

Safety Case Development Manual

DAP/SSH/091

Edition	:	2.1
Edition Date	:	13 Oct 2006
Status	:	Released Issue
Class	:	EATM Stakeholders

DOCUMENT CHARACTERISTICS

TITLE		
Safety Case Development Manual		
EATMP Infocentre Reference:		
Document Identifier	Edition Number:	2.1
DAP/SSH/091	Edition Date:	13 Oct 2006
Abstract		
<p>This Safety Case Development Manual provides the reader with an overview of the methodology being proposed for the construction and development of Safety Cases. Version 2.0 is a complete rewrite of Version 1.3 which was published in 2003, taking into consideration user needs and recent experience with Safety Case developments.</p> <p>This Manual includes the concept of a Safety Case as presenting the entirety of argument and evidence needed to satisfy oneself and the regulator with respect to safety. It does not provide guidance on the generation or documentation of the evidence itself. Where separate guidance is available, such as the ANS Safety Assessment Methodology (SAM) then this is referenced accordingly. For further guidance on Safety Assessment see the SAM, or contact DAP/SSH.</p>		
Keywords		
ESARR 3	Safety Argument	Safety Case Lifecycle
Goal Structured Notation	Safety Case	Safety Management
		Safety Objectives
		Safety Requirements
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STATUS, AUDIENCE AND ACCESSIBILITY					
Status		Intended for		Accessible via	
Working Draft	<input type="checkbox"/>	General Public	<input type="checkbox"/>	Intranet	<input type="checkbox"/>
Draft	<input type="checkbox"/>	EATM	<input checked="" type="checkbox"/>	Extranet	<input type="checkbox"/>
Proposed Issue	<input checked="" type="checkbox"/>	Stakeholders	<input type="checkbox"/>	Internet (www.eurocontrol.int)	<input checked="" type="checkbox"/>
Released Issue	<input type="checkbox"/>	Restricted Audience			

ELECTRONIC SOURCE		
Path:		
Host System	Software	Size
Windows_XP	Microsoft Word 2002	1180 Kb

DOCUMENT APPROVAL

The following table identifies all management authorities who have successively approved the present issue of this document.

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DOCUMENT CHANGE RECORD

The following table records the complete history of the successive editions of the present document.

EDITION NUMBER	EDITION DATE	REASON FOR CHANGE	PAGES AFFECTED
1.3	07.07.03	Proposed Issue – Including editorial corrections	All
1.41	29.11.04	Initial Draft of Revised Version	All
1.42	13.12.04	Working Draft of Revised Version	All
1.43	23.12.04	Further Draft of Revised Version	All
1.44	01.02.05	Update following DAP/SAF internal review	All
1.45	11.02.05	Chapter 5 and Appendix updated following DAP/SAF internal review	Chap 5 and Appdx C
1.5	25.02.05	Minor changes following final DAP/SAF internal review	All
2.0	28.09.05	Proposed Issue following external stakeholder review	All
2.1	13.10.06	Released Issue, incorporating final stakeholder comments	4, 6, 8, 19

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PREFACE

Background

Version 2.0 of the Safety Case Development Manual has been developed based on recent experience, user feedback and lessons learned since Version 1.3 was published in July 2003.

The new Manual tries to explain in simple terms the ‘Essentials’ of how to construct a Safety Case and then provides supporting ‘Guidance’ and ‘Examples’. It is intended primarily for use within the EUROCONTROL Agency but may also be used (where appropriate¹) by the Member States.

Related Documents

The provisions of the Manual are intended to be consistent with ESARRs and the EUROCONTROL ANS Safety Assessment Methodology (SAM), to which numerous references are made herein. In particular, the Manual as a whole is intended to satisfy the requirements of paragraph 5.3 of ESARR 4 concerning the documentation of the arguments and evidence associated with the risk assessment and mitigation processes.

EATM SMS Context

The Manual provides a product description for the Safety Case described in Element 5 (Risk Assessment and Mitigation) of the EATM Safety Management Handbook. Organisational issues are dealt with in Element 3 (Organisation and Structure).

User Community

The Manual is intended primarily for safety professionals who have received training in SMS and the EUROCONTROL SAM.

We believe that it will be of most immediate use to the *willing developer* but accept that it could present some difficulties for the *uncertain starter*; we also believe that it has something to offer to the *confident adopter*².

Therefore, the contents of the Manual will be supported by related training, and readers (particularly, but not exclusively *willing developers* and *uncertain starters*) are urged to undertake this training and the related EUROCONTROL SAM training before embarking on the development of a Safety Case for an operational application.

Feedback

The users of this Manual are invited to provide any feedback and suggestions for improvement on this current version to me, which will be taken into consideration when a future updated Version is produced.

“Health Warning” !!

Finally, this Manual cannot give a complete insight into all aspects of Safety Assessment and Safety Case development nor provide ready made solutions to fit every situation.

¹ “Where appropriate” is inserted here because there is no explicit requirement in ESARRs for ANSPs to produce Safety Cases. EUROCONTROL has chosen the Safety Case approach for EATM Programmes and Domain Activities because experience has shown this approach to be effective for these applications.

² See EUROCONTROL SAM [5] for explanation of these terms

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CHAPTER 1

– Introduction

1. Purpose of the Manual

What does it do?	<p>This Safety Case Development Manual provides guidance on the development of Safety Cases as a means of structuring and documenting the demonstration of the safety of an ATM service or new / modified System³.</p>
Who is it for?	<p>The Manual is intended for use by those, employed on projects or in service-provider organisations, who have to:</p> <ul style="list-style-type: none">• Produce Safety Cases – eg safety practitioners;• Approve Safety Cases – eg programme managers and heads of ATSUs;• Review Safety Cases – eg safety department staff.
What is it for?	<p>The aim is to achieve sound, well-presented Safety Cases through the adoption of a logical, rigorous, consistent and accurate approach that is based on good safety practice.</p>
What does it <u>not</u> do?	<p>Whereas this Manual should aid the process of developing and presenting a Safety Case, it cannot give assurance of the validity of the end product, and it does <u>not</u>, therefore, relieve its users of their responsibility to provide such assurance.</p> <p>The Manual does <u>not</u> provide guidance on how to carry out a safety assessment – see the EUROCONTROL SAM [5] for that – rather it describes how to present the results of a safety assessment, in the context of a Safety Case.</p>

³ The term 'System' is used throughout this manual to include airspace, equipment, people and procedures.

As the Manual is intended to be used within the framework of a Safety Management System (SMS), it does not address questions, such as what is a change and when should a Safety Case be produced – these are assumed to be addressed by the SMS⁴. Rather, the starting point for the Manual is the point at which it has been decided to produce a Safety Case for a particular ATM service or change (a so-called “substantial change” in this document).

2. Structure of the Manual

The remainder of this Manual is presented in a further 4 Chapters, covering the **Essentials** of Safety Case Development and supporting **Guidance**, as follows.

Essentials - Getting Started

Chapter 2 explains the background to Safety Cases and provides the key points in planning the development of a Safety Case.

Essentials – Argument and Evidence

Chapter 3 presents the essentials of the Safety Case itself.

Guidance – Process and Techniques

Chapter 4 provides guidance in support of Chapters 2 and 3, including the use of Goal-structuring Notation (GSN). The Guidance may be accessed directly or via links embedded in the relevant parts of those Chapters.

Guidance - Examples

Chapter 5 provides generic examples of structured Safety Arguments using GSN. The main example is the introduction of a substantial change to an ATM service / system. Variations of that Safety Argument for an on-going ATM service and for a typical limited-scope Safety Case are also explained.

References

Appendix A provides a list of the references called up in the Manual.

Glossary

The EATMP Glossary document [4] facilitates the search and use of acronyms, abbreviations, terms and definitions most frequently used within the EATM Programme. As the EATMP Glossary document includes more than 5,800 acronyms and 2,000 definitions, a summary of the terms commonly used in Safety Case development is provided at **Appendix B**.

Checklists

Appendix C contains checklists for use by Safety Case developers, reviewers and approvers in assessing the quality of the argument structure and presentation of the Safety Case.

⁴ For guidance on “what is a change” please see the SAM [5] Guidance Material, Part IV, Appendix H.

CHAPTER 2

– Essentials –

Getting Started

1. What is a Safety Case for?

A Lesson from History

In the investigation into the Piper Alpha accident [14] Lord Cullen wrote:

*“Primarily the Safety Case is a matter of ensuring that every company produces a formal safety assessment to **assure itself** that its operations are safe.*

Only secondarily is it a matter of demonstrating this to a regulatory body. That said such a demonstration both meets a legitimate expectation of the workforce and the public and provides a sound basis for regulatory control.”

ICAO Obligation

ICAO Annex 11 places an obligation on the providers of Air Traffic Management services to ensure the safety of air traffic, in respect of those parts of the ATM System and supporting services within their managerial control.

The Burden of Proof

Implicit to this obligation is the requirement on those with managerial control to **demonstrate** positively that the relevant Safety Regulations are satisfied. In essence there is a “burden of proof” on Air Navigation Service Providers to show that acceptable levels of safety⁵ are, and continue to be, achieved.

⁵ As defined by the Safety Criteria – see Chapter 4, section 2

Primary Purpose	Broadly, the Safety Case is the documented assurance (ie argument and supporting evidence) of the achievement and maintenance of safety. It is primarily the means by which those who are accountable for service provision or projects ⁶ assure themselves that those services or projects are delivering (or will deliver), and will continue to deliver, an acceptable level of safety.
Relationship with Regulatory Approval	As the main objective of safety regulation is to ensure that those who are accountable for safety discharge their responsibilities properly, then it follows that a Safety Case which serves the above primary purpose should also provide an adequate means of obtaining regulatory approval for the service or project concerned.
Relation to Safety Management System	In the context of a Safety Management System, the Safety Case can be a means of documenting and recording the safety of a service or system. Conversely, the implementation of a Safety Management System would provide evidence to support a Safety Case.
Relation to Safety Assessment	The development of a Safety Case is not an alternative to carrying out a Safety Assessment, in accordance with, for example, the EUROCONTROL SAM [5]; rather, it is a means of structuring and documenting a summary of the results of a Safety Assessment, and other activities (eg simulations, surveys etc), in a way that a reader can readily follow the logical reasoning as to why a change (or on-going service) can be considered safe.

2. Which Kind of Safety Case?

Types

Safety Cases may come in many forms but most, if not all, can be thought of as falling into one of two categories, as follows:

- those which are used to demonstrate the safety of an **on-going service** – these are known herein as Unit Safety Cases; and
- those which are used to demonstrate the safety of a substantial **change** to that service (and/or underlying system) – these are known herein as Project Safety Cases.

The two categories are interrelated, as explained below.

Unit Safety Case

An ATSU (or other major, safety-related service / facility) may decide to produce, and maintain, a (Unit) Safety Case in order to show that the on-going, day-to-day operations are safe and that they will remain so indefinitely.

⁶ The distinction between services and projects / systems is to emphasise the difference between Unit and Project (or System) Safety Cases – see section 2. The generic term “project” should be taken to include EATM Programmes and Domain Activities.

A Unit Safety Case would include typically an *a priori* safety assessment (to show that service / system is predicted to be safe), together with the results of safety audits, surveys and operational monitoring (to show that, up to that point in time, it actually has been safe). It should also demonstrate that processes are in place to ensure that all future changes to the ATSU's system will be managed safely through, inter alia, Project Safety Cases.

Project Safety Case

An ATSU (or other responsible organisation) may also decide to produce a Project Safety Case when a particular substantial change to an existing safety-related service / system (including the introduction of a new service / system) is to be undertaken.

A Project Safety Case would normally consider only those risks created or modified by the change and rely on an assumption (or evidence from the corresponding Unit Safety Case) that the pre-change situation is at least tolerably safe.

Project Safety Cases are used to update, and are usually subsumed into, Unit Safety Cases⁷.

Further details of both Unit Safety Cases and Project Safety Cases are given in section 3 below and in Chapter 5.

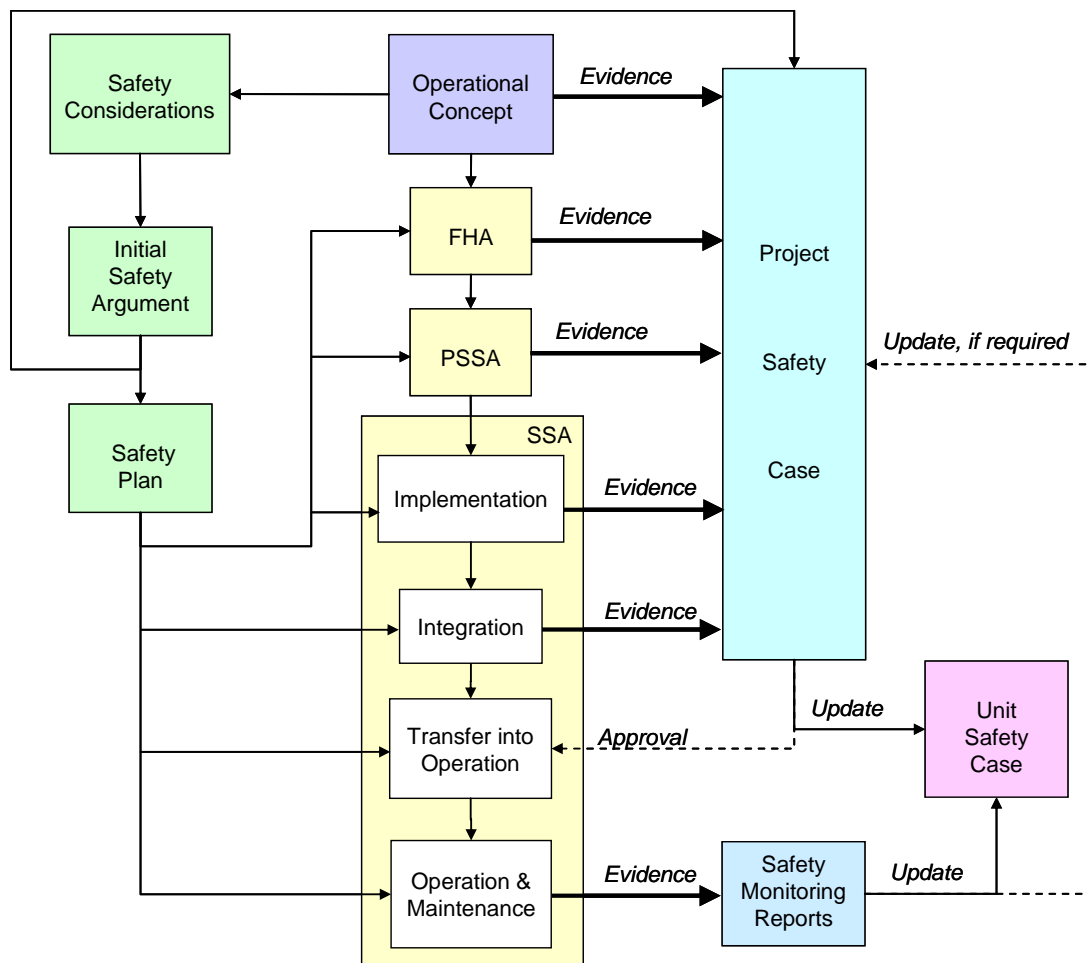
3. Safety Cases and the Project Safety Lifecycle

A simplified view of a typical project lifecycle is shown in the diagram overleaf.

Safety Considerations

This is an EATM SMS process to identify the main safety issues associated with a project as soon as possible after an Operational Concept has been developed and to help in deciding whether a full Safety Plan and Safety Case are required. It provides an initial assessment of the safety implications of the project, as the basis for developing a Safety Plan in which the detailed safety activities will be specified. It should address, inter alia, what the project is seeking to achieve (eg to deliver benefits in capacity, efficiency and/or safety), the possible impact on safety (in general terms only, since a safety assessment would not have been started at this stage), the criteria for deciding what is "safe" in the context of the Project and, in broad terms, the strategy for demonstrating safety.

⁷ However, this is not meant to imply that a Unit Safety Case is merely a collection of project Safety Cases!



Initial Safety Argument

Building on the Safety Considerations, the initial Safety Argument should be as complete as possible and at least sufficient to provide a set of goals for the Safety Plan to address. It also provides the starting point, and framework, for the development of the Project Safety Case, although it needs to be recognised that the initial view of what the Safety Argument should look like may need to change, depending on the results of the subsequent safety assessment.

