

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 ASIEN 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:

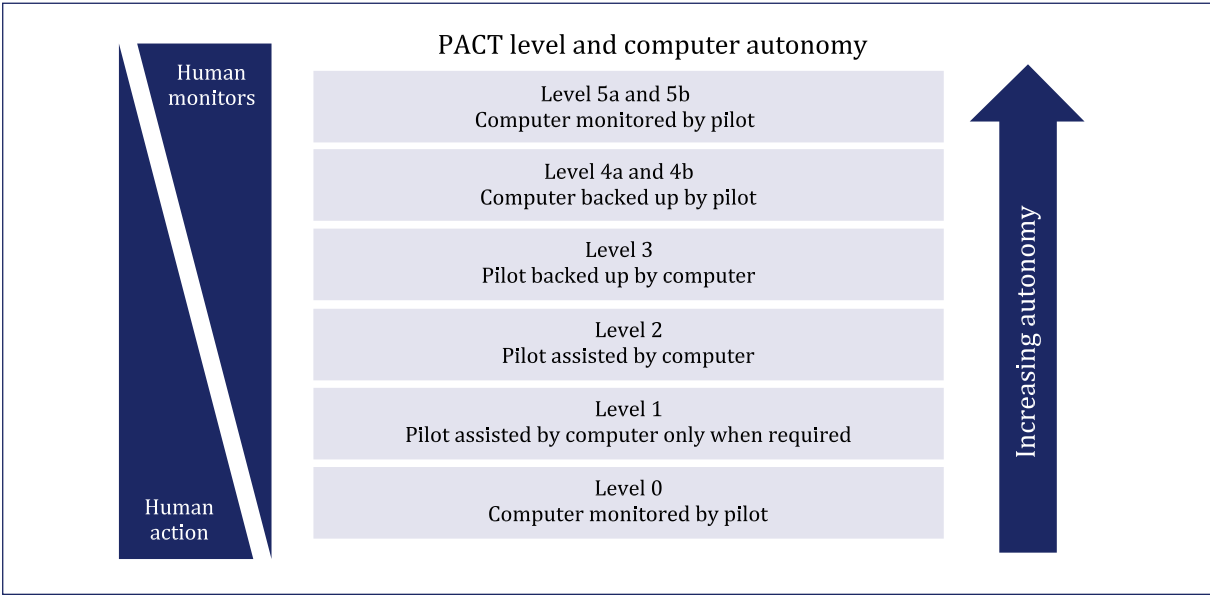
- autonomous aircraft: an unmanned aircraft that does not allow pilot intervention in the management of the flight; and
- autonomous operation: an operation during which a remotely piloted aircraft is operating without pilot intervention in the management of the flight.

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.

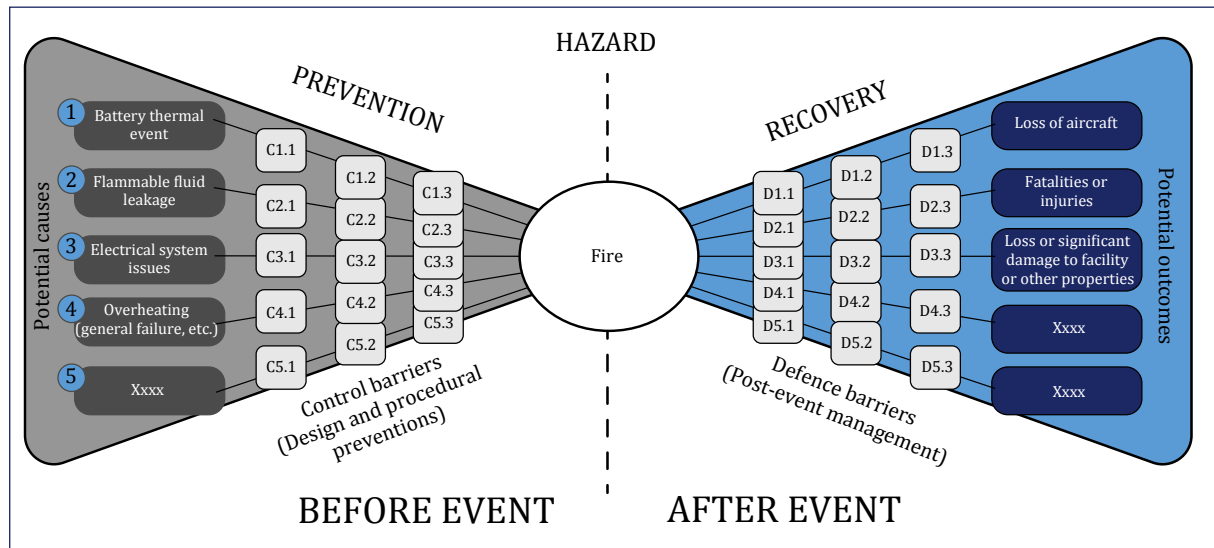
- c) hazard management or mitigations:
 - 1) determination of barriers (prevention controls) that could act to prevent or manage the hazard occurring, e.g. design features such as multiple systems, interlocks and safety trip devices, scheduled maintenance, operating procedures, competency training and skills; and
 - 2) 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.

