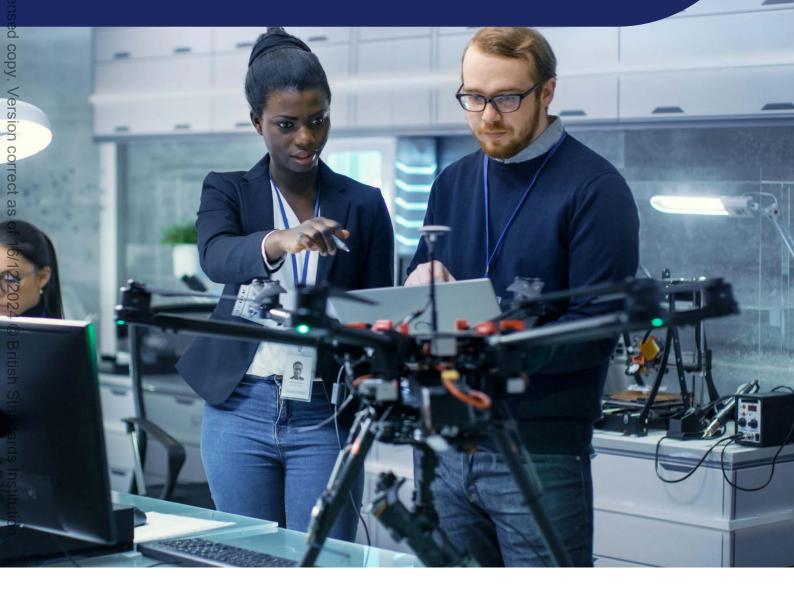
# PAS 1905:2024

Future flight systems – Regulatory principles, management systems and life cycle assurance processes – Guide



This report was commissioned by the Future Flight Challenge





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# Foreword

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## **Relationship with other publications**

This BSI Flex is part of the Future Flight programme, which includes the following standards:

- BSI Flex 1903 v.2.0:2024-06, Future flight systems Vocabulary;
- BSI Flex 1904 v.1.0:2024-09, Operational design domain taxonomy for a future flight aircraft system – Specification;
- BSI Flex 1906 v1.0, Future flight systems Acceptable means of compliance to Specific Operation Risk Assessment (SORA) for uncrewed aircraft systems (UAS) – Guide<sup>1)</sup>

<sup>&</sup>lt;sup>1)</sup> In preparation.

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## Use of this document

As a guide, this PAS takes the form of guidance and advisory recommendations. It is not to be quoted as if it were a specification or a code of practice.

### **Presentational conventions**

The guidance in this document is presented in roman (i.e. upright) type. Any recommendations are expressed in sentences in which the principal auxiliary verb is "should".

Additional commentary, explanation and general informative material is presented in smaller italic type.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. "organization" rather than "organisation").

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#### Compliance with a PAS cannot confer immunity from legal obligations.

In particular, attention is drawn to the following specific Acts and regulations:

- a) Convention on International Civil Aviation [1], including its annexes;
- b) UK Acts and regulations pertinent to unmanned/uncrewed aircraft systems (UAS) and their operation, including:
  - 1) Civil Aviation Act 1982 [2];
  - 2) Air Navigation (Amendment) Order 2022 [3];
  - 3) Standardised Rules of the Air UK Reg. (EU) 923/2012 [4];
  - 4) Basic Regulation (implementing rules and UK CAA AMC GM CS) UK Reg. (EU) 2018/1139 [5];
  - 5) UAS Delegated Regulation UK Reg. (EU) 2019/945 [6];
  - 6) UAS Implementing Regulation UK Reg. (EU) 2019/947 [7];

- 7) UK General Data Protection Regulation (UK GDPR) Regulation (EU) 2016/679 [8]; and
- 8) Data Protection Act 2018 [9].

**NOTE 1** The UK Civil Aviation Authority (CAA) provides additional guidance on these regulations and associated processes in various Civil Aviation Publications (CAPs).

- c) European Union Aviation Safety Agency (EASA) regulations pertinent to UAS and their operation, including:
  - 1) Basic Regulation Reg. (EU) 2018/1139 [10];
  - 2) UAS Delegated Regulation Reg. (EU) 2019/945 [11];
  - 3) UAS Implementing Regulation Reg. (EU) 2019/947 [12];
  - 4) Initial airworthiness Reg. (EU) 748/2012 [13];
  - 5) Continuing airworthiness Reg. (EU) 1321/2014 [14];
  - Requirements for the management of information security risks, Implementing Regulation Reg. (EU) 2023/203 [15];
  - Requirements for manned aviation operating in the U-space, Implementing Regulation Reg. (EU) 2021/666 [16];
  - 8) Requirements for ATM/ANS and other traffic management functions in the U-space, Implementing Regulation – Reg. (EU) 2021/665 [17]; and
  - 9) Regulatory framework for the U-space, Implementing Regulation Reg. (EU) 2021/664 [18].

**NOTE 2** The EASA regulations are provided to support those who are considering operating within member states of the European Union.

# Introduction

This PAS has been developed as part of the Future Flight Standards Programme, in which BSI is working with Future Flight members and a wider ecosystem of industry stakeholders to prioritize and progress areas for standardization to support the safe development and trialling of innovative aircraft and drones, as well as infrastructure and operations.

The aim of this PAS is to provide a general overview of the aviation regulatory management and assurance systems used in this sector, so that when it comes to regulation and other future standards, all those involved have a common understanding of them and of their objectives.

The context of the information is for potential operations within the regulatory regime of the United Kingdom (UK). It is also broadly applicable to UK overseas territories that maintain their own regulatory frameworks based on UK systems.

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## 1 Scope

This PAS provides guidance on key aviation regulatory principles, management systems and assurance system frameworks that underpin the aviation product life cycle, support safe routine operations within the shared airspace, and which are essential for successful scaling and industrialization.

As well as providing an overview of the aviation systems, this PAS provides signposts to existing regulations and standards, highlighting the core information applicable to the wide range of emerging types of aircraft and their systems as covered within the scope of the Future Flight Challenge, including unmanned/uncrewed aircraft systems (UAS), remotely piloted aircraft systems (RPAS) and advanced air mobility (AAM) aircraft.

This PAS provides practical guidance and, where practicable, basic examples, including appropriate, generic use cases.

This PAS does not include:

- examples of compliance documents;
- major indexes of material;
- locations of existing regulations and standards; or
- recreational use cases.

This PAS is of use to new entrants who are developing, deploying, operating or supporting future flight systems, including supply chain partners, as well as existing organizations considering to scale within the sector.

It might also be of interest to wider stakeholder communities, including investment and insurance organizations looking to assess risk management aspects, local authorities and business opportunity planners, as well as communities across society that have concerns and an interest in how these new aviation sectors are regulated.

## **2** Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions, or limits the application, of this document. For dated references, only the edition cited applies.<sup>2)</sup> For undated references, the latest edition of the referenced document (including any amendments) applies.

BSI Flex 1903 v2.0:2024-06, Future flight systems - Vocabulary

<sup>&</sup>lt;sup>2)</sup> Documents that are referred to solely in an informative manner are listed in the Bibliography.

## 3 Terms, definitions and abbreviated terms

### 3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in BSI Flex 1903 v2.0:2024-06 apply.

## **3.2 Abbreviated terms**

For the purposes of this document, the following abbreviated terms apply.

AAM	advanced air mobility
AMC	acceptable means of compliance
AOC	air operator certificate
BSI	British Standards Institution
BVLOS	beyond visual line of sight
CAA	Civil Aviation Authority
CAMO	Continuing airworthiness management organization
CAP	Civil Aviation Publication
CONOPS	concept of operations
DOA	design organization approval
EASA	European Union Aviation Safety Agency
EUROCAE	European Organisation for Civil Aviation Equipment
eVTOL	electric vertical take-off and landing
GM	guidance material
ICAO	International Civil Aviation Organization
ISO	International Organization for Standardization
JARUS	Joint Authorities for Rulemaking of Unmanned Systems
NAAs	national aviation authorities
OA	operational authorization
OSC	operating safety case
PACT	pilot authorization and control of tasks
POA	production organization approval
QMS	quality management system
RPAS	remotely piloted aircraft systems
SAE	Society of Automotive Engineers
SMS	safety management system
SORA	Specific Operations Risk Assessment
TLOS	target level of safety
TSO	technical standards organization
UAS	unmanned/uncrewed aircraft systems
UTM	unmanned/uncrewed aircraft systems traffic management
VLOS	visual line of sight

## **4 Key principles**

## 4.1 General

#### 4.1.1 Aviation regulatory system

The UK aviation regulatory system, which is aligned with the Convention on International Civil Aviation (Chicago Convention) [1], provides a national framework for the design, manufacture, operation and maintenance of all types of aircraft along with associated services, including aerodromes, air traffic control and accident investigation.

Within this framework, an operator-centric approach is typically used. This means that the operator, as a recognized legal entity, is subject to the legal framework of the country in which the company is registered, and can therefore be held responsible under that state's oversight, governance and enforcement processes.

