the "Plan for Software Aspects of *Approval* (PSAA)" in DO-278A. The difference is that *certification* is the legal recognition that the subject complies with the applicable requirements; *approval* refers to the formal declaration that the subject may be implemented. See also Section 4.2.1 in (Rierson, 2013) for an explanation of the differences between DO-278A and DO-178C.

The less trivial differences between the documents primarily address the fact that CNS/ATM system developers and certification authorities are said to be more accepting of reused proven technology than their counterparts in airborne systems – even if that technology was not developed in accordance with DO-278A<sup>12</sup>. This opens the possibility of using Commercial Off The Shelf (COTS) and legacy software.

The difference is reflected in the DO-278A assurance levels, which have one level between DAL3 and DAL4 of the airborne standard. This level can be used for the certification of COTS or legacy without the need for a plan for the full development process. Instead, the level requires some design-level

<sup>&</sup>lt;sup>12</sup> DO-278A and DO-178C are more or less the same thing... aren't they? - LDRA.







verification but focuses on the software to fulfil its intended function and does not require any codelevel analysis. The following levels are considered in DO-278A<sup>13</sup>:

- Level AL1: Software whose anomalous behaviour, as shown by the system safety assessment process, would cause or contribute to a failure of a CNS/ATM system function resulting in a *catastrophic* failure condition for the aircraft.
- Level AL2: Software whose anomalous behaviour, as shown by the system safety assessment process, would cause or contribute to a failure of a CNS/ATM system function resulting in a hazardous failure condition for the aircraft.
- Level AL3: Software whose anomalous behaviour, as shown by the system safety assessment process, would cause or contribute to a failure of a CNS/ATM system function resulting in a major failure condition for the aircraft.
- **Level AL4** is not associated with any failure condition category. Annex A summarises those objectives, activities, and other attributes to be applied to the software assigned to AL4.
- Level AL5: Software whose anomalous behaviour, as shown by the system safety assessment process, would cause or contribute to a failure of a CNS/ATM system function resulting in a *minor* failure condition for the aircraft.
- Level AL6: Software whose anomalous behaviour, as shown by the system safety assessment
  process, would cause or contribute to a failure of a CNS/ATM system function with no effect
  on aircraft operational capability or pilot workload. If a software component is determined to
  be AL6 and this is confirmed by the approval authority, no further guidance contained in this
  document applies.

## 3.5.4 ATM/ANS equipment manufacturer

Certification of ATM/ANS equipment manufacturers involves ensuring that the equipment meets strict standards for safety, reliability, and interoperability within the broader aviation system. The method to demonstrate their capability as a design or production organisation for ATM/ANS equipment is provided in Annex II of (EU 2023/1769). The method is largely similar to that of aircraft design organisations.

# 3.5.5 Air Navigation Service Providers (ANSP)

Providers of ATM/ANS, also referred to as Air Navigation Service Providers (ANSP), are also required to hold a certificate. And so do organisations involved in the design, production, or maintenance of ATM/ANS systems. The certification of these organisations involves a rigorous process, to ensure that the organisation meets regulatory standards and safety requirements for providing air traffic control and related services:

- 1. **Regulatory Framework**: EASA establishes regulations, standards, and guidelines that ANSPs must comply with to ensure safe and efficient provision of air navigation services.
- Application Process: The ANSP submits an application for certification to the relevant regulatory authority. This application includes detailed information about the organisation's structure, capabilities, personnel, facilities, operational procedures, and safety management systems.

<sup>&</sup>lt;sup>13</sup> Reference to ED-109A / DO-278A







- 3. **Pre-Certification Assessment**: Before granting certification, regulatory authorities conduct a thorough assessment of the ANSP's capabilities and compliance with regulatory requirements. This assessment may include audits, inspections, reviews of documentation, and interviews with key personnel to evaluate the organisation's readiness for certification. Regulatory authorities assess the ANSP's organisational structure, management systems, and governance arrangements to ensure effective oversight, accountability, and decision-making. This includes evaluating the qualifications, training, and experience of key personnel responsible for safety, operations, maintenance, training, and quality management.
- 4. **Safety Management System (SMS)**: ANSPs are required to implement a Safety Management System (SMS) to proactively manage safety risks and hazards associated with air traffic control operations. The SMS includes processes for hazard identification, risk assessment, safety reporting, safety training, and continuous improvement. Regulatory authorities review the ANSP's SMS to ensure it meets regulatory requirements and is effectively implemented.
- 5. **Operational Capabilities**: Regulatory authorities evaluate the ANSP's operational capabilities to provide air traffic control, airspace management, communication, navigation, and surveillance services. This includes assessing the organisation's procedures, systems, facilities, and personnel training to ensure safe and efficient provision of air navigation services.
- 6. Quality Management System (QMS): ANSPs may be required to implement a Quality Management System (QMS) to ensure consistent delivery of high-quality air navigation services. The QMS includes processes for service quality monitoring, performance measurement, customer feedback, and corrective action. Regulatory authorities review the ANSP's QMS to ensure it meets regulatory requirements and supports continuous improvement.
- 7. **Certification Issuance**: If the ANSP meets all regulatory requirements and demonstrates compliance with certification criteria, the regulatory authority issues a certification or approval allowing the organisation to provide air navigation services. This certification may specify the scope of services, any conditions or limitations, and requirements for ongoing compliance.
- 8. **Ongoing Compliance Monitoring**: Certified ANSPs are subject to ongoing monitoring and oversight by regulatory authorities to ensure continued compliance with certification requirements. This may include regular audits, inspections, safety assessments, performance reviews, and reporting obligations to identify and address any deficiencies or safety concerns.

