

**SAFETY REGULATION COMMISSION DOCUMENT
(SRC DOC)**

SRC DOCUMENT 12

**ASSESSMENT OF THE EATM 'AIR
NAVIGATION SYSTEM SAFETY
ASSESSMENT METHODOLOGY' AS
A MEANS OF COMPLIANCE WITH
ESARR 4**

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Abstract		
This document was prepared by the Safety Regulation Commission. It was developed, validated and completed by the SRC Expert Panel in charge of assessing the extent to which the EATM ‘Air Navigation Safety Assessment Methodology’, (SAF.ET1.ST03.1000-MAN-01) (FHA) Edition 2.0, dated April 2004 complies with ESARR 4, Edition 1.0. This document compiles the outcome of the SRC’s assessment. It is intended to be used as a decision-making tool for the SRC to develop its own judgement on the acceptability of the EATM methodology as one means of compliance with ESARR 4.		
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F.3 DOCUMENT APPROVAL

The following table identifies all management authorities who have approved this document.

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F.4 AMENDMENT RECORD

The following table records the complete history of this document.

Edition No.	Date	Reason for Change	Pages Affected
0.01	18-Jul-01	Creation – First working draft 0.01 to SRU. Distributed to kick-off meeting.	All
0.02	09-Aug-01	New working draft including initial contents for sections 2, 3 and 4. Circulated to SQS and SRU for review and as an input to 1 st progress meeting (3 rd Sept. 2001).	All
0.03	10-Sep-01	New working draft incorporating feed back from SQS and SRU. Sections 1, 2, 3 and 4 consolidated. Initial contents for Section 5 included. Circulated to SRC Panel.	All
0.04	12-Oct-01	Draft version incorporating comments received from SRU and SRC Panel.	All
0.1	15-Oct-01	Edition produced as a proposed issue for submission to SRC for review and approval by correspondence.	All
1.0	01-Feb-02	Edition produced as a released issue after final SRC consultation by correspondence to validate the outcome of the Expert Panel	-
1.01	17-Jul-05	Creation – First working draft 0.1 to SRU	All
1.02	02-Sep-05	Update incorporating comments from SRU and EATMP. Incorporating new material.	All
1.03	20-Sep-05	Comments incorporated from 2 nd review meeting.	All
1.04	11-Nov-05	Comments added following review of the remaining material.	All
1.05	28-Nov-05	Update after review meeting.	All
1.06	15-Dec-05	SRU internal review and quality check.	All
1.07	29-Jan-08	Finalisation of the PMC incorporating UK SRG comments	§4.3
1.08	20-Mar-09	Incorporation of the UK SRC latest comments	§4.3
1.1	27-May-09	SRU quality review.	All
2.0	26-Oct-09	Document formally released following RFC No. 0907.	-

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F.6 EXECUTIVE SUMMARY

The initial version of this document will be presented to the SRC Expert Panel to assess the extent to which the SAM V2.0 ("EATMP Air Navigation System Safety Assessment Methodology") complies with ESARR 4. It will compile the outcome of the SRC's assessment and provides the basis for the SRC's judgement on the acceptability of the SAM as a Means of Compliance with ESARR 4.

The sections of ESARR 4 are grouped according to their nature. Advisory and mandatory statements are grouped into separate chapters. For each statement of ESARR 4, the statements of SAM that meet the intention of ESARR 4 are specified. In the Appendix a complete mapping of ESARR 4 and the SAM is provided. It also provides a set of conclusions and recommendations to support the final SRC judgement and also lists the proposed areas of improvement for the SAM.

The SAM provides detailed guidelines regarding the application of best practices for risk assessment for Air Navigation Service Providers only. Due to the amount of information provided, a guideline on who-should-read-what is also provided.

An in-depth description concerning functional approach to hazard identification as well as complementary approaches is provided. But there is some imbalance in the information for FHA and the one provided for SSA and PSSA as more detailed information concerning the processes for FHA than for SSA and PSSA is provided. Many PSSA and SSA Guidance Material have not been assessed as either being too low level of detail for this assessment (e.g. maintenance intervention, fault tree) or partially addressing other ESARR scope (e.g. software, human procedure).

SAM is a living document; therefore there are ongoing activities to reconcile information and best practices due to increasing experience in this domain. Due to the amount of information already available it is proposed for further development to provide a detailed list of definitions and a glossary to ensure consistency and to ensure that the SAM Level 1 provide sufficient information for compliance with ESARR 4 on a high level and that Level 2 only provides guidance for the implementation of the requirements of Level 1.

SAM provides comprehensive and detailed guidance for the implementation of ESARR 4. As the SAM is a guidance document, certain statements are not applicable for the SAM

The recently developed Guidance Material for FHA Chapter 3: "E: Process for Deriving Risk Classification Scheme and Specifying Safety Objectives in ATM "in compliance with ESARR 4" has been developed as a EUROCAE standard and was designed to also be used as a stand alone document. Therefore, this document does not fit into the existing SAM straight forwardly and well explained structure of the documentation.

The Level 3 document, FHA Appendixes: "E: Examples of Safety Targets for NAV application Guidance Material (GM)" is the only Level 3 document provided for the evaluation as an AMC. The methodology used is in line with ESARR 4 requirements. The need for this document (different scope of Navigation with regard to ESARR 4) is not explicitly explained. The assumptions and input data were not verified and validated within the scope of this evaluation and, therefore, full compatibility of the results with ESARR 4 cannot be stated.

The implementation of the Proposed Means of Compliance SAM (Safety Assessment Methodology) V2.0 meets the mandatory provisions of ESARR 4, Appendix A-1 (3). However, taking into account that EUROCAE document ED125 has been provided in a version which has not been approved by all Panel members, it has been proposed that the final position with regard to ED125 will be done after EUROCAE approval.

1. INTRODUCTION

Pursuant to international treaties such as the Chicago Convention safety regulation of civil aviation is a national responsibility. Indeed, every State has complete and exclusive sovereignty over the airspace above its territory.

Each State that has signed the Chicago Convention undertakes to keep its own Regulations, its air navigation equipment and operations compliant, as far as possible, with those established by the International Civil Aviation Organisation (ICAO) under the Chicago Convention.

Recent amendments to ICAO Annex 11 require States to assess the potential safety impacts of proposed changes¹ to the ATM System to show that an acceptable level of safety will be met, before implementing the proposed changes.

EUROCONTROL Safety Regulatory Requirement “Risk Assessment and Mitigation in ATM” (ESARR 4), approved by the EUROCONTROL Permanent Commission in April 2001, strengthens these ICAO requirements and recommended practices. Their implementation and enforcement within their national legal framework is binding for States as of April 2004.

In this context, the EUROCONTROL Safety Regulation Commission (SRC) has the task of ensuring the uniform implementation of ESARR 4 across Europe, hence the need for SRC to recognise a number of acceptable Means of Compliance to help this uniform implementation of ESARR 4.

2. PURPOSES AND SCOPE

The Safety Regulation Commission has approved an internal procedure by which a panel of experts is set up to review the acceptability of Proposed Means of Compliance (PMC) to ESARR. The Proposed Means of Compliance are submitted to the assessment by the SRC.

A number of EATMP programmes already propose to the SRC the use of the EATMP Safety Assessment Methodology² as a mean of compliance with the provisions of ESARR 4.

The purpose of this document is to provide the results of the SRC assessment of the EATMP Methodology against ESARR 4 in the form of text and matrices in order to form an overall judgement on its acceptability with regard to ESARR4 requirements. A statement of compliance has been established in order to summarize the final result.

The documents which are compared are:

Reference	Title	Version / Date
ESARR 4	Risk Assessment and Mitigation in ATM	Edition 1.0 / 05-Apr-01
SAM	EATMP Air Navigation Safety Assessment Methodology. (SAF.ET1.ST03.1000-MAN-01)	Edition 2.0 / April 2004

Table 1 – List of documents with regard to the comparison

¹ Such as airspace re-organisation, provision of ATS procedures, introduction of new equipment, systems or facilities.

² EATMP Air Navigation Safety Assessment Methodology, Released Issue, Ed. 2.0, Dated April 2004 (SAF.ET1.ST03.1000-MAN-01)

The following document is used for further information on the intended interpretation of ESARR 4:

Reference	Title	Version / Date
EAM 4 / GUI 1	Explanatory Material on ESARR 4 Requirements	Edition 1.0 / 18-Feb-03

Table 2 Guidance material for the interpretation of ESARR4

The EATMP Air Navigation Safety Assessment Methodology describes a generic approach for the safety assessment and mitigation process of Air Navigation Systems.

This consists of three major steps:

- Functional Hazard Assessment (FHA);
- Preliminary System Safety Assessment (PSSA);
- System Safety Assessment (SSA).

The documentation provides three levels of material. Taking into account the numerous documents of SAM and in order to facilitate the navigation throughout the documentation an additional tool has been provided (SAM Electronic). The scope of the analysis covers the documents listed below:

SAM Documents	ID	No	V
SAM V2.0 Intro	L1-0	1	2.0
Part I - FHA:FHA methodology:V2.0 Intro	L1-1	2	2.0
Chapter 1: Initiation	L1-2	3	2.0
Chapter 2: Planning	L1-3	4	2.0
Chapter 3: Safety Objectives Specification	L1-4	5	2.0
Chapter 4: FHA Evaluation	L1-5	6	2.0
Chapter 5: Completion	L1-6	7	2.0
Part II - PSSA: PSSA methodology: V2.0 Intro	L1-7	8	2.0
Chapter 1: Initiation	L1-8	9	2.0
Chapter 2: Planning	L1-9	10	2.0
Chapter 3: Safety Requirements Specification	L1-10	11	2.0
Chapter 4: PSSA Evaluation	L1-11	12	2.0
Chapter 5: Completion	L1-12	13	2.0
Part III - SSA: SSA methodology:V1.0 Intro	L1-13	14	1.0
Chapter 1: Initiation	L1-14	15	1.0
Chapter 2: Planning	L1-15	16	1.0
Chapter 3: Safety Assurance and Evidence Collection	L1-16	17	1.0

SAM Documents	ID	No	V
Chapter 4: SSA Evaluation	L1-17	18	1.0
Chapter 5: Completion	L1-18	19	1.0
Level 2: Guidance Material (GM)			
GM for SAM			
A: SAM content (Level 1, 2 & 3 material)	L2-1	20	2.0
B: ESARR4 requirements compliance matrix	L2-2	21	2.0
GM for FHA V2.0 sub-steps			
GM for FHA - Chapter 1			
A: OED (Operational Environment Definition)	L2-F1	22	2.0
GM for FHA - Chapter 2			
A: Planning FHA activities	L2-F2	23	2.0
GM for FHA - Chapter 3			
A: Planning and conducting FHA session	L2-F3	24	2.0
B: Identification of failure modes, external events and hazards	L2-F4	25	2.1
C: Identification of Hazards effects	L2-F5	26	2.0
D: Severity Classification Scheme	L2-F6	27	2.0
E: Risk Classification Scheme (EC 125)	L2-F7	28	2.1
F: Safety Objective Classification Scheme	L2-F8	29	2.0
G: Methods for setting Safety Objectives	L2-F9	30	2.0
H: Results records	L2-F10	31	2.0
GM for FHA - Chapter 4			
A-B-C: FHA Evaluation	L2-F11	32	2.1
GM for Chapter 5			
A: FHA Report	L2-F12	33	2.0
GM for PSSA sub-steps			
GM for PSSA - Chapter 1	L2-P1	34	2.0
GM for PSSA - Chapter 2	L2-P2	35	2.0
GM for PSSA - Chapter 3	L2-P3	36	2.0
A: Safety Requirement and Assurance Level Allocation (SWAL, PAL)	L2-P4	37	2.0
GM for PSSA - Chapter 4			
A-B-C: PSSA Evaluation	L2-P5	38	2.1
GM for PSSA - Chapter 5			

SAM Documents	ID	No	V
A: PSSA Report	L2-P6	39	2.0
GM for SSA sub-steps			
GM for SSA - Chapter 3			
GM for SSA - Chapter 4			
A-B-C: SSS Evaluation	L2-S3	40	1.1
GM for SSA - Chapter 5			
A: SSA Report	L2-S4	41	1.0
GM for SAM			
Part IV Annex A: Acronyms	L2-A1	42	2.0
Part IV Annex B: Glossary	L2-A2	43	2.0
Part IV Annex H: "what is a change"	L2-A4	44	2.1
Part IV Annex I: "Safety Case"	L2-A4	45	2.0
Level 3: Guidance Material (GM)			
FHA Appendixes			
E: Examples of Safety Targets for NAV application	L3-F1	46	1.0

Table 3 Scope of the analysis (PMC)

The references to the respective parts of ESARR 4 are provided for the Level 1 documents.

If a document at Level 1 is not compliant then the references for Level 2 are added in the tables. The mapping of ESARR 4 to SAM is listed in a separate EXCEL document in addition to this report. To support the understanding of each requirement EAM 1 / GUI 1 was used. The statements of EAM 1 / GUI 1 are also added. The mapping of the SAM Level 1 Guidance material against SAM Level 2 Guidance material is listed. This mapping is done in a separate EXCEL document in addition to this report.

3. ANALYSIS

3.1 General

Section 3.2 addresses those provisions of ESARR4 which are considered mandatory, whereas Section 3.3 addresses those provisions which are of advisory nature:

- The mandatory provisions are currently captured in sections 3, 5, 6 and 7 of ESARR 4;
- Related advisory material is currently captured in sections Executive Summary, 1, 2, 4 and 8 of ESARR 4.

Note 2: ESARR 4 Appendix A is being referred to in section 5 and is therefore considered as including mandatory provisions.

Note 3: ESARR 4 Appendix B is being referred to in section 8 and is therefore considered as including advisory material.

ESARR 4 has been developed by the EUROCONTROL Safety Regulation Commission. It is aiming at the harmonisation of the safety regulatory requirements which shall be enforced by all EUROCONTROL Member States. Its main objective is to ensure that changes to the ATM system, meet tolerable safety levels.

Explanatory material on ESARR 4 Requirements has been used to support the assessment.

With regard to the particular case of the assessment of changes; ESARR 4 does not provide criteria with regard to their categorisation; however there is some information provided in EAM 4 / GUI 2 which have been taken into consideration for the assessment.

