

TECHNICAL GUIDANCE MATERIAL

for

Safety Case

SUBJECT: TECHNICAL GUIDANCE MATERIAL FOR SAFETY CASE

EFFECTIVE DATE: 18 OCTOBER 2021

APPLICABILITY

This guidance is applicable to all persons involved in the aviation industry who are seeking an improved application understanding of the process of management of change. It explains the concept of safety case in support of management of change primarily in the regulatory context and scope of SMS thus provides guidance for the development of a safety case.

PURPOSE

To provide guidance in support of management of change process application when required. The focus is on:

1. assessment and prioritization of risks based on collection and analysis of data;
2. application of safety management principles to support risk-based decision-making; and
3. management and monitoring of CAA approvals considering the flexibility needed across the aviation system to continue safe operations

REQUIREMENTS

SA CAR PART 140.01.3 and SA CATS 140.01.3(2.5) which reads together with SA CATS 140.01.3(2) (2.6) (2)

1. REFERENCE:

- i. ICAO Annex 19
- ii. Civil Aviation Regulations 2011 as amended
- iii. SA CAR Part 140
- iv. SA CATS 140
- v. TGM: Safety Risk Management

2. TERMS AND ABBREVIATIONS:

TERM	DEFINITION
Safety Case	A document which provides substantial evidence that the system to which it pertains meets its safety objectives. (extracted from ICAO <i>Guidance Material on Building A Safety Case for Delivery of an ADS-B Separation Service, Version 1.0 – September 2011</i>)
Safety Management System	Means a systematic approach to managing safety, including the necessary organizational structures, accountabilities, policies and procedures
Safety Risk	Means the predicted probability and severity of the consequences or outcomes of a hazard

ABBREVIATION	DESCRIPTION
AMoC	Alternative Means of Compliance
POI	Principal Operations Inspector
SACAA	South African Civil Aviation Authority
SACAR	South African Civil Aviation Regulations
SACATS	South African Civil Aviation Technical Standards
SMS	Safety Management System
TGM	Technical Guidance Material

3. GENERAL

- 3.1** Safety Case is a tool for accomplishing safety assurance. When applied correctly it breeds clear and amazing benefits to the organisation, such as reducing costs, reducing injuries, improve staff satisfaction etc. One main advantage of safety cases, is that it produces at your own time whilst developing the system, providing an opportunity for predictive SMS.
- 3.2** Safety case is nothing more than collection of supportive evidence towards a conclusion, including facts, arguments and possibilities. As a structured document, it is targeting a compelling, comprehensive and valid conclusion regarding safety for a given application, system, or process in a given operating

environment. The most important part of a safety case is ensuring that the process in question meets all applicable legislation and regulation. It should not however remain limited to only this. Hazard identification and risk management should be part of the safety case, including an assessment, information and guidance on the integration process of the element into the overall system. Further to this, it must provide clear lines of communicating the process, the relevant (and residual risks) and furthermore define the tracking mechanisms for monitoring. In simpler terms, it describes what needs to be managed.

3.3 The referenced Safety Case understanding should be taken in the context as:

3.3.1 A Safety Case is the documented assurance that includes a structured argument, supported by evidence, intended to justify that an operation is acceptably safe. A safety case aims to show that specific safety claims are substantiated and can be maintained.

3.3.2 The development of a Safety Case is not an alternative to carrying out a Safety Assessment. It is a means of structuring and documenting a summary of the results of a Safety Assessment, and other activities (e.g. simulations, surveys etc.), in a way that a reader can readily follow the logical reasoning as to why a change (or ongoing service) can be considered safe.

3.3.3 Such an evidence-based approach can be contrasted with a prescriptive approach to safety certification, typically used, which require safety to be justified using a stipulated process. Prescribed standards typically do not require an explicit argument for safety and instead rest on the assumption that following the process will generate the required standard for safety.

3.3.4 A safety case regime is an objective-based regime whereby legislation sets broad safety objectives and the operator, who accepts direct responsibility for the ongoing management of safety, develops the most appropriate methods to achieve those objectives. Essentially, the operator must make a 'case' demonstrating how it is going to effectively manage safety in its operations.

3.3.5 The thinking behind a safety case regime is that safety is best managed through positive measures rather than a prescriptive 'one size fits all' mentality — that is, safety is best managed if organisations anticipate possible risks instead of merely complying with prescribed technical rules. Whilst the safety case must ultimately be accepting or reject the SACAA; it is up to the operator to be proactive rather than simply compliant in the safety management of its operations.

3.3.6 Systematic analysis of risks, such as proposed changes to equipment or procedures, can identify and mitigate weaknesses before they combine with other factors to result in undesired costly outcomes. Rather than focusing solely on the level of risk, this approach creates a structured appraisal of how the risk can be managed effectively and efficiently.

3.3.7 A good Safety Case should include, at least:

- i. What the Safety Case is trying to demonstrate - this should be directly related to the Claim that the subject of the Safety Case is acceptably safe.
- ii. Why is the Safety Case being written and for whom?
- iii. A description of the system/change and its operational/physical environment, sufficient only to explain what the Safety Case addresses and for the reader to understand the remainder of the Safety Case;
- iv. For any Safety Case, the justification for introducing the change (and therefore potentially for incurring some risk);
- v. A reasoned and well-structured Safety Argument, showing how the Aim is satisfied;
- vi. Supporting safety evidence to substantiate the Safety Argument;
- vii. All assumptions, outstanding safety issues, and any limitations or restrictions on the operation of the system;
- viii. A simple statement to the effect that the safety objective has been satisfied, subject to the stated caveats.