#### 3.5.6 Air Traffic Controllers

Certification for air traffic controllers involves a comprehensive process to ensure that individuals meet the necessary knowledge, skills, and competencies to perform their duties safely and effectively. This process typically includes training, assessment, and licensure:

1. Training: Prospective air traffic controllers undergo initial training at an accredited training facility or academy. This training covers a wide range of topics, including aviation regulations, airspace structure, aircraft performance, meteorology, communication procedures, radar operation, air traffic control techniques, and emergency procedures. After completing initial training, air traffic controller trainees undergo on-the-job training (OJT) at a designated air traffic control facility under the supervision of experienced controllers. During OJT, trainees gain practical experience in managing air traffic, using radar and other equipment, communicating with pilots, and handling various traffic scenarios under simulated and live conditions. Throughout training, trainees are assessed on their knowledge, skills, and





- performance in various aspects of air traffic control. This assessment may include written exams, practical simulations, evaluations of communication skills, situational awareness, decision-making ability, and adherence to standard operating procedures.
- 2. Licensing Examination: Upon completion of training and OJT, air traffic controller trainees are required to pass a licensing examination administered by the regulatory authority responsible for aviation safety. This examination typically includes written, practical, and oral components covering relevant regulations, procedures, airspace knowledge, radar operation, communication skills, and emergency protocols. Air traffic controllers must undergo regular medical examinations to ensure they meet the medical standards required for safe performance of their duties. These examinations assess physical fitness, vision, hearing, and overall health to ensure controllers are capable of managing the demands of air traffic control responsibilities.
- 3. **Licensure**: Upon successfully completing training, assessment, and examination requirements, air traffic controllers are granted a licence or certificate by the regulatory authority. This licence authorises them to perform air traffic control duties within specified airspace and facilities. The licence may include ratings or endorsements for specific types of airspace, radar operation, and traffic control positions.
- 4. **Continuing Education and Recurrence Training**: Air traffic controllers are required to undergo regular continuing education and recurrence training to maintain and update their knowledge, skills, and proficiency. This training may cover changes in regulations, technology, procedures, airspace structure, and equipment upgrades to ensure controllers remain competent and up to date throughout their careers.
- 5. **Supervision and Oversight**: Licensed air traffic controllers are subject to supervision and oversight by their employing organisation and regulatory authorities to ensure compliance with regulations, adherence to procedures, and maintenance of safety standards. Controllers may undergo performance evaluations, proficiency checks, and audits to assess their continued competence and suitability for duty.





# 4 Suitability and challenges of current certification methods in case of advanced automation and AI-powered technologies

This report has provided an overview of the state-of-the-art of regulations and certification methods for airborne systems, ATM systems and aerodromes, including their operational context. In this section, we discuss the suitability of the current certification approaches for operations that are supported by advanced automation and AI.

Section 4.1 describes the certification context of Al-based technology in human-centred operations. Section 4.2 provides challenges for safety and certification for increasingly autonomous systems and Al-supported operations. Section 4.3 discusses a number of related legal aspects. Section 4.4 provides an evaluation of prime current certification methods. Section 4.5 provides conclusions.

# 4.1 Certification of Al-powered technology in human-centred operations

# 4.1.1 HMI interaction, AI ethics and certification

Al-based systems are strategic assets for the aviation domain, serving as clear enablers for a wide range of applications that support aircraft design and operations (EASA, 2023b). Compared to previous technologies, the most disruptive aspect of Al-based systems is their potential for evolving **autonomy in task execution** (EC, 2021). By generating outputs such as content, predictions, recommendations or decisions and influencing their interacting environments, these technologies introduce advanced automation applications that significantly impact human-machine interactions (OECD, 2023).

This means that emerging certification systems should take into account novel aspects associated with **human-Al collaboration**. It is important not only to incorporate existing requirements but also to read and implement them in light of Al ethical principles, with particular regard to ensuring human agency in HMI instances. Moreover, it appears crucial to promote situational awareness and responsibility and to avoid risks such as human dependency, manipulation, complacency and over-reliance (EASA, 2023b).

#### 4.1.2 Human-centred Al

In this context, human-centred AI (HCAI) represents a pivotal approach to the development of artificial intelligence, considering human well-being, values and ethical considerations as core principles (Schmager, Pappas, & Vassila, 2023). Driven by transparency, fairness, accountability and inclusivity, the HCAI methodology aims to ensure that AI technologies are aligned with human needs and societal values by prioritising **user-centred design** and **fostering collaboration between humans and AI systems**. All of the above is supported by AI policy governance initiatives, which strive to create technological applications that not only enhance efficiency but also respect human agency, autonomy and privacy. By taking a proactive stance on such ethical considerations, the HCAI approach reflects a commitment to the **responsible and sustainable use of AI**, fostering trust and acceptance in society at large (HLEG-AI, 2019).