3.2 ESARR 4 Mandatory Provisions: Sections 3, 5, 6 and 7

3.2.1 Coverage Analysis of Mandatory Provisions Analysis

With regard to the mandatory provisions of ESARR 4, the table number 4 provides a coverage analysis of the contents of the SAM documents identified in Chapter 2.

The table provides an analysis per section of ESARR4 if those related sections or text exist in SAM V2. Detailed information concerning the coverage is available additional annexed documents.

Legend

- When the provisions of SAM V2 are seen as:
 - equivalent or equal to the relevant requirement of ESARR4, the sign “=” is used.
 - encompassing and exceeding the relevant requirement of ESARR4, the sign “+” is used.
 - less demanding than the relevant requirement of ESARR4, the sign “-” is used.
- When the provisions of SAM V2 differ or are inconsistent with the relevant requirement of ESARR4, the sign “#” is used.

Analysis on “E. Process for Deriving Risk Classification Scheme and Specifying Safety Objectives in ATM” in compliance” with ESARR 4 (ED-125 Version 5)” is provided in chapter 4.3.

Traceability of the Assessment to the SAM

The column entitled “coverage” shows the traceability to the cross references provided in Excel sheets in external documents.

In order to find the reference in the set of SAM documents the traceability code is the following:

- L1 or L2 means the SAM Level of the document, a SAM document is designated as *Li-j* where *i* is “1” or “2”, and *j* is the number of the document in the “ID” column of the table provided in Chapter 2 (Table 3 Scope of the analysis (PMC));
- After the comma, the figures *k-l* are referring the section in the SAM document and the number of the paragraph, in addition some bullets can be referenced.

More information are provided in additional the Excel document.

Summary of Initial conclusions

- 1) SAM V2 provides an in-depth description concerning functional approach to hazard identification as well as complementary approaches. But there is some imbalance in the information provided for FHA and the one provided for SSA and PSSA. More detailed information concerning the processes for FHA than for SSA and PSSA is provided. Due to the limitation of the assessment exercise many PSSA and SSA Guidance Material have not been assessed as either being too low level of detail for this assessment (e.g. maintenance intervention, fault tree) or partially addressing other ESARR scope (e.g. software, human procedure). It is advised to perform further complementary assessment in order to better appreciate the balance between the different phases of the process.
- 2) SAM addresses the three different types of ATM elements (human, procedures and equipment). Their interaction is not considered in detail in the provided documents for the assessment however detailed information can be found in Guidance Material for SAM Level 2 Part IV Annex F and Annex G. Therefore a comment in PSSA and SSA Level 1 document should be added that detailed information can be found in SAM Level 2 Part IV Annex F and Annex G.
- 3) SAM V2 document E³ and G⁴ provide guidance on the safety objective derivation models, it is noticed that the depth of the description for those models is different.

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³ “E: Process for Deriving Risk Classification Scheme and Specifying Safety Objectives in ATM” in compliance” with ESARR 4 (ED-125 Version 5”)

⁴ “G: Methods for setting Safety Objectives “provide guidance on defining safety objectives not only considering the worst credible case”

ESARR 4	Covered by SAM	Coverage	Related Comments
SECTION 3-APPLICABILITY			
3.1	YES =	L1-0, 1-1 L1-0, 1-4 L1-0, 1-5	<p>Section 3.1 of ESARR 4 specifies that "This requirement shall apply to all providers of ATM services with respect to those parts of the ATM System and supporting services that are within their managerial control⁵."</p> <ul style="list-style-type: none"> (=) Introduction Section of SAM mentions that "the methodology aims at reflecting best practices for safety assessment of Air Navigation Systems and to provide guidance for their application". (=) Section 2 of SAM specifies that "However, SAM aims at supporting ANSP to achieve an acceptable level of risk (See FHA chapter 3 GM E for definitions of "tolerable" and "acceptable")." (=) SAM is "proposed" to providers of ANS. As it is a "proposal" it does not specify that the guideline is applicable to all ATM Systems within the managerial control of service providers of ATM. <p>INITIAL CONCLUSION:</p> <p>As it is a proposal its application to all ATM systems within the managerial control of service providers of ATM is possible but not enforced; therefore SAM is considered compliant with this statement.</p>
3.2	YES =	L2-F1, 2	<p>Section 3.2 of ESARR 4 specifies that "This requirement shall apply to military ATM service providers except in those cases in which military ATS or Air Defence are only and exclusively involved in the control of military aircraft, in a segregated military airspace environment."</p> <ul style="list-style-type: none"> (=) SAM does not limit the scope to the civil military ATM service providers. EATMP MAN (Guidance Material for A: OED (Operational Environment Definition – FHA Chapter 1) states that the characteristics of the operational environment shall be described. As an example for the "Traffic Characteristics" "Military operations" are mentioned. <p>INITIAL CONCLUSION:</p> <p>SAM does not limit the scope.</p>

⁵ *Whatever the national or international institutional arrangements supporting the provision of ATM services are, the provisions of this requirement have to be met.*

SECTION 5-SAFETY REQUIREMENTS			
5.1	YES +	L1-0, 1-1 L1-0, 1-3 L1-0, 2-7 L1-7, 2-2 L1-5, 1-1 L1-5, 1-1n1 L1-5, 1-2 L1-5, 1-3 L1-5, 1-4 L1-5, 1-5 L1-5, 1-6 L1-5, 1-7 L1-5, 2-1 L1-5, 3-1n1 L1-5, 3.1-1 L1-5, 3.1-1n1 L1-5, 3-1.1n2 L1-5, 3.2-1 L1-5, 3.2-2 L1-5, 3.2-3 L1-5, 3.2-4 L1-5, 3.2-6n1 L1-5, 3.2-5 L1-5, 3.2-6n1 L1-5, 3.3-1 L1-5, 3.3-1n1 L1-5, 3.3-1n2 L1-5, 4-1	<p>Section 5.1 of ESARR 4 specifies that "An ATM service provider shall ensure that hazard identification as well as risk assessment and mitigation are systematically conducted for any changes to those parts of the ATM System and supporting services within its managerial control, in a manner which:"</p> <p>(=) The Guidance Material for SAM provides guidance as to how the hazard identification as well as risk assessment and mitigation are conducted systematically.</p> <p>(+) In addition to this detailed information on best practices for hazard identification, risk assessment as well as risk mitigation are provided.</p> <p>(=) For the FHA, PSSA and SSA SAM provides guidance for a systematic execution of the following processes:</p> <ul style="list-style-type: none"> • Initiation • Planning • Execution • Verification, Validation and Process Assurance • Completion <p>(=) The definition that hazard identification as well as risk assessment and mitigation are conducted for any change including changes identified during the different steps of PSSA and SSA.</p> <p>Guidance Material for SAM provides information on how to assess a “change”, whether it deserves a safety assessment and what will be the extent of this safety assessment.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides detailed guidance</p> <ul style="list-style-type: none"> • as to how to assess whether SAM needs to be applied for revisions • on how hazard identification, risk assessment and mitigation are conducted systematically <p>In addition, best practices derived from practical experience are provided. <i>cont...</i></p>

		L1-5, 4-2 L1-5, 4-2(i) L1-5, 4-2(ii) L1-5, 4-2(iii) L1-7, 1-1 L1-9, 3-2 L1-10, 2-1 L1-10, 3-1(iii) L1-10, 3.3-2 L1-10, 3.3-3 L1-10, 3.3-3(i) L1-10, 3.3-3(ii) L1-10, 3.3-4 L1-10, 3.3-4(i) L1-10, 3.3-4(ii) L1-10, 3.3-4(iii) L1-10, 3.4-1 L1-10, 4-1 L1-14, 2.1-4 L1-16, 3.2.4-1 L1-16, 3.3.1-1 L2-A3	
5.1a (first a)	YES =	L1-0, 2-2 L1-1, 2-2 L1-3, 3-1 L1-6, 1-1 L1-6, 3-1 L1-7, 2-1 L1-9, 3-1 L1-12,1-1	<p>Section 5.1a (first a) of ESARR 4 "addresses the complete life cycle of the constituent part of the ATM System under consideration, from initial planning and definition to post-implementation operations, maintenance and de-commissioning";</p> <p>(=) SAM "Introduction Guide/1 PURPOSE" (page 3 and 4) describes the different risk assessment and mitigation activities within the complete life cycle of the ATM System."</p> <p>The FHA-related guidance material describes the activities during the system definition phase.</p> <p>The PSSA-related guidance material describes the activities during the system design phase.</p> <p>The SSA-related guidance material describes the activities during the implementation, integration, transfer into operations, operation and maintenance and decommissioning phase.</p>

		L1-12, 3-1 L1-13, 2-1 L1-14, 1-1 L1-14, 2.4-2 L1-14, 3-1 L1-15, 3-1 L1-15, 3-2 L1-15, 3-3 L1-16 (whole document) L1-18, 1-1 L1-18, 3-1	INITIAL CONCLUSION: SAM addresses the whole life cycle of the constituent part of the ATM System under consideration. Nevertheless, it is the understanding that decommissioning has to be treated as a change.
5.1a (second a)	YES =	L1-0, 2-1 L1-2, 2.2-1 L1-3, 3-1 L1-4, 3-1n1 L1-4, 3.2-4 L1-9, 3-1 L1-15, 3-1	Section 5.1a (second a) of ESARR 4 "addresses the airborne and ground components of the ATM System, through cooperation with responsible parties"; (=) SAM covers "ground-based (including space-based components) and air-based components" that are required by ESARR 4". (=) SAM mentions the co-ordination (approval) of the Planning for FHA, PSSA and SSA. In addition, it mentioned the appropriate involvement of pilots and operational staff. (=) SAM recommends coordination with the stakeholders. It does not address recommendation for the approval process. For the FHA emphasis is made on the presence of ATCO and Pilot for the assessment of impact on operations. INITIAL CONCLUSION: SAM addresses ground-based (including space-based components) and air-based components.

5.1b	YES =	L1-0, 2-1 L1-0, 3-2 L1-1, 2-3 L1-1, 2-4 L1-1, 2-6 L1-4, 3-1n1 L1-4, 3-1-2 L1-10, 1-1 L1-10, 3-1(iv) L1-10, 3.1-3 L1-10, 3.2-2(i) L1-10, 3.2-2(ii) L1-13, 1-1 L1-13, 1-2 L1-13, 2-2 L1-14, 2.1-5 L1-14, 2.1-6 L1-16, 1-1(i) L1-16, 2-1 L1-16, 3-1-1(ii) L1-16, 3-1-2(ii) L1-16, 3-1-4 L1-16, 3.1.1-2(v) L1-16, 3.1.2-1 L1-16, 3.1.2-2 L1-16, 3.1.2-3 L1-16, 3.1.2-4 L1-16, 3.4-1 L1-16, 4-1-14	<p>Section 5.1b of ESARR 4 “addresses the three different types of ATM elements (human, procedures and equipment), the interactions between these elements and the interactions between the constituent part under consideration and the remainder of the ATM System”.</p> <p>(=) According to the guidance material provided by SAM PSSA as well as SSA are conducted on the level of the elements (human, procedures and equipment).</p> <p>(=) The Operational Environment Description (OED) describes the environment of the ATM system under consideration.</p> <p>INITIAL CONCLUSION:</p> <p>SAM addresses the three different types of ATM elements (human, procedures and equipment). The interaction between the three different types of ATM elements are not considered in detail in the documents provided as an AMC but detailed information can be found in Guidance Material for SAM Level 2 Part IV Annex F and Annex G.</p>
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5.2a	YES =	L1-1, 2-1 L1-1, 2-2 L1-1, 2-3 L1-1, 2-4 L1-1, 2-5 L1-1, 2-6 L1-1, 2-7 L1-1, 2-8 L1-2, 1-1 L1-2, 2.1-1 L1-2, 2.1-2 L1-2, 2.1-3 L1-2, 2.1-4 L1-2, 2.1-4(i) L1-2, 2.1-4(ii) L1-2, 2.1-4(iii) L1-2, 2.1-4(iv) L1-2, 2.2-1 L1-2, 3-4 L1-2, 4-1 L1-2, 4-2 L1-4, 3-1 L1-7, 2-3 L1-8, 1-1 L1-8, 2.1-1 L1-8, 2.2-1 L1-8, 2.3-1 L1-8, 2.6-2 L1-8, 3-2	<p>Section 5.2a of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> • a determination of the scope, boundaries and interfaces of the constituent part being considered, as well as the identification of the functions that the constituent part is to perform and the environment of operations in which it is intended to operate;" <p>(=) SAM provides guidance on the creation of a system description that describes the high-level functions of the system and also the boundaries.</p> <p>(=) SAM guidance material provides information on how to create and update the Operational Environment Document (OED) during FHA, PSSA and SSA during the initiation process of each phase.</p> <p>INITIAL CONCLUSIONS:</p> <p>SAM provides guidance on the determination of the scope, boundaries and interfaces of the system.</p> <p>SAM provides guidance on the determination of the functions of the system to perform as well as the operational environment.</p>
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		L1-8, 3-3 L1-8, 3-4 L1-8, 3-5 L1-8, 4-1 L1-14, 1-1 L1-14, 2.1-1 L1-14, 2.1-2 L1-14, 2.1-3 L1-14, 2.1-4 L1-14, 2.1-5 L1-14, 2.1-6 L1-14, 2.2-1 L1-14, 3-1 L1-14, 4-1	
5.2b	YES +	L1-1, 1-1 L1-1, 1-3 L1-4, 1-1 L1-4, 3-1n1 L1-4, 3-2 L1-4, 4-1 L1-4, 4-1(i) L1-4, 4-1(ii) L1-4, 4-1(iii) L1-4, 4-2 L1-4, 4-4 L1-5, 1-1 L1-5, 1-1n1 L1-5, 1-2 L1-5, 1-3 L1-5, 1-4	<p>Section 5.2b i) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> • a determination of the safety objectives to be placed on the constituent part, incorporating;" <p>(+) AM pr provides detailed guidance including best practices on the identification of ATM-related hazards and failure conditions as well as the identification of the effects and the determination of the safety objectives.</p> <p>INITIAL CONCLUSION:</p> <p>AM pr provides detailed guidance including best practices for the determination of safety objectives.</p>

