EUROPEAN ORGANISATION
FOR THE SAFETY OF AIR NAVIGATION

EUROCONTROL

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EAM 1 / GUI 4

GUIDELINES FOR THE SAFETY OVERSIGHT OF CHANGES TO ATM

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Abstract

This document aims at providing National Aviation Authorities (NAAs) with guidance and recommendations to assist them in developing, documenting and implementing a process for the safety regulatory oversight of new systems and changes in ATM/CNS, in accordance with the provisions of ESARR 1, Edition 2.0 and, for those EUROCONTROL Members States where EC legislation is directly applicable, Commission Implementing Regulation (EU) No. 1034/2011.

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F.3 DOCUMENT APPROVAL

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F.4 AMENDMENT RECORD

The following table records the complete history of this document.

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0.01	05-Mar-10	Creation.	All
0.02	20-Apr-10	SRU quality review. Document sent to SRCCG for formal consultation (RFC No. 1004).	All
0.1	02-Nov-10	Update following RFC No. 1004. Document sent to SRC for formal approval.	All
0.2	30-Jan-12	Update following SRC consultation (RFC No. 1101) and internal quality review. Updated references to EU legislation/terminology.	All
1.0	15-Feb-12	Document formally released.	All

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F.5 CONTENTS

Section *Title* *Page*

Appendices

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F.6 EXECUTIVE SUMMARY

This document provides guidance to National Aviation Authorities (NAAs) on how to conduct the review of changes and how to perform audits of organisations introducing new ATM systems or making changes to existing ATM systems.

It is not possible to classify a change to the ATM system without prior analysis of its impact on the system, as ESARR 4 and Commission Implementing Regulation (EU) No. 1035/2011, for those EUROCONTROL Members States where EC legislation is directly applicable, requires that no change to the ATM System can be implemented without a clear indication that safety will not be jeopardised.

But considering the type of change, the level of analysis and of demonstration required by ESARR 4 and, where applicable, Commission Implementing Regulation (EU) No. 1035/2011 should be adjusted to the safety significance of the proposed changes.

ESARR 1, Edition 2.0 and Commission Implementing Regulation (EU) No. 1034/2011, for those EUROCONTROL Members States where EC legislation is directly applicable, identifies two types of process used to perform the safety oversight of changes to ATM: the audit of changes and the review of changes. Some criteria concerning the change may lead the relevant authority (or NAA) to perform the more demanding review of changes process.

This document identifies those criteria and describes the main stages of the review process and presents the processes and how the elements related to the change (i.e. safety arguments) are scrutinised by the NAA during the review and audit phases.

As such, this document is structured as follows:

- Part 1: Classification of changes to the ATM system and notification of the change.
- Part 2: NAA audit of change process.
- Part 3: NAA review changes process.
- Part 4: Check List for helping the reviewer in case of Major changes to ATM systems.

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F.7 GLOSSARY

Although the following terms are used in this document, they are not defined in either ESARR 1, Edition 2.0 or Commission Implementing Regulation (EU) No. 1034/2011. By default, the definitions used in EUROCONTROL ESARRs and SES regulations apply.

Term	***Definition***
Audit Management	The function responsible in an NAA for determining, implementing and following up the annual programme of safety regulatory audits required in ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011. This includes the management of the audit process and the auditors.
Complete	This adjective is dealing with criteria to assess the trustworthiness of the safety argument. The usual meaning of this term in the review of change context is: • having every necessary part or element (or entire part); • ended or finished.
Comprehensive	This adjective is dealing with criteria to assess the trustworthiness of the safety argument. The usual meaning of this term in the review of change context is: • of broad scope or content; including all element to be assessed or eventually much; • providing protection against most risks.
Consistent	This adjective is dealing with criteria to assess the trustworthiness of the safety argument. The usual meaning of this term in the review of change context is: • used in comparative forms; • agreement or accordance with facts, form, or characteristics previously shown or stated; • agreement or harmony between parts of something complex; compatibility; • conformity with previous practices, norms, standards or rules.
Review of Changes Management	The function responsible in an NAA for determining, implementing and following up the annual programme of reviews. This includes the operational management of the review process and human resources management process.
Relevant	This adjective is dealing with criteria to assess the trustworthiness of the safety argument. The usual meaning of this term in the review of change context is: • having direct bearing on the matter in hand; • pertinent.