These aspects influence the safety of technologies in a broad sense and certification schemes in aviation need to recognise the value of these requirements as a prerequisite for type approval and





certification. In this regard, there is a need to develop design and validation methodologies that consistently monitor the ethical compliance of concepts and solutions in the developmental process of autonomous AI systems, serving as a gate analysis for certification (EASA, 2023a). This underlines the importance of considering ethical dimensions alongside technical aspects in the certification process to ensure the responsible and ethically sound use of AI throughout the lifecycle of these technologies, supporting the substantial implementation of HCAI approaches.

# 4.1.3 HAT, human oversight and explainability

In contemplating various levels of automation and diverse interactions, spanning not only between humans and machines but also between machines, it is crucial to recognise that the impacts of these interactions will, in some instances, affect individuals, if humans play some part in the overall sociotechnical system. Throughout the workflow pipeline, there will then ultimately always be an individual tasked with interfacing with the consequences of outcomes or actions generated by the AI.

**Human-AI Teaming (HAT)** refers to the collaborative and coordinated interaction between humans and artificial intelligence (AI) systems in various contexts, aiming to combine the strengths and capabilities of both entities to achieve shared goals (Berretta et al., 2023). The concept emphasises **cooperation**, **collaboration**, and **effective communication** between human operators and AI technologies to enhance overall system performance and decision-making (EASA, 2023a). HAT involves designing interfaces, systems, and workflows that facilitate seamless interaction, information sharing, and adaptive responses, fostering a symbiotic relationship between human and AI elements.

In this context, HCAI recalls the concept of **human oversight** and emphasises the critical role of human operators in monitoring and managing AI systems to ensure that decisions are consistent with ethical standards and intended outcomes. To achieve effective human oversight, it is imperative to incorporate **well-designed interfaces** that allow humans to understand and intervene in AI decision-making processes. At the same time, the **explainability** of AI systems is essential to provide clear insights into how decisions are made and to foster trust and understanding among users. This requires transparent design practices that reveal the inner workings of algorithms and models. Transparency, both ex-ante (before deployment) and ex-post (after deployment), involves open communication about how AI systems work, including the rationale behind decisions (EASA, 2023a).

Certification schemes must be designed to verify the authenticity of the relationship between humans and Al-based systems. This requires careful consideration of the intricacies of human-machine interaction. Effective collaboration within the Human-Al Teaming (HAT) framework requires the design of Al-based systems that not only enable but also facilitate the sharing of elements of situational awareness. These systems should have the ability to identify abnormal situations, perform diagnostics, evaluate the relevance of solutions proposed by end-users, engage in negotiation/argumentation, and exhibit adaptability. The certification process should therefore focus on assessing how well these elements are integrated into the design and functionality of Al systems, ensuring that they contribute to a harmonious and effective collaboration between humans and Al (EASA, 2023b).

## 4.1.4 Trust, predictability and consistency

Considering the introduced points, it is clear that explainability is only one element among several factors that contribute to establishing and improving end-user trust in the system. The effectiveness of an explanation in fostering trust and improving the end user's perception of a system's





trustworthiness depends heavily on variables such as context, situation, and human experience or training.

In addition, these findings fundamentally challenge traditional approaches to certification, regulation, organisational accreditation and standardisation. As a matter of fact, a need arises for traditional processes to evolve beyond their current focus on safety profiles in an effort to encompass the **broader dimensions of liability, ethics, and societal considerations associated with AI**. In this regard, such a consideration appears crucial given how, unlike conventional technologies, which best suit traditional approaches, AI systems developed using machine learning techniques are dynamic and have the ability to learn and evolve over time. This critical feature poses a challenge for certification processes, as static testing methods may prove inadequate. Therefore, the implementation of continuous monitoring mechanisms to assess the adaptability and responsiveness of AI systems in real-world human interactions will be critical to certification (EASA, 2023) and follows a similar principle of extensive accountability and surveillance related to machine learning applications as seen in recent AI-specific legislative European initiatives (Product Liability Directive Revision Proposal, AI Liability Directive Proposal, 2022).<sup>14</sup>

While the primary objective of certification remains focused on ensuring safety and minimising human factors risks, assessment systems need to be fine-tuned to adapt assurance frameworks. This includes addressing the specificities of identified AI techniques, correcting design flaws in AI-based systems and their components, addressing the challenges of maintaining a comprehensive description of intended behaviour, and establishing robust frameworks for knowledge and data management. Certification processes must also address the limits of predictability and explainability of the behaviour of AI applications, taking into account the intricacies of inference mechanisms and model complexity.

## 4.1.5 Fair allocation of authority

Assuming that human interaction will inherently involve cooperation and collaboration with intelligent artificial systems, it becomes crucial to consider the respective areas of expertise of the involved entities and the nature of their interactions. This recognition underscores the importance of thoughtful consideration in the allocation of authority and agency during the design and implementation of Alrelated systems. Authority, defined as the ability to make decisions and take actions independently (EASA, 2023a), can be distributed between humans and Al-based systems in different ways. **Full authority** for the end user involves active monitoring and the ability to intervene or override Al decisions, with no oversight capabilities for the Al-based system. **Partial authority** allows the end user some control over Al decisions, retaining the ability to override them if necessary, fostering a collaborative relationship. Authority for the end user upon alerting grants full control to the Al-based system, with passive monitoring for the end user to revert to 'full' or 'partial' authority based on operational events.