Safety Plan

Specifies the safety activities to be conducted throughout the project lifecycle and the responsibilities for their execution.

Safety Assessment:

The three main phases of safety assessment (FHA, PSSA and SSA) provide much of the Evidence needed for the Project Safety Case, as follows:

FHA

- FHA produces Safety Objectives to limit the frequency of occurrence of hazards, such that the associated risk would be acceptable, and the external means of mitigating the effects of the hazards, including those means that are not pre-existing and need to be captured subsequently as Safety Requirements in the PSSA.

PSSA

- PSSA produces Safety Requirements and Assurance Levels for the system elements.

SSA

- SSA produces the assurance that the Safety Requirements and Safety Objectives are met in the implemented system

	and that risk is acceptable.
	For further information on safety assessment, see the SAM [5].
Implementation & Integration	This phase covers all the preparation needed in order to bring the new / modified system – the subject of the Safety Case – into operational service.
Transfer into Operation	Transfer into Operation of the new/modified system would normally be subject to a risk assessment and mitigation for this phase itself (part of the Project Safety Case) and be concluded by finalisation and regulatory approval of the Project Safety Case.
Operational Service	Because most, if not all, of the preceding safety assessment work is predictive in nature, it is important that further assurance of the safety is obtained from what is actually achieved in operational service. If the operational experience differs significantly from the results of the predictive safety assessment, it may be necessary to review and update the Project Safety Case.
Unit Safety Case	Once a satisfactory steady state has been achieved, it would be appropriate to update the Unit Safety Case (if one exists) with the information from the Project Safety Case thus establishing a new safety baseline for the on-going operational service.

4. Contents of a Safety Case

	A good Safety Case (of whichever type) should include, at least:
Aim	<ul style="list-style-type: none"> what the Safety Case is trying to show - this should be directly related to the Claim that the subject of the Safety Case is acceptably <i>safe</i>;
Purpose	<ul style="list-style-type: none"> why is the Safety Case being written and for whom;
Scope	<ul style="list-style-type: none"> what is, and is not, covered - see section 5 below;
System Description	<ul style="list-style-type: none"> 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 – see section 6 below;
Justification	<ul style="list-style-type: none"> for project Safety Cases, the justification for introducing the change (and therefore potentially for incurring some risk);
Argument	<ul style="list-style-type: none"> a reasoned and well-structured Safety Argument showing how the Aim is satisfied – see Chapter 3, section 2 below;
Evidence	<ul style="list-style-type: none"> supporting Safety Evidence to substantiate the Safety Argument – see Chapter 3, section 3 below;
Caveats	<ul style="list-style-type: none"> all Assumptions, outstanding safety Issues, and any Limitations or restrictions on the operation of the system;

Conclusions

- a simple statement to the effect that the Aim has been satisfied, subject to the stated Caveats.

Chapter 4, section 8 provides further guidance on the content, structure and layout of a Safety Case

5. Defining the Scope and Boundaries for the Safety Case

Scope Definition

Defining the scope and boundaries of the Safety Case is an essential first step in the development of the Safety Case. It should explain clearly:

- what the Safety Case covers (and does not cover);
- boundaries of responsibility with respect to managerial control and other stakeholders;
- relationship with other Safety Cases, if applicable;
- applicability and compliance with safety regulations and standards;
- any assumptions made in defining the scope, boundaries or safety criteria.

Lifecycle Limitations

A Safety Case may be (temporarily) restricted to the safety of a new concept, and therefore be conditional on the subsequent complete and correct implementation of that concept by the responsible organisation. This is the situation on those EATM Programmes (and similar activities) for which EUROCONTROL is not responsible for implementation; the output would then be a validated set of Safety Requirements (from the PSSA).

The term *Preliminary Safety Case* is used herein to cover such situations, and it should be supported by guidance material for the subsequent implementation of the Safety Requirements and for the development of a full Safety Case. An example of a Preliminary Safety Case, and the sort of guidance that should accompany it, are given in **Chapter 5, section 3**.

6. Setting the Context

Rationale

It is vital to fully describe the operational environment to which the Safety Case applies and the system configuration on which the Safety Case (and underlying Safety Analysis) is based.

Content

The description of the Context should include:

-
- the purpose of the system from a safety perspective;
 - the interfaces with other systems including people, procedures and equipment;
 - the operational environment – including all characteristics that may be affected and elements that are relied upon, when assessing acceptable levels of safety;
 - A reference to (together with a summary of) Concept of Operations that explain how the system, and the service that it supports, are intended to operate
-

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CHAPTER 3

– Essentials –

Argument and Evidence

1. Introduction

Overview

This Chapter presents the essential points of:

- the construction of Safety Arguments;
- the collation, review and presentation of Safety Evidence.

Non-prescriptive

The information presented draws on current good practice without prescribing a particular methodology, and is supported by references to the Guidance in Chapter 4.

2. Safety Argument

What is a Safety Argument?

A Safety Argument is a statement (or a set of statements) that is used to assert that the service or system concerned is *safe*, and should be developed as follows.

Making the Claim

The Safety Argument must start with a top-level statement (Claim) about what the Safety Case is trying to demonstrate in relation to the safety of the service or system.

Supporting the Claim

The Claim must be supported by:

- **Safety Criteria**, which define what is *safe* in the context of the Claim;
 - for Project Safety Cases, the **Justification** for introducing
-

Structuring the Argument

the change to the service or system concerned;

- the **Operational Context** for the Claim;
- any fundamental **Assumptions** on which the Claim relies.

The decomposition of the Claim into lower-level Arguments provides the essential links between the Claim and the wealth of Evidence needed to show that the Claim is valid.

In performing this decomposition, it is important that:

- each Argument in the structure is expressed as a simple predicate – ie a statement that can be only true or false;
- the Argument structure does not contain any negative or inconclusive Arguments⁸;
- the set of Arguments at each level of decomposition is necessary and sufficient to show that the parent Argument is true;
- a valid counter-Argument, which would negate the parent Argument, does not exist⁹;
- where the rationale for decomposition of an Argument into lower-level Arguments is not self evident, it is explained by supporting text;
- the number of levels of decomposition is appropriate to the complexity of the Safety Case and/or supporting Evidence;
- each branch of the Safety Argument structure is terminated in supporting Evidence;
- there is a clear distinction between, and correct use of, **Direct** (product-based) and **Backing** (process-based) Arguments and related Evidence.

Guidance

Further guidance on the structuring of Safety Arguments is given in **Chapter 4, section 3**, and generic ATM examples are presented in **Chapter 5**.

3. Safety Evidence

What is Safety Evidence?

Safety Evidence is information, based on established fact or expert judgement, which is presented to show that the Safety Argument to which it relates is valid (ie true).

The essential rules of Evidence are as follows:

Necessity

-
- Evidence must be presented only to the degree and extent
-

⁸ The main point here is that lack of Evidence of risk is not Evidence of lack of risk!

⁹ This point is concerned only with the sufficiency of the Argument – sufficiency of the Evidence is covered in section 3.

necessary to support the related Argument;¹⁰

Sufficiency

- Evidence must show that the related Argument is true in a way that is clear, unequivocal, conclusive and, wherever possible, objective;

Appropriateness

- the type of Evidence – from safety analysis, design, simulation, test, previous usage, compliance with standards etc – must be appropriate to the Argument;

Rigour

- the rigour of the Evidence must be appropriate to the associated risk;

Relevance

- Evidence must actually relate to the correct configuration of the system under consideration.

Guidance

Further guidance on the gathering, assessing and presenting Evidence is given in **Chapter 4, section 4**.

¹⁰ The point here concerns only irrelevant Evidence. Clearly any Evidence which actually counters the Argument must not be ignored; on the contrary, the validity (or at the very least the phrasing) of an Argument must be reconsidered in the light of such Evidence

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CHAPTER 4

– Guidance –

Process and Techniques

1. Overview

Context

This Chapter provides guidance in support of the requirements stated in Chapters 2 and 3 above. Whereas this guidance is based on experience gained on the development of Safety Cases by EUROCONTROL on a wide range of EATM Programmes, it is intended to be applicable also to other environments – eg service provision.

Scope

The guidance covers the following areas:

- determining the Safety Criteria - **section 2**;
 - constructing a Safety Argument, using a recognised notation that is considered to be good practice – ie Goal-structuring Notation (GSN) - **section 3**;
 - general issues concerning gathering, collating, assessing and presenting Safety Evidence - **section 4**;
 - specific issues concerning Evidence of Safety Requirements *determination* - **section 5**;
 - general issues concerning Safety Requirements *satisfaction* - **section 6**;
 - developing a Safety Plan - **section 7**;
 - deciding the format, structure and layout of a Safety Case - **section 8**;
-

-
- verifying the Safety Case - **section 9**;
 - ESARR compliance - **section 10**.
-

2. Determining the Safety Criteria

Safety Criteria are essential to the definition of what is *safe* in the context of the top-level Safety Claim

Basically, they fall into three categories as follows:

Absolute

- Compliance with a defined target – eg the ESARR 4 Risk Classification Scheme (RCS) or ICAO Target Level of Safety (TLS) – or portion thereof. Such criteria are usually quantitative;

Relative

- Relative to an existing (or previous) level of safety. Such criteria may be quantitative or qualitative;

Reductive

- Where the risk is required to be reduced as far as reasonably practicable. Such criteria are usually qualitative.

Selecting Criteria

In general, absolute criteria are preferred since satisfaction of them does not depend on proof of past safety achievement and such proof may be difficult if a suitable baseline does not exist or sufficient historical data is not available.

However, in some cases, there may be a problem in establishing what would be a suitable target on which to base the criterion because either:

- a regulatory target has not been set for the operational environment concerned¹¹; or
- for Project Safety Cases, it may not be feasible to determine what portion of the overall target it would be reasonable to allocate to the system concerned.

As an alternative to the absolute approach, a relative Safety Argument (ie based on a relative criterion) could be used for a Project Safety Case¹² if:

- a well-defined baseline, prior to the introduction of (or change to) a 'system', could be established; and
- it can be shown, or at least reasonably be assumed, that the baseline situation was *safe*.

The justification for a relative approach is the ATM 2000+ [1] Safety Objective which requires that risk shall not increase and preferably decrease, relative to historical achievement. The

¹¹ This is being addressed by the current (2005) EUROCONTROL TLS study

¹² For Unit Safety Cases an absolute approach should always be the primary criterion.

ESARR 4 RCS, although normally considered to be an absolute measure, is actually a quantified interpretation of the ATM 2000+ Safety Objective¹³.

A reductive approach is called for by ESARR 3 (paragraph 5.1.4), which requires ANSPs to reduce risk as far as reasonably practicable. It is an important criterion for in-service safety monitoring – especially regarding incident investigation and corrective action.

Multiple Criteria

It is usual to specify more than one type of criterion, and sometimes all three. In ATM, reducing risk *as far as reasonably practicable* is rarely adequate on its own¹⁴ but it is often useful in support of one (or both) of the other two criteria.

Use of Risk Classification Schemes

Risk classification schemes (RCS)¹⁵ are often used as criteria on which to base absolute Arguments. However, experience has shown that a lack of understanding by the user as to how the RCS was originally derived can lead to inappropriate use. If RCS are used, it is important that the user understands:

- at what level in the system hierarchy the values are intended to be applied;
- where the probability/frequency values used in the scheme came from and whether they are (still) valid;
- to what operational environment the values apply – eg type of airspace, traffic patterns, traffic density, spatial dimension, phase of flight etc;
- how the aggregate risk, as specified in ESARR 4 for example, can be deduced from analysis of individual hazards, in restricted segments of the total system.

The last three bullets should not be a problem for the user in an organisation that has a single, well-founded RCS, applicable to all operational environments.

All other RCS users should be aware of, and address, the issue raised in the first bullet.

For further guidance on RCS, please see SAM FHA Chapter 3 GM E, based on ED-125 [15].

3. Constructing a Safety Argument

Requirements

Since the Safety Argument forms the framework of a Safety

¹³See ESARR 4 [9], Appendix A, Endnote (2)

¹⁴Both ATM 2000+ and ESARR 4 require, as a minimum, that risk must not increase – reducing risk *as far as reasonably practicable* on its own does not ensure that this minimum requirement is met.

¹⁵The comments here are aimed at the use of Risk Classification Schemes to determine what is a tolerable level of risk, not at the use of Severity Classification / Categorisation Schemes proposed in, inter alia, ESARR 2, ESARR 4 and the EUROCONTROL ANS Safety Assessment Methodology.

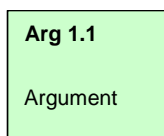
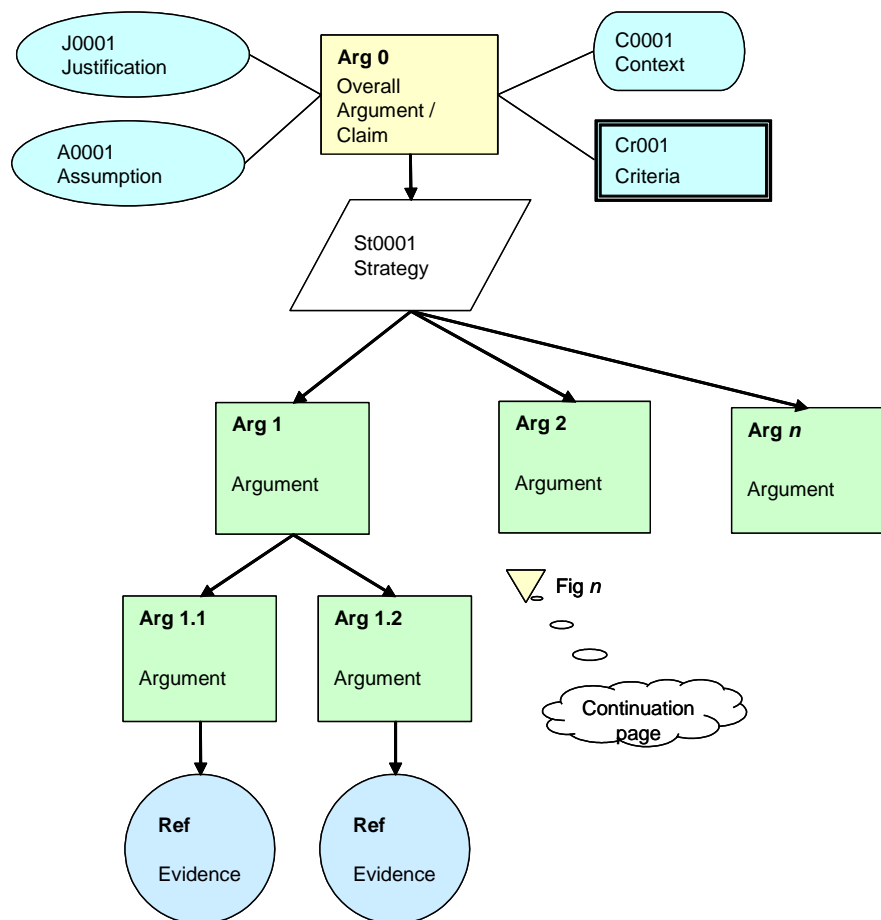
Case, it is important that the Argument is set out in a rigorous, hierarchical and well-structured and easily-understood way.

GSN Solution

Goal-structuring Notation (GSN), developed by the University of York, provides a graphical means of setting out hierarchical Safety Arguments, with textual annotations and references to supporting Evidence.

The logical approach of GSN, if correctly applied, brings some rigour into the process of deriving Safety Arguments and provides the means for capturing essential explanatory material, including assumptions, context and justifications, within the argument framework.

The diagram below shows, in an adapted form of GSN, a specimen *Argument* and *Evidence* structure to illustrate the GSN symbology most commonly used in EUROCONTROL ATM Safety Cases.



An *Argument* should take the form of a simple predicate - ie a statement which can be shown to be only true or false.