Safety Arguments	All the **safety-related conditions that exist** with regard to a system or change; i.e. the collection of specific objectives or measures whose implementation is found necessary to ensure safety as regards a system or change. The safety-related conditions are identified[1] through the application of applicable safety regulatory requirements and arrangements needed to implement them. This is the case of: • Safety objectives and safety requirements obtained from the implementation of ESARR 4 by service providers; • Safety-related conditions that could be contained in 'EC Declarations of Verification of Technical Systems' and/or 'EC Declarations of Conformity or Suitability for Use of Constituents of Technical Systems'.
Safety Assurance Documentation	All existing documentation which provide assurance that safety related requirements are identified and implemented and which describes systematic actions necessary to provide adequate confidence that a product, a service, an organisation or a system achieves acceptable or tolerable safety.
Safety Cases	Safety Case is the ***documented*** assurance (i.e. argument and supporting evidence) of the achievement and maintenance of safety. It is primarily the means by which those who are accountable for service provision or projects[2] assure ***themselves*** that those services or projects are delivering (or will deliver), and will continue to deliver, an acceptable level of safety.
Safety Regulatory Audit	A systematic and independent examination conducted by, or on behalf of, a NAA to determine whether complete safety-related arrangements or elements thereof, to processes and their results, to products or to services, comply with required safety-related arrangements and whether they are implemented effectively and are suitable to achieve expected results.
Safety Oversight	The function undertaken by a designated authority to verify that safety regulatory objectives and requirements are effectively met.
Verification	Confirmation through the provision of objective evidence that specified requirements have been fulfilled.

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[1] *Safety-related conditions can also be defined by means of safety directives issued by NAAs where an unsafe condition is determined to exist in a system.*

[2] *The distinction between services and projects/systems is to emphasise the difference between Unit and Project (or System) Safety Cases.*

1 INTRODUCTION

1.1 General

The introduction of new systems and changes to the increasingly complex and integrated ATM system constitutes a potential hazard which needs particular attention.

The existing regulatory frameworks have addressed this issue by requiring service providers to implement specific processes, such as risk assessment and mitigation as required in ESARR 4 and for those EUROCONTROL Members States where EC legislation is directly applicable, Commission Implementing Regulation (EU) No. 1035/2011, or the EC verification of technical systems as required in Regulation (EC) No. 552/2004 to ensure the safe implementation of changes.

ESARR 1, Edition 2.0 and, where applicable, Commission Implementing Regulation (EU) No. 1034/2011 require National Aviation Authorities (NAAs) to establish a process in order to verify the compliance of ATM service providers with applicable safety regulatory requirements. This process shall use documented procedures to eliminate discrepancies in its application and be supported by documentation specifically intended to provide safety oversight personnel with guidance to perform their functions[1].

It requires the NAA to perform a number of regulatory oversight functions. One of the key functions is to ensure that Air Navigation Service Providers (ANSPs) or Organisations apply regulatory requirements to any changes to existing ATM system.

The conclusion of regulatory oversight functions (review, audit) is an *acceptance* provided by the NAA. This acceptance is given at the end of the review of changes and after auditing the safety procedures of an ANSP. The NAA should have subsequent resources and competences to perform the oversight tasks and the acceptances activities under its responsibilities. Appendix A of this document provides a description of NAA management tasks and advices regarding its resources. When the NAA has not enough internal staff to perform part of oversight activities, these tasks could be outsourced to specific companies as “recognised organisations” as per Commission Implementing Regulation (EU) No. 1034/2011 or their equivalent “qualified entities” as per ESARR1, Edition 2.0.

This document deals with the process to be used by NAAs when deciding if a given change should be submitted to the review or audit processes of ESARR 1, Edition 2.0 or, where applicable, Commission Implementing Regulation (EU) No. 1034/2011 (Articles 6-10). It also provides NAAs with guidance and recommendations for developing, documenting and implementing a process for the safety regulatory oversight of new systems and changes in ATM/CNS.

More specifically, its objective is to facilitate the implementation of ESARR 1, Edition 2.0 or, where applicable, Commission Implementing Regulation (EU) No. 1034/2011 provisions, whilst ensuring homogeneous practices when developing a strategy to verify the implementation of the applicable safety regulatory requirements, namely when:

- Providing a rationale for the acceptance, or non-acceptance, of reviewed changes,
- Auditing the changes which have been implemented by ATM services providers.