From a practical point of view, it is essential to take into account the **real needs and expectations of operators** with regard to their supervisory duties in relation to AI and how technology practically changes working conditions. Following, it appears that ensuring that the introduced innovations do

<sup>&</sup>lt;sup>14</sup> Proposal for a Directive of the European Parliament and of the Council on liability for defective products, COM/2022/495 final and Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI liability directive), COM/2022/496 final.





not lead to a deterioration of work autonomy and personal and professional development is a crucial and principal priority (Eurofound, 2022). In this regard, it is necessary to promote a fair balance between technological automation and the enhancement of human skills, yet without reducing operators to mere passive recipients of instructions from machines (De Stefano, 2018). Continuing, the overall goal should be to develop more meaningful job profiles by eliminating mundane or repetitive tasks, ensuring that individuals make better use of their time and devote it to more stimulating tasks (Bankins & Formosa, 2023).

Regardless of the specific allocation of authorities and agencies in Al-based systems, it is paramount that their functioning and consequences align with ethical principles for both operators and end-users, as already discussed with respect to HCAI and XAI approaches, amongst others. This consideration is crucial for establishing trust and ensuring both the responsible and trustworthy development and deployment of AI technologies.

Above all considered, new AI certification systems should, therefore, thoroughly implement these ethical aspects in order to guarantee that the certification process reflects and promotes similar practices in the development and implementation of AI-based systems from a substantial point of view.

# 4.2 Safety and certification challenges of AI-supported operations

There exist various challenges that AI and increasingly autonomous systems pose for **safety and certification** (Alexander et al., 2007). In support of the development of increasingly autonomous systems, models must be built of the environments. Evaluation of these models against the real environment is a challenging task. Furthermore, software safety standards are largely prescriptive and process-based without paying attention to autonomy. These standards may not be easily applicable to increasingly autonomous systems, considering the size and complexity of the software and of the input and state domains. Also, autonomous systems use several classes of technologies which present novel challenges for software certification:

- Model-based systems, which make decisions based on an explicit model of itself and the
  environment. For such systems, conventional techniques for safety analysis are not immediately
  applicable.
- Model-building systems, which build models during operation and where it is not possible to validate the model ahead of operation.
- Learning or adaptive systems, which attempt to extract explicit patterns or rules automatically from data. Problems are, among others, the difficulty of understanding the model that the system has learned, preventing violation of identified safety requirements and managing trade-offs between safety and performance.
- Effective exploitation of system or world models requires the use of planning techniques, and it is difficult to show that a given planning system will behave safely in all combinations of models and situations.
- Many of the technologies proposed for use in autonomous systems provide probabilistic functions.
   Probabilistic functions can be subjected to statistical testing, but such testing cannot give a satisfactory level of safety assurance on its own.





Alves et al. (2018) provide a broad overview of implications for safety assurance of increasingly autonomous systems (IASs), where human roles are reduced or even eliminated. A leading case in the report concerns a reduced crew operation replacing one of the pilots in a commercial operation by an Al-based system. It is argued that existing processes, criteria and metrics in verification and validation in current assurance approaches (ARP4754A and DO-178C) are limited for application to the increasing complexities of modern distributed systems and the new dynamic, intelligent functions of IASs. Identified challenges in human-Al interaction include the following:

- A critical consideration is the sharing of responsibilities between a human pilot and an IAS component within a Crew Resource Management (CRM) context, which introduces new failure modes in terms of human-machine interactions. When defining requirements for the IAS, one has to account for the differences between a human vs. automation performing the tasks in both normal and abnormal operational scenarios.
- A related challenge is that rules, dependencies and relationships between instruments and flight situations that are known to the pilot may not have been **documented in a systematic manner** to capture them as requirements for the IAS. Differences between how a human pilot and IAS access the instruments have to be considered while capturing requirements. While the pilot may "see" the instruments, the IAS may have direct, seamless access to the instruments.
- The **expected behaviour in abnormal/anomalous situations** is often not well defined. To define the requirements of an IAS to perform the Pilot flying role in emergency situations, one has to prioritise and enlist all the actions that are appropriate for every emergency situation. The challenge is that for humans, this relates to their knowledge of operating the aircraft, experience handling situations at various levels of emergency, general common sense and intuition; whereas for IAS, all these have to be factored in.
- A common concern with automation is "automation surprises", i.e. situations where crews are surprised by actions taken (or not taken) by the automation. The IAS shall unambiguously communicate what it is doing to the pilot as well as explain the rationale and intent of its actions when queried by the crew mate in a way that can be "understood" by the human. Hence, one of the aspects when defining the requirements of an IAS is to obtain agreement before it performs any action that is not prompted by the crew mate; in the same way, if an action is called out by the pilot, the IAS shall either confirm after performing the action or clearly explain why the action was not taken.

# 4.3 Legal aspects

In the future of aviation, AI is expected to play a key role in autonomous operations. Actual autonomous operations will involve fewer or no persons, but the operation is dependent on the designed system by the **manufacturers**, therefore they must bear a **higher burden of proof**. When this is the case, Sharma (2016) argues that courts must consider not only airline liabilities but also **product liability** for the purpose of **protecting safety**. This is in line with the approach of the European Commission in its report on AI and safety and liability (EC, 2020).

Various approaches have been provided for the allocation of responsibility of human operators and developers of AI systems (Yeung, 2019).