Figure 7 – Bowtie diagram – Examples of hazard considerations



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.

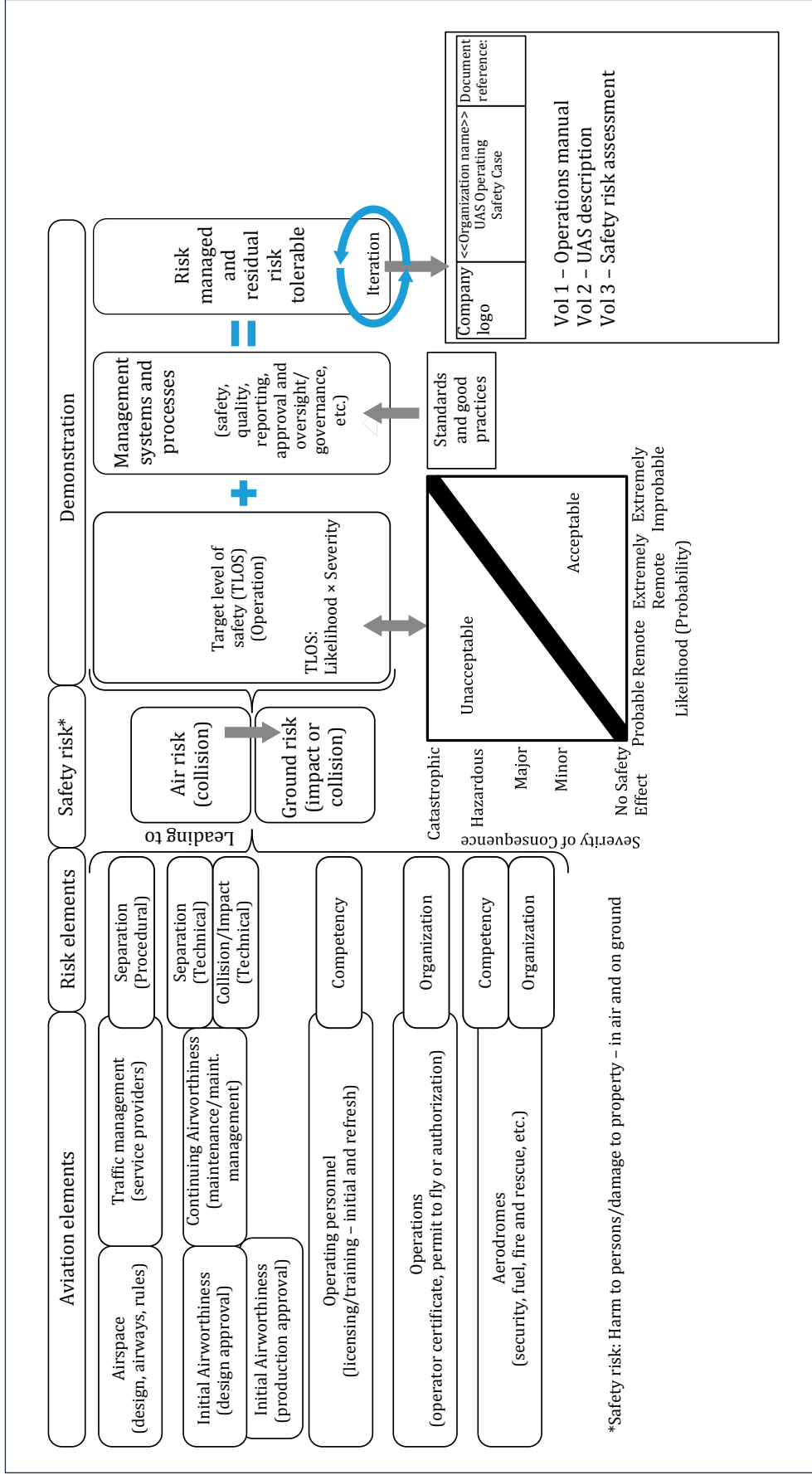
The safety assessment ranges from wholly qualitative assessments where judgement and textual arguments provide a means to determine appropriateness, to specific system analyses that have data supporting detailed failure logic modelling and use of failure modes and rates of failure that can quantify the 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.