In terms of regulation, the level of governance is applied in a proportionate manner that looks to balance operational viability and safety with the process and information needs of the compliance demonstration, as well as the demands placed on the regulator or enforcement agencies. A key criterion for the regulations and their application is safety – and the management of risks that could result in the desired safety outcomes not being achieved. This means the highest degree of regulatory process and governance is applied to operations that are likely to result in the most significant outcomes, and less so for those that have more limited effects. This might be described as a proportionate, risk-based approach.

Initial compliance with the regulations and requirements serves as the entry criteria to obtain or maintain an approval, authorization or other form of certificate or licence. With continued clear achievement of compliance providing confidence in an organization's capabilities, the concept of performance-based oversight can be used by the regulator to enable flexibility in its oversight regimes. Within governance frameworks, operating entities are typically required to define their organizational structures, responsible and accountable persons, and the mechanisms, systems and processes by which the organization functions to address all necessary considerations. This includes basic business procedures and specific aspects of safety management, such as the competency of personnel, risk identification, outcome assessment and management/mitigation measures.

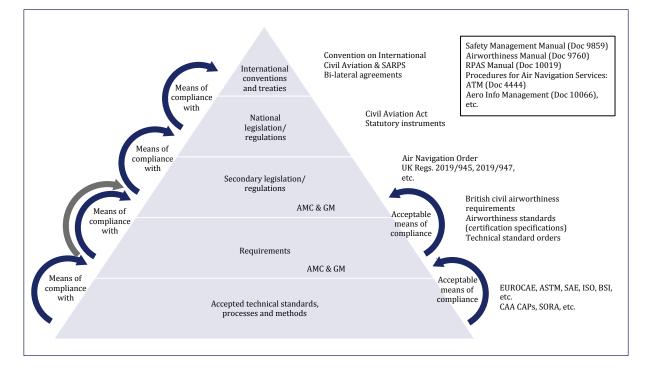
These are typically addressed in one or more documents (depending on complexity), with the top level typically referred to as an operations (or operating) manual. All other supporting processes and procedures are included either within the one document, or by simple reference to other supporting documents (in hard copy and/or electronic formats).

**NOTE** In UAS regulatory material, the term "operations manual" is generally used, whereas "organization handbook" and "organization exposition" are typically used in wider aviation organization approval regulations.

#### 4.1.2 Regulation, requirements, guidance material and acceptable means of compliance

The aviation regulatory framework, like most legislative systems, is a multi-layered system that at its highest level sets key principles, which are expanded through increasing levels of detail as the specific topics are developed into usable material.

The main elements might also have associated material that explains the established acceptable means of compliance (AMC), along with associated guidance material (GM). However, in order to not constrain innovation, AMC is not the only means to do this, and organizations can propose alternatives. The general GM typically explains the background and detailed intent of the requirements or regulations such that a full and proper understanding of the purpose is known, again facilitating innovation and new approaches to the specific subject. A simple graphical representation of the respective layers is shown in Figure 1.



#### Figure 1 – Pyramid of regulations, requirements and standards

#### 4.1.3 Certification, approval and licensing

The aviation system described in the Convention on International Civil Aviation [1] and annexes is a complex framework with many independent yet interconnected parts. In order to function efficiently, a number of common principles are used.

Those that relate to individuals and their competency are typically addressed under the term "licensing", which facilitates individuals' ability to manage and demonstrate their capability.

Those aspects that relate more to organizations and recognized capability are typically addressed using terms that reflect an approval, permission or authorization that is reflected in issuance of a certificate.

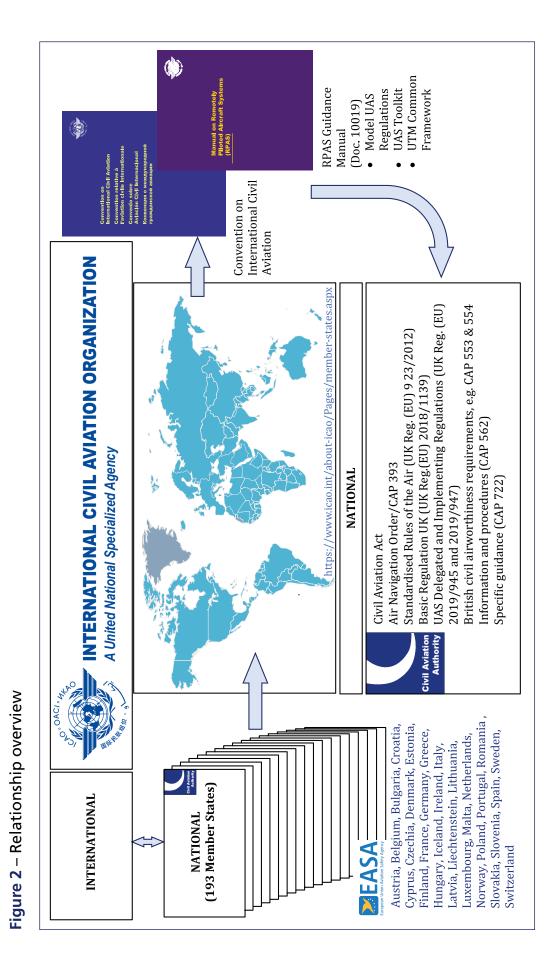
Those aspects that relate more to products or services provided by these organizations are typically addressed using terms that reflect a process of certification resulting in an "approval", which is also reflected in issuance of a certificate.

## 4.2 Regulatory framework overview

#### 4.2.1 General

Aviation is a global business in which common high safety standards are a prerequisite foundation to enable all participating countries to have confidence in the aircraft that could fly within their territorial airspace. This is facilitated by the Convention on International Civil Aviation [1], developed, managed and maintained by the International Civil Aviation Organization (ICAO).

An overview of the relationship between the ICAO, and UK and wider member states, including EASA member states, and the CAA is given in Figure 2.



#### 4.2.2 International overview

The Convention on International Civil Aviation [1] defines the aviation framework that facilitates cross-border operations, including operations within another country's sovereign territory. It recognizes the principle that each sovereign state/country retains the right to manage and govern its territorial areas and communities as it deems appropriate, but also recognizes that a viable aviation system needs to operate across many countries and thus requires a consistent approach.

The convention [1] currently has 19 annexes [referred to as standards and recommended practices (SARPs)] that cover the principal elements of the aviation system, supported by a range of other manuals, GM and supportive documents that together describe the globally agreed aviation systems, processes and methods.

Each member state concurs with the described systems (unless formally defining a difference), and implements them into its national legislative and procedural frameworks, thus enabling a globally harmonized regulatory approach for international aviation.

This harmonized approach provides the mechanisms for mutual recognition of each member state's safety assurance and operating practices, and enables the benefits of operations between, and within, the airspace of each country with a minimum of process friction.

Under this framework and the associated governing assessment/audit processes, each state is responsible for aircraft on its state registry, such that they conform to the defined standards, and are sufficiently airworthy, maintained and operated by appropriately competent persons in accordance with applicable standards and practices. In meeting these obligations, the flight operation is eligible to make use of the benefits of the convention [1], including flying over and within another country's airspace without prior checks, investigation or specific permission.

## **NOTE 1** Aircraft registration provides individual aircraft with a unique reference that includes the identification of the country (state) that is responsible for its regulatory oversight.

## **NOTE 2** Applicable national standards and practices might not always address compliance with international regulations, limiting operations to within that country.

The regulations pertinent to AAM aircraft, typically intended to carry passengers or cargo, such as electric vertical take-off and landing (eVTOL) aircraft, are under review and development internationally and by national aviation authorities (NAAs). Principally, these aircraft are perceived to be similar in intent to current transport aircraft, which means the current initial airworthiness approval (type certification/validation) requirements and processes are applicable. These processes and procedures<sup>3)</sup> fully enable innovation of new technologies and different approaches, and include the definition of new or revised requirements. Such new or amended requirements might be project specific, e.g. documented within Certification Review Items, or be more generic in nature and published as initial new requirements, e.g. EASA Special Conditions, such as SC-VTOL or SC E-19 – Electric/Hybrid Propulsion System. UK CAA certification of eVTOL aircraft is described in CAP 2537 [19].

The initial regulations for international RPAS operations under the benefits of the convention [1] have been revised and published within Annex 1, Annex 6 (Part 4) and Annex 8. Other regulations, such as air traffic services considerations, are in development. Other annexes and documents are able to be used as is, e.g. Annex 7 (Aircraft nationality and registration marks) and Annex 13 (Aircraft accident and incident investigation), or will be amended as further insight is gained from operating experience.

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<sup>&</sup>lt;sup>3)</sup> Type certification and validation processes and procedures are the responsibility of each aviation authority. Those published by EASA, for airworthiness of type design, might be a useful reference – see https://www.easa.europa.eu/en/document-library/certification-procedures/airworthiness-type-design.