• Intention/culpability-based approaches. Two conditions should be met in this approach. The first condition is that the developer should have control over the prescribed conduct of the





- system. In this case, the developer should be able to have a free and voluntary choice to act. The second condition is the agent should be aware that his/her own conduct may be harmful.
- **Risk/Negligence-based approaches**. This type of responsibility determines whether the operators are legally obliged to repair the harm caused due to the lack of duty to care.
- Strict responsibility. The human operator is strictly responsible without proof of fault. This is regardless of whether the operator is directly involved in the conduct or not. The mental status of the operator is also irrelevant in this type of responsibility. Strict responsibility concerns the following types of strict liability:
  - Right-based strict liability: relevant to the violation of legal rights of the damaged. If the harm is caused towards fundamental rights, this type of strict liability is applicable.
  - Outcome-based strict liability: relevant to any outcome that is adverse, regardless of the good or bad intention of the human intervention. Current EU product liability regimes follow this approach.
  - O Activity-based strict liability: the activity of the human operator is relevant, e.g. carrying out dangerous activities. This generally leads to corporate liability in the end, although the perpetrator has a direct connection to the activity.
- Mandatory insurance. Despite the allocation of responsibility, mandatory insurance can be a tool to compensate for the damage. This tool can be used in the case of an adaptive autonomous system, as it is difficult to allocate fault as the system is continuously developing and improving. Without further discussion of who is at fault, compensation can be prioritised with the mandatory insurance policy. The funding can be made from various industry stakeholders.
- Prospective responsibility. This approach is in favour of identifying responsibility derived from
  a specific role and obligation. At each stage of the development of the system, i.e. design,
  development and deployment of the system, ethical concerns and seriousness of the
  commitment should be addressed.
- **Responsible Al/robotics initiatives**. This is the movement that professionals must be self-governing in their own conduct. Corporate social responsibility is at the core of this approach.

The behaviour, risk assessment and oversight of AI-based systems should be part of the legal framework (EC, 2020). Under current applicable legislation, safety assessments for the lifetime of the system are already mandatory for manufacturers to conduct. Hence, manufacturers are required to provide instructions for the use. However, with a self-learning system, it is difficult to assess risks at once as the performance and behaviours of the AI would change constantly by learning and enhancing. This means that adaptive autonomous systems may not fully be covered by the current framework. However, manufacturers are supposed to notify the competent authorities and take action. If applied in aviation, the competent authorities would be a national authority, but also be other authorities depending on domestic law. This leads to the oversight of the government towards autonomous systems as a safeguard. Currently, in aviation, government surveillance is one of the pillars of the State safety program. Although the implementation is therefore not required, it is still in question if the inspectorate is in possession of the expertise in the potential extension of the oversight obligation.

Al is sensitive to data faults and faulty algorithms, and these can cause damage to the users (EC, 2020). It is, however, uncertain whether or not the safety legislation should contain such specific requirements to maintain the quality of the data. It is also difficult to clarify decisions due to the potentially large amount of data used in the decision-making of the self-learning system. Transparency, robustness, and accountability of algorithms should be considered to be included in the Union product





safety legislation. One of the obligations proposed to be imposed is for developers to disclose the design parameters and metadata of datasets in case of accidents. This will, however, have an impact on cybersecurity.

In terms of liability, according to the Commission, the complexity of the value chain makes it hard to determine the liability. While liability concern is not yet fully determined, compensation should always be available if damage is caused by defective products, in this case, AI. If implemented, this will be part of the Product Liability Directive. Who is supposed to prove the fault is still in question. The opacity of the decision-making process and the amount of data to be used makes it complicated to prove the fault of the product. This is currently regulated differently per country. Specific risk profiles are significant in this regard. Strict liability can be applicable, but it is still regulated under national laws, but that does not provide clarity to all the product manufacturers within the EU. The Commission is considering combining the insurance condition to be connected with the strict liability, for cases of damage which cannot be paid by the manufacturer.

The certification procedures are jointly governed by EASA and Member State organisations. Member states can transfer their duties to other Member States, which become fully responsible, but they can also pinpoint EASA as the certifier. Furthermore, third-qualified organisations can be transferred duties and rights of certification instead of either agent. This means that a Member State could theoretically end up with no power over the certification and approval of AI for Aviation in their state. This creates a lack of democratic basis, which may get worse as more functions are delegated to AI and lead to liability problems.

Most rules examined state that applications "must work as intended under all foreseeable operational circumstances", which are also essential to certify the applications themselves. The question then arises: will it ever be possible for an autonomous system to work as intended, always? Case law suggests that it is not the case, alongside AI studies about a lack of foreseeability for autonomous agents (scholars define it as "cognitive uncontainability"). A good method should be able to take account of uncertainty about the future of the system itself and of the environment in which the system operates. So, the challenge for current methods is specifically to be able to deal with uncertainty regarding the level of automation and the changing environment in which advanced automation needs to survive.

The AI Act fails to establish provisions for **Explainable AI** (XAI). It does state that the output of models must be interpretable, but it is tied to notions of transparency. Also, without delving into specificities, we mention that the AI Act cannot support Explainability obligations on producers nor deployers, and if it does, the causality presumptions of the AI Liability Directive Proposal crumbles. Aviation AI is extremely advanced and complex. In the domain, it is widely mentioned that equipment must be used with proficiency by the crew. Lack of suitable Explainability may impair the ability to use it with proficiency. This can especially be problematic for black-box AI systems in safety-critical operations.