[1] *ESARR 1, Edition 2.0, Edition 2.0, Attachment A, Article 5, §2 (a) and (b) and Article 9, §2 (a) and (b).*

It also provides recommended practices forming a comprehensive approach for NAAs to undertake some key activities, which are summarised as follows:

- To provide its position regarding the classification of the new systems or changes proposed by ATM service providers prior to the review process;
- The procedures used by ATM service providers and their acceptance by the NAA;
- The procedures are subject to regular safety regulatory auditing conducted as part of the verification of continuous compliance of ATM services with applicable safety regulatory requirements.
- The analysis by the NAA of the safety arguments associated with new systems or changes to the ATM system which are reviewed;
- The acceptance by the NAA of the implementation of the reviewed changes;

1.2 Reference Documents

Prior knowledge of ESARR 1, Edition 2.0 and/or Commission Implementing Regulation (EU) No. 1034/2011 is essential as these documents address the oversight of the ANSP/Organisation's activities related to the introduction of changes and the verification of the safety requirements and other safety-related conditions associated with the implementation of that change.

In addition, as the supervision of compliance achieved by NAAs embraces all applicable requirements, the safety requirements derived from ICAO SARP(s) and ESARR(s) should also be familiar. In particular, the standards contained in ICAO Annex 11[1] should also be considered part of the applicable safety regulatory requirements.

ESARR 4[2] is part of the safety regulatory requirements applicable to ATM service providers[3]. It requires that the ATM system shall be subject to a risk assessment and mitigation process[4] to support its safe introduction and operation. As such, EAM 4 / GUI 2 '*ESARR 4 and Related Safety Oversight'* may be of particular use in relation to the safety oversight of changes to the ATM system.

As the review of changes and the safety regulatory auditing activities are strongly interconnected, knowledge of EAM 1 / GUI 2 *"Verification of Compliance with ESARR 1,"* and EAM 1 / GUI 3, *"Guidelines for Safety Regulatory Auditing"* is also recommended.

For those EUROCONTROL Members States where EC legislation is directly applicable, the SES regulatory framework should be known, specifically the regulations which have specific links with this guidance material:

- Regulation (EC) No. 550/2004 of 10 March 2004 on the provision of air navigation services in the single European sky (the service provision Regulation);

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1 *Among those relative to changes, some of them (ICAO Annex 11, Sections 2.27.3, 2.27.4) are covered by the requirements of ESARRs 3 and 4, although some (Sections 2.20.2, 2.20.3) related to the co-ordination between the ANSP/Organisation and AIS are not explicitly in ESARRs.*

2 *Part of ESARR 4 requirements are transposed in Commission Implementing Regulation (EU) N° 1035/2011.*

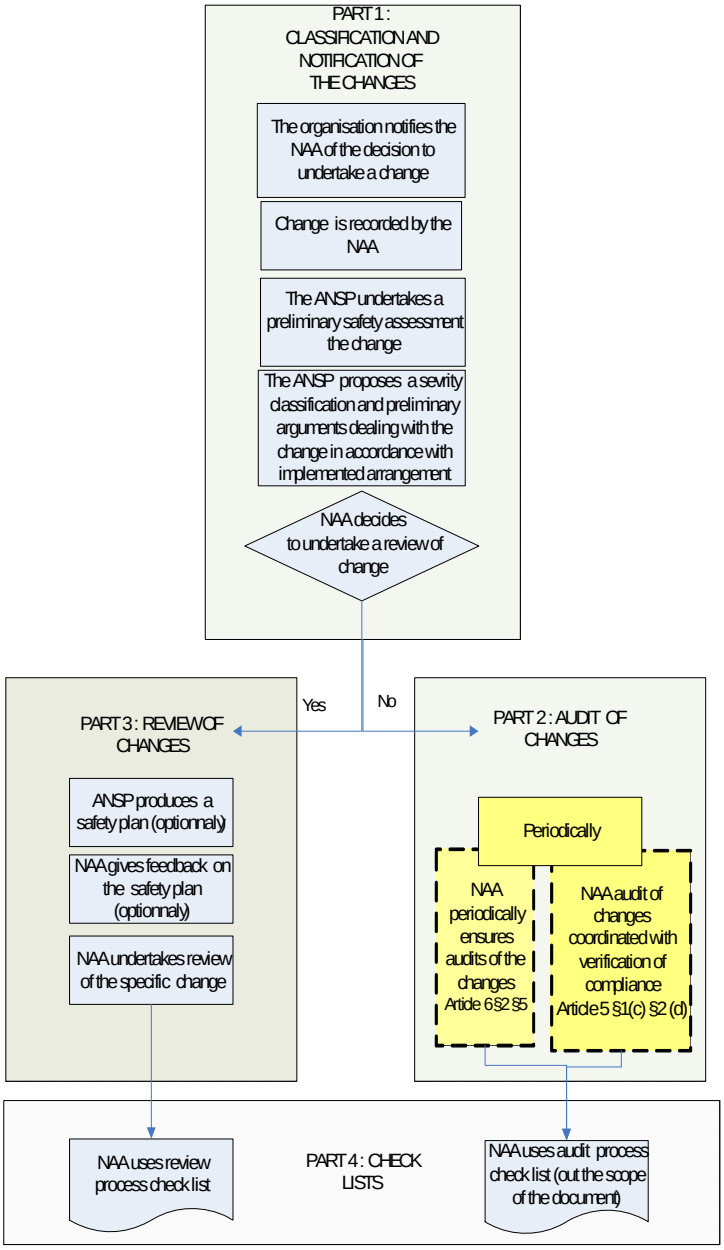
3 *ESARR 4 requires that an ATM service provider shall ensure that hazard identification as well as risk assessment and mitigation are systematically conducted for any changes to those parts of the ATM System (ground as well as onboard) and supporting services within his managerial control. This concerns the human, procedural and equipment (i.e. hardware or software) elements of the ATM System as well as its environment of operations at any stage of the life cycle of the ATM System. The aim of this process is to demonstrate that the ATM operations will remain within tolerable safety levels. ESARR 4 has been partly transposed by Commission Implementing Regulation (EU) N° 1035/2011.*