Figure 8 – Aviation elements within safety risk considerations



NOTE 1 Not all sectors of the aviation system provide quantifiable TLOSs. A safety case is likely to be qualitative and, where required, supported by elements that are quantitative.

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].

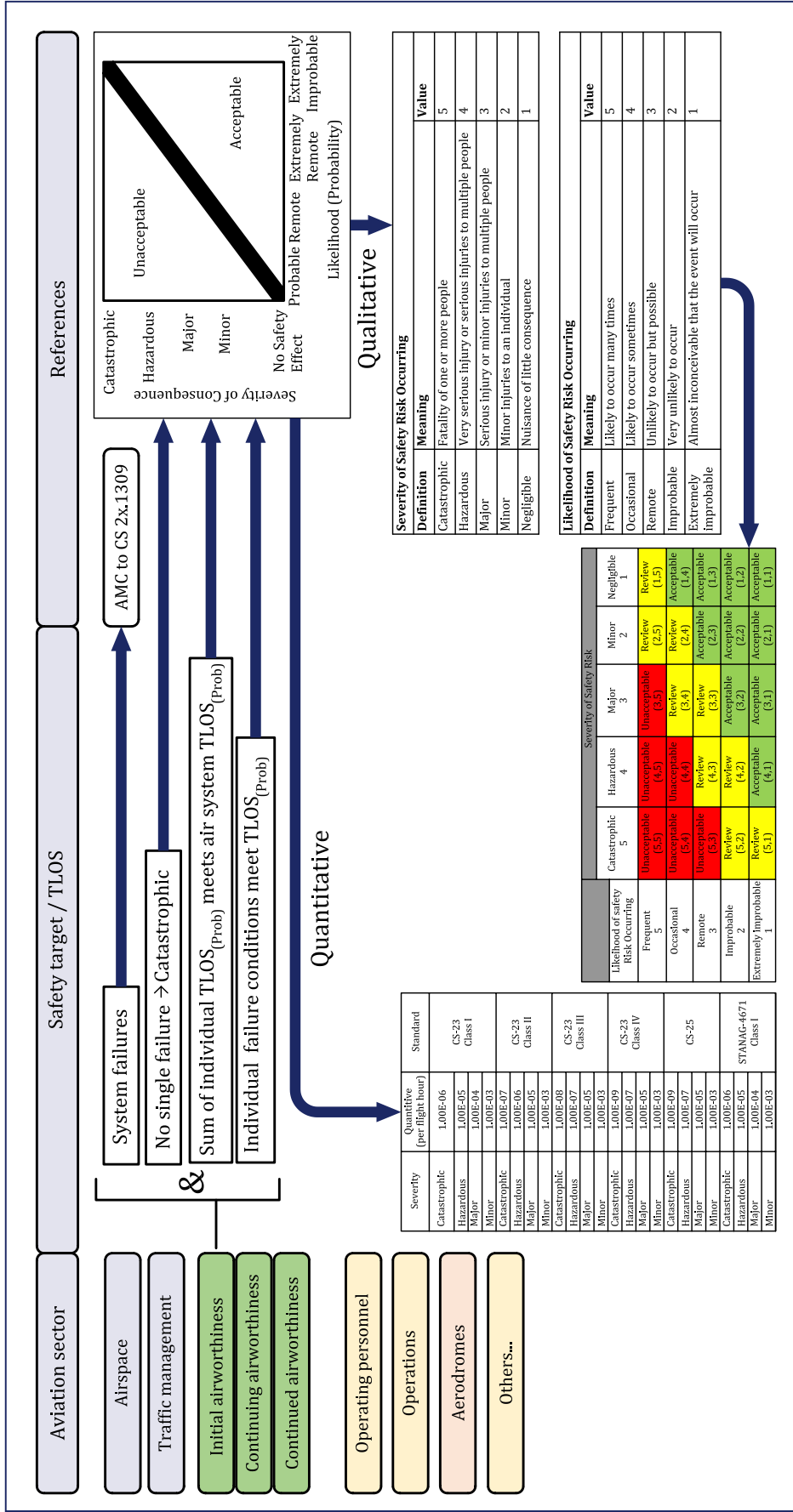
NOTE 3 *CAA guidance on SORA is available at <https://www.caa.co.uk/drones/digitising-specific-category-operations-disco-project/uk-specific-operations-risk-assessment-sora/>.*

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/specific-operations-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.

Figure 9 – Initial airworthiness – Safety target/TLOS 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).