#### 4.4 Evaluation of current certification methods

Chapter 3 describes three methods that go into more detail when it comes to providing input to demonstrate that aviation-related technology complies with regulations and standards. These methods are SAE ARP4761, DO-178C/DO-278A and FMEA/FMECA. The subsections below provide the benefits and limitations of these methods for application to automation and AI-powered technology.





#### 4.4.1 SAE ARP4761

ARP4754A and ARP4761 both support new and changed aircraft systems, taking into account the overall aircraft operating environment and functions. The applicability of ARP4754A and ARP4761 is CS-25 (large aeroplanes), but according to [SAE web], they may be applicable to other regulations as well, such as CS-23 (normal, utility, aerobatic and commuter aeroplanes), CS-27 (small rotorcraft), CS-29 (large rotorcraft), CS-E (engines), and CS-P (propeller). There is also attention to the interfaces with the operating environment, e.g., pilot actions, airport operations, and ATM systems. However, regarding pilot actions, the airworthiness regulations (see, e.g. (EASA, 2018), page 711) state that "Quantitative assessments of crew errors are not considered feasible" and that related flight crew and maintenance tasks should be appropriate and reasonable. Reasonable tasks are those for which full credit can be taken because they can realistically be anticipated to be performed correctly when they are required or scheduled. For other risk-reducing actions, however, no credit is taken in an assessment.

ARP4754A and ARP4761 are the main guidance documents used in the certification of civil aircraft. The original ARP4754 and ARP4761 have both been used effectively for decades. EASA has recognised ARP4761 as a related industry standard in AMC CS-25.1309. ARP4754A and ARP4761 have proven themselves in practice, and no alternative standards for the same objective are known. A main benefit of ARP4761 compared to other methods is that it comes with ARP4754A, i.e. a full-scale aircraft development programme.

#### Limitations

- ARP4761 defines a hazard as a potentially unsafe condition resulting from failures, malfunctions, external events, errors, or a combination thereof. The FHA first considers all failures and classifies them with respect to severity (from Catastrophic down to No Safety Affect). Next, the PSSA determines how the failures can lead to functional hazards. Therefore, ARP4761 treats safety as a reliability problem where particular components have failed. Accidents or incidents that may occur in more complex ways due to other types of causes or where no components have failed are not considered. This is a limitation for the assessment of AI-based systems.
- The use of reliability engineering tools, such as FTA and FMEA, leads designers to rely on redundancy and monitoring as the most appropriate or best design solution, while these are not always the most effective to solve hazards like unintended interactions among system components and functions or software problems.
- ARP4761 does not analyse the effects of software, which may or may not include AI. Rather it
  uses the concept of a development assurance level (DAL), which specifies the level of rigour
  that applicants must use to ensure the implementation of the requirements is correct.
  However, it does not ensure that the requirements themselves are correctly reducing the risk
  to acceptable levels. This is a limitation since the safety contribution of software depends on
  the larger system context. It can be safe in one system context and can cause an accident if
  used in another system context.
- Feedback loops and non-linear interactions are not considered. It means that interactions that
  do not progress or develop smoothly from one stage to the next (e.g. sudden changes or
  developing in different directions at the same time) are not considered. Most AI systems are
  intrinsically non-linear.





- Lack of proficient crew performance is not addressed. Crew and other operators are not
  included in the analysis except as mitigators for the physical system component failures, i.e.
  their presence is used to lower the severity classification of the hardware or software failures.
  No additional analysis is included to determine whether there are conditions under which the
  pilot might not be able to perform such a mitigation (e.g. to correct an action of an AI system)
  successfully.
- The primary model used is Fault Trees (FTs). This model is known to have several major limitations:
  - 1. Fault Trees cannot address situations where the stochastic behaviour of the system components (i.e. the state change and variables that characterise it) depends on the state of other components or, in general, on the state of the system.
  - 2. Fault Trees do not address the dynamics of the failure and recovery logic in relation to the time-dependent interactions between system elements, the environment and operator behaviour.
  - 3. Fault Trees do not consider the dynamics of process variables and their potential influence on logical variables (e.g. failed states of the system components and associated rates of transition).
  - 4. Fault Trees do not model human behaviour variability and its potential influence on the logical variables. They only address human performance through a simplistic binary view (correct/erroneous).

In an analysis of the applicability of ARP4761 to UAS, Evans (2006) found the following main limitations:

- ARP4761's criteria of 10<sup>-9</sup> per flight hour are driven by large transport aircraft and are not suited for UAS.
- ARP4761's criteria do not consider UAS aspects such as having no occupants, the remote/autonomous nature of their crew, and (implicit) differences in system arrangements.
   The severity classes need to be redefined, for example, redefine 'Catastrophic' as "UAS uncontrolled flight followed by an uncontrolled crash, potentially leading to fatalities or severe damage on the ground."
- Criteria are required to deal with the effects on the ATM environment, such as effects of hazards on aircrew, on air traffic controllers, on aircraft functional capabilities, on functional capabilities of the ground part of the ATM System, and on the ability to provide safe Air Traffic Management Services.
- Because of the loose and fluid nature of the UAS system boundary, the complex interaction
  with the environment, and the variable nature of how functions are controlled (through
  autonomy), there may be numerous 'exchanged functions' that will be difficult to identify and
  assess, until at least initial UAS system high-level architectures are outlined.
- Extensions to the guidelines and methods are necessary to deal with (in particular) the people, processes and software that characterise complex systems and their interactions with other systems. For example, the zones in Zonal Hazard Analysis and particular Risk Analysis need to be redefined and extended to, e.g. critical navigation elements and datalink.