4. WHEN TO SUBMIT A SAFETY CASE

- 4.1** A Safety Case would provide specific documented evidence that shows the organization not only identified and implemented the appropriate change management necessary to deliver new activity/equipment, but that the associated risk assessments were also conducted in support of implementation and ongoing activities associated with that change.
- 4.2** The SACAA utilizes Safety Cases as transitional evidence to support a regulatory application, exemption or variation. The Safety Case will include the applicable change and risk management activities in addition to revised operating procedures/exposition that will apply to the changed operations/activities. When accepted, these revisions should be incorporated into the relevant operating procedures/exposition. Activities must always be conducted in accordance with the relevant operating procedures/exposition rather than the Safety Case itself.
- 4.3** SACAA may require an organization to submit a Safety Case in the following circumstances:
- 4.3.1 In support of an application for activities that do not fit within the current regulatory regime and/or are without existing precedent
 - 4.3.2 In support of an application for exemption/variation from current regulatory requirements
 - 4.3.3 When otherwise requested by SACAA to support decisions/approvals requested.
- 4.4** Each service provider will be required to submit a safety case to demonstrate how they will comply in the form of a Safety Case, to the SACAA. The submission must consider following a risk-based approach

process that shall also focus on the applicable situations through management of change as outlined in SACATS 140.01.3(2) (2.6) (2). Each affected operator will directly engage their responsible SACAA Principal Operations Inspector (POI) to submit the Safety Case unless it's for Exemption; AMoC or Special approval application purposes, where further guidance to this effect is provided in the TGM: Exemption; AMoC or Special approval for the related process to be followed.

4.5 Furthermore, SACAA also encourages consideration of human factors (HF) risk

5. SAFETY CASE SUBJECTS AND CONTENTS

5.1 The safety case should include at least the following subjects as:

- 5.1.1 Executive summary
- 5.1.2 Introduction
- 5.1.3 System description
- 5.1.4 Assumptions used
- 5.1.5 Progress in integration
- 5.1.6 Safety requirements meet
- 5.1.7 Emergency and contingency arrangements
- 5.1.8 Operational information
- 5.1.9 Independent safety audit/ review
- 5.1.10 Conclusions and recommendations
- 5.1.11 References
- 5.1.12 Safety arguments
- 5.1.13 Safety evidence
- 5.1.14 Issues arisen
- 5.1.15 Limitation
- 5.1.16 Hazard identification and risk assessment

5.2 These subjects are to consider the inclusion of the following contents illustrations to include:

- 5.2.1 Description of the planned change (What is the change to be made)
- 5.2.2 Description of the reason for the change (Why is the change being made)
- 5.2.3 Description of the organisational context (What is the broader operational context of the organisation pertinent to the change)
- 5.2.4 Description of all identified hazards associated with the change (Consider hazards associated with the change process (transition hazards), as well as those associated with normal operations)

once the change has been implemented)

- 5.2.5 Details of risk management activities associated with identified hazards (Demonstrate that any risks associated with operations will remain acceptable during (transition) and following the planned change
- 5.2.6 Description of the controls necessary to ensure the risks are managed to an acceptable level (Controls are any activity or process designed to mitigate a risk including equipment, process, procedures and training etc.
- 5.2.7 Note: Controls can be detailed in the risk management activities.
- 5.2.8 Management of Change plan outlining how the organisation plans to transition from current operations to the proposed future operations, taking identified hazards and risk management strategies into account.

5.3 Safety cases must be reviewed and updated periodically.

5.4 The above listed information does not have to be reproduced in a specific Safety Case document. Wherever possible, a safety case submission should simply reference the applicable documentation necessary to cover the content details above. Provided the above points are covered, a Safety Case could simply be the Change Management, Risk Assessment, and revised corresponding procedures documentation as approved by the Authority. A Safety Case may also include any other evidence to support the submission, including training records, training materials etc.

6. COMPLIANCE WITH THE CIVIL AVIATION REGULATIONS 2011

6.1 In line with SA CATS 140.01.3(2) (2.6) (2) requirements, this SACAA shall consider the submitted Safety Case in the form of Management of Change Plan for evaluation for acceptance by the SACAA where, the following steps shall be intensely considered as part of acceptance:

6.2 Step 1 –

- 6.2.1 Assessment of the nature, scope and impact of the change
- 6.2.2 Review the submitted documentation to understand the change has been included the context and its impact internally and externally.

6.3 Step 2 –

- 6.3.1 Assessing hazard and consequence identification
- 6.3.2 Ensure that an appropriate hazard identification process has been carried and the range of consequences have been identified and documented.

6.4 Step 3 –

- 6.4.1 Evaluation of the way that the risk has been assessed and accepted

6.4.2 Review and evaluate that probability and severity classifications are appropriate, justified and applied consistently to manage risks to an acceptable level.

6.5 Step 4 –

6.5.1 Assessing the risk mitigation actions

6.5.2 Evaluate the risk mitigations to determine the effectiveness of the actions taken to control the risk.

6.6 Step 5 –

6.6.1 Assessing the justification and supporting evidence.



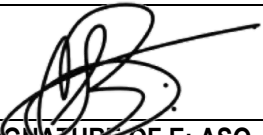
6.6.2 Assessment of any supporting evidence and arguments used to justify that the change is valid and does not have an adverse effect on safety.

6.7 Step 6 –

6.7.1 Assessing the assurance plan to manage the residual risk

6.7.2 Review how the organization plans to monitor the change implementation and verify that risks mitigations are effectively managed after the change has been completed.

7. AUTHORISATION

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