		<p>L1-5, 1-5 L1-5, 1-6 L1-5, 1-7 L1-5, 2-1 L1-5, 3-1n1 L1-5, 3.1-1 L1-5, 3.1-1n1 L1-5, 3-1.1n2 L1-5, 3.2-1 L1-5, 3.2-2 L1-5, 3.2-3 L1-5, 3.2-4 L1-5, 3.2-5 L1-5, 3.2-6n1 L1-5, 3.3-1 L1-5, 3.3-1n1 L1-5, 3.3-1n2 L1-5, 4-1 L1-5, 4-2 L1-5, 4-2(i) L1-5, 4-2(ii) L1-5, 4-2(iii) L1-6, 1-1 L1-6, 2-1 L1-6, 3-1 L1-6, 4-1</p>
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5.2b i)	YES +	L1-1, 1-2 L1-4, 1-1(i) L1-4, 3-1 L1-4, 3-1(i) L1-4, 3-1(ii) L1-4, 3-1-1 L1-4, 3-1-2 L1-4, 3-1-3 L1-4, 3-1-4 L1-4, 3-1-5 L1-4, 3-1-6 L1-4, 3-1-7 L1-4, 3-1-8 L1-4, 3-1-9	<p>Section 5.2b i) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> • a determination of the safety objectives to be placed on the constituent part, incorporating: <ul style="list-style-type: none"> - an identification of ATM-related credible hazards and failure conditions, together with their combined effects;" <p>(=) SAM provides guidance on the identification of ATM-related credible hazards and failure conditions, together with their combined effects.</p> <p>It considers that the "scope of the hazard analysis is not limited to the boundaries of the system being changed, but should include all components and systems involved in the service provided in the environment of operations". It provides guidance on how to focus on credible hazards and failure conditions.</p> <p>(+) SAM provides detailed guidance on the process to identify failure modes, external events and hazards considering best practices.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on the identification of ATM-related credible hazards and failure conditions, together with their combined effects.</p>
5.2b ii)	YES +	L1-4, 1-1(i) L1-4, 1-1(ii) L1-4, 1-1(iii) L1-4, 1-1(iv) L1-4, 3-1 L1-4, 3-1(i) L1-4, 3-1(ii) L1-4, 3-1(iii) L1-4, 3-1n1 L1-4, 3-1-1 L1-4, 3-1-2 L1-4, 3-1-3 L1-4, 3-1-4 L1-4, 3-1-5 L1-4, 3-1-6	<p>Section 5.2b ii) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> • a determination of the safety objectives to be placed on the constituent part, incorporating: <ul style="list-style-type: none"> - an assessment of the effects they may have on the safety of aircraft, as well as an assessment of the severity of those effects, using the severity classification scheme provided in Appendix A," and <p>(+) In addition to the guidance provided by SAM on the assessment of the effects hazards may have on the safety of aircraft as well as on the assessment of the severity of the effects, SAM also provides information on different methods to set the safety objective.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on the assessment of the effects hazards may have on the safety of aircraft as well as on the assessment of the severity of the effects.</p>

		L1-4, 3.1-7 L1-4, 3.1-8 L1-4, 3.1-9 L1-4, 3.2-1 L1-4, 3.2-2 L1-4, 3.2-3 L1-4, 3.2-4 L1-4, 3.2-5 L1-4, 3.3-1 L1-4, 3.3-2 L1-4, 3.3-3 L1-4, 3.3-4 L1-4, 3.3-5 L1-5, 4-2(i)	
5.2b iii)	YES +	L1-4, 1-1(iv) L1-4, 1-2 L1-4, 1-3 L1-4, 1-4 L1-4, 2-3 L1-4, 2-4 L1-4, 3-1(iv) L1-4, 3-1(v) L1-4, 3.4-1 L1-4, 3.4-2 L1-4, 3.4-3 L1-4, 3.4-4 L1-4, 3.4-5 L1-4, 3.5-1 L1-4, 3.5-2	<p>Section 5.2b iii) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> • a determination of the safety objectives to be placed on the constituent part, incorporating: <ul style="list-style-type: none"> - a determination of their tolerability, in terms of the hazard's maximum probability of occurrence, derived from the severity and the maximum probability of the hazard's effects, in a manner consistent with Appendix A;" <p>(+) SAM provides different methods (quantitative as well as qualitative) on the determination of the safety objectives considering the maturity of the organisation applying this method.</p> <p>(+) SAM provides practical examples for the calculation of the risk classification scheme.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on the determination of safety objectives considering the severity of hazard effect as well as the probability of the hazard's effect.</p>

		L1-4, 3.5-3 L1-4, 3.5-4 L1-4, 3.5-5 L1-4, 4-1(ii) L1-4, 4-1(iii)	
5.2c	YES =	L1-7, 1-1 L1-7, 1-2 L1-7, 2-1 L1-7, 2-2 L1-7, 2-3 L1-7, 2-4 L1-7, 2-5 L1-9, 1-1 L1-9, 2-1 L1-9, 3-1 L1-9, 3-2 L1-9, 3-3 L1-9, 4-1 L1-10, 1-1 L1-10, 2-1 L1-10, 3-1 L1-11, 4-1 L1-11, 4-2 L1-12, 1-1 L1-12, 2-1 L1-12, 3-1 L1-12, 4-1	<p>Section 5.2c of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> the derivation, as appropriate, of a risk mitigation strategy which:" <p>(=) SAM provides in the description of the PSSA activities a detailed description on the methodology for the activities required to derive an appropriate risk mitigation strategy.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides detailed guidance on the development of the derivation of risk mitigation strategies for the elements of the ATM system based on the safety objective defined during the FHA phase.</p>

5.2c i)	YES =	L1-7, 1-1 L1-10, 3-1 L1-10, 3-1(i) L1-10, 3-1(ii) L1-10, 3-1(iii) L1-10, 3-1(iv) L1-10, 3-1(v) L1-10, 3-2 L1-10, 3.1-1 L1-10, 3.1-2 L1-10, 3.1-3 L1-10, 3.1-4 L1-10, 3.1-4(i) L1-10, 3.1-4(ii) L1-10, 3.2-1 L1-10, 3.2-2 L1-10, 3.2-2(i) L1-10, 3.2-2(ii) L1-10, 3.2-2(iii) L1-10, 3.2-2(iv) L1-10, 3.2-3 L1-10, 3.3-1 L1-10, 3.3-2 L1-10, 3.3-3 L1-10, 3.3-3(i) L1-10, 3.3-3(ii) L1-10, 3.3-4 L1-10, 3.3-4(i) L1-10, 3.3-4(ii)	<p>Section 5.2c i) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> the derivation, as appropriate, of a risk mitigation strategy which: <ul style="list-style-type: none"> specifies the defences to be implemented to protect against the risk-bearing hazards;" <p>SAM provides guidance on refining the systems functions into sub-functions, evaluating the system architecture and the contribution of each sub-function to safety objectives as well as the application of risk mitigation strategies.</p> <p>INITIAL CONCLUSION:</p> <p>SAM Provides guidance on the definition of a determination of a risk mitigation strategy for risk-bearing hazards as well as the defences to be implemented to protect against the risk-bearing hazards.</p>
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		L1-10, 3.3-4(ii)	
5.2c ii)	YES =	<p>L1-10, 3.3-1 L1-10, 3.4-1 L1-10, 3.4-2 L1-10, 3.4-3 L1-10, 3.4-4 L1-10, 3.4-4n1</p>	<p>Section 5.2c ii) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> the derivation, as appropriate, of a risk mitigation strategy which: <ul style="list-style-type: none"> includes, as necessary, the development of safety requirements potentially bearing on the constituent part under consideration, or other parts of the ATM System, or environment of operations;" <p>(=) SAM provides guidance on the development of safety requirements potentially bearing on the constituent part under consideration, or other parts of the ATM System, or environment of operations.</p> <p>It includes the apportionment of final Safety Objectives and the specification of Safety Requirements for each individual system element.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on the development of safety requirements potentially bearing on the constituent part under consideration.</p>
5.2c iii)	YES =	<p>L1-10, 3-1(v) L1-10, 3-2 L1-10, 3.5-1 L1-10, 3.5-2 L1-10, 3.5-3 L1-10, 4-1 L1-10, 4-2 L1-11, 1-3 L1-11, 3.2-1 L1-11, 3.2-1(i) L1-11, 3.2-1(ii) L1-11, 3.2-1(iii) L1-11, 3.2-1(iv) L1-11, 3.2-1(v) L1-11, 4-1 L1-11, 4-2</p>	<p>Section 5.2c iii) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> the derivation, as appropriate, of a risk mitigation strategy which: <ul style="list-style-type: none"> presents an assurance of its feasibility and effectiveness;" <p>(=) Part IV Annex I: "Safety Case" of SAM provides guidance on the development of Safety Cases as a means of demonstrating the safety of an ATM service or new / modified System.</p> <p>(=) SAM provides guidance to balance/reconcile the Safety Requirements.</p> <p>(=) SAM provides guidance on the verification and validation as well as the process assurance of the PSSA phase.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance how to derive an appropriate risk mitigation strategy covering the feasibility as well as the effectiveness.</p>

		L1-16, 3.3.1-2 L2-A4 (whole document)	
5.2d	YES =	L1-13, 0-1 L1-13, 1-1 L1-13, 1-2 L1-13, 1-3 L1-13, 2-1 L1-13, 2-2 L1-13, 2-3 L1-13, 2-4 L1-16, 1-1 L1-16, 1-1(i) L1-16, 1-1(ii) L1-16, 1-1(iii) L1-16, 1-1(iv) L1-16, 1-1(v) L1-16, 2-1 L1-16, 3-1 L1-16, 3-1-6 L1-16, 3-1-7 L1-16, 3-1-8 L1-16, 4-1-1 L1-16, 4-1-2 L1-16, 4-1-3 L1-16, 4-1-4 L1-16, 4-1-5 L1-16, 4-1-6 L1-16, 4-1-7 L1-16, 4-1-8	<p>Section 5.2d of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> verification that all identified safety objectives and safety requirements have been met;" <p>(=) SAM provides guidelines on how to collect evidence and provides assurance from implementation until decommissioning that the system achieves an acceptable (or at least a tolerable) risk and consequently satisfies its Safety Objectives and that the system elements meet their Safety Requirements.</p> <p>(=) SAM provides guidelines on how to monitor the safety performance of the system during its operational life.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidelines on the definition on a process that includes the verification that the identified safety objectives and safety requirements have been met.</p>

		L1-16, 4-1-9 L1-16, 4-1-10 L1-16, 4-1-11 L1-16, 4-1-12 L1-16, 4-1-13 L1-16, 4-1-14 L1-16, 4-1-15	
5.2d i)	YES =	L1-16, 3-1-1 L1-16, 3-1-1(i) L1-16, 3-1-1(ii) L1-16, 3-1-1(iii) L1-16, 3-1-1(iv) L1-16, 3-1-4 L1-16, 3-1-4(i) L1-16, 3.1.1-1 L1-16, 3.1.1-2 L1-16, 3.1.1-2(i) L1-16, 3.1.1-2(ii) L1-16, 3.1.1-2(iii) L1-16, 3.1.1-2(iv) L1-16, 3.1.1-2(v) L1-16, 3.1.2-1 L1-16, 3.1.2-2 L1-16, 3.1.2-3 L1-16, 3.1.2-4 L1-16, 3.1.3-1 L1-16, 3.1.3-1n1 L1-16, 3.4-1	<p>Section 5.2d i) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> • verification that all identified safety objectives and safety requirements have been met: <ul style="list-style-type: none"> - prior to its implementation of the change;" <p>(=) SAM provides guidance on:</p> <ul style="list-style-type: none"> • the reassessment of the results of the FHA and PSSA phase, • verification that system elements meet Safety Requirements, • verification that the system as implemented meets Safety Objectives (as far as possible). <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on the "SSA during Implementation & Integration (including Training)" but not "prior to its implementation of the change," as stated in ESARR 4.</p>

5.2d ii)	YES =	L1-16, 3-1-2 L1-16, 3-1-2(i) L1-16, 3-1-2(ii) L1-16, 3-1-2(iii) L1-16, 3-1-2(iv) L1-16, 3.1.4-1 L1-16, 3.2.1-1 L1-16, 3.2.1-2 L1-16, 3.2.2-1 L1-16, 3.2.2-2 L1-16, 3.2.3-1 L1-16, 3.2.3-2 L1-16, 3.2.4-1	<p>Section 5.2d i) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> • verification that all identified safety objectives and safety requirements have been met <ul style="list-style-type: none"> - during any transition phase into operational service;" <p>(=) SAM provides guidance on:</p> <ul style="list-style-type: none"> • continuous data collection • validation that risk is acceptable <p>during the transfer phase.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on the "SSA during Transfer into Operations".</p>
5.2d iii)	YES =	L1-16, 1-1(ii) L1-16, 3-1-3 L1-16, 3-1-3(i) L1-16, 3-1-3(ii) L1-16, 3.3.1-1 L1-16, 3.3.1-2 L1-16, 3.3.1-3 L1-16, 3.3.1-4 L1-16, 3.3.1-5 L1-16, 3.3.2-1	<p>Section 5.2d i) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> • verification that all identified safety objectives and safety requirements have been met <ul style="list-style-type: none"> - during its operational life;" <p>(=) SAM provides guidance on:</p> <ul style="list-style-type: none"> • continuous data collection, • monitoring safety performance <p>during operation and maintenance.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on the "SSA during Operations & Maintenance".</p>
5.2d iv)	YES =	L1-16, 1-1(ii) L1-16, 3-1-5 L1-16, 3-1-5(i) L1-16, 3-1-5(ii) L1-16, 3.5-1 L1-16, 3.5-2	<p>Section 5.2d i) of ESARR 4 specifies that "The hazard identification, risk assessment and mitigation processes shall include:</p> <ul style="list-style-type: none"> • verification that all identified safety objectives and safety requirements have been met <ul style="list-style-type: none"> - during any transition phase until decommissioning;" <p>(=) SAM provides guidance on Safety assessment during commissioning.</p> <p>INITIAL CONCLUSION:</p>