**NOTE 3** In the UK, accident investigation is undertaken by the Air Accident Investigation Branch for the purpose of understanding and dissemination of safety learning. Air accident investigation methods and processes, as well as the results of investigations, are given on its website at https://www.gov.uk/government/organisations/air-accidents-investigation-branch.

ICAO undertakes activities to amend SARPS or develop new material with the support of a wide range of subject matter experts from around the world, who work in topic panels, e.g. RPAS Panel, Airworthiness Panel, thus acting to provide a globally harmonized regulatory framework. For topics that might require some initial work in order to understand a subject and determine the scope, detail or which existing panel(s) might be assigned potential work, ICAO might form a study group consisting of similar subject experts, e.g. the AAM Study Group. This working group process is also the basis by which technical standards organizations (TSOs), e.g. European Organisation for Civil Aviation Equipment (EUROCAE), ASTM International, Society of Automotive Engineers (SAE), International Organization for Standardization (ISO), BSI, and other collaborative organizations, such as Joint Authorities for Rulemaking of Unmanned Systems (JARUS), undertake the development of a wide range of supportive material.

ICAO has recently been made responsible for coordinating and developing global SARPs, procedures and GM for uncrewed aviation with the goal of facilitating the safe, secure and efficient integration of these aircraft into the global aviation system. Work is under way to develop and provide this material to member states in support of their national regulatory framework evolution, with the overall aim of helping them to implement this material, as far as is practicable, with limited differences that might be encountered by operators from other countries. The material includes:

- Model UAS Regulations<sup>4</sup>;
- UAS Toolkit<sup>5)</sup>; and
- Unmanned aircraft systems traffic management (UTM): A common framework with core principles for global harmonization [20].

Recently, ICAO has been tasked to consider the regulatory systems for the wide-ranging scope of AAM. This encompasses ongoing work around UAS and UTM, previously undertaken by the UAS Advisory Group, to the broad and diverse new and novel types of aircraft, e.g. eVTOL aircraft, and the different types of operating models being proposed in both urban environments and regional networks.

The Convention on International Civil Aviation [1] might not be considered necessary for some national operations, provided these do not compromise any international operation taking place. Hence, each state is able to develop its own regulations and processes to suit its particular circumstances. However, the international standards and recommended practices, as well as the globally collaborated and developed GM from ICAO, can be utilized as the basis for these national regulations and as such contribute to common approaches and, as far as practicable, harmonize the regulatory aspects.

The degree of use and adaptation of the ICAO material, or development of alternate processes, remains the decision of the (sovereign) member state. This is an essential factor in enabling local aspects to be considered, including how innovation is managed.

Alternative arrangements have been developed between specific states to provide similar confidences of safe operation. These are typically referred to as bi-lateral agreements and cover as little or as much as the two states wish to collaborate on. Hence, these might also facilitate broader collaboration and harmonization between states with a clear need to facilitate their operational industry.

<sup>&</sup>lt;sup>4)</sup> Available at https://www.icao.int/safety/UA/Pages/ICAO-Model-UAS-Regulations.aspx.

<sup>&</sup>lt;sup>5)</sup> Available at https://www.icao.int/safety/UA/UASToolkit/Pages/default.aspx.

#### 4.2.3 National overview

In the UK, the obligations and wider civil aviation regulatory framework is addressed within a range of statutory instruments and supporting documents. These address various aspects, including safety, airspace constructs and consumer protection.

This framework consists of several layers, as shown in Figure 1. The second and third layers refer to national and secondary legislation, which are the responsibility of the government, supported by the Department for Transport and technical expertise from the CAA.

Requirements are in the next layer, which refer to means of compliance with the regulations. These are often technically or procedurally focused and are typically developed by the Department for Transport and the CAA, and published by government or directly by the CAA.

The final layer consists of detailed standards and methods that support compliance with the defined requirements. These are typically developed and published by TSOs such as BSI, with input from interested parties from government, aviation authorities and industry subject matter experts.

The UK framework is best understood by referring to the officially published material from the CAA, which is available at https://regulatorylibrary.caa.co.uk/home/Content/ARL\_Home\_Page.htm.

The CAA website also provides considerable guidance on regulations, methods of showing compliance with them, and the associated processes and methods to be followed – see www.caa.co.uk/drones and https://www.caa.co.uk/our-work/innovation/advanced-air-mobility-challenge/.

For UAS operations, the key information in UAS operations in UK airspace – Guidance (CAP 722) [21], including associated annexes, describes an operation-centric, proportionate, risk-based approach. The approach used is similar to that used for other sectors of aviation and also aligns with the wider international approach being developed, including that developed by EASA and used across EASA member state NAAs.

#### 4.2.4 UAS regulation key principles

#### 4.2.4.1 General

The key UAS regulatory approach addresses the concepts of "safe to fly" and "safely flown".

"Safe to fly" considers aspects associated with the flightworthiness and technical capability of the UAS to perform as intended. "Safely flown" considers aspects associated with the adequately safe operation of intended flights, including the organization, its processes and procedures, and competency of personnel.

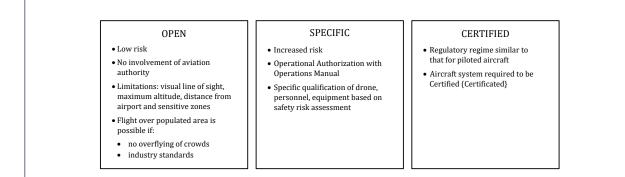
Both "safe to fly" and "safely flown" are evaluated using three criteria:

- operating organization (or individual) the processes and methods to identify and manage risk to achieve safe operation;
- competency how the required skills and knowledge are established and maintained relevant to what is being done; and
- technical understanding of the aircraft system in terms of its capability, performance and limitations, including applicable maintenance regime and actions, so that it is fit for its intended use.

Underpinning each of these is the overarching consideration of safety risk and how potential problems, whether due to technical failures or unexpected external issues, are identified and managed and, where this does not remove or sufficiently limit the potential harm, how harm can be mitigated.

The UAS regulation structure uses a proportionate risk-based approach to separate the applicable regulations into three categories that relate to different levels of safety risk or potential to cause harm. These categories are defined as open, specific and certified, and are outlined in Figure 3.

#### Figure 3 – UAS risk-based framework



#### 4.2.4.2 Open category

UAS operations that pose little risk of harm to others (low risk) are subject to an appropriately simple regulatory system. The potential risk is not ignored, but the mitigations for an adequate degree of safety are defined within the regulatory approach. To be achievable, this means reliance is placed on basic knowledge, skills and the ability to adhere to the simple-to-understand rules and limitations.

Open category operations are limited to the use of UASs that are flown within the direct visual line of sight (VLOS) of the operator and have a mass of up to 25 kg.

#### NOTE More information on open category operations is given in CAP 2012 [22].

This VLOS element is an important aspect of the mitigation considerations, as it underpins the principle that the operator is able to see potential safety concerns and discharge their responsibility to take reasonable actions to prevent harm.

Within this category, typical considerations around safe operation or potential concerns of the general public are described in the CAA drone information<sup>6)</sup>, including possible restrictions set by other statutory bodies, such as local authorities, and respect for people and their privacy. The CAA and police work together to monitor adherence to these rules and behaviours.

#### 4.2.4.3 Specific category

UAS operations that pose the potential for greater harm (higher safety risk), but which is considered to be lower than that posed by piloted aircraft, are addressed within the specific category.

Within this broad category, the UAS operation is required to be authorized by the aviation authority. This approval process requires the operator to substantiate how they are able to identify, manage and mitigate the potential safety risks that could occur. This is typically addressed via the use of documented processes and procedures within an operating manual, including:

a) descriptions of the organization, such as:

- 1) key personnel and their roles and responsibilities;
- competency, skills and knowledge of personnel (showing an understanding of their responsibilities and the ability to discharge them);
- 3) training, including recurrency, to maintain or enhance competency; and
- 4) business processes, procedures etc. for undertaking UAS operations;

<sup>&</sup>lt;sup>6)</sup> For more details, see https://www.caa.co.uk/drones/.

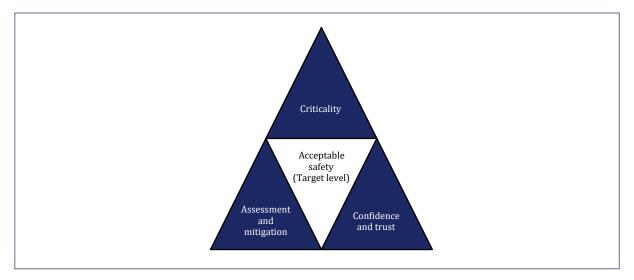
- b) descriptions of UAS equipment and its technical and performance capabilities; and
- c) risk assessment and management method [e.g. operating safety case (OSC)] commensurate with the operations to be undertaken, clearly addressing how potential safety issues are to be managed or mitigated.

These elements align with the piloted aircraft elements that are needed for operations, e.g. the operator governance aspects, the aircraft capability and flightworthiness, and the competency of the operational personnel.