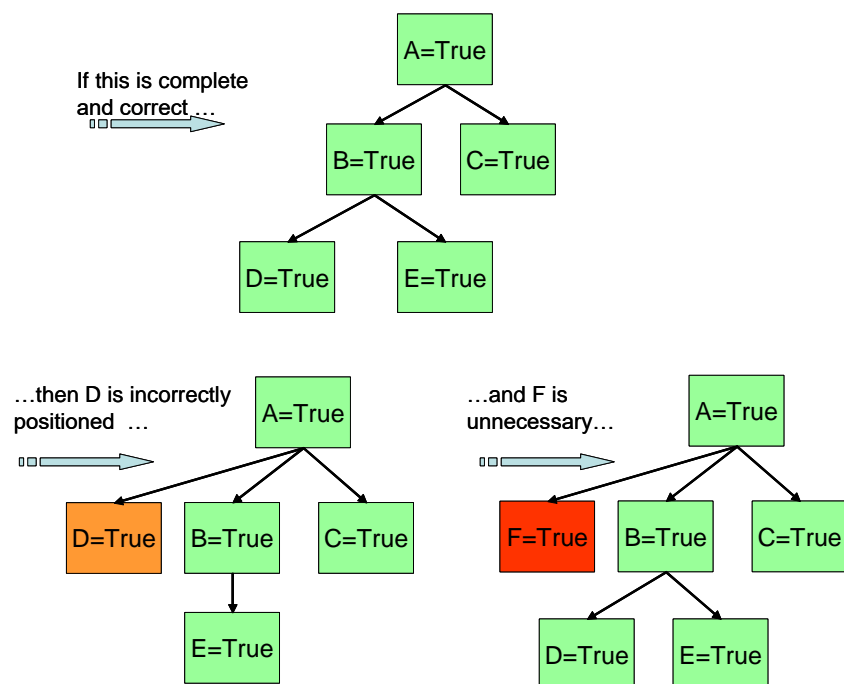
GSN provides for the structured, logical decomposition of *Arguments* into lower-level *Arguments*. For an *Argument* structure to be *sufficient*, it is essential to ensure that, at each level of decomposition:

- the set of *Arguments* covers everything that is needed in order to show that the parent *Argument* is true;
- there is no valid (counter) *Argument* that could undermine the parent *Argument*.

In the above diagram, for example, if it can be shown that **Arg 1** is satisfied by the combination of **Arg 1.1** and **Arg 1.2**, then we need to show that **Arg 1.1** and **Arg 1.2** are true in order to show that **Arg 1** is true.

If this principle is applied rigorously all the way down through and across a GSN structure, then it is necessary to show only that each *Argument* at the very bottom of the structure is satisfied (ie shown to be true) in order to assert that the top-level *Claim* has been satisfied. Satisfaction of the lowest-level *Arguments* is the purpose of *Evidence*.

Unnecessary (or misplaced) *Arguments* do not in themselves invalidate an *Argument* structure; however, they can seriously detract from a clear understanding of the essential *Arguments* and should be avoided. The cover-up method illustrated in the three GSN diagrams below can be used to determine identify unnecessary and misplaced *Arguments*.

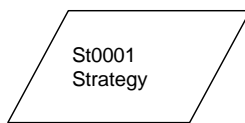


It follows from the above that, for an *Argument* structure to be considered to be complete, every branch must be terminated in a reference to the item of *Evidence* that supports the *Argument* to which it is attached.

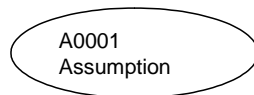
Evidence therefore must be:

- appropriate to, and necessary to support, the related *Argument* - spurious *Evidence* (ie information which is not relevant to an *Argument*) must be avoided since it would serve only to confuse the "picture";
- sufficient to support the related *Argument* - inadequate

evidence undermines the related *Argument* and consequently all the connected higher levels of the structure.

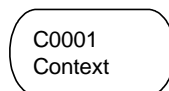


Strategies are a useful means of adding “comment” to the structure to explain, for example, how the decomposition will develop. They are not predicates and do not form part of the logical decomposition of the *Argument*; rather, they are there purely for explanation of the decomposition.



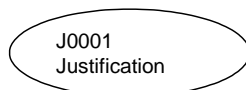
An *Assumption* is a statement whose validity has to be relied upon in order to make an *Argument*.

Assumptions may also be attached to other GSN elements including *Strategies* and *Evidence*.

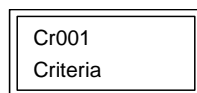


Context provides information necessary for an *Argument* (or other GSN element) to be understood or amplified.

Context may include a statement which limits the scope of an *Argument* in some way.



A *Justification* is used to give a rationale for the use or satisfaction of a particular *Argument* or *Strategy*. More generally it can be used to justify the change that is the subject of the Safety Case.



Criteria are the means by which the satisfaction of an *Argument* can be checked.

Numbering

It is recommended that *Arguments* be numbered hierarchically (eg, **Arg 1.1**) to reflect their logical structure.

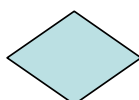
Strategies, *Assumptions*, *Context*, and *Criteria* should be numbered sequentially (eg, **St0001**) since they elaborate, but do NOT form part of, the logic of the structure.

It is recommended that *Evidence* be numbered according to its source reference and that the *Evidence* ‘bubble’ contains a brief indication of the form that the *Evidence* takes.

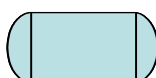
Other Symbolology



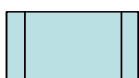
A **Choice** can be used while a Safety Argument is being developed to show a decision point between alternative *Strategies*. However, they must be removed before a Safety Argument is finalised.



A **Model** is some representation of the system, sub-system or environment – eg Simulations, Data Flow Diagrams, Circuit Layouts, State Transition Diagrams etc.



A **Stakeholder** is the person or role responsible for ensuring satisfaction of an *Argument*, *Strategy*, or *Choice*.



Constraints are used to restrict the way in which an *Argument* can be solved; they are restrictions imposed on the interpretation of the parent *Argument*.



A **Problem** is attached to an *Argument* to indicate that there is a possible obstacle to showing that it is true. *Problems* can also be attached to other GSN elements.

Examples of the application of GSN to generic Safety Arguments are presented in **Chapter 5**.

4. Gathering, Assessing and Presenting Safety Evidence

Importance

Evidence is the heart of every case and ultimately it is on the quality and completeness of the Evidence that the validity of a Safety Case depends. Of course, a well-structured Safety Argument is very important but only insofar as it provides the context for, and thus facilitates interpretation of, the Evidence.

Direct and Backing

In decomposing the Safety Arguments, the following two main types of Argument (and related Evidence) are used:

- that which shows that a particular objective has been achieved (ie that a higher level Argument or Claim has been satisfied) – this is referred to as **Direct** Argument and Evidence;
- that which shows that the Direct evidence is trustworthy (ie that it can be relied upon) – this is referred to as **Backing** Argument and Evidence.

Direct Evidence may be thought of as being that which relies directly on the observable properties of a **product** (ie the output of a process), supporting a logical Argument as to how the product satisfies its safety objectives or requirements, as appropriate.

Backing Evidence is obtained from the properties of the **processes** by which Direct Evidence was obtained, and shows that those processes, tools and techniques, human resources etc were appropriate, adequate and properly deployed.

General Attributes

The points below expand upon the “essential rules” outlined in **Chapter 3, section 3** above.

Necessity

Evidence must be presented only to the degree and extent necessary to support the related Argument.

The issue here is that, in the context of an Argument-based approach, any “Evidence” which is unrelated to a part of that Argument is not only of no value but could also serve as a distraction from those aspects of the Safety Case that are relevant. On the other hand, any Evidence which actually undermines the validity of an Argument must not be ignored – the existence of such Evidence must be acknowledged and explained fully in the Safety Case.

Sufficiency:	Evidence must be sufficient, as follows.
<ul style="list-style-type: none"> ○ Clarity, and Conclusiveness 	<p>It is bad (but unfortunately not uncommon!) practice to present an element of a structured Argument and then refer to a mass of information as “Evidence” to substantiate the Argument.</p> <p>It is vital to the integrity of the Safety Case that the Evidence be presented in such a way that is clear to the reader that the Evidence does actually show the related Argument to be true, “beyond all reasonable doubt”.</p> <p>Where Evidence is contained in appendices or external documents, a summary justifying the adequacy of the Evidence should be presented (in the Safety Case) along with the associated Argument. It is <u>not</u> sufficient to merely reference the Evidence with statements such as “Evidence to support the Argument is presented in”</p>
<ul style="list-style-type: none"> ○ Objectivity 	Wherever possible, Evidence should consist of proven facts – eg, the results of a well-established process such as simulations and testing. Only where such objective Evidence is not available should Evidence based on expert opinion be used, and then only when the credentials of the expert(s) and the means of eliciting the opinion are adequate and have been presented as Backing Evidence.
Appropriateness	The type of Evidence, from safety analysis, design, simulation, test, previous usage etc, must be appropriate to the Argument – see sections 5 and 6 below.
Rigour	The rigour of the Evidence must be appropriate to the associated risk. This is the principle behind the Assurance Level concept in ESARR 6 [11] (for software) and the EUROCONTROL ANS Safety Assessment Methodology [5] for software, procedures and human aspects.
Relevance	<p>Evidence must relate to the configuration of the system and operational environment under consideration - eg a correct and known:</p> <ul style="list-style-type: none"> • version of the equipment, procedures, training, etc.; • documentation used in the production of that version; • range of configuration data.
Application	How the above should be applied specifically to the two main stages of the safety development lifecycle – <i>requirements determination</i> and <i>requirements satisfaction</i> - is discussed below, in sections 5 and 6 respectively.

5. Evidence – Safety Requirements Determination

What are Safety Requirements	To paraphrase ESARR 4 [9] , Safety Requirements are means by which the necessary risk reduction measures identified in the hazard and risk analysis are formally ¹⁶ specified. Necessary in
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¹⁶ In the normal English meaning of the word.

	<p>this context means necessary in order to achieve the required safety levels, as defined by the Safety Criteria (see section 2 above) and translated into specific Safety Objectives during the Functional Hazard Assessment [5]</p>
Role of Safety Requirements in ATM	<p>The primary purpose of ATM is to reduce the risk of accident to air traffic that would otherwise exist. The amount of risk reduction is determined primarily by the functionality and performance of the ATM systems elements, including equipment, people and procedures. However, failure within the ATM system can cause risk to increase again, either by reduction in functionality or performance, or by the introduction of new risk caused by corruption of the outputs of ATM functions.</p>
Types of Safety Requirement	<p>Therefore, in order to achieve a <u>net</u> safety benefit from ATM, the reduction in risk afforded by the desired functional and performance properties of ATM needs to be substantially greater than any increase due to failure¹⁷. It follows therefore that Safety Cases are critically dependent on the determination and satisfaction of a complete and correct set of Safety Requirements in which system functionality and performance are appropriately considered alongside system integrity.¹⁸</p>
Direct Evidence of Safety Requirements Determination	<p><i>Direct</i> Evidence of Safety Requirements Determination is concerned with the requirements themselves and should show, inter alia, that:</p> <ul style="list-style-type: none"> • all relevant Hazards have been identified; • the potential outcomes of the Hazards have been categorised correctly; • Safety Objectives have been specified to control the frequency of occurrence of the Hazards such that an acceptable level of risk (as defined by the Safety Criteria) is achieved; • Safety Requirements have been specified to control the causes of the Hazards such that the Safety Objectives are satisfied, and to capture the external means of mitigation of the Hazard effects. <p>The key issue here is to ensure that the Safety Requirements are complete – ie that all risks are taken into account. It would not be sufficient to show that the Safety Requirements satisfy the Safety Criteria if those Safety Requirements were based on an incomplete / incorrect Hazard assessment.</p>
Backing Evidence of Safety Requirements Determination	<p><i>Backing</i> Evidence of Safety Requirements Determination is concerned with the process of deriving the requirements and should show, inter alia, that:</p> <ul style="list-style-type: none"> • the Safety Requirements were determined using an established and appropriate process;

¹⁷ SAM **[5]** expresses the distinction in terms of the “success approach” and the “failure approach”

¹⁸ This point is emphasised here because of a popular misconception that safety is dependent mainly on integrity. Neglect of functionality and performance can lead to systems that are “reliably unsafe”.

- the techniques and tools used to support the Safety Requirements Determination were verified and validated;
- the Safety Requirements Determination process was executed by suitably competent and experienced personnel.

Relationship to EUROCONTROL Safety Assessment Methodology

The Functional Hazard Assessment (FHA) and Preliminary System Safety Assessment (PSSA) stages of the EUROCONTROL, Air Navigation System Safety Assessment Methodology [5] provides an appropriate and sound process for the determination of ATM Safety Requirements – demonstration of adherence to the FHA and PSSA processes could therefore be used as *Backing Evidence* as in the first bullet point above.

6. Evidence – Safety Requirements Satisfaction

Sources of Evidence

Evidence of Safety Requirements satisfaction may be used from three main sources, as follows:

- **Service Experience** of previous usage
- **Verification and Validation**
- Compliance with **Standards**

Service Experience¹⁹

Service Experience is data from previous operational use of the product concerned. *Direct Evidence* is concerned with analysis of data from Service Experience and what the results of that analysis showed in terms of satisfaction of the safety requirements. *Backing Evidence* is concerned with showing that the environment from which the data was obtained is sufficiently similar to that to which the re-used product will be subjected, that adequate performance-assessment and fault-recording processes were in place when the product was originally deployed, and that the analysis of the outputs of those processes was adequate and properly carried out.

Direct Evidence from-Service Experience

In assessing and presenting Direct Evidence from Service Experience, it is important to ensure that:

- an analysis process, with pass/fail criteria, was specified for each aspect of the product safety requirement whose satisfaction is being justified using service experience;
- analysis of the service records shows that the criteria for each product safety requirement, whose satisfaction is being justified using service experience, have been met;
- all of the details relevant to the argument being made (eg of length of service, history of modifications, list of users) are included in the Evidence;

¹⁹ Further guidance on Service Experience, specific to CNS/ATM software, may be found in ED-109 [13]. Note, however, that ED-109 makes no distinction between Direct and Backing evidence.

Backing Evidence from Service Experience

- any product capabilities that are not necessary to satisfy the Safety Requirements cannot have an adverse effect on the safe operation of the system.

In assessing and presenting Backing Evidence from Service Experience, it is important to ensure, inter alia, that:

- the subject of the Safety Case and the product for which the Service Experience Evidence is available are identical or sufficiently similar;
- the conditions of use of the product for which the Service Experience is available is taken into account in the analysis;
- the proposed operational environment and the operational environment for which the Service Experience Evidence is available are identical or sufficiently similar;
- any changes made to the operational environment, conditions of use, or product during the period of the Service Experience are analysed to determine whether those changes alter the applicability of the data obtained from Service Experience for the period preceding the changes;
- all aspects of those product functions whose safety requirements that are being justified from Service Experience have been exercised in the (previously) deployed product;
- the extent of the Service Experience is sufficient to demonstrate that each aspect of the product safety requirement has been met;
- a Defect Reporting, Analysis and Corrective Action System (DRACAS) is in place for the deployed product, and is operated in a reliable manner, and is adequate to support the Service Experience Evidence;
- the procedures and tools used to support the creation and analysis of Service Experience Evidence were verified and validated;
- for all reported failures of an aspect in the product component, the underlying fault has been corrected, or it has been shown that the fault is not relevant because it has no safety impact;
- the collection and analysis of Service Experience Evidence was done by suitably competent and experienced personnel.

Verification and Validation

Evidence from system Verification and Validation (V&V) may be based on, inter alia, analysis and/or testing.

Analysis, in this context, covers any proof of requirements satisfaction that is obtained from the design or other representation of the product, including models, prototypes, software source code etc. It includes, for example, simulation formal proof, hardware reliability prediction, inspection, and software static and dynamic code analysis.

Testing is restricted largely to tests of the final product in an environment which is as close as possible to the operational environment. Its purpose, broadly, is to demonstrate that what has been built satisfies the requirements, and it is used to supplement (sometimes replace) *Analysis*.

It is beyond the scope of this Manual to discuss the relative merits of analysis and testing, or of the various techniques within those two broad categories. Suffice it to say that a Safety Case should set out clear justifications of the selected techniques according to the nature and integrity required of the system to which the Safety Case applies. The following guidance is however given concerning the principal requirements of *Direct* and *Backing* V&V Evidence.

Direct Evidence - V&V

However obtained, *Direct* evidence is concerned with the output of the V&V processes, and should include, as a minimum: ²⁰

- specifications of what V&V activities were carried out;
- evidence that the V&V activities and pass/fail criteria were sufficient to demonstrate that the related requirements were satisfied;
- the results of the V&V activities;
- analysis of the results to show that all the specified pass/fail criteria were met;
- explanation and justification of any discrepancies in the results.