## Conclusion

ARP4761 has limitations when being applied to advanced automation and AI-powered technology, since these require the ability to study dynamics, the complex interaction with the environment,





feedback loops and non-linear interactions, etc., rather than component failures. The method focuses on functional failures rather than on other hazards. The modelling techniques used (such as fault trees) are not suitable for the analysis of human performance or procedural aspects since they are not sufficiently able to deal with dependencies and dynamics.

A unique element of this approach is that safety objectives on the output, in terms of a maximum allowed level of risk, are traced back to the causes, and the causes of those causes, to ultimately set safety requirements as the maximum probability of failure of the primary causes. This has been an advantage since the manufacturers responsible for the system elements behind the primary causes thus obtain specific requirements for the failure probabilities of those design elements. This feature also has disadvantages since looking back into the causes prohibits the identification of emergent risks, which occur due to interactions between system elements, hence requires looking forwards rather than backwards. More generally, it is more difficult to take account of non-local interdependencies.

#### 4.4.2 DO-178C and DO-278A

DO-178C applies to those aspects of airworthiness certification that pertain to the production of software for airborne systems and equipment used on aircraft or engines. The main outputs of the application of DO-178C are software for airborne use that performs its intended function with a level of confidence in safety that complies with airworthiness requirements and associated documentation and evidence (e.g., software requirements data, software design description, source code, executable object code). Tables are provided that detail the required output, depending on the assurance level.

DO-278A applies to software contained in CNS/ATM systems used in ground or space-based applications shown by a system safety assessment process to affect the safety of aircraft occupants or airframe in its operational environment. The main outputs of the application of DO-278A are software for ATM/CNS use that performs its intended function with a level of confidence in safety that complies with applicable requirements, and the associated evidence. Tables are provided that detail the required output, depending on the assurance level.

Both DO-178C and DO-278A use the concept of assurance levels to deal with uncertainty. The assurance level is determined in a system-level safety assessment and determines the rigour by which compliance is required to be demonstrated and whether this is required to be done with independence. The underlying assumption is that developing the software in line with these assurance levels sufficiently ensures a low error probability. DO-178C and DO-278A have proven themselves in practice, and they are the main guidance documents used in the certification of civil aircraft. No alternative standards for the same objective are known.

A main limitation of the approaches used in DO-178C and DO-278A is that they are focused on the analysis of the software and tend to ignore the world in which they operate. This is especially a problem for Al-based software in increasingly autonomous systems, which have to operate in complex environments, as explained in Section 4.2. This is especially a problem if the environment is changing and the software is responding to changes in the environment. This leads to different behaviour in different situations.





#### 4.4.3 FMEA and FMECA

FMEA is specifically intended for aircraft system development, which usually considers hardware and software. Following (SAE ARP4761), the method is integrated in an overall safety assessment process, usually providing the input for a Fault Tree Analysis. For software, related dedicated methods exist (e.g., Software Failure Modes and Effects Analysis, SFMEA). Unlike Hardware FMEA, which analyses both the severity and likelihood of the failure, an SFMEA usually analyses only the severity of the failure mode.

FMEA and FMECA are widely considered the main aircraft system reliability methods. Their advantages include:

- The methods are systematic and comprehensive. In particular, information on single failure modes and their effects are well-structured, and the methods directly link the system safety process to expected reliability objectives.
- The methods can provide essential input to a Fault Tree Analysis or a similar numerical method. This can be done in a way that includes analysis of the detection of component failures and the identification of safety-critical equipment where a single failure would be critical for the system.
- The methods are supported by standardised forms.
- The methods are widely used and well-understood and can be performed by a single analyst.

FMEA and FMECA are also widely adopted in other industries (e.g., defence, the automotive industry, and sea transport). FMECA is considered to be well acceptable for the safety assessment of technical equipment.

### Limitations

- The methods focus on single-point failures of technical systems. They do not consider other hazards, e.g., associated with normal operations, and are not good at identifying hazards caused by humans or the environment. FMEA and FMECA are specifically not well suited for analysis of human factors in aviation safety, while in aviation, most accidents have a significant human contribution. Also, procedures and processes and the effects of human performance on the functioning of systems are not considered. Accordingly, they are useful for safety-critical mechanical and electrical equipment but should not be the only hazard identification method.
- The methods are not very suitable for complex systems, especially systems that involve dynamic interactions between failures. For this, additional techniques are required. The methods are static, there are no temporal aspects.
- A comprehensive FMEA or FMECA may be very time-consuming and expensive. This
  specifically holds true for applications to larger systems, for which the use of some form of
  computer assistance is nearly always necessary. Further factors are that not all component
  failure modes affect safety on the same level and that the methods may be applied at a level
  too deep. Duplication of effort and significant amounts of redundant documentation are not
  uncommon.
- The methods sometimes lead to inconsistencies, ambiguities, or difficulties in understanding.
   One reason for this is that there are sometimes so many failures that they are described in a





very brief way. Also, the methods do not provide a systematic approach for identifying failure modes or for determining their effects, and no real means for discriminating between alternate courses of improvement or mitigation. Effects that arise from multiple causes are generally not grouped. Information overload from the large but scattered data sometimes obscures the relations in an FMEA or FMECA. Finally, the benefit of the methods depends significantly on the experience of the analyst.