			SAM provides guidance on the "SSA during Decommissioning".
5.2 (Note 1)	YES =	L1-15, 3-1 L1-18, 1-1 L1-18, 3-1	<p>Section 5.2 (Note 1) of ESARR 4 specifies "(Note: It is considered as essential that the activities depicted in a), b), c) and d) are fully coordinated between those parties responsible for developing and implementing the safety requirements bearing on the constituent parts of the ATM System). See 5.1 (b) above."</p> <p>(=) SAM mentions the coordination (approval) of the Planning for FHA, PSSA and SSA. In addition, it mentioned the appropriate involvement of pilots and operational staff.</p> <p>INITIAL CONCLUSION:</p> <p>SAM recommends co-ordination with the stakeholders. It does not address recommendation for the approval process. For the FHA emphasis is made on the presence of ATCO and Pilot for the assessment of impact on operations.</p>
5.2 (Note 2)	YES +	L2-F7, 4 and 5	<p>Section 5.2 (Note 2) of ESARR 4 specifies "(Note: It is recognised that a combination of quantitative (e.g. mathematical model, statistical analysis) and qualitative (e.g. good working processes, professional judgement) arguments may be used to provide a good enough level of assurance that all identified safety objectives and requirements have been met)."</p> <p>(+) SAM E. Process for Deriving Risk Classification Scheme and Specifying Safety Objectives in ATM provides detailed guidance on the usage of different models to derive the Safety Objectives based on the experience of the user.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on different methods models to derive the Safety Objectives including qualitative and quantitative elements.</p>
5.3	YES =	L1-0, 2-8 L1-1, 6-1 L1-1, 6.1-1 L1-1, 6.2-1 L1-7, 6-1 L1-7, 6.1-1 L1-7, 6.2-1 L1-13, 6-1 L1-13, 6.1-1 L1-13, 6.2-1	<p>Section 5.3 of ESARR 4 specifies that "The results, associated rationales and evidence of the risk assessment and mitigation processes, including hazard identification, shall be collated and documented in a manner which ensures:"</p> <p>(=) SAM configuration management procedures have to be applied to track the output of each process (FHA, PSSA and SS) and the relationship between the different outputs.</p> <p>(+) SAM provides high-level requirements for the configuration management procedure to be implemented.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on appropriate configuration management procedures.</p>

5.3a	YES =	L1-5 (whole document) L1-11 (whole document) L1-16 (whole document) L1.17 (whole document) L1-13, 1-1 L1-13, 1-2 L2-A4 (whole document)	<p>Section 5.3a of ESARR 4 specifies that "The results, associated rationales and evidence of the risk assessment and mitigation processes, including hazard identification, shall be collated and documented in a manner which ensures:"</p> <ul style="list-style-type: none"> that correct and complete arguments are established to demonstrate that the constituent part under consideration, as well as the overall ATM System are, and will remain, tolerably safe including, as appropriate, specifications of any predictive, monitoring or survey techniques being used; <p>(+) SAM provides guidelines to support the involved persons to ensure the correctness and completeness of the process at each step (FHA, PSSA and SSA), including checklists.</p> <p>(=) SAM provides guidelines for the process to collect evidence and provide assurance from implementation until decommissioning that the system achieves an acceptable (or at least a tolerable) risk and consequently satisfies its Safety Objectives and that the system elements meet their Safety Requirements.</p> <p>(=) SAM deals with the monitoring of the safety performances of the system during its operational life. Extensive guidance on appropriate predictive, monitoring or survey techniques is available but has not been provided as part of the AMC. Right now there is no explicit reference in the PMC for PSSA and SSA to this guidance material (Part IV Guidance Material D).</p> <p>(=) SAM Part IV Annex I: "Safety Case" of SAM provides guidance on the development of Safety Cases as a means of demonstrating the safety of an ATM service or new / modified System3.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance to ensure the correctness and completeness of the process at each step. It also provides guidance for collecting evidence to provide assurance that the system achieves an acceptable (or at least a tolerable) risk and consequently satisfies its Safety Objectives and that the system elements meet their Safety Requirements. It does not specify appropriate predictive and surveying techniques to be used for monitoring that the system remains tolerably safe.</p>
5.3b	YES =	L1-5, 3.2-4 L1-11, 3.2-1(iv) L1-17, 3.2-1(iv)	<p>Section 5.3b of ESARR 4 specifies that "The results, associated rationales and evidence of the risk assessment and mitigation processes, including hazard identification, shall be collated and documented in a manner which ensures:</p> <ul style="list-style-type: none"> that all safety requirements related to the implementation of a change are traceable to the intended operations/functions." <p>(=) SAM Guidance Material for FHA Chapter 3 (B1) "B: Identification of failure modes, external events and hazards;" describes the:</p> <ul style="list-style-type: none"> Identification of hazards,

			<ul style="list-style-type: none"> • Identification of failure modes, • Identification of external events <p>as well as the identification of hazards to allow traceability to abnormal events.</p> <p>(=) SAM provides guidance on appropriate configuration management.</p> <p>(=) SAM provides guidance for the analysis of the traceability as part of the evaluation activities for each step (FHA, PSSA, SSA).</p> <p>INITIAL CONCLUSION:</p> <p>SAM implicitly recommends traceability in PSSA Chapter 3, paragraph 3.1. The verification is explicitly recommended in the evaluation activities.</p>
SECTION 6-IMPLEMENTATION			
6.1	NA	-	<p>Section 6.1 of ESARR 4 specifies that "The provisions of this requirement are to become effective within three years from the date of adoption by the EUROCONTROL Commission."</p> <p>SAM only intends to harmonise good working practices in safety assessment, and as such does not require any target implementation date.</p> <p>INITIAL CONCLUSION:</p> <p>SAM is not supposed to be “enforced”.</p>
SECTION 6-EXEMPTIONS			
7	NA	-	<p>Section 7 of EASRR 4 specifies that there are no exemptions.</p> <p>SAM mentions that “the methodology aims at reflecting best practices for safety assessment of Air Navigation Systems and to provide guidance for their application”.</p> <p>INITIAL CONCLUSION:</p> <p>SAM, at a level of a methodology, is not supposed to be “enforced”.</p>
APPENDIX A			
APPENDIX A 1-Hazard Identification and Severity Assessment in ATM			
A-1.1	YES =	L1-0, 1-1 L1-0, 2-1 L1-1, 1-1 L1-1, 1-2 L1-1, 2-1 L1-1, 2-2	<p>Section Appendix A-1, A-1.1 of ESARR 4 specifies that "Before the risks associated with introduction of a change to the ATM System in a given environment of operations can be assessed, a systematic identification of the hazards shall be conducted."</p> <p>(=) SAM provides detailed information on the methodology to be used as well as the guidance on the implementation on the different stages for the implementation of the FHA, PSSA and SSA. For each of this phases the following steps are foreseen:</p>

		L1-4, 1-1 L1-4, 1-1(i) L1-4, 1-1(ii) L1-4, 1-1(iii) L1-4, 1-1(iv)	<ul style="list-style-type: none"> Initiation Planning Implementation (for FHA: Safety Objective Specification, PSSA: Safety Requirements Specification, SSA: Safety Assurance and Evidence Collection) Evaluation Completion <p>(=) SAM requires the operational environment to be defined during the initiation phase of FHA.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on systematic identification of the hazards before the risks associated with introduction of a change to the ATM System in a given environment of operations is to be assessed.</p>
A-1.2	YES (+)	L2-F6 (whole document)	<p>Section Appendix A-1, A-1.2 of ESARR 4 specifies that "The severity of the effects of hazards in that environment of operations shall be determined using the classification scheme shown in Figure A-1."</p> <p>(+) SAM Guidance Material: EATMP MAN D: Severity Classification Scheme and G: Methods for setting Safety Objectives provide guidance on defining safety objectives not only considering the worst credible case.</p> <p>EATMP MAN D: Severity Classification Scheme and G: Methods for setting Safety Objectives provide guidance on defining safety objectives using quantitative methods.</p> <p>INITIAL CONCLUSION:</p> <p>SAM Guidance Material: FHA D: Severity Classification Scheme refers to the severity classification of ESARR 4. In addition the classification scheme is customises based on the indicators considering the ones listed in ESARR4 in order to adequately reflects the operational environment and make it meaningful in the context of the sub-system under assessment.</p>
A-1.n1 Note	NA	-	<p>Section Appendix A-1, Note 1 of ESARR 4 specifies that " (Note: Figure A-1 provides a framework for assessing the severity of effects of hazards in a specific environment of operations. It does this by providing a qualitative ranking scheme for the severity/magnitude of the effect of hazards on operations, which may arise from the various failure modes of elements of the ATM System.)</p>
A-1.3	YES =	L2-F6 L2-F7 L2-F9	<p>Section Appendix A-1, A-1.1 of ESARR 4 specifies that "As there is no such scheme today as an accident/incident causation model, the severity classification shall rely on a specific argument demonstrating the most probable effect of hazards, under the worst case scenario."</p> <p>(=) SAM E: Process for Deriving Risk Classification Scheme and Specifying Safety Objectives in ATM "in compliance" with ESARR 4 describes the following models for risk classification:</p> <ol style="list-style-type: none"> Quantitative Model Semi-Quantitative Model

			<p>3. Semi-Prescriptive Model 4. Fixed-Prescriptive Model</p> <p>whereas G: Methods for setting Safety Objectives describes the following models for risk classification:</p> <ol style="list-style-type: none"> QUANTITATIVE METHOD (see 1) PRESCRIPTIVE METHOD (see 3 and 4) CRITICALITY METHOD QUALITATIVE METHOD <p>INITIAL CONCLUSION:</p> <p>SAM FHA E: Risk Classification Scheme; (ED 125) and G: Methods for setting Safety Objectives provide guidance on defining safety objectives not only considering the worst credible case. Whereas the title and the depth of the description for some models are different.</p>
A-1.n2 Note	see A-1.3	see A-1.3	Section Appendix A-1, Note 2 of ESARR 4 specifies that "Note: The potential for a hazard to lead to an accident or an incident (i.e. considering both the proximity of the accident and the degree of ability to recover from the hazardous situation) is dependent on many factors. Therefore, it is not usually practicable to identify and evaluate the severity explicitly without assessing the effects of the hazards on the various constituent parts of the ATM System.)" see A-1.3
A-1.4	YES =	L1-4, 3.2-2 L1-4, 3.2-3 L1-4, 3.3-3 L2-F6 (Table D-2)	<p>Section Appendix A-1, A-1.4 of ESARR 4 specifies that "In order to deduce the effect of a hazard on operations and to determine its severity, the systematic approach/process shall include (but not be restricted to) the effects of hazards on the various elements of the ATM System, such as:</p> <ul style="list-style-type: none"> - Effect of hazard on air crew, (e.g. workload, ability to perform his/her functions); - Effect of hazard on the Air Traffic Controllers, (e.g. workload, ability to perform his/her functions); - Effect of hazard on the aircraft functional capabilities; - Effect of hazard on the functional capabilities of the ground part of the ATM System; - Effect of hazard on the ability to provide safe Air Traffic Management Services; (e.g. magnitude of loss or corruption of Air Traffic Management Services/functions)." <p><u>Effect of hazard on air crew, (e.g. workload, ability to perform his/her functions):</u></p> <p>(=) The analysis on the effects of a hazard to the various elements of the ATM System is addressed in SAM.</p> <p>(=) The Guidance Material for FHA, Chapter 3, C: Identification of Hazards effects – Chapter 1.1 specifies the effects on Air Navigation Services that should be considered.</p> <p>(=) The Guidance Material for FHA, Chapter 3, D: Severity Classification Scheme – Table D-2</p>

		<p>specifies the severity indicators for the severity classification.</p> <p><u>Effect of hazard on the Air Traffic Controllers, (e.g. workload, ability to perform his/her functions);</u></p> <p>(=) The analysis on the effects of a hazard to the various elements of the ATM System is addressed in SAM.</p> <p>(=) The Guidance Material for FHA, Chapter 3, C: Identification of Hazards effects – Chapter 1.1 specifies the effects on Air Navigation Services that should be considered.</p> <p>(=) The Guidance Material for FHA, Chapter 3, D: Severity Classification Scheme – Table D-2 specifies the severity indicators for the severity classification.</p> <p><u>Effect of hazard on the aircraft functional capabilities;</u></p> <p>(=) The analysis on the effects of a hazard to the various elements of the ATM System is addressed in SAM.</p> <p>(=) The Guidance Material for FHA, Chapter 3, C: Identification of Hazards effects – Chapter 1.1 specifies the effects on Air Navigation Services that should be considered.</p> <p>(=) The Guidance Material for FHA, Chapter 3, D: Severity Classification Scheme – Table D-2 specifies the severity indicators for the severity classification.</p> <p><u>Effect of hazard on the functional capabilities of the ground part of the ATM System;</u></p> <p>(=) The analysis on the effects of a hazard to the various elements of the ATM System is addressed in SAM.</p> <p>(=) The Guidance Material for FHA, Chapter 3, C: Identification of Hazards effects – Chapter 1.1 specifies the effects on Air Navigation Services that should be considered.</p> <p>(=) The Guidance Material for FHA, Chapter 3, D: Severity Classification Scheme – Table D-2 specifies the severity indicators for the severity classification.</p> <p><u>Effect of hazard on the ability to provide safe Air Traffic Management Services; (E.g., magnitude of loss or corruption of Air Traffic Management Services/functions)."</u></p> <p>(=) The analysis on the effects of a hazard to the various elements of the ATM System is addressed in SAM.</p> <p>(=) The Guidance Material for FHA, Chapter 3, C: Identification of Hazards effects – Chapter 1.1 specifies the effects on Air Navigation Services that should be considered.</p> <p>(=) The Guidance Material for FHA, Chapter 3, D: Severity Classification Scheme – Table D-2 specifies the severity indicators for the severity classification.</p> <p>INITIAL CONCLUSION:</p> <p>SAM addresses identification of the effects as well as the severity classification as described in ESARR4.</p>
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A-1.n3 Note	YES (=)	L1-4, 3.2-2 L2-F6 (Table D-2)	<p>Section Appendix A-1, Note 3 of ESARR 4 specifies that "(Note: These should be seen as characteristics which need to be considered in order consistently to identify all the hazards and assess the severity of their effects on operations.)"</p> <p>(=) The Guidance Material for FHA, Chapter 3, D: Severity Classification Scheme – Table D-2 specifies the severity indicators for the severity classification based on the various elements of the ATM system.</p> <p>INITIAL CONCLUSION:</p> <p>SAM addresses the different characteristics (various elements of the ATM system) described in ESARR4 which need to be considered.</p>
A-1.n4 Note	YES (=)	L1-4, 3.1-2 L1-4, 3.1-7	<p>Section Appendix A-1, Note 4 of ESARR 4 specifies that "(Note: The scope of the hazard identification and severity assessment is not limited to the boundaries of the components of the system being changed, but should include all components and systems involved in the service provided in the environment of operations.)"</p> <p>(=) SAM provides guidance on the identification of hazards are the consequences of failures within the system, combination of failures and interactions with other systems and external events in the environment of operation. It provides guidance on the identification of hazards at the boundaries of the system or service under assessment.</p> <p>INITIAL CONCLUSION:</p> <p>SAM addresses the identification of hazards and the consequences of failures within the system, combination of failures and interactions with other systems and external events in the environment of operation at the boundaries of the system or service under assessment.</p>
A-1.n5 Note	YES (=)	L1-4, 3.1-6 L2-F6 (Table D-2)	<p>Section Appendix A-1, Note 5 of ESARR 4 specifies that "(Note: The severity assessment should also include considerations of:</p> <ul style="list-style-type: none"> - various types of exposure to the hazard (e.g. Number of aircraft exposed to the hazard, geographical region exposed, etc.); - characteristics of the environment of operations." <p>(=) The Guidance Material for FHA, Chapter 3, D: Severity Classification Scheme – Table D-2 specifies the severity indicators for the severity classification based on the various elements of the ATM system. It considers:</p> <ul style="list-style-type: none"> • The exposure time to the hazard; • The ability to detect the hazard and the external event occurrence; • The rate of development of the hazard (sudden or fast or slow). <p>INITIAL CONCLUSION:</p>