Backing Evidence - V&V

Whether obtained from analysis or testing, *Backing* evidence is concerned with the V&V processes themselves, and should include, as a minimum Evidence that:

- the processes were specified and performed independently from design;
 - the methods and techniques used are appropriate and adequate, for the properties of the product under consideration;
 - the tools used to support the processes were verified and validated to a level appropriate for the assigned assurance level and were properly used;
 - the V&V processes were properly and completely executed, and the guidance, procedures, and standards were adhered to;
 - for previously existing V&V evidence, obtained for COTS or re-used products, the evidence is entirely valid for the new system application;
 - any differences between the operational and V&V
-

²⁰ The list is intended to provide only an overview of the main issues. Further detail on V&V, specific to CNS/ATM software, may be found in section 3 of ED-109 [13].

	environments were identified, and the impact on the results was assessed and justified.
Compliance with Standards	Evidence of compliance with standards can be a significant contribution to the safety case. However, the way in which adherence to a particular standard can be used to demonstrate compliance with Safety Requirements will depend on the nature of the standard itself.
Product Standards	<p>Product standards specify precisely what is required of a specific item of equipment in terms of function, performance, integrity and, in some cases, form and fit. A good example is the Arinc 700 series of standards, which define digital avionics systems and equipment installed on civil aircraft. Currently, product standards are not common in ATM.</p> <p>Compliance with product standards could be used as <i>Direct Evidence</i> of system safety, subject to it being shown that the standard was appropriate to the particular application and to the provision of sufficient <i>Backing Evidence</i> concerning the adequacy of the process by which compliance was demonstrated.</p>
Process Standards	<p>At the other end of the spectrum, are standards which address the processes of development and manufacture – examples range from the very broadly based ISO 9000 series to the more specific ED-78A (Guidelines for the Approval of the Provision and Use of ATS Supported by Data Communications) and ED-109 (Guidelines for CNS/ATM System Software Integrity Assurance). In none of these cases would it appropriate to certify a product against them, from a safety viewpoint; however, compliance with such standards, especially the more specific ones, could provide excellent Backing Evidence for safety requirements determination and/or satisfaction.</p> <p>The distinction between product- and process-based safety assurance is clearly fundamental since the former is concerned with getting the right product and the latter with getting the product right.</p>
Relationship to EUROCONTROL Safety Assessment Methodology	The System Safety Assessment (SSA) stage of the EUROCONTROL, Air Navigation System Safety Assessment Methodology [5] provides further guidance on the application of the above approaches to requirements-satisfaction.

7. Developing a Safety Plan

Introduction	A Safety Plan specifies, inter alia, the safety assurance activities that are to be carried out in order to create necessary and sufficient Evidence for the production of a Safety Case.
Basic Requirements	The SRC-EATM Interface process [6] specifies the following contents for a Safety Plan:
Safety Activities	<ul style="list-style-type: none"> the Safety Activities needed to meet the (high-level) safety objectives, as well as the links and relationships between

	safety activities and safety objectives;
Resources	<ul style="list-style-type: none"> the means and resources to carry out safety activities within the Programme;
Roles and Responsibilities	<ul style="list-style-type: none"> responsibilities and accountabilities for Safety Activities;
Safety Deliverables	<ul style="list-style-type: none"> the safety deliverables associated with the Safety Activities;
The Safety / Programme Lifecycle	<ul style="list-style-type: none"> the allocation of Safety Activities and Safety Deliverables in the progression of the Programme;
Safety Activity / Deliverables Mapping	<ul style="list-style-type: none"> the relationships and dependencies between successive Safety Activities and associated Safety Deliverables;
Schedule	<ul style="list-style-type: none"> the detailed schedule and milestones for conducting Safety Activities and releasing associated Safety Deliverables.
Specific Recommendations	It is recommended that the following items, specific to the creation of a Safety Case, also be included in the Safety Plan:
Safety Argument	<ul style="list-style-type: none"> an initial version of the Safety Argument. The rationale for this is that most of the Safety Activities (see above) should be directed at the collection and assessment of Evidence to support the Safety Argument;
Safety Case Development	<ul style="list-style-type: none"> planned development stages of the Safety Case and their relationship to the overall Programme milestones;
Reviews and Approvals	<ul style="list-style-type: none"> requirements for review and approval of the Safety Case;
Handover	<ul style="list-style-type: none"> arrangements for the proper handover of Safety Case activities or obligations;
Safety Regulation	<ul style="list-style-type: none"> arrangements for the approval of the Safety Case by the regulatory authorities;
Safety Case Maintenance	<ul style="list-style-type: none"> arrangements for the maintenance of the Safety Case during operations.

8. Format, Structure and Layout of the Safety Case

	<p>This section presents guidance on Safety Case layout. Examples, relating to EATM can be found in the EUROCONTROL Pre- and Post-Implementation Safety Cases for RVSM, [2] and [3] respectively. More-recent examples can be provided on request.</p>
Executive Summary	This should provide the reader with an overview of what the Safety Case is about, what it is trying to show and for whom, a summary of the conclusions and caveats (see below) and recommendations (if any).
Introduction:	The Introduction should include:
Background	<ul style="list-style-type: none"> an outline of, for example, the circumstances which led to

	the need for, and development of, the Safety Case;
Aim	<ul style="list-style-type: none"> a simple statement of the aim – ie what the Safety Case seeks to demonstrate. It should be related directly to the top-level Claim (see below);
Purpose	<ul style="list-style-type: none"> the purpose of the Safety Case – ie why, and for whom, it has been produced;
Scope	<ul style="list-style-type: none"> the scope and boundary of the Safety Case. It is important to explain what is included <u>and</u> what is not included;
Layout	<ul style="list-style-type: none"> the purpose of each of the sections of the document. In general, the main part of the document should be structured along the lines of the Safety Argument.
Service / System Description	Provide a description of the system to which the Safety Case applies, including its operational environment, interfaces and boundaries of responsibility.
Overall Safety Argument	This section should describe and explain the highest levels of the Safety Argument structure, including:
Claim	<ul style="list-style-type: none"> the Claim – ie the top-level statement which asserts that the service / system (etc) is <i>safe</i>;
Criteria	<ul style="list-style-type: none"> the Safety Criteria which define what is meant by safe in the context of the Claim;
Context	<ul style="list-style-type: none"> a description of the operational context to which the Safety Case applies;
Justification	<ul style="list-style-type: none"> the justification for the change, where the Safety Case addresses a change to a service and/or system that is <u>not</u> being made mainly for reasons of improving safety, and therefore potentially for incurring some risk;
Principal Safety Arguments	<ul style="list-style-type: none"> the principal Safety Arguments – ie the first level of decomposition of the top-level Claim – these should be reasoned and well structured, showing how the Safety Criteria are satisfied and the rationale for the approach taken in the decomposition;
High-level Assumptions	<ul style="list-style-type: none"> the key Assumptions on which the highest levels of the Safety Argument critically depend – for example, the level of risk prior to the introduction of a change is acceptable. Other Assumptions, applicable to the lower levels of the Safety Argument structure should be included in the Assumptions section – see below.
Safety Argument and Evidence sections	<p>These sections should present each of the principal Safety Arguments (see above) in turn, together with the supporting Evidence which shows that each of the Arguments is valid. It is recommend that, where applicable, each section be structured as follows:</p> <ul style="list-style-type: none"> Objective (of the section) – related directly to the principal Safety Argument; <u>Strategy (breakdown of the principal Safety Argument into</u>

	<p>lower-level arguments);</p> <ul style="list-style-type: none"> • Rationale (for the Strategy); • Lower-level Arguments / Evidence; • Conclusions (of section).
Assumptions	<p>Present directly, and/or by reference, all the Assumptions on which the Safety Case depends, including the high-level Assumptions mentioned above. Assumptions usually relate to matters outside of the direct control of the organisation responsible for the Safety Case but which are essential to the completeness and/or correctness of the Safety Case. Each Assumption must be shown to be valid or at least reasonable according to the circumstances.</p>
Issues	<p>List any outstanding safety issues that must be resolved before the Claim can be considered to be valid, together with the responsibilities and timescales for clearing them.</p>
Limitations	<p>State and explain any Limitations or restrictions that need to be placed on the deployment and/or operation of the system.</p>
Conclusions	<p>Do not merely repeat the conclusions from each section here. The main conclusion should refer to the original Claim and, if applicable, reassert its validity, subject to the following caveats:</p> <ul style="list-style-type: none"> • the Scope – especially what the Safety Case does not cover; • the operational Context to which the Safety Case applies; • the Assumptions that have had to be made; • the outstanding Issues; • any Limitations placed on the deployment and/or operation of the service / system.
Recommendations	<p>Recommendations are not mandatory and any that are made should not be temporary in nature. For example, it might be appropriate to make recommendations on the use of the Safety Case by its recipients, but not concerning its approval.</p> <p>Recommendations must <u>not</u> contain any statements that would undermine, or add further caveats to, the Conclusions.</p>

9. Verifying the Safety Case

Further guidance on what to look for in developing and reviewing a Safety Case can be found in the detailed checklists in **Appendix C**.

10. ESARR Compliance

Overview

Compliance with ESARRs may be used in support of a Safety Case. However, as indicated below, ESARRs are largely concerned with processes and, therefore, compliance with ESARRs should normally be used as **Backing** Evidence, not as Direct Evidence²¹.

ESARR 2

Reporting and Assessment of Safety Occurrences in ATM

The rationale for ESARR 2 is that the achievement of consistent high levels of aviation safety and the management of safety in ATM require, as a priority, the successful implementation of harmonised occurrence reporting and assessment schemes. Such schemes will lead to more systematic visibility of safety occurrences and their causes, and will allow identification of appropriate corrective actions as well as areas where flight safety could be improved by changes to the ATM system.

Compliance with ESARR 2 can be used as (Backing) Evidence of having an adequate in-service safety monitoring process in support of:

- a Project Safety Case – see for example Arg4 / St005 in **Figure 11 of Chapter 5**;
- a Unit Safety Case – see for example Arg2.5 in **Figure 12 of Chapter 5**.

ESARR 3

Use of Safety Management Systems by Service Providers

The rationale for ESARR 3 is that an ATM service provider has a responsibility to ensure that all relevant safety issues have been satisfactorily dealt with, and to provide assurance that this has been done. Safety management is that function of service provision, which ensures that all safety risks have been identified, assessed and satisfactorily mitigated. A formal and systematic approach to safety management will maximise safety benefits in a visible and traceable way.

Because a typical SMS includes a very wide range of safety processes in support of ATM operations, compliance with ESARR 3 can be used in many areas of a Safety Case - for example:

- in a Project Safety Case, SMS processes could be used as **Backing** Evidence under Arg2.1 and Arg2.2, in **Chapter 5**, **Figure 8** and **Figure 9** respectively;
- in a Unit Safety Case, SMS processes could be used as **Direct** Evidence under Arg2.2 / St003, in **Figure 14 of Chapter 5**.

In both cases, the SMS-process Evidence would be strengthened if it could be shown that the SMS was compliant with ESARR 3 – ie ESARR 3 compliance would provide **Backing** Evidence.

²¹ A possible exception to this statement could be a Safety Case which is based mainly on the satisfaction of the requirements of the ESARR 4 Risk Classification Scheme.

ESARR 4**Risk Assessment and Mitigation in ATM**

ESARR 4 concerns the use of Risk Assessment and Mitigation, including hazard identification, in Air Traffic Management when introducing and/or planning changes to the ATM System. In this

requirement, Risk Assessment and Mitigation are addressed via a total-aviation-system approach.

There are two aspects of ESARR 4 which can be used in a Safety Case, as follows:

- subjective to the provisos of **Chapter 4, section 2** above, the Risk Classification Scheme in Appendix A to ESARR 4 could be used as the basis of **quantitative** Safety Criteria – see, for example, Cr001 / #1 in **Chapter 5, Figure 1**;
- compliance with the **qualitative** (process) requirements of section 5 of ESARR 4 could be used as Backing Evidence as, for example, in Arg 1.10 in **Chapter 5, Figure 6**.

ESARR 5**ATM Services' Personnel**

ESARR 5 documents general safety regulatory requirements for all ATM services' personnel responsible for safety related tasks within the provision of ATM services across the ECAC area, including the specific safety regulatory requirements for air traffic controllers and engineering/technical personnel.

Compliance with ESARR 5 could be used in a Unit Safety Case to show that the human aspects of the on-going operation are based on, inter alia, competent personnel. This would appear, for example in the lower levels of decomposition of Arg2.1 and Arg2.2 in **Chapter 5, Figure 14**.

ESARR 6**Software in ATM Systems**

ESARR 6 deals with the implementation of software safety assurance systems to ensure that the risks associated with the use of software in safety-related ground-based ATM systems are reduced to a tolerable level.

Compliance with ESARR 6 could be used, for example, in:

- a Project Safety Case - software processes could be used as **Backing** Evidence under Arg2.1 / St011 and Arg2.2 / St015, in **Figure 8** and **Figure 9** respectively of **Chapter 5**²²;
- a Unit Safety Case - software processes could be used as **Direct** Evidence under Arg2.2 / St003, in **Figure 14** of **Chapter 5**.

²² **Direct** Evidence would be the outputs of those processes

CHAPTER 5

Guidance -

GSN Safety Argument Examples

1. Example Application of GSN – A “Project” Safety Case

Figure 1 to Figure 11 overleaf show a structured Safety Argument for a hypothetical substantial change (“SGxy”) to an ATM service which could form the basis of what is known herein as a *Project* Safety Case.

The structure is intentionally not complete in all areas of the decomposition; however, it is intended to be sufficient, in breadth and depth, to illustrate the use of the GSN notation. A commentary on the development of the Safety Argument is also provided below. This commentary is also not exhaustive but is intended to bring out all the main points concerning the application of GSN.

Relationship to the EUROCONTROL SAM

Where applicable references are given to those process(es) in the SAM [5] that would generate the required Evidence.

Claim

The Safety Argument starts, in **Figure 1**, with the top-level *Claim (Arg 0)* that the ATM service, following the change, will be *acceptably safe*.

Justification

J001 indicates that the change is justified operationally and this justification would need to be elaborated in the Safety Case.

Context

C001 provides an essential marker that the change itself needs to be defined in terms of the ATM service / system and accompanying operational concept – such descriptions would need to be provided in the related Safety Case.

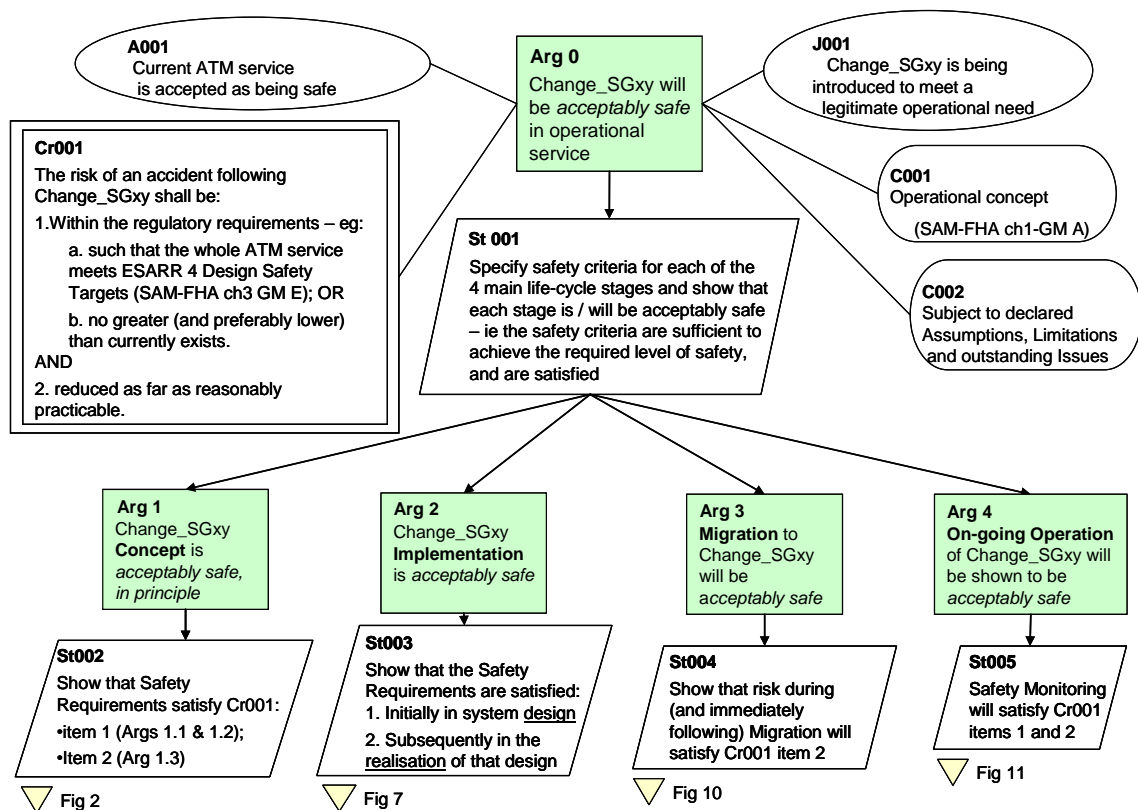


Figure 1 – Arg 0: Safety Argument

Safety Criteria

Acceptably safe is defined in terms of the three criteria summarised in **Cr001**. These criteria reflect the three main ways of expressing a Safety Argument – ie:

- Absolutely: as compliance with a (numerical) target level of safety – eg ESARR 4 (or local regulatory interpretation thereof), OCP, ICAO, JAR 25 etc;
- Relatively: in relation to a current / previous (usually qualitative) level of safety;
- Reductively: showing risk to be further reduced as far as reasonably practicable;

Choice of Criteria

The first two bullets are alternative ways of expressing a typical regulatory minimum safety level²³ and specify what is sometimes known as *tolerable* risk. In the further development of the Safety Argument for Change SGxy, only the absolute criterion is actually used²⁴, and is supported by the reductive criterion in order to specify what is sometimes known as an *acceptable* level of risk.

