



EAC

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1. References

This Advisory Circular (AC) should be read in conjunction with the Egyptian Civil Aviation Regulations (ECAR) Part 172 – Air Traffic Service Providers.

2. Purpose Of This AC

The ECAR Part 172 regulatory standards covering air traffic service providers require, in specified circumstances, the preparation of safety cases to support a new service or a proposed change to an existing service.

3. Status Of This AC

This is the first issue of AC 172-(). It remains current until re-issued, withdrawn or superseded.

4. DEFINITIONS

The following definitions are applicable to this AC. They are not necessarily definitions that apply to ECAR Part 172.

Service: An air traffic service as defined in ECAR Part 172.

Hazard: A state, or set of conditions of a service, or an object, with the potential to cause an aircraft accident or air safety incident.

Hazard Identification: The Process of Recognizing That a Hazard Exists and defining its characteristics.

Operational Requirement: The stated purpose of the service.

Risk: The probability of occurrence, together with the severity of the consequences, of a hazardous event.

Risk Assessment: The process of determining the risk involved in the occurrence of a hazardous event, and the tolerability of that risk.

Risk Management: The systematic application of management policies, procedures and practices to the tasks of identifying hazards and assessing and controlling risks.

Safety Management System (SMS): the policies, procedures and activities by means of which safety management is undertaken by a service provider.

Safety Case: Safety cases provide documented evidence and argument that a service or facility, or a proposed change to the design of a service or facility, meet safety objectives or levels for the service or facility.

Chapter 1 **SAFETY MANAGEMENT SYSTEM**

1.1-SAFETY MANAGEMENT SYSTEM

The primary purpose of a safety management system is to predict what accidents or incidents may occur, how they may happen, and how they may be prevented. The processes for safety assurance in various industries may differ in detail, however they all prescribe the systematic undertaking of safety risk assessment and the presentation of evidence and arguments that the particular system is safe.

One way of presenting such evidence and arguments is by preparing a safety case. A safety case provides documented evidence and argument that a service or facility, or a proposed change to the design of a service or facility, meets safety objectives or levels for the service or facility

This document provides guidelines for the preparation and maintenance of safety cases covering ECAR Part 172 services

1.2-ECAA REQUIREMENTS FOR A SAFETY MANAGEMENT SYSTEM

ECAR Part 172 requires air traffic service providers to have a Safety Management System (SMS). One of the elements of the SMS is a requirement for a process for assessing the safety implications and safety hazards involved in their operations, and determining the action necessary to reduce the risk of those hazards to acceptable levels.

One appropriate methodology for addressing the above requirement is through the preparation and maintenance of a safety case.

Chapter 2 REQUIREMENTS FOR A SAFETY CASE

2.1 REQUIREMENTS FOR A SAFETY CASE

ECAR-Part 172 sets the basic standards for a safety case, or another equivalent safety assessment process, to be prepared by service providers, to support a new service or a proposed change to an existing service:

2.1.1 The effect of which would be that the service would no longer be in accordance with the certificate issued to the ATS provider under regulation 172.

2.1.2 That requires prior notification to ECAA because of a requirement to do so in the ATS provider's safety management system.

2.2 SAFETY PLANNING

It is expected that safety will be built into any new ECAR Part 172 service from its early inception and the management of safety related activities will be undertaken in a planned manner over the lifecycle of the service.

The safety plan may be a discrete element of a project management plan, if applicable, or it may stand-alone. Either way, the safety plan should provide the basis for developing the parts of the safety case at defined milestones as the development and implementation of the service progresses.

For those services that have a lifecycle consisting of several distinct phases, the hazards and associated risks may differ in type and degree in each phase, and their identification and control treatment will be more appropriately undertaken at a particular phase in the lifecycle. Accordingly, safety cases need to be developed to separately consider the safety situation in each of the lifecycle phases. This may require several parts of the safety case, with each part building on the previous part.

Some services which are essentially procedurally based or less complex may have less distinct life-cycle phases, or the phases may merge, or essentially occur at a similar time. For these types of service, the safety case might be defined in one document part.

The distinct phases in the development of a new service or service change that would be covered by a safety case are normally:

2.2.1 **The Operational Requirements Phase**, when the role and broad functionality of the new service or service change is determined. This phase should identify the safety objectives of the service and its applicable safety requirements, (these may be based on ICAO SARPS, ECAA regulatory requirements, and the service provider's internal safety standards);

2.2.2 **The Design Phase**, when the new service or service change is designed and developed to meet the specified operational requirements. In this phase, the configuration and operation is defined, incorporating the safety objectives and requirements within the evolving design. A full hazard and risk assessment is usually undertaken;

2.2.3 **The Pre-Commissioning Phase**, when the service is subject to procedural and/or operational

readiness testing against the design specifications, followed by operational trials, such as ghosting or mimicking. At this phase, the risk assessment is tested and validated by actual trials and testing, and specific safety related operational and/or management procedures are developed to obviate or control the identified risks; and

2.2.4 The Commissioning And Routine Operations Phase, when the safety of the service continues to be monitored and improved as any hazards are identified as they arise, and the risks are mitigated during actual operations.