			The Severity Classification Scheme described in SAM considers the various types of exposure to the hazard but it does not consider the characteristics of the environment of operations.
A-1.n6 Note	YES (=)	L1-3, 3-1 L1-3, 4-1 L2-F1, 1	<p>Section Appendix A-1, Note 6 of ESARR 4 specifies that "(Note:- It is advisable that elements of the environment of operations which can be used as compensating factors in the severity assessment be identified and agreed with the safety regulators before initiating the safety assessment process)."</p> <p>(=) SAM specifies that as part of the creation of the OED cases where elements of the environment of operation may be used as compensating factors in the assessment of the severity of the identified hazard effects, the best practise is that they should be identified and agreed with the regulatory authorities before initiating the safety assessment process.</p> <p>INITIAL CONCLUSION:</p> <p>The co-ordination with the safety regulator to agree on the elements of the environment of operations which can be used as compensating factors in the severity assessment is covered in SAM</p>
A-2.n7 Note	see A-1.2 and A-1.3	see A-1.2 and A-1.3	<p>Section Appendix A-2, Note 1 of ESARR 4 specifies that "Note: The worst credible effect in the environment of operations determines the severity class. *:- The Severity Classification of effects is common to that in ESARR 2 but the examples chosen relate to a priori assessment. This list is by no means exhaustive."</p> <p>see A-1.2 and A-1.3</p>
APPENDIX A-2-Risk Classification Scheme in ATM			
A-2.1	YES (+)	L2-F7 L2-F8 L2-F9	<p>Section Appendix A-2, A-2.1 of ESARR 4 specifies that "Safety objectives based on risk shall be established in terms of the hazards maximum probability of occurrence, derived both from the severity of its effect, according to Figure A-1 and from the maximum probability of the hazard's effect, according to Figure A-2."</p> <p>(=) SAM provides guidance on the specification of the safety objectives according to Figure A-1 and Figure A-2 of ESARR4.</p> <p>(+) In addition to the maximum probability of the hazard's effect for severity class 1 as described in SAM FHA E: Risk Classification Scheme; (ED 125) provides guidance on the calculation of the maximum probability of the hazard's effect for severity class 2, 3, 4 and 5.</p> <p>See also A-1.3</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on the definition of safety objectives as required in ESARR 4.</p> <p>SAM FHA E: Risk Classification Scheme; (ED 125) and G: Methods for setting Safety Objectives provide guidance on defining safety objectives not only considering the worst credible case. The methods described in the two documents are not consistent.</p>

A2.n1 Note	YES (+)	L2-F7 (Chapter 2)	<p>Section Appendix A-2, Note 1 of ESARR 4 specifies that "Note: Figure A-2 should be considered as a Risk Classification scheme (i.e. a Severity Classification/Probability Classification relationship matrix). It associates a Severity Class, as determined using Figure A-1, with a tolerable probability (i.e., a maximum tolerable probability of ATM directly contributing to safety occurrences) to show that the more severe the effect of the hazard the less desirable it is that the hazard occurs."</p> <p>(+) SAM FHA E: Risk Classification Scheme; (ED 125) provides guidance on the specification of a Risk Classification Scheme for the NSA as well as the ANSP.</p> <p>INITIAL CONCLUSION:</p> <p>SAM FHA E: Risk Classification Scheme; (ED 125) provides guidance on the specification of a Risk Classification Scheme. The Risk Classification Scheme defined in this document is based on an empirical model rather than a formal and rigorous ATM performance model. However, validation with some ATMSP actual data was ensured. The remarks in chapter "2.5 Advantages and Limitations of ATMSP RCS" should carefully be considered.</p>
A2.n2 Note	YES (=)	L2-F7 (Chapter 2)	<p>Section Appendix A-2, Note 2 of ESARR 4 specifies that "(Note: Figure A-2 only refers to an overall safety performance of ATM at ECAC and national level and is not directly applicable to the classification of individual hazards. To achieve this, a method of apportionment of the overall probability to the constituent parts of the ATM system may need to be developed- This apportionment may be done per phase of flight and/or, per accident types.)."</p> <p>(=) SAM FHA E: Risk Classification Scheme; (ED 125) provides guidance on apportionment per phase of flight but not per accident type.</p> <p>INITIAL CONCLUSION:</p> <p>SAM FHA E: Risk Classification Scheme; (ED 125) provides guidance on apportionment per phase of flight but not per accident type.</p>
A2.n3 Note	see A2.n1 Note	see A2.n1 Note	<p>Section Appendix A-2, Note 3 of ESARR 4 specifies that "(Note:- Figure A-2 assumes an ECAC Safety Minimum of a "maximum tolerable probability of ATM directly contributing to an accident of a Commercial Air Transport aircraft of $1,55 \times 10^{-8}$ "accidents per Flight Hour".)"</p> <p>see A2.n1 Note</p>
A2.n4 Note	see A2.n2 Note	see A2.n2 Note	<p>Section Appendix A-2, Note 4 of ESARR 4 specifies that (Note:-The quantitative definitions for the safety objectives associated with the maximum tolerable probabilities of ATM directly contributing to incidents of severity class 2, 3, 4 and 5 in the ECAC region remain to be determined once enough and consistent safety data have been collected by EUROCONTROL, which are consistent with the requirements outlined in ESARR 2)."</p> <p>see A2.n2 Note</p>

A2.n5 Note	Yes (+)	ED 125	<p>Section Appendix A-2, Note 5 of ESARR 4 specifies that "(Note:-The quantitative definitions for the safety objectives associated with the maximum tolerable probabilities of ATM directly contributing to incidents of severity class 2, 3, 4 and 5 should be determined at national level based on past evidence on numbers of ATM-related incidents and associated severity classes)."</p> <p>INITIAL CONCLUSION:</p> <p>SAM ED 125 § 2.1.4 provides guidance for defining the quantitative definitions for the safety objectives associated with the maximum tolerable probabilities of ATM directly contributing to incidents of severity class 2, 3, 4 and 5. The calculation has to be adapted to each national framework. The method takes into account the historical data based on past evidence on numbers of ATM-related incidents and associated severity classes. It takes into account other contributing factors as: the average level of traffic, apportionment between phase of flight and provides example for the calculation. It advice to review the numerical assumptions on a regular basis.</p>
A-2.2	YES (=)	L2-F7 (Chapter 2)	<p>Section Appendix A-2, A-2.2 of ESARR 4 specifies that "As a necessary complement to the demonstration that these quantitative objectives are met, additional safety management considerations shall be applied so that more safety is added to the ATM system whenever reasonable."</p> <p>(=) SAM FHA E: Process for Deriving Risk Classification Scheme and Specifying Safety Objectives in ATM "in compliance" with ESARR 4) chapter 2 provides guidance on the specification of a RCS for the ATMSP based on the RCS of the National Regulator RCS by using an ambition factor.</p> <p>INITIAL CONCLUSION:</p> <p>This statement in ESARR 4 does not clearly address how regulatory minima shall be complemented by additional safety management considerations nevertheless the ambition factor described in (=) SAM FHA E: Risk Classification Scheme; (ED 125) chapter 2 could serve as such an additional safety management considerations.</p>
A2.n6 Note	NA	-	<p>Section Appendix A-2, Note 6 of ESARR 4 specifies that "(Note: A similar approach is also recommended for designing the ATM System in areas where exclusive General Aviation operations are carried out)."</p> <p>INITIAL CONCLUSION:</p> <p>This statement is only a recommendation. No equivalent could be found in SAM.</p>

A2.n7 Note	YES (=)	L1-1, 2-6 L1-10, 2-1 L1-10, 3-1 L1-10, 3-1(i) L1-10, 3-1(iii) L1-10, 3.1-1 L1-10, 3.1-4(i) L1-10, 3.3-2 L2-F6 L2-P4 (?)	<p>Section Appendix A-2, Note 7 of ESARR 4 specifies that "(Note: In order to deal with specific constituent parts of the ATM system (sub-systems), the table (Fig A-2) will have to be refined so that it adequately reflects the operational environment of the sub-system under consideration (e.g. interfaces with other systems, phases of flight, classes of airspace). This will necessitate the:</p> <ul style="list-style-type: none"> a) redefinition of the severity categories such that they are meaningful in the context of the sub-system under consideration, and b) accommodation of mitigations in other sub-systems for events in the sub-system under consideration which may lead to a hazard. <p>No guidance is given here as to how the refinement should be achieved.)"</p> <p>(=) SAM provides guidance on how to derive Safety Requirements based on sub-system level during PSSA.</p> <p>(=) SAM provides guidance in the Level 2 document “D: Severity Classification Scheme” for the practical and effective use of the Severity Classification Scheme within the FHA stage.</p> <p><i>Remark: The reference to Fig A-2 should be replaced by reference to A-1.</i></p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance for the practical use of the Severity Classification Scheme within the FHA stage it also provides guidance on how to derive Safety Requirements based on sub-system level during PSSA but it does not provide guidance on redefinition of the severity categories such that they are meaningful in the context of the sub-system under consideration.</p>
A2.n8 Note	YES (=)	L2-F7 (Chapter 2)	<p>Section Appendix A-2, Note 8 of ESARR 4 specifies that "(Note: Units used to describe risk may need to be changed depending on: the sub-system under consideration, phases of flight and classes of airspace)."</p> <p>(=) SAM FHA E: Risk Process for Deriving Risk Classification Scheme and Specifying Safety Objectives in ATM "in compliance" with ESARR 4) provides guidance on apportionment per phase of flight but not per type of airspace.</p> <p>INITIAL CONCLUSION:</p> <p>SAM FHA E: Risk Classification Scheme; (ED 125) provides guidance on apportionment per phase of flight but not per type of airspace.</p>

Table 4 Coverage Analysis – Mandatory Provisions

3.3 ESARR 4 Advisory Sections: Executive Summary, 1, 2, 4 and 8

3.3.1 Coverage Analysis of Advisory Sections

Analysis

With regard to the non mandatory provisions of ESARR4, the table number 5 provides a coverage analysis of the contents of the SAM documents identified in Chapter 2.

The table provides an analysis per section of ESARR if those related sections or text exist in SAM V2. Detailed information concerning the coverage is available additional annexed documents.

Legend

- When the provisions of SAM V2 are seen as:
 - equivalent or equal to the relevant requirement of ESARR4, the sign “=” is used.
 - encompassing and exceeding the relevant requirement of ESARR4, the sign “+” is used.
 - less demanding than the relevant requirement of ESARR4, the sign “-” is used.
- When the provisions of SAM V2 differ or are inconsistent with the relevant requirement of ESARR4, the sign “#” is used.

Summary of Initial Conclusions

1. SAM provides guidance on safety monitoring during the SSA phase. The aspects dealing with ESARR 2 have not been analysed.
2. SAM V2 provides detailed guidance with regard to the advisory parts of ESARR4 except for the chapter 2 providing rational for ESARR4.