Assumption

If a relative *Argument*, were to be used it would be necessary to establish that the pre-change baseline is safe. This is addressed in **A001** which is shown on **Figure 1** for illustration only.

Arg1 to 4

As indicated in *Strategy St001*, *Claim Arg 0* is decomposed into

²³ It would not normally be necessary to comply with both.

²⁴ For examples of developing Safety Arguments using relative criteria, please contact DAP/SAF

four principal Arguments which, in this case, relate to the four main, contiguous stages of the lifecycle of the Change. The outcome of each stage is argued to be acceptably safe and **St002** to **St005** are used to indicate, by reference to **Cr001** what is defined as acceptably safe for each stage:

- **Arg 1** (through **St002**) asserts that the Change is acceptably safe in principle – ie subject to subsequent complete and correct implementation of the Safety Requirements;
- **Arg 2** (through **St003**) asserts that the Implementation of the Change is acceptably safe, through satisfaction of the Safety Requirements, and that the rigour of the Assurance (ie lower-level *Arguments* and *Evidence*) to support this is appropriate to the risk associated with the Change;
- **Arg 3** (through **St004**) asserts, in effect, that the Migration from the current state to the post-Change state will not endanger the on-going operational service. The change in tense in Arg3 is deliberate since the Safety Argument would be expected to be finalised once all the Implementation and Migration steps, except the final “switchover” to the new state, had been completed satisfactorily. Note that, because of the short time for which the service is at risk, during Migration, only Criterion Cr001, item 2 can be applied to this *Argument*;
- **Arg 4** (through **St005**) asserts that the monitoring of the on-going operational service, post Migration, will be sufficient to show the Change to be acceptably safe

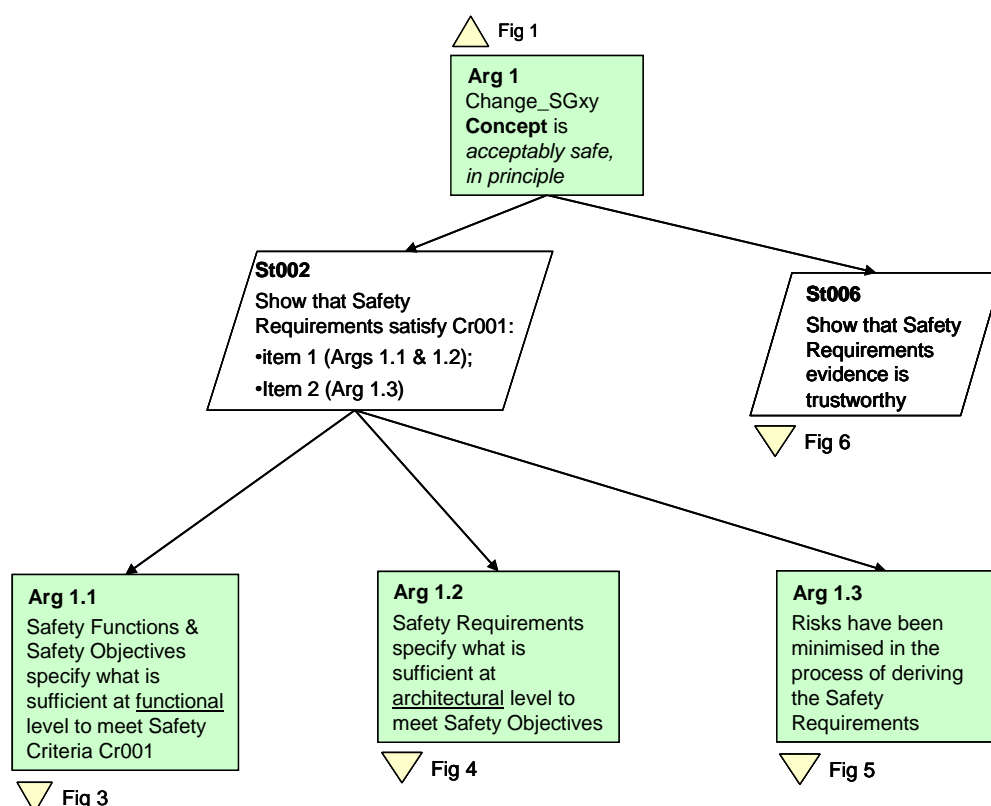


Figure 2 – Arg 1: Safety of the “Change SGxy” Concept

Arg 1

Arg 1 focuses on the output of the Concept stage of the lifecycle – ie a set of Safety Requirements for the Change that ultimately satisfy the three safety criteria which define an acceptable level of safety.

Arg 1 is achieved through a two-fold *Strategy*, which uses the principle of *Direct Evidence* and *Backing Evidence*, as follows:

- **St002** shows, through a sequential set of Arguments (**Arg 1.1** to **Arg 1.5**), that the eventual outputs of the Concept phase – the Safety Requirements – satisfy the three safety Criteria. This is clearly a *Direct* approach since it is concerned with the outputs of each stage in the sequence, rather than with the processes that produce those outputs;
- **St006** shows that the Direct Evidence is trustworthy – ie can be relied upon. The **Arguments** to achieve **St006** are shown in **Figure 6** below, and are considered to be of the *Backing* type since they are concerned with the processes that produce the above outputs, rather than with the outputs themselves (ie they are complementary to **St002**).

Arg 1.1, **Arg 1.2** and **Arg 1.3** are decomposed below in **Figure 3**, **Figure 4** and **Figure 5** respectively.

In **Figure 3**, the *Context* for **Arg 1.1** is an FHA (**C004**) associated with the Change. **C005** is simply a reminder that the FHA must encompass all aspects of the Change.

Arg 1.1.1 to **Arg 1.1.6** relate to the outputs of the main stages of a typical FHA. **Safety Functions** are concerned with specifying the **desired** (correct) operation of a system in order to provide safe ATM services (what the SAM [5] describes as the “success approach”) whereas **Safety Objectives** limit the frequency of **failure**.

The type of *Evidence* expected to be provided to support each strand of the *Argument* is also shown on **Figure 3**, together with the relevant references to the SAM [5].

The use of the term “adequately” in **Arg 1.1.2** and **Arg 1.1.4** illustrates what is sometimes a fine distinction between *Direct* and *Backing Evidence*. In general:

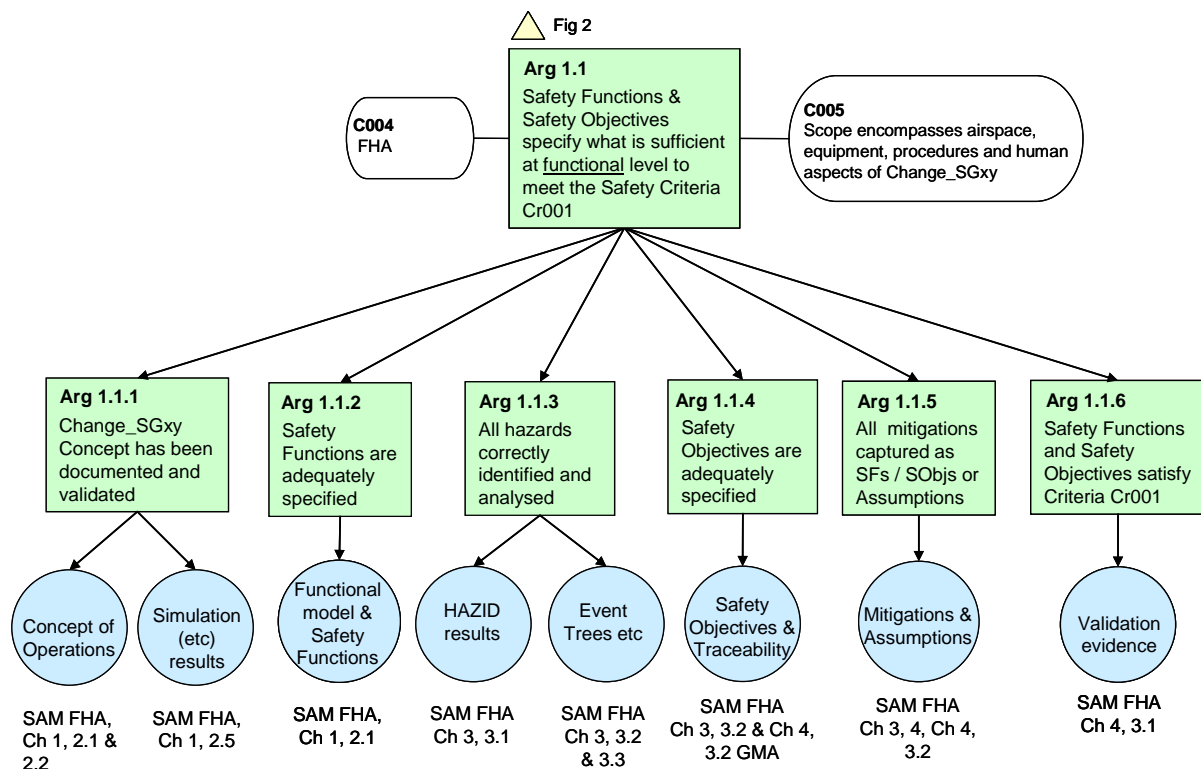


Figure 3 – Arg 1.1: Safety Functions and Safety Objectives

- If the *Argument / Evidence* is concerned with observable attributes of an output (product) then it should be considered to be *Direct* – for example, traceability of Safety Objectives back to Safety Functions and Safety Criteria would be Direct since it would be observable (with the assistance of cross-referencing) from the Safety Objectives, Safety Functions and Safety Criteria themselves.
- On the other hand, if the *Argument / Evidence* cannot be deduced from observable attributes of an output itself, but is related only to the process, then it should be considered to be *Backing* – for example it would be impossible to deduce from a set of Safety Objectives that they had been developed by a team with Appropriate expertise – see **Figure 6** below.

The decomposition of **Arg 1.2** (see **Figure 4** below) is similar in principle to that for **Arg 1.1** above. The Context (**C004**) is the PSSA – ie the derivation of Safety Requirements – and in this case is the first stage of PSSA, expressed at the recommended, Logical-architecture level.

St007 emphasises the importance of considering the safety of the system when it is working (what the SAM [5] calls the “success approach”, expressed in terms of Safety Requirements for function and performance) as well as when it fails (expressed in terms of Safety Requirements for reliability and integrity).²⁵

²⁵ This mirrors the distinction between Safety Functions and Safety Objectives, which needs to be made at the FHA stage.

The type of *Evidence* expected to be provided to support each strand of the *Argument* is also shown in **Figure 4**.

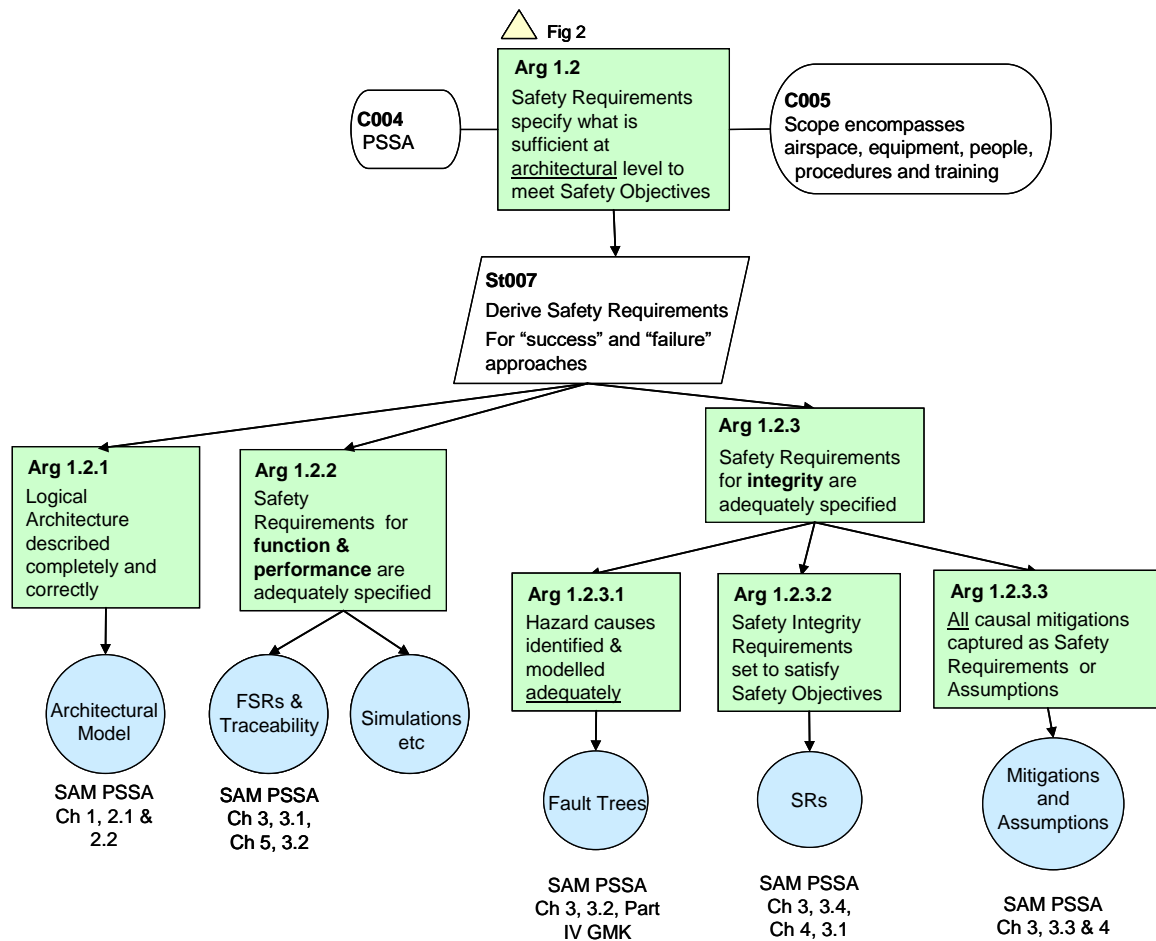


Figure 4 – Arg 1.2: Safety Requirements

Arg 1.3 (see **Figure 5** below) presents the Argument and Evidence that the qualitative Safety Criteria have been satisfied via the processes that led to the Safety Requirements for Change SGxy.

The difficulty with **Arg 1.3.1** is that most changes in ATM involve some inherent risk because the service in general needs to respond to an ever increasing demand on its capacity to deliver. Therefore, it is necessary to find safety benefits – in the form of removal or mitigation of areas of risk – to offset the inherent risk of change. In most cases the relative *Argument* involved has to be made on the basis of qualitative *Evidence*.