Depending on the degree and robustness of information provided in the operating manual, the authorization process can enable an individual specific operation or a range of operations. As shown in Figure 4, this scope (and associated limitations and conditions) is dependent upon:

- the level of safety criticality of the operations;
- the robustness of the safety arguments and mitigations from the preventative aspects (prior to a
  problem) to the management of issues if a problem occurs; and
- confidence and trust in the organization being able to apply safety management controls effectively.

#### Figure 4 – Factors in safety assurance



Typical UAS operations within this category include:

- those that require flying close to persons or property, thereby reducing the time to be able to deal with problems if they arise;
- the use of larger mass aircraft; and
- operating beyond visual line of sight (BVLOS) of the operator/pilot and thus placing reliance on a range of technical solutions to be able to identify and manage the potential hazards that could compromise safe flight, such as obstacles, other aircraft or even unforeseen conditions that exceed the capability of the aircraft.

**NOTE** BVLOS need not be of great distance, only that the ability to discharge responsibility for safety cannot be achieved through direct VLOS, e.g. if the aircraft is obscured by a building or other obstacle. One approach to deal with this, and remain within the scope of VLOS, is via the use of flight observers who can directly report and assist the responsible operator/pilot, since the key principle of responsibility remains due to direct observation and action to address potential safety issues.

#### 4.2.4.4 Certified (certificated) category

UAS operations that are considered to be of comparable safety risk to that of traditional piloted aircraft are required to be treated in a similar way and hence the aircraft system is required to be certified (certificated). As such, these aircraft and their operation are approved using similar processes, procedures, requirements and standards that apply to a comparable/equivalent piloted aircraft.

**NOTE 1** Further information on EASA's certification procedures is available at https://www.easa.europa. eu/en/document-library/certification-procedures/airworthiness-type-design.

Given the key functional differences between piloted aircraft and UAS, and how they operate, there might not be a clearly comparable/equivalent aircraft and risk view. The certification requirements for piloted aircraft, as per the proportionate risk-based approach, are defined using criteria such as:

- the intended use, e.g. recreational, personal or commercial transport of goods/people;
- possible number of occupants;
- aircraft mass; and
- technical complexity.

These provide a view of risk factors such as likely frequency of operation and locations, the difficulty and challenges of managing/maintaining and assuring technical systems, and the potential severity of any undesirable event and the societal concerns around this.

The existing certification requirements address a wide range of aircraft, including balloons, very light/ sport aircraft, general aviation and high-performance business jets, rotorcraft and large complex cargo and passenger aircraft. As such, there is likely to be a comparable type of aircraft and operational model to act as a reference point to develop a more specific set of requirements within the approval process that suit the individual case.

**NOTE 2** The UK regulations relating to the certified category are still in development. Until unique UAS regulations are available, the principles set out in the relevant manned aviation regulations for airworthiness, operations and licensing are to be used as the basis for regulating the certified category [5].

#### 4.2.4.5 General operating considerations

The other aspect within this framework that needs to be taken into account is the common resource that is the airspace, its structure and organization, and how aircraft operations need to work within them.

The international framework describes the airspace within a volume classification schema, e.g. class A to class G, which principally sets out the rules (visual or instrument flight rules) and the aircraft equipment that are needed to access that class of airspace and specific limitations associated with each class. The rules and equipment also define the wider capability for specific competency (licensing) requirements. A visualization of the airspace overview is available from NATS (National Air Traffic Services) at https://i0.wp.com/www.nats.aero/wp-content/uploads/2022/05/NATS-ATS-AE-Diagram.png?resize=768%2C580&ssl=1.

This airspace rule and classification schema has been derived for traditional crewed aircraft, hence does not fully detail the considerations for UAS that can operate at very low levels. Whilst much work is in progress to assess what changes might be needed, there is further guidance for UAS in the CAA's *Drone and Model Aircraft Code* (CAP 2320) [23], which is intended predominantly for UAS operations that fit within the open category.

For UAS operations within the specific and certified categories, the risk/safety management approach is required to be described through the OSC, in accordance CAP 722A [24], or UK Reg. (EU) 2019/947, Article 11 Operational Risk Assessment (ORA) [7].

Where the airspace constraints of the *Drone and Model Aircraft Code* [23] are unsuitable for the operating purpose and the limits are therefore within the wider airspace construct, it is necessary to define alternate parameters or approaches and substantiate how these can achieve a suitable level of safety risk. This might include proposing alternate methods and mitigations to those typically identified, such as the use of suitably robust flight-limiting systems, conspicuity methods and/or UTM services. A key consideration is understanding of the safety implications of the proposed operation, and any disruption or difficulty on other airspace users and third parties, and working so that these can be adequately addressed within the relevant risk assessment and safety management processes.

Within this approach, flight trials can provide a safe way of testing that the proposed mitigations and procedures work as intended. As trials, these are limited duration operations conducted in safe environments and are an important part of gathering evidence to support the transition to routine operations.

These safety case arguments need to provide a reasonable level of confidence that the independent assessor in the CAA can accept, which includes consideration of their experience of the operator from any activity undertaken within a performance-based oversight programme.

#### 4.2.5 European overview

Prior to the European Union (Withdrawal Agreement) Act 2018 [25] and the Exiting the European Union Civil Aviation – The Unmanned Aircraft (Amendment) (EU Exit) Regulations 2020 [26], the UK was a member state and contributor to EASA, including in the development and use of the common regulations. Hence, much of the UK regulatory material has a common source to that from EASA and used by other European member states.

An understanding of this historical context, whilst recognizing the potential deviations made by the UK since then, provides a mechanism for operators to address what might be required if they wish to undertake operations in European member states.

It is also worth understanding the particular relationship between EASA and NAAs.

EASA was empowered in September 2023 to represent, with appropriate legal authority, various aspects of EU member states' aviation-related obligations and responsibilities [15]. The principal responsibilities are defined in EASA Basic Regulation – Regulation (EU) 2018/1139 [10] and provide for a high and uniform level of safety and environmental protection within proportionate, risk-based rules.

EASA member states continue to hold responsibility for what has not been transferred to EASA, which means that within the EU there is a sharing of responsibilities between EASA and NAAs. This typically reflects EASA undertaking common regulations development and aircraft type certification, including associated organization approvals. The NAAs maintain responsibility for those aspects typically related to operations, including certificates of airworthiness, operating certificates/authorizations and associated aspects such as registration.

The NAAs also remain responsible for what is not covered by the EASA Basic Regulation, such as all aspects of aircraft and operations for military, customs, police, search and rescue, firefighting, border control, coastguard or similar, including where military services provide civil capability, e.g. use of aerodromes, air traffic management (ATM)/air navigation services systems.

#### 4.2.6 EASA UAS regulatory framework

EASA has developed a regulatory framework which covers the UAS and their respective operation ([11], [12]), and which relate to UK regulations ([6], [7]). EASA has defined a range of supportive material for UAS risk assessment, including the Specific Operations Risk Assessment (SORA)<sup>7)</sup>, which is based on the JARUS methodology. EASA has also defined an airspace construct – the U-space – that could facilitate their accommodation and eventual integration into the airspace, including U-space traffic management services. ([17], [18]). However, these have not been adopted by the UK.

#### 4.2.7 Regulation and technical standards development

International, EASA and national regulations are under a continuous evolutionary process to adapt from the lessons of in-service events, as well as to be able to address innovation and the development of new technologies, methods and approaches.

ICAO, EASA and NAAs can, therefore, set up working groups of industry experts to help develop the required amendments or new material.

TSOs such as EUROCAE, ASTM International, SAE, ISO and BSI, having identified a need, can define the task and establish one or more working groups, and typically call for subject matter experts to join and assist in the development of updating material or generating new material.

This open and collaborative approach aims to establish a harmonized view that provides maximum benefit to the widest possible range of users.

<sup>&</sup>lt;sup>7)</sup> For more information, see https://www.easa.europa.eu/en/domains/drones-air-mobility/operating-drone/ specific-category-civil-drones/specific-operations-risk-assessment-sora.

## **5** Routes to operations

### 5.1 Operational approval – Overview

#### 5.1.1 General

The aviation regulatory framework is an operating-centric system. As such, almost all aspects are structured around enabling safe and efficient operations. However, given the diverse and broad range of operations, and associated use cases, there are numerous ways to be able to fly an aircraft under the risk-based considerations. This means it is necessary to understand which of the many routes and processes are applicable to a specific use case and, within these, what the appropriate process requirements are. This includes taking into account regulations and guidance beyond aviation flight safety, including:

electromagnetic spectrum (radio frequency) licensing requirements;

**NOTE 1** Radio licensing aspects are the responsibility of Ofcom, which provides information in support of UAS radio equipment at https://www.ofcom.org.uk/spectrum/radio-equipment/spectrum-for-unmanned-aircraft-systems/.

noise; and

**NOTE 2** Guidance on noise considerations is covered in a number of publications, such as the CAA's CAP 1766 [27], CAP 2505 [28] and CAP 2506 [29]; EASA's Guidelines on noise measurement of UAS lighter than 600kg in Specific Category (low and medium risk) [30]; and BS ISO 5305:2024.

privacy.