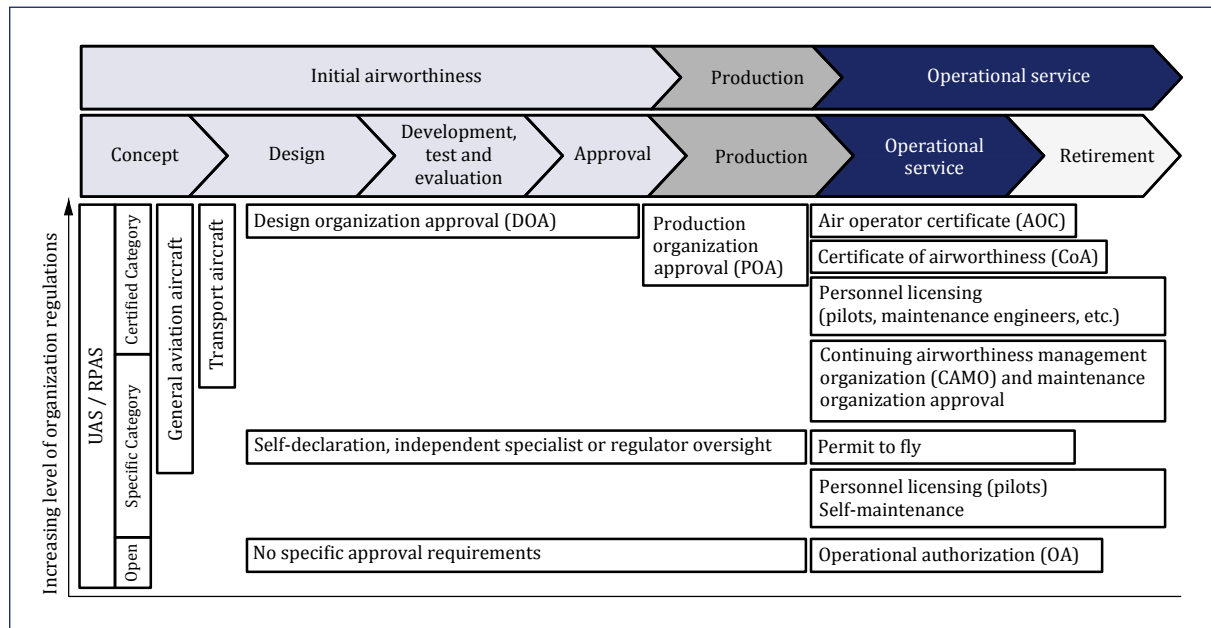
7.2 Organization life cycle – Design, production, maintenance and operation

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.

Figure 10 – Life cycle aspects



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 | <p>The general consideration here is the higher risk from new/novel technologies and respective experience in their use.</p> <p>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.</p> <p>This typically means restrictions on location and possible formal segregation by airspace restrictions to constrain third-party risk.</p> |
| Routine service operations | <p>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.</p> <p>This might utilize alternate procedures that facilitate initial operations (accommodation).</p> <p>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.</p> <p><i>NOTE The CAA's Airspace Modernisation Strategy⁸⁾, and adaptations to the construct design, influences particular aspects and how this can be achieved.</i></p> <p>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.</p> |

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

Table 1 – Risk considerations (*continued*)

| Operating case | DOA | POA | 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 | <p>OA based on operating manual/OSC that addresses:</p> <ul style="list-style-type: none"> • capability of the aircraft and its technical systems (flightworthiness); • processes and procedures that support safe conduct of the intended operations; and • crew competency in the aircraft/ systems, operations and established abnormal and emergency procedures. |
| UAS – Specific Category (BVLOS) | N/A | N/A | N/A | Yes | Remote pilot assessment | <p>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.</p> <p>These systems need to address the intended operations and the range of potential risks that might occur during them, e.g.:</p> <ul style="list-style-type: none"> • aircraft and command/control technical system problems, including support service issues, e.g. global navigation satellite system, or communications service provider problems; • ability to detect and respond, within suitable timeframes, to issues that have safety of flight implications, e.g. other aircraft, birds; and • 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. <p>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.</p> |

Table 1 – Risk considerations (*continued*)

| Operating case | DOA | POA | AOC | OA | Competency | Comment |
|---|-----|-----|-----|----|------------------------------|---|
| UAS – Certified Category (BVLOS) | — | — | — | — | — | <p>The regulations for UAS certification are still under development, hence it is not possible to state what the requirements are.</p> <p>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.</p> |
| AAM – Personal | — | — | — | — | Pilot licensing | <p>The regulations for AAM certification are still under development, hence it is not possible to state what the requirements are.</p> |
| AAM – Aerial work | — | — | — | — | Pilot licensing | <p>However, as aircraft capable of carrying people or goods/cargo, similar potential safety risk concerns to established types of aircraft are anticipated.</p> |
| AAM – Transport (people or goods/cargo) | — | — | — | — | Pilot licensing (commercial) | <p>As such, similar organization approvals, licensing (through approved training providers) and AOCs are envisaged.</p> |

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