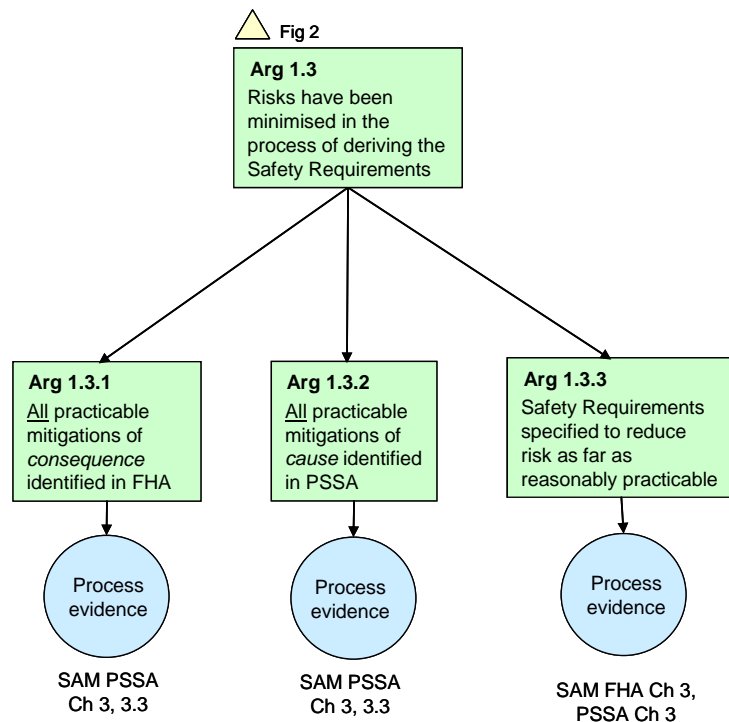


Figure 5 – Arg 1.3: Satisfaction of Qualitative Safety Criteria

The *Arguments* and *Evidence* for **Arg 1.3.3** are intended to show that a (properly conducted) FHA and PSSA Stage 1 will yield safety requirements that, when implemented, will result in a risk that has been reduced as far as reasonably practicable, at that stage²⁶.

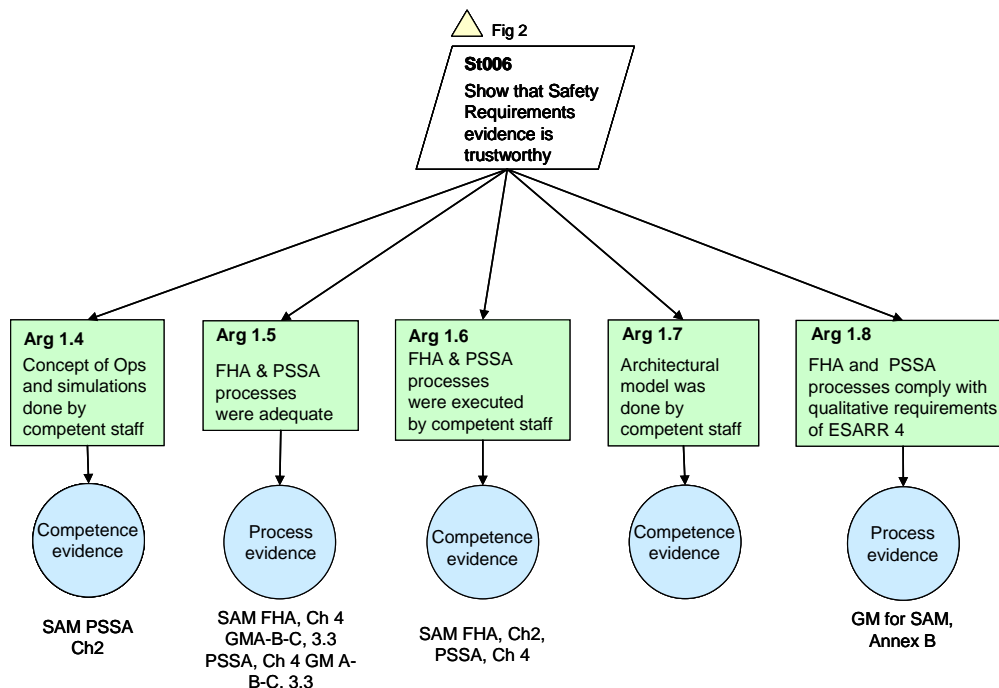


Figure 6 – St0006: Safety of the Concept (Backing)

²⁶ The reduction of risk as far as reasonably practicable is further covered in **Arg 3** below

As with most *Backing Evidence*, **St0006**, in Figure 6 above, is based on arguing the adequacy of the processes (including techniques and tools) involved and on the competence of the personnel who executed those processes. In practice, some of the *Arguments* may need to be decomposed to a lower level of detail than shown in this example.

Arg 2

Figure 7 below addresses the Implementation of Change SGxy, in two stages: physical-level design and realisation of the design in the physical system – these are further decomposed below in **Figure 8** and **Figure 9** respectively.

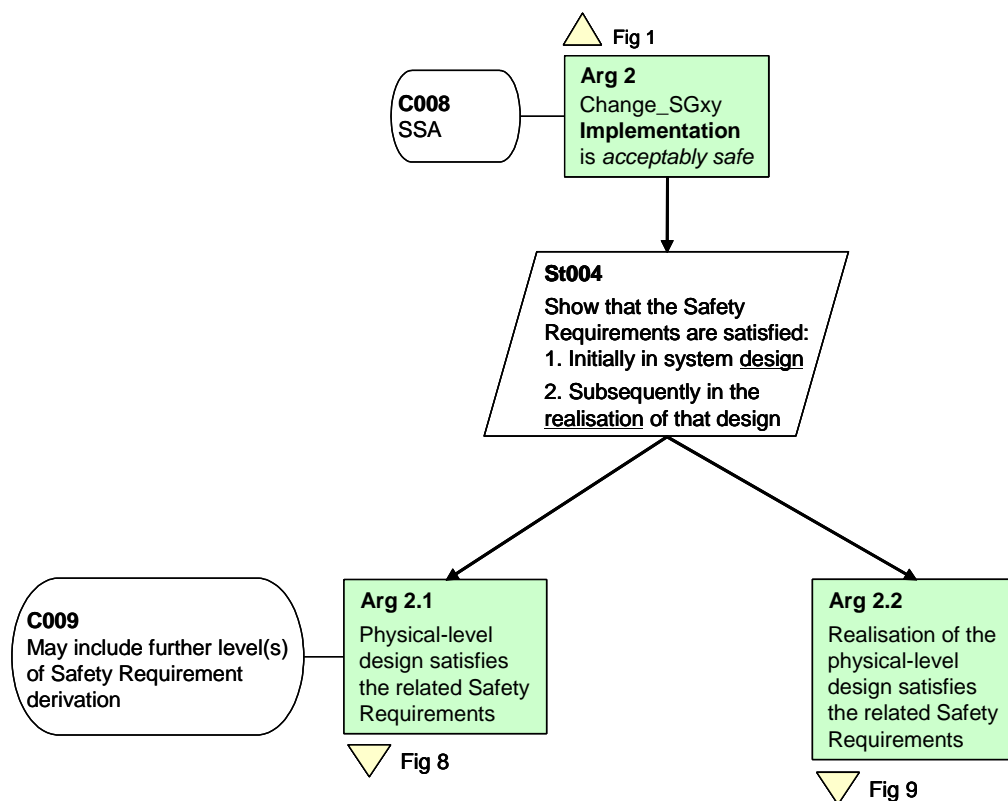


Figure 7 – Arg 2: Safety of Implementation

In this example, **Arg2** is decomposed only far enough to show the elements of the ATM system that might be involved.

For the Implementation of Airspace Design, ATC Procedures and Operational Training, most of the *Evidence* of compliance with the Safety Requirements comes at the Design stage – ie under **Arg 2.1**.

For the Implementation of the Equipment aspects, the *Evidence* of compliance with the Safety Requirements should also come from the Design stage – ie under **Arg 2.1** – but should be further substantially supported by testing in the subsequent Realisation stage – ie under **Arg 2.2**.

The decomposition of **Arg 2.1** would need to include *Backing* assurance covering the adequacy of the processes, tools and techniques employed in the design and realisation, and of the

competence of the personnel involved. Full use should be made of existing operational and engineering procedures in the organisation's quality and safety management systems.

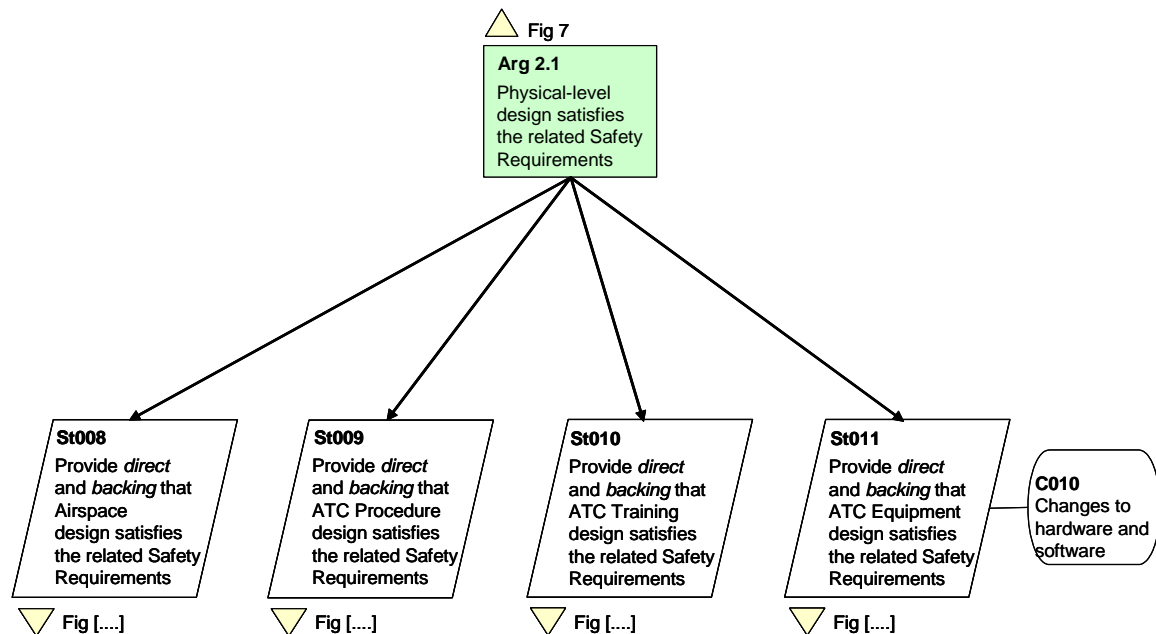


Figure 8 – Arg 2.1: Safety of Design

The decomposition of **Arg 2.2** mirrors that for **Arg 2.1** above and is shown in **Figure 9**.

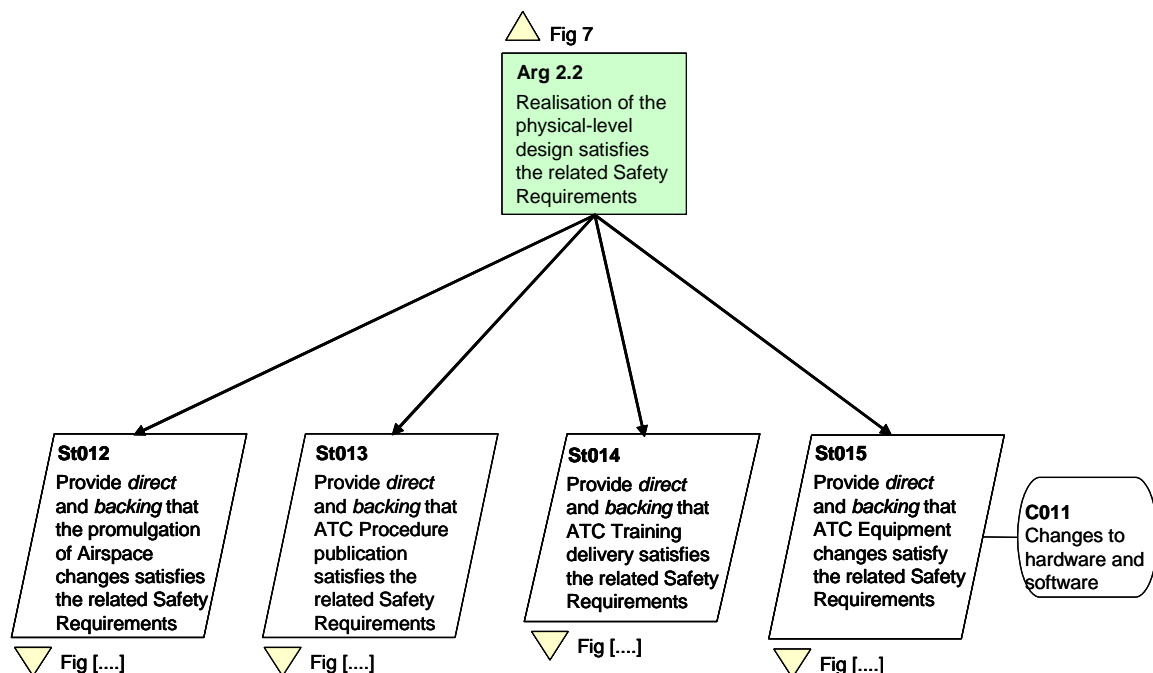


Figure 9 – Arg 2.2: Safety of Realisation

In the case of equipment aspects of Realisation, most of the *Evidence* will come from analysis and testing. The *Backing* for this is not decomposed herein but should address the V&V requirements covered in **Chapter 4, section 6** above.

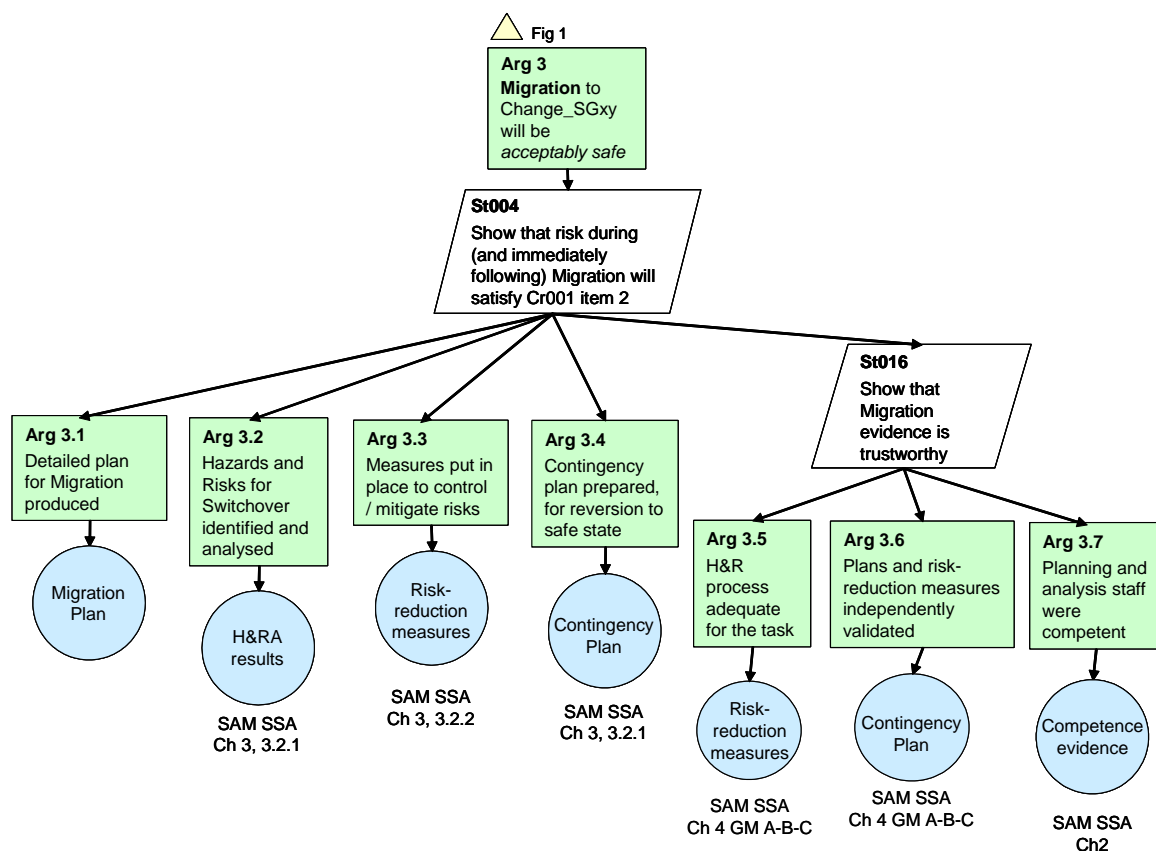


Figure 10 – Arg 3: Safety during Migration

Arg 3

Clearly, in introducing a substantial change (or new system) the safety of the existing ATM service must be preserved during the period of Migration from the pre-change to post-change state.