**NOTE 3** Guidance on other persons' privacy is provided in the Drone and Model Aircraft Code [23]. Attention is also drawn to the UK General Data Protection Regulation [8] and Data Protection Act 2018 [9].

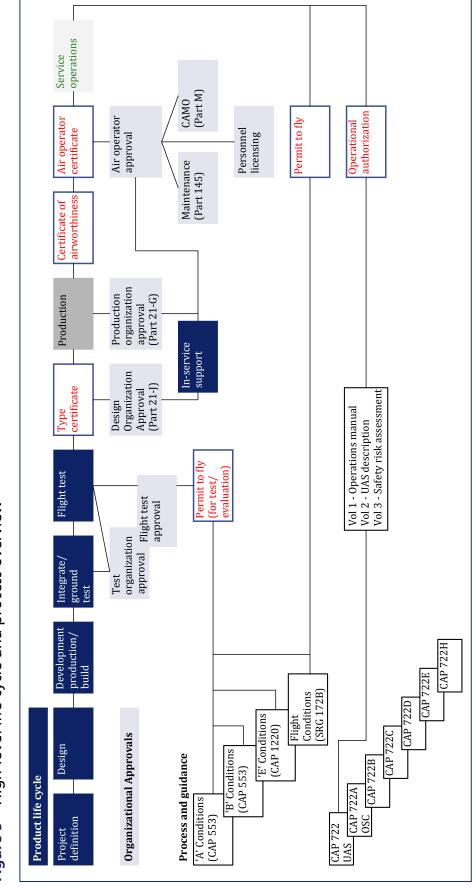
In addition, other organizations, e.g. local authorities, might have regulations, by-laws and approval/ permission requirements that need to be complied with before operations can commence.

The aviation life cycle plays a part in the considerations that influence the most appropriate route to be taken to comply with aviation regulations. The difference in risk associated with the flight purpose is an important factor, e.g. the risks associated with experimental, test and evaluation flying, and the safety mitigations used can be quite different to those for routine day-to-day service operations. The regulations support both of these use cases, but clearly the differing risk aspects mean the detailed processes and how the respective levels of safety are demonstrated and assured can also be different. A high-level overview (i.e. not a detailed complete picture) of a number of elements within the life cycle, from concept to service operation, is given in Figure 5.

This shows three of the potential routes to service operation:

- UAS operation via an operational authorization (OA);
- aircraft under cover of a permit to fly, as used for aircraft not able to be type certificated, such as
  vintage, ex-military aircraft and some recreational or general aviation aircraft, and their operation
  within personal use or limited aerial work-type processes, for operation of development/prototype
  aircraft during their approval process, e.g. test/development flying, or for flight of type-certificated
  aircraft outside of a valid certificate of airworthiness (maintenance checks, ferry flights, etc.); and
- aircraft with a certificate of airworthiness based upon a type certificate (certification) process
  and suitable to be operated under commercial transport-type processes that require an air
  operator certificate (AOC). An AOC also requires the use of supporting approved organizations
  [maintenance organizations and continuing airworthiness management organizations (CAMOs)]
  and licensed personnel/crew.

**NOTE 4** Certification, depending upon the requirement basis, can be either international or national. A national type certificate does not afford the operator the benefits of mutual recognition and flight in another state's sovereign territory under the Convention on International Civil Aviation [1], but might support the transport of goods and people within that country's territory.



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#### 5.1.2 Test and evaluation – Overview

There are also several routes to flight for the purpose of trial, test and evaluation, and the collection of data in support of an approval that would enable routine day-to-day service operations. This includes UAS OA or the permit to fly process, which are used for piloted aircraft, and can also be used for revalidating certificates of airworthiness as might be necessary after maintenance or upgrade work, or on occasion to relocate aircraft for rectification work (i.e. ferry flight).

#### 5.1.3 Other aspects

Within each of these routes to service operations, a range of other regulatory aspects need to be addressed within the operating manual to obtain the operational approval. These relate to other elements of the aviation systems, including:

- a) rules of the air that define the key responsibilities and behavioural expectations;
- b) airspace constructs and the need to have:
  - 1) specific equipment to access particular classes (or volumes), e.g. carriage of radios to converse with air traffic control (and potentially radio licences to do this); and
  - 2) electronic conspicuity capability to facilitate awareness of position and help inform an airspace picture that supports avoiding conflict and potential collisions;
- c) wider situational awareness information, such as published Aeronautical Information and Notices; and
- requirement to file flight plans to share intent, and aid strategic (pre-flight) separation/ deconfliction considerations.

Much of the published information and associated processes and procedures reflect the experience around traditional aviation and the well-established roles and knowledge held by long-standing relationships with the piloted aviation communities. This means both the regulatory and industry sectors are expected to be suitably knowledgeable of the regulations, requirements and processes that need to be complied with and the technologies used.

#### 5.1.4 Regulator engagement aspects

Within regulator engagement are a few aspects that might not be obvious but insight could aid applicants' journey with the CAA when dealing with new or novel technologies and use cases, such as UAS operations.

First, the CAA regulatory oversight team's role is to be the independent assessor that establishes that compliance with all the relevant regulations has been demonstrated. This independence means that within an application for authorization/approval, the CAA cannot guide, advise or generally provide input on how compliance is to be demonstrated beyond identifying relevant guidance and AMC material; assistance beyond this could challenge their independence and create problems when assessing their own input, especially if this does not provide the desired results.

Second, the aviation authority approval teams are resourced for their regulatory roles. This places an expectation that applicants are familiar with and understand the process steps and how to clearly articulate and demonstrate compliance with the published regulations and requirements using recognized standards and techniques. The authority team are not expected to inform or provide training on this during an application.

One area where specific dialogue might be appropriate, however, is around determining the extent to which requirements are relevant and if new ones might need to be developed. This would be a joint development task, typically within the application process, but it could be undertaken by advance activities such as under innovation-type projects.

Overall, this means that operators should hold or obtain appropriate insight, e.g. via training, so that they are familiar with these expectations and in order to aid timely and successful outcomes.

Outside of the approval processes, the authority teams also develop policy and support the development of regulations, and the evolution of technical standards and wider aviation frameworks. However, whilst this might be informed by ongoing approval work, this is typically a separate task because of the much longer timeframes involved and the need to more fully understand the implications of innovative technology or operations. It might be carried out by separate teams (or jointly with oversight experts) and could use techniques such as sandbox environments and focused trials to develop the knowledge needed for appropriate direction.

#### 5.1.5 Operator organization and competency

As the operator sits at the top of the approval process, it should be established who is responsible for complying with all appropriate responsibilities and applicable legislation and regulations, e.g. the responsible person/accountable manager. This should be clearly documented, and each person should be aware of and accept their responsibilities. This is typically achieved within the organization's operating manual.

#### 5.1.6 Operating manual

The operating manual is a key document that defines and describes:

- the organization and any relationship to any parent organization or if stands alone, including key
  information around company registrations and location address, etc.;
- what the organization is set up to do, e.g. the types of operations to be undertaken;
- the organizational structure and key roles/role holders, such as responsible person/accountable
  manager (nominated individual) and their responsibilities, including specific accountabilities and
  the lines of authority to wider teams or individuals within the organization; and
- within included content, or by reference to a wider document set, the processes, procedures and methods that govern the functioning of the business.

Typically, these processes and procedures document compliance with statutory duties such as health and safety. Of particular interest to the obtaining, maintaining and use of an aircraft operational approval are those that relate to the following.

- Competency the establishment, maintenance and demonstration of competency of individual
  personnel where this is needed to evidence support that they hold the requisite knowledge, skills
  and understanding to carry out their duties and discharge their responsibilities in an appropriate
  way. This applies not only to operating personnel, but also the accountable management chain.
  This would typically also require information as to how any training undertaken was assessed as
  suitable and achieved its intended purpose.
- Operational safety the processes, procedures and methodologies used to address the potential safety risks that can be caused by flight operations.

As with all documents used to support or attest to an independent or external view, the operating manual should be constructed with clear elements that show its governance, completeness, version etc.

For typical UAS operations, the basic content of the operating manual is described in CAP 722A [24]. For complex organizations and those that undertake more challenging types of operation, it might also be appropriate to take into account some of the other sources of similar information on how such an operating manual might be constructed and what it might contain. These include material associated with AOC holders, as well as design, production and maintenance (and maintenance management) organizations.

#### 5.1.7 Quality management systems

Quality management systems (QMSs) describe objectives and responsibilities for a systematic and proactive approach to how an organization provides consistent performance and delivery of services, with a central pillar being the principle of continuous improvement. A key aspect is that it also provides confidence, via the accrual of recorded evidence, that the quality manual is used, maintained, updated and improved from lessons of experience. If the QMS is assessed and accredited by a recognized independent specialist, additional confidence in the system might be supported.