The safety case should describe the historical and current safety status of the service as it develops throughout its entire lifecycle.

2.3 PURPOSE AND SCOPE OF THE SAFETY CASE

A safety case is essentially a structured, comprehensive statement of the hazards surrounding the provision of an operational service, including the significance of the hazards in terms of their likelihood of occurrence and potential effects on aviation safety, and the means whereby they are to be managed. The essential features of a safety case are that it should fully describe the service which it covers (i.e. the configuration and the boundaries of the system), identify the hazards, assess the associated risks, and establish the controls necessary to ensure the risks are tolerable. Hazard/risk management should ensure that all possible failure and fault modes have been identified and appropriate controls put in place so safe operation of the system is preserved under all modes.

The purpose and scope of the safety case should be clearly stated in its introductory paragraphs, and should include:

- 2.3.1 A statement of the purpose and role of the service under consideration including the system Operational Requirement and a description of how it operates. The description of the service should include: its location; its configuration including the sub-system elements; the service boundaries; the elements of the service which have been considered within the scope of the document, i.e., whether it covers equipment, procedures, personnel, etc.; and the interfaces with other external services and systems.
- 2.3.2 A statement of the assumptions upon which the safety case is based. This should include the defined or known levels of safety, or integrity, of each of the interfacing or support systems/services, and those other services externally provided by third parties, such as those provided by telecommunications service providers, electrical power service providers, etc.
- 2.3.3 The relevant phases of the system, covered by the particular part/s of the safety case should also be defined

2.4-SAFETY OBJECTIVES AND SAFETY REQUIREMENTS

2.4.1 The overall safety objectives of the system, consistent with, and in support of, the Operational Requirement, should be defined.

2.4.2 The safety requirements to achieve the overall safety objectives then need to be defined.

These safety requirements should be derived by assessing the effect of possible functional failure or fault modes as the source of safety hazards and the associated effect on the operation of the system.

2.4.3 The fault modes analysis should cover conceivable faults or eventualities affecting system performance including the possibility of human errors, common mode failures, simultaneous occurrences of more than one fault, and external eventualities which cause or result in the loss of, or affect the integrity of, external data, services, security, power supply, or environmental conditions. The assessment of the safety requirements may then result in an iterative process of revision and further development of the system design, the adoption of modified operational procedures, or the establishment of contingency arrangements. For this reason, the safety requirements should be expressed in a form that is clear and unambiguous so that they can be tested against, and the compliance of the service determined.

2.4.4 The selection of an appropriate way of expressing the safety requirements is important. Quantitative statements of safety requirements should be used where possible, however, in many areas (e.g. where people and procedures are involved) it may not be feasible to define quantitative values. For these areas, qualitative values can be established. Where possible, these should be equated to corresponding quantitative values, within an accepted risk tolerability classification scheme (refer to the next section).

Chapter 3 **RISK MANAGEMENT**

3.1 Methodology

3.1.1 The methodology for risk management may vary depending upon the type and safety implications of the proposed new service or service change, and the use of different methods, or combinations thereof, may be appropriate for the different elements and lifecycle phases included in the safety case

3.2 Hazard identification and risk assessment

3.2.1 Techniques for hazard identification/risk assessment may include:

- the use of data or experience with similar services/changes undertaken by overseas or other respected providers of similar Part 172 services;
- quantitative modeling based on sufficient data, a validated model of the change, and analyzed assumptions;
- the application and documentation of expert knowledge, experience and objective judgment by specialist staff;
- trial implementation of the proposed change by simulation, or under surveillance and with sufficient backup facility to revert to the existing service before the change, if risks cannot be mitigated;
- a formal analysis / “Risk management”, or another accepted standard or text on risk analysis/system safety;
- event tree analysis (ETA);
- quantified risk analysis (QRA);
- failure modes and effects analysis (FMEA);
- human factors analysis (HFA);
- Hazard and operability studies (HAZOPs).

3.3 Safety risk assessment criteria

3.3.1 In order to ensure that the range of possible safety risks are appropriately classified and controlled, service providers should develop criteria for safety risk assessment. Such a safety risk classification scheme provides a structure for deriving the safety requirements for services, as well as the criteria for risk control decisions. Typically, such schemes provide a standard relationship between the probability of occurrence of each risk and the categorized severity of the risk in terms of its potential impact on safety, finally equating that to a risk acceptability criterion. The acceptability rating thus indicates the necessity for, and extent of control required for each risk.

Lesser impacts on safety might arise where the integrity of a system is degraded or lost, but where there are alternative back-up systems, or contingency arrangements, in place to maintain separation.

3.3.2 A safety case document should include the risk assessment criteria (also termed a risk tolerability classification scheme) adopted by the service provider for safety management.