Figure 10 shows a typical decomposition of the *Argument*, with supporting *Evidence*, covering both the *Direct* and *Backing* aspects.

Arg 4

Arg 4 in effect recognises that Evidence provided under **Arg 1** to **Arg 3** is necessarily predictive in nature and needs to be confirmed by Evidence of what is actually achieved in practice, from a safety perspective.

This is illustrated in the decomposition of **Arg 4**, in **Figure 11**.

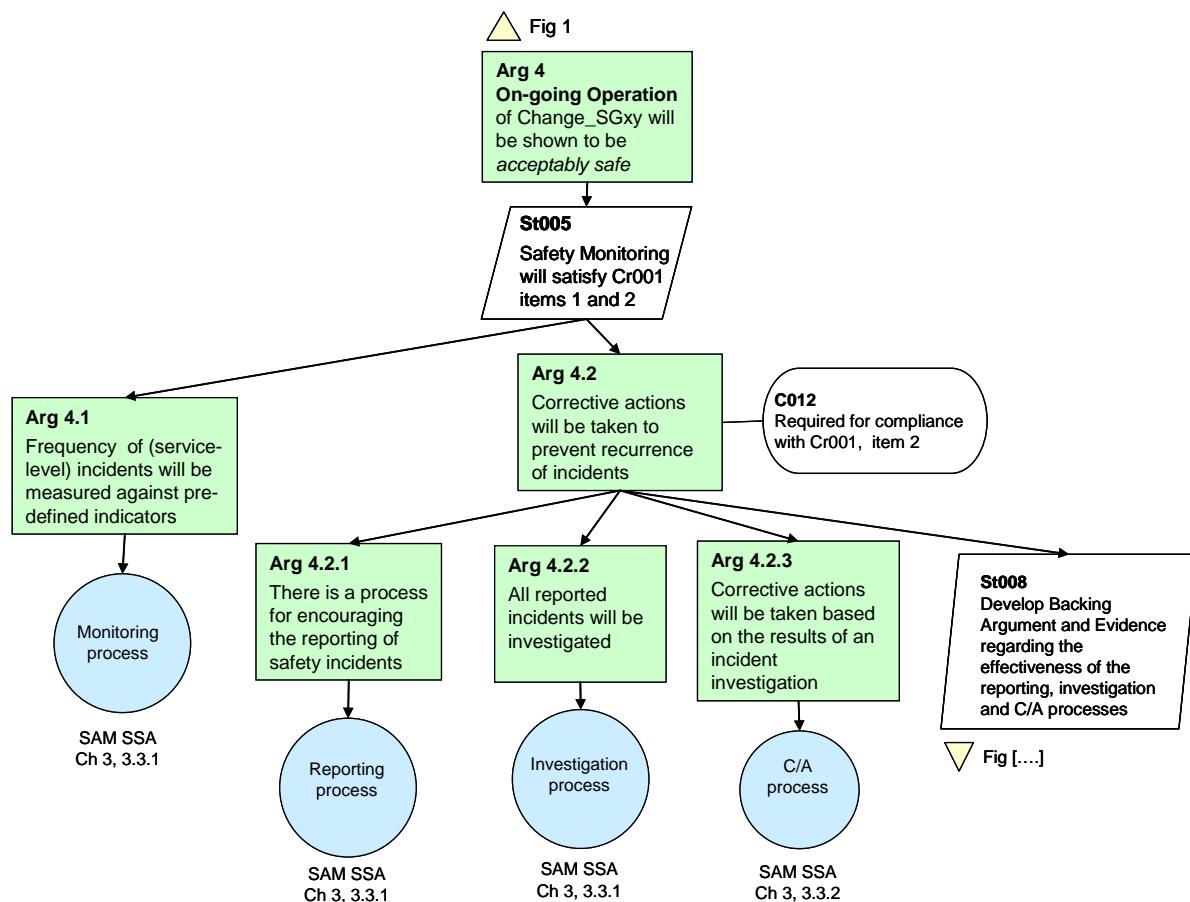


Figure 11 – Arg 4: Safety Monitoring

2. Example Application of GSN – Unit Safety Cases

Unit Safety Case is a commonly used term for the Safety Case for an on-going operational service. **Figure 12** below shows the high-level Safety Argument for this example application of GSN, for a hypothetical ATSU.

Claim

Arg 0 is the overall Claim, equivalent to that for Change “SGxy” in **Figure 1** above. **C001** defines the type(s) of service provided and **C002** is a reminder that the full operational environment – eg airspace boundaries, structure, classification, rules, separation minima etc – needs to be fully described in order to define the Context in which the Claim is being made.

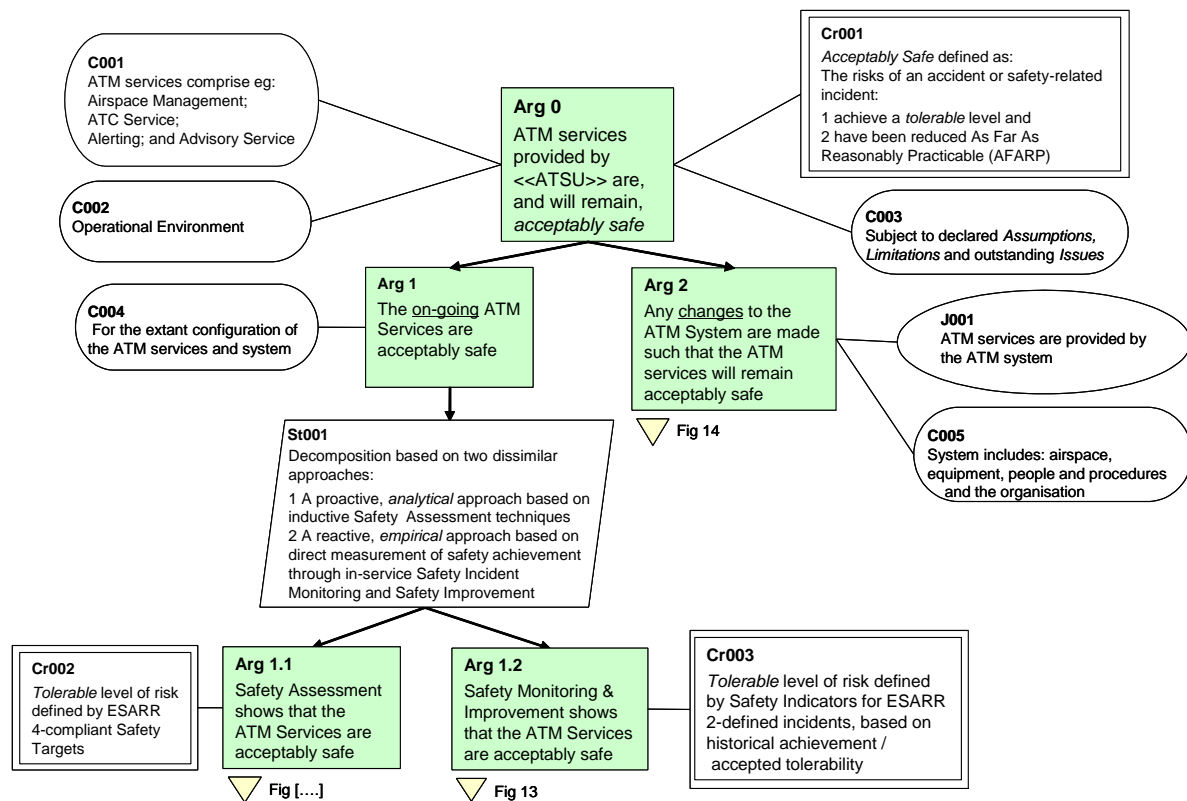


Figure 12 –: Overall Safety Argument for a Unit Safety Case

C003 is a reminder that the eventual conclusion of the Safety Case will probably be subject to certain Assumptions and outstanding Issues that need to be addressed and possibly to some Limitations on the ATM service(s).

The definition of what is acceptably safe is captured in **Cr001**, – note that item 1 (as elaborated in **Cr002** and **Cr003**) is an absolute measure, as is appropriate to an on-going service.

The Claim (Arg 0) is decomposed into two principal Safety Arguments (**Arg 1** and **Arg 2**) that, in effect, the services are safe “today” (ie for the current system baseline – **C004** refers) and will remain so because any changes to the baseline will be managed so as to maintain the safety of the services.

Arg 1

The decomposition of **Arg 1** is very similar to that for “Change SG_{xy}” but, generally, on a much larger scale; in other words, this part of the Unit Safety Case (although not related to change) treats the Unit as a large ATM system for which:

- Safety Requirements (for the system) are derived and satisfied in a predictive Safety Assessment (**Arg 1.1**);
- actual safety achievement is monitored and improved through empirical Safety Monitoring (**Arg 1.2**).

Arg 1.1

Arg 1.1 is not decomposed further herein but should follow a similar pattern to the equivalent Argument for Change “SG_{xy}” except that the underlying FHA, PSSA and SSA activities should be carried out for the ATSU as a whole.

Arg 1.2

The decomposition of **Arg 1.2**, shown in **Figure 13** below, is the equivalent to that for Arg 4 for “Change SGxy” shown in **Figure 11** above, except that the context for the former is the “present” time, rather than the future.

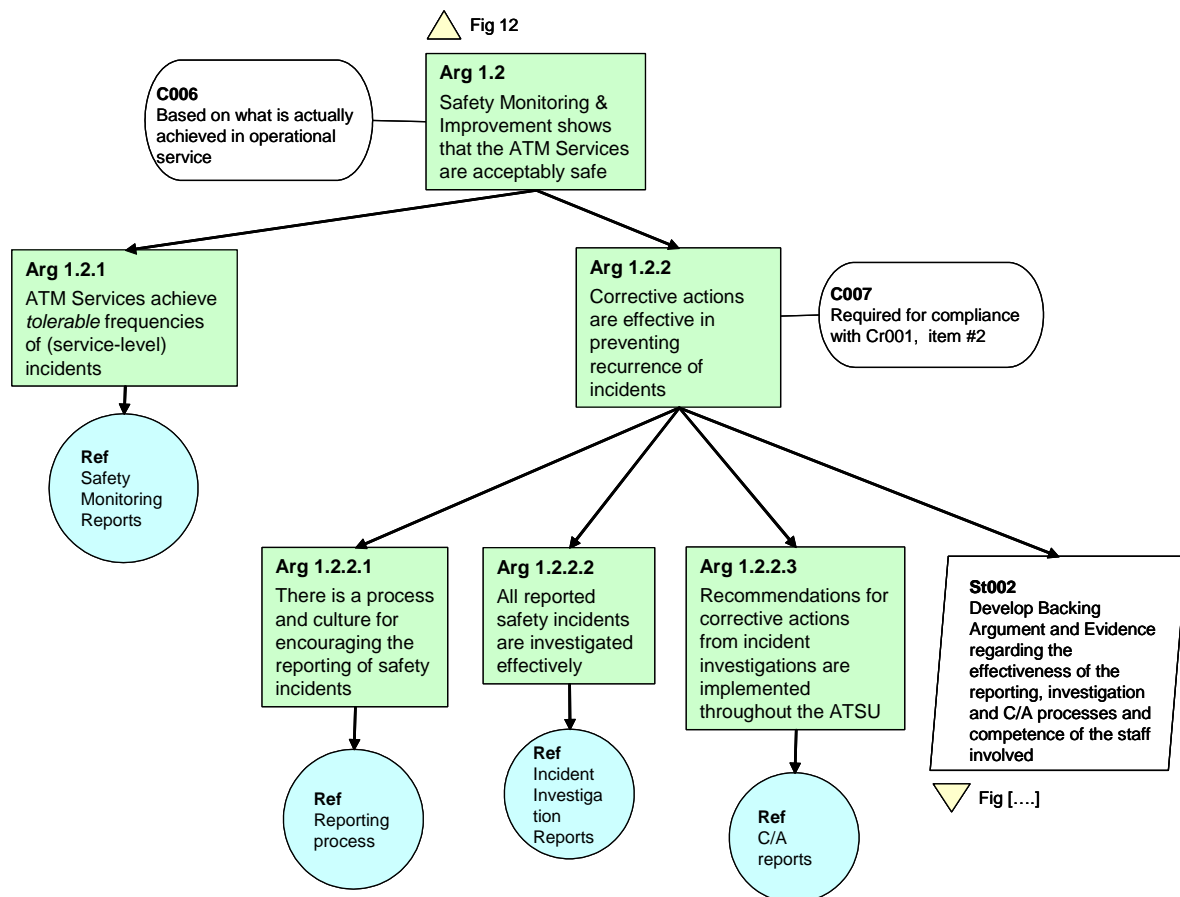


Figure 13 – Safety Monitoring and Improvement

Arg 2

For most *Unit* Safety Cases the system baseline is not fixed but is updated periodically by *Project* Safety Cases produced for significant changes – eg Change SGxy above.

Arg 2, decomposed in part in **Figure 14** below is concerned with showing that all the necessary processes are in place (and are properly executed) to ensure that such changes are managed safely in terms of the on-going service – both during the period of introducing the change (“Migration”) and in the subsequent in-service period.

Note that this is one of the few situations that processes are used as *Direct* Evidence. Adherence to those same processes would be used as *Backing* Evidence in the related Project Safety Cases.

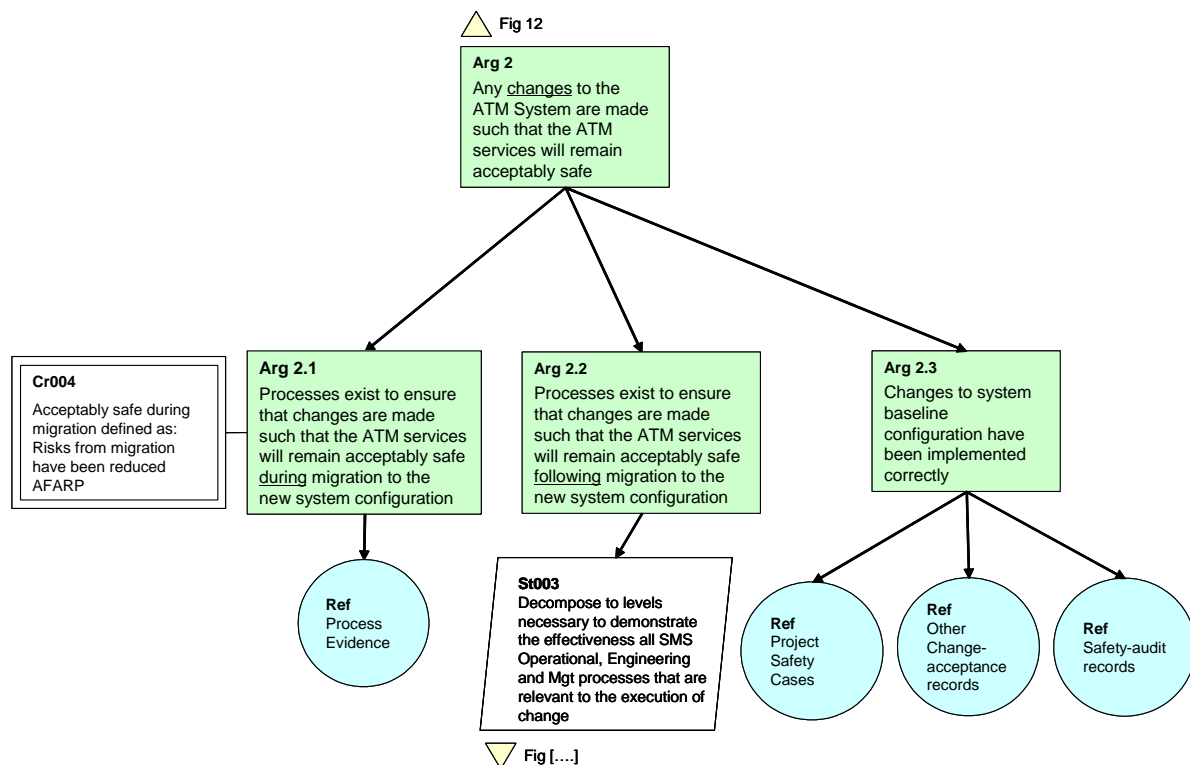


Figure 14 – Change Management

3. Example Application of GSN – Preliminary Safety Cases

Preliminary (or Outline) Safety Case is a term used in EUROCONTROL for the Safety Case that it restricted in both scope and responsibility. It is particularly applicable to EATM programmes since EUROCONTROL's responsibility is usually restricted to proving the concept behind a change (or new system) – ie to proving that the service / system will be safe *in principle*.