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ESARR 4	Covered by SAM V2	Coverage	Related comments
SECTION 1-SCOPE			
1.1	YES =	L1-0, 2-7 L1-4, 3.4-5 L1-16, 3.1.1-2(ii) L1-0, 1-1 L1-1, 2-4 L1-4, 3.4-2 L1-0, 2-1 L1-0, 3-4	<p>Section 1.1 of ESARR 4 specifies that "This requirement concerns the use of a quantitative risk-based approach in Air Traffic Management when introducing and/or planning changes to the ATM System."</p> <p>(=) SAM V2 addresses</p> <ul style="list-style-type: none"> • the quantitative risk-based approach • In Air Traffic Management • introducing and/or planning changes to the ATM System <p>but in "SAFETY OBJECTIVES SPECIFICATION/1 OBJECTIVES" it is stated that Safety Objectives may also be of qualitative nature. Other paragraphs mention the combination of the qualitative and quantitative method (5.2. Note 2).</p> <p>(=) SAM V2 limits the scope to Air Traffic Management; nevertheless, SAM V2 advises to apply SAM to all changes to the Air Navigation System which could have a potential safety impact. SAM addresses the Air Navigation Systems including the underlying CNS infrastructure supporting the provision of ANS and ATM services.</p> <p>Refer also to 5.1b, chapter 3.2.1 Coverage Analysis Mandatory Provisions.</p> <p>INITIAL CONCLUSION:</p> <p>SAM V2 provides guidance on a risk-based approach that also considers a combination of the qualitative and quantitative method, in addition to a quantitative approach.</p>
1.2	YES =	L1-0, 2-1 L1-10, 1-1 L1-0, 3-1 L1-1, 1-2 L1-8, 3-5 L1-11, 3.2-1(ii) L1-14, 1-1 L1-16, 3.1.3-1n1 L1-16, 3.2.2-1	<p>Section 1.2 of ESARR 4 specifies that "This requirement covers the human, procedural and equipment (hardware, software) elements of the ATM System as well as its environment of operations."</p> <p>SAM addresses:</p> <ul style="list-style-type: none"> • People • Procedure • Equipment <p>as well as its environment of operations.</p> <p>Refer also to 5.1c, chapter chapter3.2.1 Coverage Analysis Mandatory Provisions .</p>

ESARR 4	Covered by SAM V2	Coverage	Related comments
			<p>INITIAL CONCLUSION: The scope of the SAM includes the three elements, people, procedures and equipment, and, in that respect, is compliant with ESARR 4. It should, however, be noted that a specific focus is being placed on the equipment side of the ANS system, either in the terminology used or in the examples provided.</p>
1.3	YES =	L1-0, 1-1 L1-0, 2-2	<p>Section 1.3 of ESARR 4 specifies that "This requirement covers the complete life-cycle of the ATM System, and, in particular, of its constituent parts."</p> <p>SAM addresses the complete life cycle of the Air Navigation System, from initial planning and system definition to de-commissioning.</p> <p>Refer also to 5.1a, chapter 3.2.1 Coverage Analysis Mandatory Provisions.</p> <p>INITIAL CONCLUSION: SAM addresses the complete life cycle of the Air Navigation System, from initial planning and system definition to de-commissioning.</p>
1.4	YES =	L1-0, 2-3 L1-0, 2-6	<p>Section 1.4 of ESARR 4 specifies that "This requirement does not address the assessment of introducing and/or planning organisational or management changes to the ATM service provision."</p> <p>In the SAM introduction part the assessment of introducing and/or planning organisational or management changes is explicitly excluded.</p> <p>INITIAL CONCLUSION: SAM definitively excludes from its scope the organisational aspects of safety assessment.</p>
SECTION 2-RATIONALE			
2.1	NA	-	<p>INITIAL CONCLUSION: The rationale is not applicable for SAM.</p>
2.2	NA	-	<p>INITIAL CONCLUSION: The rationale is not applicable for SAM.</p>
2.3	NA	-	<p>INITIAL CONCLUSION: The rationale is not applicable for SAM.</p>
2.4	NA	-	<p>INITIAL CONCLUSION: The rationale is not applicable for SAM.</p>

SECTION 4-SAFETY OBJECTIVE			
4.1	YES +	L1-0, 1-4 L1-0, 1-5 L1-1, 2-8 L1-3, 1-1 L1-9, 1-1 L1-5, 3.2-1	<p>Section 4.1 of ESARR 4 specifies that "Within the overall objective of ensuring safety, the objective of this requirement is to ensure that the risks associated with hazards in the ATM System are systematically and formally identified, assessed, and managed within safety levels, which as a minimum, meet those approved by the designated authority."</p> <p>(=) SAM specifies that it:</p> <ul style="list-style-type: none"> • should potentially support the demonstration that safety is being managed within safety levels meeting as a minimum those approved by the designated authority; • intends to be a Means of Compliance to ESARR 4. <p>(+) SAM FHA, PSSA and SSA, chapter 4 (A-B-C) provides guidance material on how to assess the process to assure that a systematic process has been carried out.</p> <p>(=) SAM provides detailed guidance on the required link between "the national safety minima in ATM and the quantified criteria against which the tolerability of risks are assessed at national level" (GM for FHA chapter 3: E: Risk Classification Scheme; (EC 125).</p> <p>For detailed information refer also to 5, chapter 3.2.1 Coverage Analysis Mandatory Provisions.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides the information on the required link between "the national safety minima in ATM and the quantified criteria against which the tolerability of risks are assessed at national level".</p> <p>SAM also provides guidance to ensure that risks associated with hazards in the ATM System are systematically and formally identified, assessed, and managed within safety levels.</p>
SECTION 8-ADDITIONAL MATERIAL			
8.1.1	YES =	L1-2, 2.5-1 L1-2, 2.5-4 L1-2, 2.5-5 L1-8, 2.6-2	<p>Section 8.1.1 of ESARR 4 specifies that "For existing parts of the ATM System, an analysis based on available historical data, such as safety occurrence (i.e. accident, incident, ATM-specific occurrence) statistics, human errors, equipment faults, mostly based on system safety monitoring and occurrence reporting schemes may contribute evidence to the safety assurance process, hence complementing the safety analysis depicted in section 5 of this requirement."</p> <p>(=) SAM Guidance material for FHA chapter 1, "Initiation" provides guidance that data derived from experience from similar systems (e.g. performance monitoring results, user feedback, lessons from incident investigation) as well as other inputs (e.g., hazard databases, incident investigation reports, lessons learned, etc.) should be used as an input for the FHA.</p> <p>(=) SAM Guidance material for PSSA chapter 1, "Initiation" provides guidance that data coming from hazard databases, incident investigation reports, lessons learned should be used as an input for the PSSA.</p>

			<p>In addition to this "E: Risk Classification Scheme; (ED-125)" and Level 3 document FHA appendices" E: Examples of Safety Targets for NAV application" provides extensive guidance on the usage of historical data.</p> <p>INITIAL CONCLUSION:</p> <p>ESARR 4 provides guidance on the usage of historical data to complete the safety analysis process.</p>
8.2.1	NA		<p>Section 8.1.1 of ESARR4 specifies that "EATMP SAM SAF ET1.ST03.1000-MAN- (Ed 1.0) is considered a useful guidance when implementing this safety regulatory requirement. The applicability of the methodology would need to be specified at the beginning of any risk assessment and mitigation process."</p> <p>and</p> <p>"(Note: Future revisions of that document are also to be foreseen to encompass assessment of the human, equipment and procedural elements and develop further the system safety assessment process beyond the Functional Hazard Assessment)." </p> <p>INITIAL CONCLUSION:</p> <p>Not applicable for SAM.</p>
8.2.2.1	YES =	L1-10, 3-1 L1-10, 3-1(i) L1-10, 3-1(ii) L1-10, 3-1(iii) L1-10, 3-1(iv) L1-10, 3-1(v) L1-10, 3.3-3 L1-10, 3.3-3(i) L1-10, 3.3-3(ii) L1-10, 3.3-4 L1-10, 3.3-4(i) L1-10, 3.3-4(ii) L1-10, 3.3-4(iii) L1-10, 3.4-1 L1-10, 3.4-2 L1-10, 3.4-3	<p>Section 8.2.2.1 of ESARR 4 specifies that "The safety objectives allocated to each hazard drive the determination of specific means to attain the proper level of confidence in the success of implementing the mitigation strategies and related safety requirements.</p> <p>These means may include a set of different levels of constraints being set on specific software elements of the ATM System."</p> <p>(=) SAM provides guidance on the allocation of mitigation strategies as well as safety requirements to each element of the system according to the safety objectives defined during the FHA process.</p> <p>INITIAL CONCLUSION:</p> <p>SAM associates a level of confidence to safety requirements. It provides guidance to allocate the following assurance levels by PSSA;</p> <ul style="list-style-type: none"> • PAL: Procedure Assurance Level; • SWAL: SoftWare Assurance Level; • HWAL: HardWare Assurance Level.

		L1-10, 3.4-4 L1-10, 3.4-4n1 L1-10, 3.5-1 L1-10, 3.5-2 L1-10, 3.5-3 L1-16, 2-1	
8.2.3.1	YES =	L1-13, 1-1 L1-13, 1-2 L1-13, 1-3 L1-16, 3.3.1-1 L1-16, 3.3.1-2 L1-16, 3.3.1-3 L1-16, 3.3.1-4 L1-16, 3.3.1-5 L1-16, 3.3.2-1	<p>Section 8.2.3.1 of ESARR 4 specifies that "Safety monitoring and data collection mechanisms could be specifically developed as an enabling tool to the validation of the safety assumptions and requirements as identified during the risk assessment and mitigation processes, including hazard identification, as well as the assessment of the safety added value of the programme. For example, such mechanisms could be used for the validation of theoretical data such as Mean Time Between Failures) and models (such as fault tree, reliability flow charts) used in the safety assessment and safety assurance processes."</p> <p>(=) SAM provides guidance for safety monitoring and data collection mechanisms to be developed as an enabling tool for the validation of the safety assumptions and requirements as identified during the risk assessment and mitigation processes, including hazard identification as well as the assessment of the safety added value of the programme.</p> <p>Refer also to 5.2d, chapter3.2.1 Coverage Analysis Mandatory Provisions.</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance for continuous data collection and monitoring of safety performances during operation and maintenance.</p>
8.2.3.2	NA		<p>Section 8.2.3.2 of ESARR 4 specifies that "In addition, safety monitoring and data collection mechanisms consistent with the provisions of ESARR 2 could also be developed as enabling tools to define global safety indicators in order to control and monitor the safety levels reached in operation by the ATM System."</p> <p>INITIAL CONCLUSION:</p> <p>SAM provides guidance on safety monitoring during the SSA phase. SAM does not aim covering the ESARR 2 "part" of the safety management system.</p>
8.2.3.3	YES =	L1-16, 3.2.1-1 L1-16, 3.2.1-2 L1-16, 3.2.2-1 L1-16, 3.2.2-2 L1-16, 3.2.3-1	<p>Section 8.2.3.2 of ESARR4 specifies that "Safety monitoring should therefore be seen as a complementary means of qualification before and during operational use."</p> <p>(=) SAM provides guidance relating to continuous data collection and monitoring of safety performances during transition, operation and maintenance. SAM mentions that safety performance indicators shall be defined during transfer as well as reviews as a means of</p>

		L1-16, 3.2.3-2 L1-16, 3.3.1-1 L1-16, 3.3.1-2 L1-16, 3.3.1-3 L1-16, 3.3.1-4 L1-16, 3.3.1-5 L1-16, 3.3.2-1	qualification during transfer and before operation. (-) SAM does not provide guidance on the definition of safety performance indicators. INITIAL CONCLUSION: SAM provides guidance on continuous safety monitoring.
8.3			See comparison of Glossary of Terms

Table 5 Coverage Analysis – Advisory Provisions

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4. CONCLUSIONS AND RECOMMENDATIONS

The comments and recommendation on the ESARR 4 coverage by SAM V2 issued by the assessment process are structured as follow:

- ❑ General content of SAM V2,
- ❑ Other documents of the SAM V2:
 - SAM V2 E (ED 125),
 - Part IV Annex H (“What is a change?”)
 - Part IV annex I (“Safety Case Development Manual PI 2.0”),
 - FHA document E Example of safety target for NAV application.

The tables below present the comments, the first column gives the reference to the documents, the second column explains the justification of the comment, the third column provides recommendation, the forth is the classification in three possible categories:

- “Issue”: indicates that complementary information is needed otherwise this part of the PMC cannot be accepted as being compliant to ESARR4.
- “Clarification”: indicates that wording should be review (ambiguity, inconsistency, completeness), some elements are missing, guarantees/justification shall be added, etc.
- “Information” : provide information on the scope and the limitation of the assessment
- “Editorial”: identifies some inadequate format or typo.

“Clarification” and “Editorial” comments have to be corrected before the proposition of the AMC to the SRC.

4.1 Comment on SAM V2 – General Content

References	Text	Recommendation	Classification
<i>Terms and definitions</i>	1) Safety Objective (Definition in SAM): SAM Definition needs to be updated. In the documents SAM uses “acceptable” whereas ESARR 4 also uses “tolerable”. 2) Definitions not specified in SAM but specified in ESARR 4.	It should be specified explicitly in SAM that the definitions of ESARR 4 are applicable.	Clarification
<i>General with regard to SAM</i>	As some steps defined in SAM can be tailored (e.g. planning, evaluation) this can lead to inefficient taylorisation	a comment should be added to inform the reader to be aware that he has to be sure not to tailor parts that are required if SAM is used as an AMC to ESARR 4.	Clarification

References	Text	Recommendation	Classification
<i>FHA - G: Methods for setting Safety Objectives: Chapter 1.1.</i>	The definition should be moved to Part IV Annex B: Glossary	Move the definition	Clarification
<i>FHA - B: Identification of failure modes, external events and hazards (B2 Chapter 1.3)</i>		Update the reference to the Appendix to mention the word "Appendix",	Editorial
<i>FHA - C: Identification of Hazards effects: Chapter 1</i>	The usage of the word "effect" in the context of "Effects on Air Navigation Services;" could be misleading	further information is provided in chapter 1.1, however clarify the words	Clarification
<i>General comment on level of detail of information provided for different phases</i>	The level of information provided for FHA is not equal to the level of information provided for PSSA and SSA. The scope of SAM evaluations reflects the scope of ESARR 4.	More information on PSSA and SSA is available for SAM but was not analysed. Therefore, references to other SAM documents that are not within the scope (refer to the list at the beginning of the document) were not assessed.	Information
<i>PSSA, Safety Requirements – General</i>	The level of information provided for people is much lower than for procedure and equipment.	As there is work ongoing. The results will be included in the next versions	Information
<i>PSSA, A-B-C: PSSA Evaluation- Chapter 3</i>	<ul style="list-style-type: none"> - Amend to the text to specify that the reporting should be done as specified in the safety management system. - For SSA it has been specified that at least for the critical systems someone else should do the tasks, here (for PSSA) this is not required. 	The information given in SSA and PSSA should be updated to be consistent with each other.	Clarification
<i>SSA, Completion Report</i>	According to the documentation it is not clear at which stage a completion report should be created.	A comment should be added to specify that for each phase defined in the planning a completion report should be created.	clarification

References	Text	Recommendation	Classification
<i>FHA, F: Safety Objective Classification Scheme- page 3</i>	In the last paragraph a reference to FHA, chapter 3, E: Risk Classification Scheme is specified.	This reference should be updated to reflect the changed document (ED-125)	Editorial
<i>Bayesian models</i>			