QMSs provide a recognized and accepted means of compliance with aspects of the regulations/ requirements framework that enables consistent performance and improvement. Team members are involved not only in the use of the described processes, but also in the capture of lessons and identification of where and what process improvements are to be made under a continuing improvement ethos.

NOTE QMS standards typically used include ISO 9001 and AS/EN 9100.

#### 5.1.8 Safety management systems

Like QMSs, the four pillars of a safety management system (SMS) describe similar objectives and responsibilities for a systematic and proactive approach to managing safety risks. Whilst risk management activities are at the heart of SMSs, an SMS goes beyond assessing and managing specific safety risk issues of particular operations, and more widely monitors, captures and learns from experience from both its own activities as well as those shared by others, and updates its documented processes and enhances team skills and knowledge. This also means there is a contributory aspect in the wider aviation SMS approach to share experience and facilitate learning benefits to help prevent or minimize others from having similar safety problems.

This system works well because the aviation industry has over many years worked hard to instantiate a just culture with open reporting systems, such as mandatory occurrence reports, European co-ordination Centre for Accident and Incident reporting systems and the confidential human factors incident reporting programme, used when mistakes are made that could potentially lead to a safety risk, whether already foreseen (and mitigations need to be reviewed) or a totally new issue needs to be taken into account. These systems are adapting to the different safety aspects of UAS and emerging AAM operations. Hence, while they might not fully reflect everyone's needs, reporting is encouraged to help make them as useful as possible.

**NOTE** A just culture is an essential part of an engaged safety culture that sits at the heart of an operating and effective SMS. Organizations need to plan to establish, maintain and nurture a just culture to enable an SMS to flourish through the course of the organizational life cycle. A just culture and treating individuals fairly when mistakes are made, for example, is not the same as a no blame culture; professionals within a professional industry are still accountable for their actions when these are reasonable within their competency, but SMS processes tend towards learning objectives rather than punitive outcomes. This can be a difficult challenge to balance, and hence why clearly defined SMS principles are of value.

### 5.2 Concept of operations

Where a concept of operations (CONOPS) document is used to describe the typical operations to be carried out, it should provide a clear and objective view of the relevant aspects that enable the successful and safe delivery of services. The degree of operational complexity, different mitigations used and how competency in this will be addressed should be described.

For example, the CONOPS for VLOS operations is predicated on the operating pilot (and use of any observer roles) being able to maintain direct sight of the uncrewed aircraft at all times, and is responsible and able through the use of minimum segregation distances or other logical mitigation measures to deal with potential problems.

In BVLOS operations, the responsible operating pilot does not have direct sight of the uncrewed aircraft for some or all of the flight. As such, alternative solutions, typically technology-based, are used to support the remote pilot to discharge the responsibility for safe flight. This includes assessing flight-based risks, such as collisions with other aircraft, as well as hazards that could compromise safe operation, e.g. from ground-based obstacles such as other vehicles, vessels or structures, to adverse weather that exceeds the limits of the aircraft to remain under control. Ground-based risks also need to be taken into account, including potential harm to people (individually and as groups) or cause damage to property. Factors for this might include population density of the area flown over.

This indicates there are two important facets: first, the sensors/technology and (automation and autonomy) actions; and second, how the remote pilot maintains situation awareness, with reliance on communication systems and data, along with the pilot user interface and human performance considerations.

### 5.3 Automation versus autonomy

The terms "automation" and "autonomy" are frequently used interchangeably. However, there are some specific aspects that can influence the regulatory view and how the means of compliance with requirements can be assessed. Hence, the correct use of language is important, so that everyone has a clear view of the degree of automation/autonomy that is being requested to be authorized/approved by the aviation authority, as this has considerable implications for the assessment and management of risks.

Both terms sit along a common technology path which has a sliding scale associated with the degree of action/intervention that a human, as an operator or system/monitor, might be able to have.

Automation considers pre-defined system actions in response to identified and scoped inputs/sensor data etc. and functions under governance of the remote pilot, who can directly adjust or override the system, much like the autopilot and flight management systems used on traditional (occupied) aircraft.

Autonomy can be viewed as a logical extension of automation, taking into account where the technology can be/is authorized to take actions with limited or no human pilot interaction.

This can occur at a simple system level under specific circumstances and limited flight phases, up to the most complex capability where the aircraft is able to undertake a complete end-to-end flight with no human involvement.

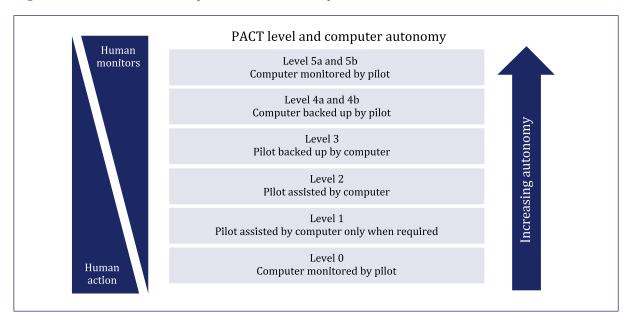
While there is no current fully agreed aviation definition of "autonomy", reference is made to that used in the ICAO *Manual on remotely piloted aircraft systems (RPAS)* [31], which describes two aspects:

- autonomous aircraft: an unmanned aircraft that does not allow pilot intervention in the management of the flight; and
- autonomous operation: an operation during which a remotely piloted aircraft is operating without pilot intervention in the management of the flight.

The important difference between automation and autonomy is around the degree of pilot intervention or ability to influence the system actions or flight operation.

This description does not stipulate that operation is, or is required to be, the complete, start-to-end flight, or that it only applies during flight and does not apply during ground operations. Hence, it could be considered that an aircraft, or even a sub-system of the aircraft, that acts autonomously for some elements or sections of the total operation are equally addressed during that period.

This description aligns with one example of how the different levels of automation/autonomy can be represented using the pilot authorization and control of tasks (PACT) levels concept [32] (see Figure 6).



#### Figure 6 – Autonomous systems – Authority transition model

## 6 Risk assessment and management – Overview

## 6.1 General

The safety risk assessment and management process typically involves a hazard assessment, followed by a preliminary safety assessment, and eventually a final safety assessment. The process aims to:

- a) identify the risks;
- b) understand the risk exposure of the proposed operation/change and to check that it is tolerable; and
- c) confirm that the identified risks are owned and managed by specific responsible people/ organizations.

There are many reference documents that describe the aviation safety risk assessment process and the development of associated safety cases. These include CAP 722A [24], AMC and GM on the airworthiness certification specifications, e.g. CS-2x.1309, and a wide range of textbooks and training courses.

**NOTE** An overview of the aviation safety risk-based approach is described in Aerospace recommended practice: Guidelines and methods for conducting the safety assessment process on civil airborne systems and equipment (*ARP4761*) [33] and in the complementary standard, Aerospace recommended practice: Guidelines for development of civil aircraft and systems (*ARP4754*) [34].

### 6.2 Hazard assessment

The core aspects of hazard assessment are:

- a) hazard identification:
  - 1) determination of potential undesirable events (hazards);
  - 2) determination of potential causes, i.e. problems, failures or issues that could lead to the hazard occurring;
  - 3) determination of potential outcomes/consequences if the hazard occurs;
- b) hazard classification:
  - 1) classification of the severity of the worst-case outcome;
  - 2) determination of any target level of safety (TLOS) set by the requirements; and

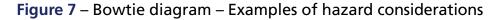
**NOTE 1** These requirements could be regulatory, e.g. for approval, customer defined, or internally set for commercial objectives.

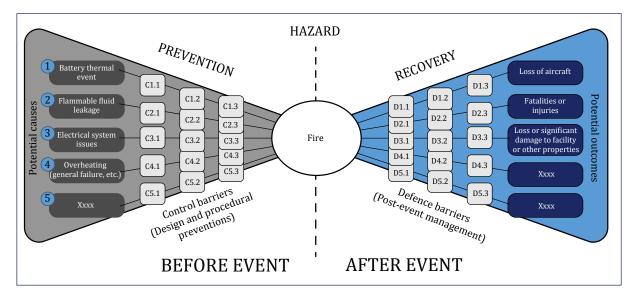
- c) hazard management or mitigations:
  - determination of barriers (prevention controls) that could act to prevent or manage the hazard occurring, e.g. design features such as multiple systems, interlocks and safety trip devices, scheduled maintenance, operating procedures, competency training and skills; and
  - determination of barriers (recovery controls) that could act to reduce the severity of the outcome if the event occurs, e.g. design features that act to limit severity, alternate procedures and emergency response plans that describe how to manage the event occurrence.

There are numerous methodologies available to support the conduct of the hazard assessment, including CAP 760 [35]. One such technique that has been used by the CAA is the bowtie method, as described in CAP 1329 [36]. A specific drone safety risk bowtie model is published in CAP 1627BT [37].