Figure 15 below shows the high-level Safety Argument for this example application of GSN. The further decomposition and accompanying commentary is limited to illustrating the main differences between a full *Project Safety Case* (eg Change “SGxy” above) and the equivalent *Preliminary Safety Cases*.

Figure 15 is the same as **Figure 1** above, except as follows:

- A new Argument (**Arg 2**) has been introduced, and forms an important bridge between the Preliminary Safety Case (of which it is a part) and the subsequent Implementation safety case / safety approval.

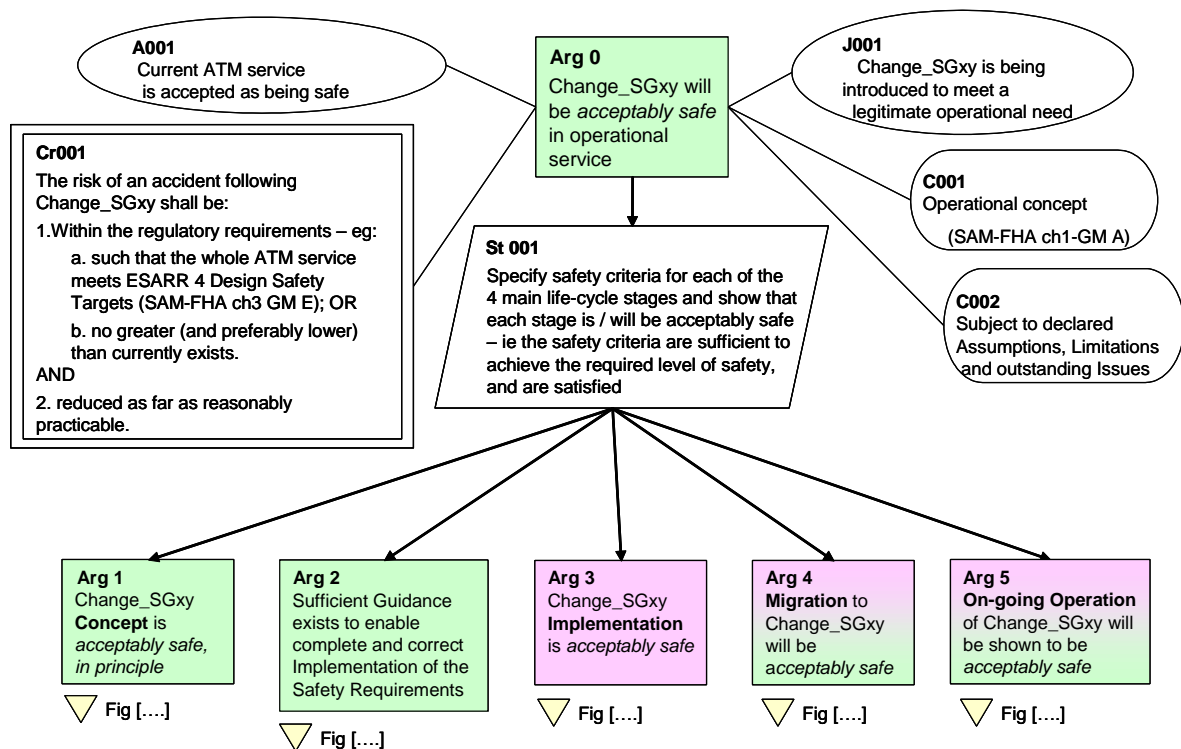


Figure 15 – Overall Safety Argument for Preliminary Safety Case

- The **Guidance** referred to in Arg 2 should include, but not be limited to, the following:
 - an amplification of the scope of the Preliminary Safety Case – ie what is, and what is not included;
 - a clear delineation of the responsibilities between EUROCONTROL and the organisation(s) responsible for Implementation;
 - clear instructions for the Implementers concerning the re-use / re-working of the safety assessment results included in (or accompanying) the Preliminary Safety Case – these should include a warning that the some of the parameters on which the original safety assessment were based may not be directly applicable to the context in which the implementation is being done because of: other changes that might have occurred during the time elapsed between the Preliminary Safety Case and the implementation, or differences between operational context / environment assumed in the Preliminary Safety Case and the local situation;
 - clear instructions for the Implementers concerning the re-use of any other information in the Preliminary Safety Case; particular attention should be drawn to the Scope, Operational Context, Assumptions, Issues and Limitations and to the importance of these being validated by the Implementer and the analysis reworked as necessary;
 - guidance on the additional safety assessment work needed to cover the Implementation, Migration and

Operational phases;

- guidance on how to develop the Preliminary Safety Case into a full (Project) Safety Case.
 - The responsibility for **Arg 3** to **Arg 5** (equivalent to Arg 2 to Arg 4 in **Figure 1**) rests with the Implementer, although some aspects of responsibility for Migration and on-going Safety Monitoring (eg specification of requirements) may rest with EUROCONTROL.
-

APPENDIX A REFERENCES

EATM References

- [1] Air Traffic Management Strategy for the Years 2000+, EUROCONTROL
- [2] The EUR RVSM Pre-Implementation Safety Case, Edition 2.0, 14 August 2001
- [3] The EUR RVSM Post-Implementation Safety Case, Edition 2.0, 28 July 2004
- [4] EATMP Glossary, European Organisation for the Safety of Air Navigation (EATMP), Edition 1.0, 1 August 2000
- [5] EUROCONTROL Air Navigation System Safety Assessment Methodology, SAF.ET1.ST03.1000-MAN-01, 30 April 2004, Edition: 2.0

SRC References

- [6] SRC-EATMP Interface Process, SRC DOC 6, Edition 2.0, Released Issue, 7th November 2002
- [7] ESARR 2: Reporting and Assessment of Safety Occurrences in ATM, Edition 2.0, Released Issue, 3rd November 2000.
- [8] ESARR 3: Use of Safety Management Systems by ATM Service Providers, Edition 1.0, Released Issue, 17th July 2000
- [9] ESARR 4: Risk Assessment and Mitigation in ATM, Edition 1.0, Released Issue, 5th April 2001
- [10] ESARR 5: ATM Services' Personnel, Edition 2.0, Released Issue, 11 April 2002
- [11] ESARR 6: Software in ATM Systems, Edition 1.0, Released Issue, 06 November 2003

ICAO References

- [12] Annex 11 to the Convention on International Civil Aviation, Air Traffic Control Service Flight Information Service Alerting Service, Thirteenth Edition, July 2001

External References

- [13] Guidelines for CNS/ATM Systems Software Integrity Assurance, March 2002.
- [14] The Public Inquiry into the Piper Alpha Disaster, Volumes 1 & 2, November 1990, HMSO Publications Centre ISBN 0-10-113102-X.
- [15] EUROCAE, ED-125, Process for Deriving Risk Classification Scheme and Specifying Safety Objectives in ATM "in compliance" with ESARR 4, Version 6 (proposed issue).

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APPENDIX B GLOSSARY AND ABBREVIATIONS**GLOSSARY**

Accident	An occurrence associated with the operation of an aircraft which takes place between the time any person boards the aircraft with the intention of flight until such time as all persons have disembarked, in which a person is fatally or seriously injured, the aircraft sustains damage or structural failure, or the aircraft is missing or is completely inaccessible (ICAO, 1994).
Adequate	In the context of the Safety Case Development Manual adequacy is interpreted to mean necessary and sufficient.
Aircraft Accident	An occurrence associated with the operation of an aircraft which takes place between the time any person boards the aircraft with the intention of flight until such time as all such persons have disembarked, in which: a) a person is fatally or seriously injured as a result of being in the aircraft, or in direct contact with any part of the aircraft,; or b) the aircraft sustains damage or structural failure which adversely affect the structural strength, performance or flight characteristics of the aircraft, and would normally require major repair or replacement of the affected component; or c) the aircraft is missing or is completely inaccessible. ²⁷
Argument	A statement asserting a fact that can be shown to be true or false.
Backing <entity>	arguments, strategies or evidence that help support and validate <i>Direct</i> (qv) evidence of the satisfaction of a goal. For example, competence, methodology, following a process, etc.
Causes	Actions, omissions, events, conditions, or a combination thereof, which led to the accident or incident. (ICAO).
Direct <entity>	Arguments, strategies or evidence that directly support the satisfaction of the Claim. For example, test results, FHA results, etc.
Functional Requirements	Operational requirements that determine what functions a system [including person] should perform; they can usually be expressed by a verb applying to a type of data, (eg display aircraft position).
Good Practice	A practice that is sufficiently recognised by various people/organisations to allow it to be used as an informal standard. The concept of Good Practice is derived from our responsibilities as professional operators, engineers and managers. We set ourselves a duty of care for all the people who use, operate, maintain and come into contact with the Air Traffic Service domain. Our objective is to ensure that we only

²⁷ See ESARR 4 for full definition

	make claims relating to safety that are supportable by the use of within current good practice.
Incident	An occurrence, other than an accident, associated with the operation of an aircraft that affects or could affect the safety of the operation of the aircraft. (ICAO, 1994).
Integrity	The assurance that all functions of a system perform within operational performance limits.
Migration	The processes involved in transitioning from the current system state to the new / modified system state.
Necessary	In the context of a Safety Argument, that which <u>must</u> be included in order to satisfy the Argument – cf <i>sufficient</i> (qv).
Preliminary Safety Case	The term used in EATM to describe a Safety Case which covers of part of the full project lifecycle – typically a Preliminary Safety Case would demonstrate the safety of a Concept subject to the subsequent Implementation being executed completely and correctly.
Product	Used herein to denote the output of a process as opposed to the process itself – the distinction between product and process is very important in structuring a Safety Argument.
Project	In the context of this Manual, “project” is used generically to denote any temporary endeavour undertaken to introduce a substantial change to an ATM system or service. It should be interpreted as including EATM Programmes.
Project Safety Case	A Safety Case which addresses the safety of a (proposed) <u>change</u> to the on-going operation of an ATSU – a Project Safety Case would normally result in an update of the corresponding Unit Safety Case (qv).
Reliability	The probability of performing a specified function without a failure under given conditions for a specific period of time.
Risk Analysis	A technique used to evaluate risks and to analyse how far forecasts might go wrong – and at what cost.
Safety Criterion	A specification of what is acceptable and/or tolerable in terms of risk.
Shall, Should	1 – Shall: denotes a mandatory requirement; 2 – Should: denotes a preferred requirement.
Sufficient	In the context of a Safety Argument, (at least) enough to entirely satisfy the Argument – cf <i>necessary</i> (qv).
System	A set of interconnected, interdependent parts, forming an identifiable, organised complex and dynamic whole. In the context of this Manual, it includes airspace, equipment, people and procedures.
Target Level of Safety	A level of how far safety is to be achieved in a given context, assessed with reference to an acceptable or tolerable risk.


Unit Safety Case A Safety Case which addresses the safety of the on-going operation of an ATSU – cf Project Safety Case (qv).

ABBREVIATIONS

ANS	Air Navigation Service
ATC	Air Traffic Control
ATM	Air Traffic Management
ATS	Air Traffic Service
ATSU	Air Traffic Services Unit
DRACAS	Defect Reporting, Analysis and Corrective Action System
EATM	European Air Traffic Management [Programme]
ECAC	European Civil Aviation Conference
ESARR	EUROCONTROL Safety Regulatory Requirements
FHA	Functional Hazard Assessment
FTA	Fault Tree Analysis
GSN	Goal Structuring Notation
ICAO	International Civil Aviation Organisation
PSC	Preliminary Safety Case
PSSA	Preliminary System Safety Assessment
RCS	Risk Classification Scheme
RVSM	Reduced Vertical Separation Minima
SMS	Safety Management System
SRC	Safety Regulation Commission
SRU	Safety Regulation Unit
SSA	System Safety Assessment
TLS	Target Level of Safety
USC	Unit Safety Case

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APPENDIX C SAFETY CASE DEVELOPERS AND REVIEWERS CHECKLIST

	<h1>Safety Case Checklist</h1>
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	Ch/S 28	Yes	No	N/A
Safety Case Presentation: General	2/-			
1. Is the aim of the Safety Case explained and clear?	2/3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is the purpose of the Safety Case explained and clear?	2/3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is the scope of the Safety Case explained and clear?	2/3,4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is a justification given as to why the introduction of the change(s) - ie the subject of the Safety Case - is necessary?	2/1,2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is the 'system' and its environment completely and correctly described and bounded?	2/3,4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Is the operational concept described?	2/3,6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is the regulatory context described?	2/5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Is the Safety Case structured along the lines of the Argument?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is the Argument structure apparent in the layout of each of the core sections?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Argument Structure	4/3			
10. Is the overall Claim a single, clear and unambiguous statement of what the Safety Case is trying to demonstrate?	3/2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Is the Claim expressed in a positive way – ie does it accept the "burden of proof"?	2/1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Is the context clear?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Are the criteria for being 'acceptably safe' appropriate and adequately specified?	4/2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Are the initial assumptions explicitly stated?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

²⁸ Reference to Chapter/Section(s) in the Safety Case Development Manual for more information

	Ch/S 28	Yes	No	N/A
15. Is the decomposition of the Argument structure adequately explained by "Strategies"?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Is the level of decomposition appropriate to the complexity of the Safety Case and/or Evidence?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Is each level of decomposition necessary <u>and</u> sufficient to show that the parent Argument is true?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Is each Argument set out as a simple predicate?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Is the Argument structure free of negative and inconclusive Arguments? [Lack of evidence of risk ≠ Evidence of lack of risk]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Does the Argument structure appear to be immune to possible counter Arguments which could undermine the top-level Claim?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Is the distinction between product- and process-based Arguments clear?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Are Arguments supposedly related to the observable properties of the related product (ie Direct Arguments) actually addressing the <u>outputs</u> of a process?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Are Arguments supposedly related to the observable properties of the related processes which generated that product (ie Backing Arguments) actually addressing the process?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Are Direct Arguments and Evidence supported by enough Backing Arguments and Evidence to give sufficient confidence in the former?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Where process-based Arguments are used as Direct Arguments, is this appropriate?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Is each branch of the Safety Argument structure terminated in Evidence?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Evidence	4/4			
27. Is all the presented Evidence necessary to support the Argument to which it relates?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Is all the presented Evidence clear, objective, relevant and conclusive in showing the related Argument to be true?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Is the rigour of the Evidence appropriate to the associated risk – ie is it to the required level of assurance?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Has the Evidence been produced from following an		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Ch/S 28	Yes	No	N/A
accepted and recognised methodology?				
31. Is the underlying safety analysis sound?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Does the safety analysis address both the desired and undesired behaviour of the 'system'?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. Are the various possible types of Evidence – design, test, previous usage etc – used appropriately?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Where Evidence is contained in appendices or external documents, is an adequate summary presented in the body of the Safety Case alongside the related Argument?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. Where Evidence is based on compliance with standards, is its usage appropriate and justified?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. Does the Evidence actually relate to the system / configuration under consideration?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Caveats	2/3			
37. Have all the Assumptions been clearly stated and validated, or responsibilities for validation been stated?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. Have all the outstanding Issues been cleared, or responsibilities for clearing them been stated?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. Have Limitations on the scope of the analysis been clearly stated?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. Have Limitations on the deployment / operation of the 'system' been clearly stated?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Conclusions	2/3			
41. Is there a clear statement of what the Safety Case concludes, which relates to the initial, overall Claim?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Is it made clear that the conclusions are subject to the stated Caveats (see above)?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments				

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