4.2 Comments on SAM E (ED 125)

Reference	Text	Recommendation	Classification
<i>General Comment- Structure and Scope of Document</i>	The structure of this Level 2 document differs from the other SAM documents as the information provided in this document covers also general information provided in Level 1 documents and quite detailed information provided in Level 3 documents. Some information provided in this document is also provided in other SAM documents	The status of this document as a EUROCAE document is different from the other documents of the SAM. However the duplications of information can lead to inconsistency in the future. It is advised to find a better balance between ED 125 and the other elements in the SAM. (e.g. Chapter 1.3.2, 1.3.4, ...). In case of conflicting information this should be specified in SAM documents.	Information
<i>General Comment- Structure and Scope of Document</i>	This document ED 125 is not identified in the SAM introduction.	The SAM introduction document should be updated to reflect the changed scope of <i>FHA, E: Process for Deriving Risk Classification Scheme and Specifying Safety Objectives in ATM</i> .	Clarification
<i>General Comment</i>	- <i>Abbreviation</i> “ATMSP”SAM and ESARR 4 use the term “ANSP”	“ATMSP” should be added to the list of abbreviations in Part IV Annex A: Acronyms.	Editorial

Reference	Text	Recommendation	Classification
<i>General Comment- Chapter 1.3.4, inconsistent information</i>	<p><i>Chapter 1.3.4, inconsistent information</i> The information provided in Figure 4 is not consistent with the information provided in other SAM documents</p>	Add “decommissioning” which is missing).	Clarification
<i>General Comment- Chapter 1.3.4, inconsistent information</i>	FHA and PSSA (life-cycle) are presented differently in the other SAM documents.	Harmonize the presentation	Clarification
<i>General Comment- Chapter 1.4.1, SHALL and SHOULD</i>	In SAM only "should" is used as it is a means of compliance but not as a standard / regulations. The usage of "shall" in this document is not consistent with other SAM documents.	Provide a statement with regard to the status of Ed 125 in the introduction of SAM	Clarification
<i>General Comment- Chapter 1.4.4, List of Acronyms</i>	The list of acronym is insufficient	The acronym list needs to be revised.	Editorial
<i>General Comment- paragraph ATM Chapter 2.1.2, 2nd</i>	System and ATM service are used in that paragraph.	As they mean the same the term "system" they should be changed to "service".	Editorial
<i>General Comment- Chapter 2.1</i>	The term "Design Target" is not used in other SAM documents. This term is used to specify explicitly that SAM and ESARR 4 are focusing only on Design.		Information
<i>General Comment- Chapter 2.1.5</i>	The text should be clarified. First and last sentence could be misinterpreted.	Clarify the text	Clarification
<i>General Comment- RCS</i>	It is expected that further updates of the methods to define the RCS will take place after having gained more experience and that this should then be reflected in the SAM.		Information

Reference	Text	Recommendation	Classification
<i>General Comment - Labels for Variables in Formula</i>	A definition wherever labels are used in the calculation (e.g. RFAcc).	To define the labels	Editorial
<i>General Comment- Classification of ATMSPs</i>	In this document ATMSPs are classified (e.g. confident user, adopter, ...). In the references, the tool to assess the specific class is mentioned but there is no link to this reference specified in the text.	A comment that refers to this reference should be added in the text.	Editorial
<i>General Comment - Chapter 5.3.8</i>	A single reference is not satisfying.	For this chapter either a real example should be created or the chapter with the example should be removed.	Clarification
<i>General Comment - Page 32, chapter 3.1.1 (Note)</i>	Inappropriate term « explain »	Replace "explain" with "illustrate".	Editorial
<i>General Comment - Page 32, chapter 3.1.4, No 2</i>	The wording should be reviewed	The text should be clarified.	Clarification
<i>General Comment - Page 33, chapter 3.5, first bullet</i>	In Figure 8 there is no "SO".	Correct the figure	Editorial
<i>General Comment - Page 34, Figure 8, chapter 3.5</i>	The figure is very difficult to understand at the first reading as the text is needed to understand the figure.	Correct / clarify/ remove the figure	Clarification
<i>General Comment - Page 37, "chapter 4.3 - "Willing Developer</i>	The list and the table is not consistent (e.g. "Fixed Prescriptive Model")	Insure the consistency of the table	Clarification
<i>General Comment</i>	Chapter 4.7, Page 44, 2nd paragraph	Remove "No1".	Editorial
<i>General Comment - Page 75</i>	1) Separation missing 2) Not all references to the tables are correct.	Correct references	Editorial

4.3 UK SRG Comments on ED125 Released Issue – V1.0 – March 09

Compliance with ESARR 4

ED 125 claims compliance with ESARR 4. Such compliance arguments should be removed as this is not the case for three reasons:

1. ED 125 is not compliant with ESARR 4
2. SRC, the body responsible for declaring such compliance, has not done so – and in the light of 1 should not do so.
3. The referenced version of ESARR 4 will be short lived.

Explicit reference to ESARR 4 has now been removed from the title of ED 125, however there are approximately 30 references to ESARR 4 within the text of which 12 are material. These references clearly imply that the purpose of ED 125 is to be compliant with ESARR 4 and imply that it is indeed compliant – a detailed analysis of these references is available on request.

The reasons for the non compliance are:

1. ED 125 uses a different definition of Hazard. In ESARR 4, by definition, all hazards must potentially lead to an accident (Severity Class 1) they will also potentially lead to incidents of other severity classes. In ED 125 a hazard does not necessarily lead to an accident.
2. ED 125 does not deal adequately with cumulative (total) risk. Worst Credible Effect, used in the Semi Quantitative Model and all subsequent models, eliminates all effects that are not responsible for setting the Safety Objective (ED 125 pg 39 - 40). The effect of this is to underestimate the cumulative (total) risk associated with each hazard (See ‘Comments on Semi Quantitative Method’ – Issue 1.2, provided previously). Moreover on page 34, N_j takes the value of the number of hazards with ‘significant contribution’. There is no such restriction in ESARR 4 and this would also serve to underestimate the cumulative risk – this form of underestimation applies to the quantitative model as well.
3. Four schemes of various levels of complexity are proposed. To be valid, simpler (and less accurate) schemes should be more conservative than more complex (and more accurate) schemes. The schemes in ED 125 do not meet this criterion.
4. The data used to establish the safety targets for incidents of severity levels 2-4 does not meet the criterion required by ESARR 4: *The quantitative definitions for the safety objectives associated with the maximum tolerable probabilities of ATM directly contributing to incidents of severity class 2, 3, 4 and 5 in the ECAC region (4) remain to be determined once enough and consistent safety data have been collected by EUROCONTROL, which are consistent with the requirements outlined in ESARR 2.* Appendix B 1 shows that the values for ST3 and ST4 are not supported by adequate and consistent data. Moreover, during the RCS mandate process several states challenged the consistency for the value for ST 2.

5. It seems that there is an assumption that a hazard can only cause a single effect in a single severity class:
 - a. In 4.5 the risk budget is divided by the number of hazards not the number of effects.
 - b. In 4.6 Pe_{ij} is used rather than Pe_{ijk} .
 - c. In the example in section 5, the risk budget is established via the number of hazards not the number of effects.

This assumption is not valid under ESARR 4 which recognises that, in general, there may be many effects (of a given severity level) associated with an individual hazard. While Appendix A demonstrates that a hazard can lead to several effects of the same severity class, the simplifications render the method of little practical utility (see ‘fitness for purpose’ – 3 - below) and the note at the beginning states that it is “**not** to be used to apply [to] the various models”. This last shows that the models are not rigorous or objective since they are not underpinned by a mathematical model.

6. The restrictions placed on Pe_{ij} in 4.6 are not supported in ESARR 4

The claim for the compliance of ED 125 against ESARR 4 is for version 1.0 of ESARR 4. This is of little practical utility and would serve to misrepresent the current state of affairs. There are differences between the ESARRs and the SES legislation and one of the recommendations of the Double Regulation Add Hoc Group (DRAHG) is that existing ESARR text should be removed and be replaced with a reference to (or a copy of) the appropriate SES regulations. Differences in approach are to be dealt with by negotiations between EUROCONTROL and the EC. ESARR 4 is one of the ESARRs for which differences exist. As far as SRG is aware the DRAHG recommendations have been accepted and consequently the context in which ED 125 exists is changing. It would therefore be more appropriate to seek compliance with the SES regulations but this is dealt with next (2).

Relationship to RCS Mandate

There is some concern at the apparent rush to publish ED 125 at this stage. ED 125 cannot validly claim compliance with ESARR 4 and due to the close relationship between ESARR 4 and the SES Common Requirements, ED 125 would not be compliant with these either. Even if ED 125 were to claim compliance with ESARR 4, such compliance will be short lived (see 1 above). It would appear that the most useful outcome of the EUROCAE work would be for ED 125 to be developed into an AMC for the RCS Implementing Rule foreseen by the SES Common Requirements.

However, after the ENPRM process for the RCS Mandate had completed, EUROCONTROL delivered a report to the EC, which clearly indicated that substantial work is still needed before proceeding with the submission of any proposal to the SSC. It recommends that the EC consider the continuation of that work. Furthermore, the report highlights a number of important issues that are still open. Two of these issues: the nature of the advisory material and inconsistencies in proposed methodologies, have a direct bearing on any AMC and therefore by implication on ED 125.

Consequently, if EUROCAE wished ED 125 to become an AMC to the SES regulations on Risk Classification Schemes, it would be premature to release it until the outcome of the development of the RCS Implementing Rule and its associated advisory material is known. To release it in the hope that it will satisfy the RCS Implementing Rule is both naive and gives the impression of a ‘solution seeking a problem’.

Usefulness/Fitness for Purpose

The scope of ED 125 is limited and does not include the solution to some more pressing issues, consequently it is difficult to see why ED 125 will be useful in its current form. Some of the guidance also makes its fitness for purpose questionable. This is because ED 125:

- provides scope for inconsistent application
- does not describe sound or useable models
- fails to provide adequate guidance on risk budget setting and limiting the scope of the change
- provides an inappropriate explanation of Ambition Factor

Inconsistent application

SRG believes that the alternative models and wide ranging data values available in ED 125 allow users too much scope so that they can generate an inappropriate RCS.

The criteria for the use of the four models are not present in ED 125. Questions such as: under what circumstances, for what purposes and by whom, each model may be used, are unanswered.

Basically ANSPs are left to select the model they wish to use. Such decisions could be based primarily on their own view of ease of use versus the cost of over engineering. There is risk that immature ANSPs will be driven towards the simpler models without fully understanding the consequences and far from over engineering the system will underestimate its safety risk and so under engineer the system. It is true that NSAs oversee the choice of model and the system solution but an immature NSA may also misunderstand the risk. There is no guarantee that a mature NSA will supervise an immature ANSP and even if this were the case, the NSA is not required to and does not have the resources to do a thorough investigation and may still have difficulty in challenging the ANSPs interpretation of ED 125.

Sound Models

Appendix A, which could provide a firm foundation for the models, has as its opening remarks: “this appendix is not to be used to apply [to] the various models as described in this document”, thus apparently destroying the objectivity of the models. The appendix was in fact derived from previous SRG work designed to show that the underpinning mathematics of early versions of ED 125 were incorrect and that assumptions made lead to impractical models. Unfortunately the assumptions remain and worse, become desirable features in the models. The effects and the conditional probability of an effect arising from a hazard (Pe) are ‘lumped’ variables (as discussed in previous exchanges). It is difficult to understand how a mid air collision and a CFIT having their roots in the same hazard could have the same accident trajectory and the same Pe. While a lumped Pe could be formed connecting a hazard to a lumped effect (in this case both mid air collision and a CFIT) it is very difficult to see why this would be of benefit since it could only be calculated by knowing the Pe’s associated with each individual hazard/effect trajectory. Consequently, while lumping both Pe and STj is a mathematical simplification it has no practical utility and to base a model on such a mathematical nicety is to render it useless.

The models rely on knowledge of the number of hazards in the ANSP’s system and ED 125 sanctions an assumption that there are approximately 125 of these. Firstly, ESARR 4 requires knowledge of the number of effects as well the number of hazards but ED 125 seems to assume that there will only be one effect (in each severity class) per hazard and secondly, while 125 hazards may be appropriate for a small airport, it is certainly a gross underestimate for an airport of the complexity of LHR. It seems that ED 125 may be dealing with hazard classes rather than actual hazards. The need for knowledge of the total number of hazards is not only the Achilles heel of the method but is probably misleading since all that is of interest in a change scenario is the hazards that are associated with the change.

Risk Budget Setting

ESARR 4 deals with a change to an ATM system i.e. only part of the ANSP’s services would be affected by the change. Table 1 describes the safety targets for the whole ECAC airspace. The risk budget for the change is only a small part of this overall safety target. Moreover, when making a change, the ANSP wishes to constrain the Risk Assessment and Mitigation activities to those parts of the system for which it is necessary to re-assess the hazards and effects. ED 125 provides no guidance on apportioning the risk budget or on setting the system limits for the change. Both are crucial in determining the total risk budget for the change. ED 125 would have been more useful if it had concentrated on providing guidance for these aspects rather than the confused guidance it does give on setting STj – sometimes it appears that STj is the total ANSP safety target (risk budget) and at others it is the safety target for the change, as in the example for 5.1 – is the change described here the total set of ANSP services or just part of those services?

Ambition Factor

No explanation of how the ambition factor is arrived at is given in ED 125. In fact the guidance given is wrong – it is unlikely that monitoring would have any bearing on the ambition factor, it is more likely the accuracy of the design analysis should have a bearing on the factor. Consequently it is not so much an ambition factor as a lack of confidence factor. The guidance given leaves the impression that, as far as ED 125 is concerned, it is an arbitrary process aimed at ensuring the service provider always meets the safety target, with some ‘headroom’.

In fact this is only one purpose of the ambition factor and has its roots in the need to accommodate ones confidence in ones predictions. The other purpose is to satisfy the safety management principle of continually trying to become safer as technology and science (knowledge of systems analysis) allows. ED 125 would have been more useful had it separated these concerns and provided guidance on how to establish confidence limits and how to use the safety management system to provide more stringent safety targets as the state of the art progresses. As it is, it provides inadequate and inappropriate guidance.