**NOTE 2** Further information on this technique is available from the CAA at https://www.caa.co.uk/ safety-initiatives-and-resources/working-with-industry/bowtie/, and offers a range of templates to address seven key safety issues.

A pictorial representation of the component parts of the hazard assessment is shown in Figure 7.





The approach should cover the complete operational situation, which might require a series of diagrams that are hierarchical with parent-child relationships, e.g. at the aircraft level, and when necessary, developing further into individual systems. Used in this way, it can be helpful to define the system architecture, be a useful tool for defining aircraft or system requirements, or establish if conceptual designs are likely to be able to meet the intended capability. As a qualitative assessment, it does not look to quantify achievement of a TLOS; instead, it helps to indicate if potential safety concerns are able to be managed within tolerable considerations.

## 6.3 Preliminary safety assessment/safety assessment

#### 6.3.1 General

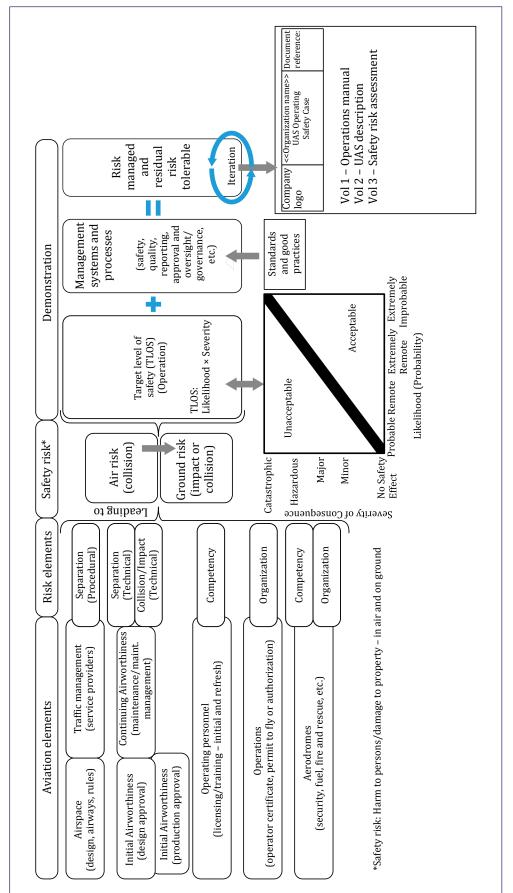
The safety assessment looks to substantiate qualitatively and, when necessary, quantitatively demonstrate, that there is a suitable inverse relationship between the severity of a potential outcome and the likelihood of it happening, e.g. minor outcomes can be tolerated more frequently than much more severe events. This addresses the proportionate risk-based approach.

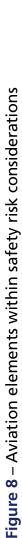
The safety assessment ranges from wholly qualitative assessments where judgement and textual arguments provide a means to determine appropriateness, to specific system analyses that have data supporting detailed failure logic modelling and use of failure modes and rates of failure that can quantify the probability of occurrence, as might be necessary under a certification process, for a quantitative demonstration of meeting the TLOS.

At the OSC level, each of the elements of the aviation system used or potentially impacted should be taken into account and addressed. The current aviation systems and regulatory framework reflect how the many independent functional and service elements work together to provide the end capability, resulting in a robust system in which each section can rely on each of the others, working to common minimum performance standards, but is resilient to problems, e.g. an aircraft can still fly if the original destination airport is unavailable due to severe weather, or if air traffic services are disrupted and alternate procedures need to be followed. This approach also means, due to the specific sector knowledge, skills etc., that the aviation authority organization structures typically reflect these functional elements.

UAS and new/novel use cases, such as envisaged by the AAM sector, increasingly look to enable different operating models or use technologies that might blur the boundaries or transfer functions from one sector to another. The safety cases should be articulated in a way that is readily understood by different sector teams and their specific knowledge, but also show how any changes to the established sector processes are taken into account, and if different, are agreed by all parties. This can help to facilitate achieving authorization or approval in a time-efficient way.

An overview of some of the elements of the aviation sectors, with a view to UAS risk assessment, is given in Figure 8.







In demonstrating that operations are safe enough, it is necessary to understand and address how each of the different, independent elements contribute to managing or mitigating issues and the overall safety claims. This enables a clear picture to be formed of where reliance and dependency on other parties could be placed, that their input to the safety arguments is reasonable, and is not accounted for multiple times within the assessment. This facilitates a clear understanding of the importance that third-party organizations play in the safety substantiation, if they are working as per the established normal sector relationships or have service agreements that define the risk sharing, e.g. via formal agreements or contracts, and therefore how reasonable the safety case is.

**NOTE 2** A safety argument can be used to demonstrate that a new system or change to an existing system maintains the risk exposure at a tolerable level. The safety argument provides a logical, traceable structure linking a safety claim with the evidence to support the claim.

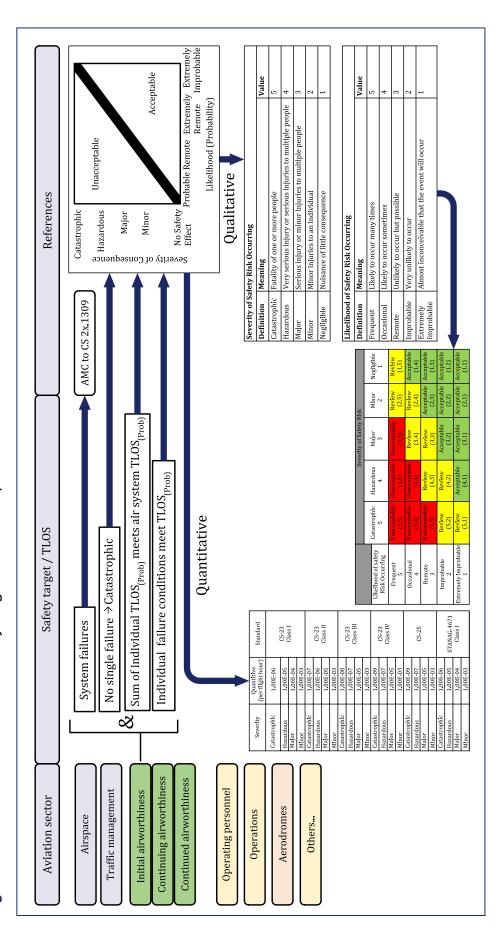
For UAS, this demonstration is made in the OSC, as described in CAP 722A [24], or using another acceptable method. Alternative methods include SORA, as developed by JARUS [38].

**NOTE 3** CAA guidance on SORA is available at https://www.caa.co.uk/drones/digitising-specific-category- operations-disco-project/uk-specific-operations-risk-assessment-sora/.

**NOTE 4** Further information from EASA on the implementation of SORA is available at https://www. easa.europa.eu/en/domains/drones-air-mobility/operating-drone/specific-category-civil-drones/specificoperations-risk-assessment-sora.

#### 6.3.2 Safety targets/TLOSs

One sector in which TLOSs are typically set is aircraft airworthiness, which includes initial, continuing and continued sub-categories. The initial airworthiness category addresses the design elements through to type certification or approval. The many requirements contained in the certification specifications include numerous approaches to the determination and demonstration of safety. Some approaches rely on conducting analyses and tests to show the achievement of specific performance criteria; others, especially for technical systems, require qualitative and quantitative demonstrations of failure probabilities to be shown to meet the set TLOS. Figure 9 provides an example.



#### 6.3.3 Verification and validation

The safety risk assessment and management process fits within the wider life cycle process for verification and validation.

Verification and validation refer to a set of independent processes that are intended to establish that something, e.g. product, system, piece of equipment or a service, meets the requirements, specifications or standards that have been set and fulfils its intended purpose.

Verification is typically a design and production phase activity which checks that the requirements, specification and standards that have been defined are met, e.g. physical measurements, performance assessment. It can be considered as confirmation that the product was built correctly.

Validation is a process in which it is established that the product, system or service meets the user needs and associated operational use case, as captured in a set of requirements, and might include procedures, protocols and methods for demonstrating achievement. It therefore feeds into the design and development phases, and can be considered to confirm that the correct product was built.

Verification and validation are key to demonstrating that a product, system, piece of equipment or service conforms to all applicable requirements, whether for the client or customer, or meets regulatory demands. Within the aviation regulation system, it might be necessary to agree the methods to be used with the aviation authority if they form the basis of the evidence in showing compliance with the particular requirements for approval or type certification.

## 7 Maturity roadmap

## 7.1 General

The aviation life cycle covers all steps from initial idea or concept to eventual retirement and managed re-use of components, through to overhaul/re-certification, where applicable. In some cases the life cycle also facilitates a "second life" within very different uses, such as private use of ex-military aircraft and those used for display operations.

Within this life cycle, there are several different safety risk maturity levels that are reflected within the safety assurance approach. For example, the safety concerns during development and test of new technology are potentially uncertain and the governance processes during this phase need to be quite different to those applied during established routine day-to-day operations or "second life" operations.