- The methods require a hierarchical system drawing as the basis for the analysis, which the analyst usually has to develop before the analysis can start.
- The methods usually do not account for uncertainties in the input data.

### 4.5 Conclusion

The certification of AI concerns the legal recognition by a certification authority that products, services, persons or organisations incorporating AI-based systems comply with requirements. Safety assessment is a key element of a certification process that can support ensuring human well-being, values and ethical considerations as core principles of human-centred AI, as discussed in Section 4.1.

In the development of AI-supported systems and operations, it is expected that there will be a shift in the level of authority towards increasingly autonomous systems with decreasing in-the-loop roles of human operators. This implies that a part of the intelligent contributions of human operators are taken over by contributions of AI-based systems and that the roles and responsibilities of human operators change. Clearly, such a shift has considerable legal implications for the allocation of responsibility and liability for product and service developers versus the organisations and persons providing services and using the products, as discussed in Section 4.3.

Safety is not an intrinsic property of an Al-based system. The safety impact of a particular Al component in a system depends on the dynamic interactions with other systems, humans working with operational procedures, and contextual conditions. Traditional safety assessment approaches like fault trees and failure mode and effect analysis have their origins in assurance schemes for physical components, which may fail/break and for which statistical quality control approaches can be applied. These approaches are known to have limitations for assessing and controlling the safety impact of software, Al-based systems, and human factors, for better or worse (see Sections 4.2 and 4.4). While these limitations also apply to systems and operations without Al components, their implications may be aggravated due to the new aspects brought by machine learning and due to the shift in contributions of humans and Al-based systems in the operations.





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# 6 List of acronyms

Table 7. List of acronyms

Acronym	Description
AI	Artificial Intelligence
ADO	Aircraft Design Organization
AMS	Apron Management Service
AMC	Acceptable Means of Compliance
ANS	Air Navigation Service
ANSP	Air Navigation Service Provider
AOC	Air Operator Certificate
ARFFS	Aerodrome Rescue and Fire Fighting Services
ARP	Aerospace Recommended Practice
ATCO	Air Traffic Control Officer
ATM	Air Traffic Management
ATPL	Air Transport Pilot License
ATS	Air Traffic Services
BFCL	Balloon Flight Crew Licensing
BR	Basic Regulation
BVLOS	Beyond Visual Line Of Sight
CAT	Commercial Air Transport
СВ	Certification Basis
CCA	Common Cause Analysis
CoA	Certificate of Airworthiness
CIS	Common Information Service
CPL	Commercial Pilot License
CRM	Crew Resource Management
DAL	Development Assurance Level
DOA	Design Organization Approval
DR	Delegated Regulation
EASA	European Union Aviation Safety Agency



EATMN	European Air Traffic Management Network
EC	European Commission
EGNOS	European Geostationary Navigation Overlay Service
ETPL	Experimental Test Pilot License
EU	European Union
EUROCAE	European Organization for Civil Aviation Equipment
EUSPA	European Union Agency for the Space Programme
FDAL	Function Development Assurance Level
FHA	Functional Hazard Assessment
FMEA	Failure Modes and Effects Analysis
FMECA	Failure Modes, Effects and Criticality Analysis
FMES	Failure Modes and Effect Summary
FTA	Fault Tree Analysis
GNSS	Global Navigation Satellite System
HAT	Human-Al Teaming
HCAI	Human-Centred Al
HMI	Human Machine Interaction
IAS	Increasingly Autonomous System
IBIS	ICAO Bird strike Information System
ICAO	International Civil Air Organization
IDAL	Item Development Assurance Level
IFR	Instrument Flight Rules
IMA	Integrated Modular Avionics
IR	Implementing Regulation
LNAV	Lateral Navigation
LNAV/VNAV	Lateral Navigation/Vertical Navigation
LPV	Localizer Performance with Vertical guidance
LUC	Light UAS Operator Certificate
MEL	Minimum Equipment List
MOPS	Minimum Operating Performance Standards
МТОМ	Maximum Take-Off Mass





MTOW	Maximum Take Off Weight
OJT	On the Job Training
PBN	Performance-Based Navigation
PBN	Performance-Based Navigation
PPL	Private Pilot Licence
PSAC	Plan for Software Aspects of Certification
PSSA	Preliminary System Safety Assessment
QMS	Quality Management System
RF	Radius to Fix
RTC	Restricted Type Certificate
SAE	Society of Automotive Engineers
SERA	Standardised European Rules of the Air
SFCL	Sailplane Flight Crew Licensing
SFMEA	Software Failure Modes and Effects Analysis
SMS	Safety Management System
SSA	System Safety Assessment
STC	Supplement Type Certificate
TC	Type Certificate
TCDS	Type Certificate Data Sheet
UAS	Unmanned Aircraft System
UAV	Unmanned Aerial Vehicle
VLOS	Visual Line of Sight
VMC	Visual Meteorological Conditions
VFR	Visual Flight Rules
XAI	Explainable AI