ECAA does not intend to impose any specific risk assessment criteria or risk tolerability classification scheme. Examples of existing risk assessment criteria for airways related services are available in the references

3.4 Risk control

3.4.1 A risk control process to eliminate or mitigate all risks categorized as intolerable, to a tolerable level, should also be defined. Risk controls may vary considerably, and employ any or a combination of, the following:

- service redesign, modification or replacement;
- process or procedures redesign;
- personnel education or training; and
- Various management controls on personnel, procedures and equipment

3.4.2 Any identified risks that cannot be controlled to a tolerable level should be explicitly included in a separate section of the safety case that includes a discussion on all relevant aspects. The rationale for any decision to proceed with the development or operation of the service while the risk prevails is to be stated.

3.5 Precedence of risk controls

In the application of the above, or other, risk control processes, a safety precedence sequence should be adopted and applied. For instance, control of identified hazards should normally be sought first through improved design or facility/equipment changes, followed then by specific procedures or training. Whichever means of control is implemented; the control process should demonstrate how the risks are being brought within the limits of the safety objectives.

Chapter 4

SAFETY CASE COVERAGE OVER THE LIFECYCLE OF THE SERVICE

1. As previously discussed, safety cases should be developed in separate parts to define the safety situation of the service over the discrete stages of its lifecycle. A four part Safety Case has been used to define the safety situation at the Operational Requirements stage, at the completion of the Design phase, at Installation and Pre-Commissioning, and for the day-to-day Operational phase
2. The contents of the safety case will differ for each part. For some services, it may be appropriate to have fewer parts of the safety case. For all parts, the level of description and detail included should be sufficient to provide a reasonably informed reader with an Understanding of the safety situation, without the need to refer extensively to supporting references.
3. A guide to the coverage of each part of a four-part Safety Case is included in Appendix A to this AC - "Safety Case Coverage for a Four Part Safety Case".

4.1 Authority for issue and change of the safety case

Safety Cases should be placed under a documentation control process.

The Safety Case should be authorized by a competent authority designated by the service provider. For Part 172 services, an authority or authorities covering the operational requirements phase, the design phase, the pre-commissioning phase, and the commissioning and routine operations phase should be appointed, and the issue of the parts of the safety case should be made under the authority of one or more of these designated bodies, as appropriate to the content of each part.

Chapter 5
AUDITS OF SAFETY CASES

5.1 Internal monitoring and audit

It is expected that airways service providers will internally monitor and audit the safety aspects of their major airways projects under their internal monitoring and quality/safety audit programs. Monitoring may entail a specific means of safety reporting and analysis, or may be integrated with the existing processes already established by the service provider for incident and fault reporting and investigation, etc. The results of the internal monitoring should be incorporated into reviews and updates of the safety case, as necessary.

5.2 ECAA audits

ECAA, under its Surveillance plan, may carry out audits of Part 172 services. The relevant documentation pertaining to the safety case may be a focus of such audits.

APPENDIX A **SAFETY CASE COVERAGE FOR A FOUR PART SAFETY CASE**

The following is a guide to the information to be included in a four-part safety case.

Safety Case Part 1 - Operational Requirements Phase

A safety case Part 1 contains the Safety Objectives and the corresponding Safety Requirements for the proposed service, and will normally be the initial document provided to ECAA to advice of the proposed project's existence and its safety significance. The safety case at this stage should be an evaluation of the proposed system, perhaps most appropriately carried out by means of a system level Failure Modes and Effects Analysis (FMEA), supplemented as necessary by overseas or previous experience, and in-house expertise and knowledge of deficiencies in existing systems the new service is to replace

Safety Case Part 2 - Design and Procurement Phase

Part 2 of the safety case is essentially to assure that the proposed new service or service change meets any necessary safety requirements. Arguments to support the design rationale of the service, and to verify and validate that such satisfies the safety requirements should be provided. The human factors aspects of the design, and the safety implications of the design of the procedures, and the ability of personnel to apply the procedures, should also be considered. Here, a full hazard and risk evaluation of the detailed design, including hardware, software, man/machine interface, human factors, equipment and administrative interfaces and external factors, should be undertaken.

Safety Case Part 3 - Installation and Pre-Commissioning Phase

Part 3 of the safety case should provide an analysis of the safety situation following the commissioning of the service. The functional testing to be carried out for installation and pre-commissioning evaluation of the safety situation is detailed in this part. A testing regime aimed at validating the risk assessment made in Part 2 of the safety case, and identifying safety hazards not previously identified at Part 2 which arise during testing and integration and related activities should be defined, with the strategy for assessing and managing these hazards and the safety issues which arise from such testing also specified.

Safety Case Part 4 - Normal Operations Phase

Part 4 of the safety case should provide the complete evidence that the service is safe in operational service. It should address all relevant operational and management issues, and take account of the safety findings from the preceding three parts of the safety case. This part of the safety case should be maintained as a living document for the life of the service, to define and document any further hazards, identified at post-commissioning or during routine operations, and the risk control actions taken to maintain compliance with safety objectives, in the light of actual day-to-day knowledge and experience with the service.

Note in respect to all Parts

It is important that all parts of the safety case be retained and maintained as necessary over the life of the service, reflecting the safety situation for any approved modifications or changes. Such amendments to the safety case should be authorized by the appropriate approval authority.