This proportionality applies across the safety landscape and enables the regulatory assurance processes to take into account the different risk driving factors, including organization knowledge and experience, technology maturity, and in-service operating experience under commercial world situations.

Within this there are also general considerations around how the existing frameworks and constructs, such as airspace design, equitable access and range of operations, might also need to be adapted to facilitate new concepts and use cases to enable their development and eventual entry to service. This is a complex balance of current and new capabilities that desire to share the finite airspace resources, whilst continuing to meet the established safety objectives.

There are, however, some key common principles that underpin the different yet scalable and proportionate safety risk management strategies for establishing and maintaining confidence and trust between the various responsible individuals, organizations, regulators and the general public. These include:

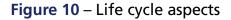
- a) the organization approval processes that provide defined organization capability scope and clearly defined responsible individuals;
- b) development of amended or new regulations for novel technologies or in response to new potential safety concerns, such as cyber security, data access and privacy;
- c) methods to require (mandate) updates to fundamental construct elements, e.g. the need for conspicuity; and
- d) methods to require (mandate) updates to existing aircraft, parts, operating processes, etc. in response to lessons learnt from operational events (continued airworthiness).

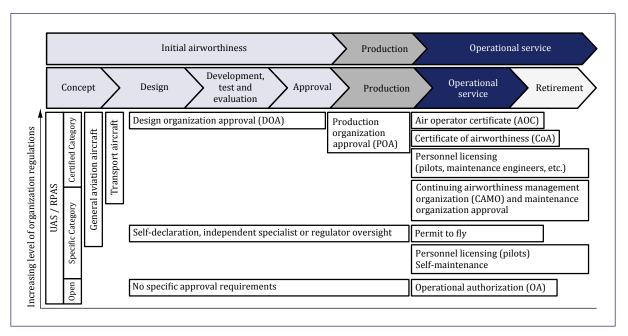
# 7.2 Organization life cycle – Design, production, maintenance and operation

The aviation system is underpinned by an implicit trust framework between the respective individuals and organization, which is exercised and challenged during each engagement. However, given the safety considerations, this cannot be the total basis and thus the regulatory processes and procedures include various requirements that help establish confidence that an individual or organization is capable and likely to discharge their responsibilities if any privilege, such as a personal licence or an authorization, approval or permission, is granted to them.

Given the fundamental aspect is around the safe operation of aircraft, it can be useful to view this across the intended use case and aircraft life cycle, from concept to end-of-life retirement (see Figure 10).

**NOTE** Similar approval views exist of other sectors, such as air traffic services or aerodromes, but are not included in Figure 10.





The aircraft life cycle can be split into the three primary stages around design, production and operation, which in common with the wider framework are principally independent of each other. Each has further layers of detail and division of additional functional elements.

The initial airworthiness element covers concept through to type approval or certification, where applicable. Within this are elements of defining the critical or non-standard production processes, in-service maintenance activities and schedules, as well as operating personnel training needs. Once type approval is achieved, the holder becomes responsible for supporting in-service operations so that any safety concerns, or events that could lead to such, are properly understood and, if necessary, addressed by modification, inspection or repair of aircraft and constituent parts under continued airworthiness actions.

For the most safety challenging aircraft, in order for the regulatory process to be timely and proportionate, it includes requirements for organizations to obtain a design organization approval (DOA) or demonstrate and obtain agreement of equivalent alternative procedures before any type of approval can be granted. Accordingly, the organization should document its structure, processes and procedures associated with all elements of the work scope, including design, development, testing, compliance demonstration, support to production and in-service support. The aviation authority reviews the associated operating manual and carries out audits to establish confidence in the organization's capability and use of these.

An initial design approval is limited to the scope of the first approval requested and the capability needed and demonstrated for this. This is defined within the terms, conditions and limitations of the approval. As the organization develops to reflect business opportunity, it can apply to expand, or reduce, its scope as appropriate.

Within this approval framework, well-performing approval holders might also be granted privileges that are beneficial to their processes, for example the ability to classify modifications or repairs, and potentially to self-approve certain changes.

A production organization approval (POA) functions in much the same manner, focusing on the manufacturing of piece parts and equipment to complete aircraft, and appropriate engagement with the design organization for resolution of any problems.

An operator certificate, permit to fly or authorization addresses the core aspects for safe flight operations. Within this are aspects such as managing personnel competency and ongoing training, including use of synthetic training devices which might require their own approval, to how maintenance is managed and carried out. For various reasons, from the practicalities of the work content to efficient use of resources, these aspects could be addressed within the operating organization, be fully contracted to other approved organizations, or be a mixture of both.

## 7.3 Operating use cases

Within the context of a wide range of UAS use cases, and potentially new types of operation within AAM, the high-level case studies in Table 1 outline various aspects of the regulatory systems that would need to be taken into account.

### Table 1 – Risk considerations

Development test and evaluation	The general consideration here is the higher risk from new/novel technologies and respective experience in their use. The limited experience with the aircraft and/or its characteristics, performance, etc. might also mean a different or increased range of competencies are appropriate. For increased levels of automation/autonomy, the implications on the knowledge and skills of the human operators/system managers needs to be fully taken into account in respect of the flight management objectives and failure scenarios. This typically means restrictions on location and possible formal segregation by airspace restrictions to constrain third-party risk.					
Routine service operations	The general consideration here is the safety risk concern from regular day-to-day operations.					
	These would be considered to be conducted alongside other airspace users with minimal disruption to them, i.e. not rely on the need for segregation/airspace restrictions that unduly negatively impact other airspace users.					
	This might utilize alternate procedures that facilitate initial operations (accommodation).					
	The more routine the operations are, the more these are expected to function within the in- place airspace constructs, i.e. able to integrate into that environment and behavioural norms without the need for alternate procedures.					
	<b>NOTE</b> The CAA's Airspace Modernisation Strategy <sup>8)</sup> , and adaptations to the construct design, influences particular aspects and how this can be achieved.					
	The operating procedures and pilot or system monitor/manager competency and workload need to be commensurate with the degree of automation/autonomy for routine flight aspects and use of standard procedures for abnormal and emergency situations based on established data and experience.					

<sup>&</sup>lt;sup>8)</sup> Available at https://www.caa.co.uk/commercial-industry/airspace/airspace-modernisation/airspacemodernisation-strategy/about-the-strategy/.

Operating case	DOA	РОА	AOC	OA	Competency	Comment
UAS – Open Category (VLOS)	N/A	N/A	N/A	No	Flyer ID required for UAS of 250 g and above	Operator ID (with drone labelling) is only required for UAS below 250 g with camera, or 250 g and above.
UAS – Specific Category (VLOS)	N/A	N/A	N/A	Yes	Remote pilot assessment	<ul> <li>OA based on operating manual/OSC that addresses:</li> <li>capability of the aircraft and its technical systems (flightworthiness);</li> <li>processes and procedures that support safe conduct of the intended operations; and</li> <li>crew competency in the aircraft/systems, operations and established abnormal and emergency procedures.</li> </ul>
UAS – Specific Category (BVLOS)	N/A	N/A	N/A	Yes	Remote pilot assessment	<ul> <li>Over and above the VLOS aspects, the operating manual/OSC addresses the specificities associated with the use of technical systems that provide situational awareness and the ability to affect safe flight when BVLOS.</li> <li>These systems need to address the intended operations and the range of potential risks that might occur during them, e.g.:</li> <li>aircraft and command/control technical system problems, including support service issues, e.g. global navigation satellite system, or communications service provider problems;</li> <li>ability to detect and respond, within suitable timeframes, to issues that have safety of flight implications, e.g. other aircraft, birds; and</li> <li>ability to detect and respond to external situations that require actions to maintain adequate safety, e.g. weather/windspeeds above defined limits, and ground-based obstacles.</li> <li>The response actions need to be such that they do not cause additional risk, e.g. auto return to home without clear view of other potential hazards en route.</li> </ul>

## Table 1 – Risk considerations (continued)

Operating case	DOA	POA	AOC	OA	Competency	Comment
UAS – Certified Category (BVLOS)	_	_	_	_	_	The regulations for UAS certification are still under development, hence it is not possible to state what the requirements are.
						However, with the general objective for equivalency of safety/risk to similar classes of crewed aircraft (and/or their type of operation, where appropriate), initial certification requirements, including considerations for DOA, POA (or alternate procedures), as well as pilot licensing (through approved training providers etc.), are likely to be commensurate with these, albeit with enhancements to address the new/ novel aspect, such as higher complexity systems.
AAM – Personal	_	_	_	_	Pilot licensing	The regulations for AAM certification are still under development, hence it is not possible to state what the requirements are.
AAM – Aerial work	_	_	_	_	Pilot licensing	However, as aircraft capable of carrying people or goods/cargo, similar potential safety risk concerns to established types of aircraft are anticipated.
AAM – Transport (people or goods/cargo)	_	_	_	_	Pilot licensing (commercial)	As such, similar organization approvals, licensing (through approved training providers) and AOCs are envisaged.

## Table 1 – Risk considerations (continued)

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