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4.4 Comments on SAM V2, Part IV "Safety Case Development Manual"

Reference	Text	Recommendation	Classification
<i>General Comment - page 3 and page 43</i>	The document covers issues which are not scope of ESARR 4 (ongoing operations, legacy).		Information
<i>General Comment- page 7</i>	The life cycle presented in chapter 3 should be reviewed with regards to the SSA part.	Review the Life cycle	Clarification
<i>General Comment-</i>	For easier handling it is proposed to mention to reference to the tool should be instead of the reference just to SAM.	Refer to the Sam electronic tool	Editorial
<i>General Comment - Page 10</i>	In the last bullet "the Concept of Operations" is referenced in the other documents the "Operational Environment Definition" is referred to. There is an inconsistency.	Clarify the inconsistency	Editorial
<i>General Comment - Page 27 - relationship to SAM</i>	In the overall documentation of SAM the "role" of the Safety Case is not displayed.	It should be reviewed if the picture for the life cycle process in the overall documentation is updated to mention the Safety Case activities.	Clarification

4.5 Comments on the Appendices to FHA “E: Examples of Safety Targets for NAV Application”

The NAV Document, FHA E: example of Safety targets for NAV Application was mainly assessed with regard to compliance with 5.2b iii).

Reference	Text	Recommendation	Classification
<i>General</i>	The process described in this document is in line with ESARR 4. As several assumptions have been made, a sensitivity analysis should be performed with changed assumptions and data near the confidence interval limit.	Perform a sensitivity analysis to validate the different assumptions	issue

Reference	Text	Recommendation	Classification
General	The need for specific figures for NAV (different from the ESARR 4 number) is not specified.	The scope of the document is not explicitly specified. Therefore a justification should be provided.	Clarification
Chapter 0 – Executive Summary paragraph (2 nd)	This document focuses on the TLS for SC1. It only considers accidents with fatalities whereas ESARR 4 also includes: <ul style="list-style-type: none"> - serious injuries to people as well as - aircraft sustains damage or structural failure - aircraft is missing or is completely inaccessible. 	With regard to the contextual assumption of IRP it is recommended that the differences are identified and the assumptions made should be justified.	Issue
Chapter 8	Chapter 8 it states that the methodology needs to be validated prior to its application.	The results of additional recommendations provided by the ESARR 4 assessment should also be taken into account.	Clarification
Chapter 6.4 - Comparison with ESARR 4 value	The statement made in chapter 6.4 challenges the commonly recognised contribution (e.g. SRC DOC 1 and SRC Policy DOC 1).	Therefore, further studies to validate this assumption are recommended.	Issue

4.6 Comments on “What is a Change?”

Reference	Text	Recommendation	Classification
General	Use of the term “derogation”	The term “derogation” should be renamed to “exemption”.	Clarification
Page H-7 (last paragraph)	The last sentence is difficult to understand.	Review the sentence.	Clarification
page H-8 (chapter 4.2)	Use of terms: “National guidance” or “regulator”.	In general, the term National Supervisory Authority should be used	Clarification

5. STATEMENT OF COMPLIANCE

The PMC SAM as listed in chapter 2 for Level 1 and 2 (except Level 3 document: FHA Appendices “E: Examples of Safety Targets for NAV application”, please see next paragraph for details) meets the provisions of ESARR 4.

The Level 3 document: FHA Appendices “E: Examples of Safety Targets for NAV application” addresses item 5.2b iii of ESARR 4:

The methodology used is in line with the ESARR4 requirements. The assumptions and input data were not verified and validated within the scope of this evaluation and, therefore, full compatibility of results with ESARR4 cannot be stated.

As there are several assumptions, a sensitivity analysis is proposed with changed assumptions and data near the confidence interval limit to identify the influence of the changed assumptions on the result. The assumptions are the weakest point in any such analysis, and they are also identified as such in chapter 8 of the document.

With regard to the contextual assumption of IRP it is recommended that the differences are identified and the assumptions made should be justified.

The statement made in chapter 6.4 challenges the commonly recognised contribution (e.g. SRC DOC 1 and SRC Policy DOC 1). Therefore, further studies to validate this assumption are recommended.

6. LIST OF ABBREVIATIONS

<u>Abbreviation</u>	<u>Definition</u>
AMC	Acceptable Means of Compliance
ANS	Air Navigation Service
ATCO	Air Traffic Coordination Officer
ATM	Air Traffic Management
ESARR	EUROCONTROL Safety Regulatory Requirement
FHA	Functional Hazard Assessment
ICAO	International Civil Aviation Organisation
NAV	Navigation
PMC	Proposed Means of Compliance
PSSA	Preliminary System Safety Assessment
SAM	EATMP Air Navigation Safety Assessment Methodology
SC	Safety Criticality
SRC	Safety Regulatory Commission
SSA	System Safety Assessment
TLS	Target Level of Safety

APPENDIX A – LIST OF REFERENCE DOCUMENTS

1. ESARR 4 “Risk Assessment and Mitigation in ATM”- Ed. 1.0
2. ESARR 4/GUI 1 "EAM 4 / GUI 1 EXPLANATORY MATERIAL ON ESARR 4 REQUIREMENTS" – Ed 1.0
3. EATMP Air Navigation Safety Assessment Methodology, Edition 2.0.
4. April 2004 (SAF.ET1.ST03.1000-MAN-01)

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APPENDIX B – TERMS AND DEFINITIONS

Term	ESARR 4 Definition	Definition	Comment
A			
Accident	<p>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:</p> <p>a) a person is fatally or seriously injured as a result of:</p> <ul style="list-style-type: none"> - being in the aircraft, or - direct contact with any part of the aircraft, including parts which have become detached from the aircraft, or - direct exposure to jet blast, <p>except when the injuries are from natural causes, self-inflicted or inflicted by other persons, or when the injuries are to stowaways hiding outside the areas normally available to the passengers and crew; or</p> <p>b) the aircraft sustains damage or structural failure which:</p> <ul style="list-style-type: none"> - adversely affects the structural strength, performance or flight characteristics of the aircraft, and - would normally require major repair or replacement of the affected component <p>except for engine failure or damage, when the damage is limited to the engine, its cowlings or accessories; or for damages limited to propellers, wing tips, antennas, tires, brakes, fairings, small dents or puncture holes in the aircraft skin; or</p> <p>c) the aircraft is missing or is completely inaccessible.</p>	Not included	Assumed use with ICAO meaning

Term	ESARR 4 Definition	Definition	Comment
A			
Air Navigation System	Not included	The aggregate of organisations, people, infrastructure, equipment, procedures, rules and information used to provide the Airspace Users Air Navigation Services in order to ensure the safety, regularity and efficiency of international air navigation.	OK
Assessment	An evaluation based on engineering, operational judgement and/or analysis methods.	An evaluation based on engineering, operational judgement and/or analysis methods	OK
ATM Service Provider	An organisation responsible and authorised to provide ATM service(s).	Not included	Not used in SAM. The term ATM Service Provision is used.
ATM Service	A service for the purpose of ATM.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
ATM System	ATM System is a part of ANS System composed of a Ground Based ATM component and an airborne ATM component.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
ATM	The aggregation of ground-based (comprising variously ATS, ASM and ATFM) and airborne functions required to ensure the safe and efficient movement of aircraft during all appropriate phases of operations.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
Assumption	Statement, principle and/or premises offered without proof.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
C			
CNS/ATM	The aggregation of functions used in provision of CNS services and used by ATM.	Not included	When referring to SAM seems to be used in the SRC sense of the term
CNS system	All the hardware and software that make up a function, tool or application that is used to provide one or more air traffic management services. The CNS system is an enabler to the provision of ATM services.	Not included	Not used in SAM. The Term CNS is used. When referring to SAM, CNS seems to be used in the SRC sense of the term.

Term	ESARR 4 Definition	Definition	Comment
C			
Commercial Transport	Air The operation of an aircraft in one or more stages on a scheduled or non-scheduled basis, which is available to the public for remuneration or hire (technical stops are counted in ICAO's statistics).	Not included	Not used in SAM.
D			
Designated authority	The competent body designated by State authority, responsible for aviation safety regulation.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
Direct (ATM system contribution to accident / Incident)	Where at least one ATM event or item was judged to be DIRECTLY in the causal chain of events leading to an accident or incident. Without that ATM event it is assumed that the occurrence would not have happened.	Not included	The same term is not used in SAM. Nevertheless, terms with similar meaning are used.
E			
Environment of operations	The environment of operations consists of the physical and institutional characteristics of the airspace within which operations occur. The environment includes ATM services being provided, technologies used, airspace organisation, ambient conditions and people.	Not included	Not used in SAM. It seems to use the term Operational Environment in the SRC sense.
Error	A mistake in specification, design, or implementation or an occurrence arising as a result of incorrect action or decision by personnel operating or maintaining the system (flight crew, Air Traffic Controller, service provider or maintenance personnel).	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
External events	Not included	An occurrence which has its origin distinct from the considered system.	Not used in SAM.
F			
Failure	The inability of any element of the Air Traffic Management System to perform its intended function or to perform it correctly within specified limits.	The inability of an Air Navigation System to perform its intended function or to perform it correctly within specified limits.	Only scope ATM/ANS differs.

Term	ESARR 4 Definition	Definition	Comment
F			
Failure Condition	A condition having an effect on the aircraft and/or its occupants, either directly or indirectly through loss of separation, which is caused or contributed to by one or more failures or errors, considering flight phase and relevant adverse operational (density of air traffic, TMA etc.) or environmental conditions.	Not included	The term is not used in SAM.
G			
General Aviation Operation	An aircraft operation other than a commercial air transport operation or aerial work operation.	Not included.	When referring to SAM it seems to be used in the SRC sense of the term.
H			
Hazard	Any condition, event or circumstance which could induce an accident.	Any condition, event, or circumstance which could induce an accident.	OK
I			
Inadequate separation	In the absence of prescribed separation minima, a situation in which aircrafts were perceived to pass too close to each other for pilots to ensure safe separation.	Not included.	Not used in SAM
Incident	An occurrence other than an accident, associated with the operation of an aircraft, which affects or could affect the safety of operation.	An occurrence, other than an accident, associated with the operation of an aircraft, which affects or could affect the safety of operations.	OK
L			
Target Level of Safety (or safety level or safety minima)	A level of how far safety is to be pursued in a given context, assessed with reference to an acceptable or tolerable risk.	A level of how far safety is to be pursued in a given context, assessed with reference to an acceptable or tolerable risk.	OK
Loss of safety margins	All situations where an aircraft is too close to something else (e.g. another aircraft, ground, obstacle, restricted area, meteorological anomalies) and the ability to recover from the hazardous situation is jeopardised.	Not included.	Note: Includes “inadequate separation” and “separation minima infringement”.

Term	ESARR 4 Definition	Definition	Comment
M			
Mitigation (or risk mitigation)	Steps taken to control or prevent a hazard from causing harm and reduce risk to a tolerable or acceptable level.	Not included.	When referring to SAM it seems to be used in the SRC sense of the term.
P			
Procedures (Refer to Operational ATC procedures in ESARR 2)	Written procedures and instructions used by ATC personnel in the pursuit of their duties directly in connection with the provision of the ATM services.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
R			
Risk	The combination of the overall probability or frequency of occurrence of a harmful effect induced by a hazard and the severity of that effect.	The combination of the overall probability or frequency of occurrence of a harmful effect induced by a hazard and the severity of that effect.	OK
Risk Assessment	Assessment to establish that the achieved or perceived risk is acceptable or tolerable.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
Risk Mitigation	See "Mitigation".		
S			
Safety	Freedom from unacceptable risk of harm.	Freedom from unacceptable risk.	OK
Safety Assurance	All planned and systematic actions necessary to provide adequate confidence that a product, a service, an organisation or a system achieves acceptable or tolerable safety.		OK
Safety Minima	Refer "to target level of safety".	Not included	Not used in SAM.
Safety objective	A safety objective is a qualitative or quantitative statement that defines the maximum frequency or probability at which a hazard can be expected to occur.	Quantitative or qualitative statement that defines the maximum frequency or probability at which a hazard can be tolerated to occur.	There is a slight difference as SAM uses "tolerated" and SAM uses "expected".
Safety level	Refer to 'target level of safety'.	Refer to 'target level of safety'.	Refer to 'target level of safety'.

Term	ESARR 4 Definition	Definition	Comment
S			
Safety requirement	A risk mitigation means, defined from the risk mitigation strategy, that achieves a particular safety objective. Safety requirements may take various forms, including organisational, operational, procedural, functional, performance, and interoperability requirements or environment characteristics.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
Separation minima infringement	A situation in which prescribed separation minima were not maintained between aircrafts.	Not included	Not used in SAM.
Safety Monitoring	A systematic action conducted to detect changes affecting the ATM System with the specific objective of identifying that acceptable or tolerable safety can be met.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
Severity	Level of effect/consequences of hazards on the safety of flight operations (i.e. combining level of loss of separation and degree of ability to recover from the hazardous situation).	Level of effect/consequences of hazards on the safety of operations, including the aircraft operations.	The definition in SAM is more comprehensive.
Severity Class	Gradation, ranging from 1 (most severe) to 5 (least severe), as an expression of the magnitude of the effects of hazards on flight operations.	Gradation, ranging from 1 (most severe) to 5 (least severe), as an expression of the magnitude of the effects of hazards on operations, including the aircraft operations.	The definition in SAM is more comprehensive.
Supporting services	Systems, services and arrangements, including Communication, navigation and Surveillance services, which support the provision of an ATM service.	Not included	Not used in SAM.
System	A combination of physical components, procedures and human resources organised to perform a function.	Not included	When referring to SAM it seems to be used in the SRC sense of the term.
T			
Target Level of Safety (or ‘safety level’ or ‘safety minima’)	A level of how far safety is to be pursued in a given context, assessed with reference to an acceptable or tolerable risk.	A level of how far safety is to be pursued in a given context, assessed with reference to an acceptable or tolerable risk.	OK

Term	ESARR 4 Definition	Definition	Comment
V			
Validation	Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled (usually used for internal validation of the design).	Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. (ISO 8402)	OK
Verification	Confirmation by examination of evidence that a product, process or service fulfils specified requirements.	Confirmation by examination and provision of objective evidence that the requirements have been fulfilled. (ISO 8402)	Slight differences but similar meanings.

Table 6 Mapping Terms and Definitions

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