4 *ESARR 4, Section 5.1.*

- Regulation (EC) No. 552/2004 of 10 March 2004 on the interoperability of Air Traffic Management network 5The interoperability regulation);
- Commission Implementing Regulation (EU) No. 1035/2011 of 17 October 2011 laying down common requirements for the provision of air navigation services and amending Regulations (EC) No. 482/2008 and (EU) No. 691/2010;
- Commission Implementing Regulation (EU) No. 1034/2011 of 17 October 2011 on safety oversight in air traffic management and air navigation services and amending Regulation (EU) No. 691/2010.

1.3 Structure of the Document

Taking into account the overall process of the safety oversight of changes presented in the previous paragraph. It has been chosen to structure this document into four parts, as follows;



- **Part 1: Classification of Changes**

  This part presents the responsibilities and tasks which should be recommended for the notification of changes by the ANSP/Organisation to the NAA and for their classification. It provides guidance regarding compliance with Articles 8.2, 8.3 and 9.1 of ESARR 1, Edition 2.0, Attachment A and Commission Implementing Regulation (EU) No. 1034/2011.

- **Part 2: NAA Processes for the Audit of Changes**

  To provide the NAA with a means to obtain objective evidence of compliance, or lack of compliance, with specified requirements relating to the initial or continued operation of the ATM service provider, as far as changes are considered. It provides guidance regarding compliance with Articles 5 and 6 of ESARR 1, Edition 2.0, Attachment A and Commission Implementing Regulation (EU) No. 1034/2011.

- **Part 3: Review of Changes Performed by the NAA**

  To assess whether the safety arguments presented (and other associated documents) demonstrate that the proposed change of the ATM system can be implemented within the applicable acceptable levels of safety in providing the rationale for the acceptance, or non-acceptance, of such a change. It provides guidance regarding compliance with Articles 9.2 and 9.3 of ESARR 1, Edition 2.0, Attachment A and Commission Implementing Regulation (EU) No. 1034/2011.

- **Part 4: Checklists**

  They are **common to both processes "Review of changes" and "Audit of changes**" processes and uses the same methods, with possibly a different weighting between them and a different level of verification. Part 4 is a proposed means to verify the compliance of the ANSP/Organisation's risk assessment and mitigation process and its results with the safety regulatory requirements and any arrangements needed to implement them.

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2. PART 1: NOTIFICATION AND CLASSIFICATION OF CHANGES

2.1 Responsibilities of the NAA

In order to ensure that the management of changes is adequately managed by all organisations, **the NAA should establish national procedures**, in accordance with the relevant requirements, **to implement the process and the working arrangements to support the safety oversight of changes.**

The NAA should **establish a procedure to ensure that planned safety-related changes are notified** by the ANSP/organisation to the NAA.

The NAA should establish procedures to:

- **identify the criteria used for the acceptance of the classification of proposed changes by the ANSP/Organisation,**
- **review and/or audit the changes**.

More specifically, these procedures should identify and describe the:

- criteria for the classification of changes, taking into account the categories of change which are submitted for review by the NAA, other than those already identified in ESARR 1, Edition 2.0 or, where applicable, Commission Implementing Regulation (EU) No. 1034/2011;
- process, documentation and traceability to be applied when the NAA decides to review the change in any other situation;
- process, documentation and traceability associated with the review of the change;
- process, documentation and traceability to be applied when the NAA decides to audit the change;
- associated corrective actions processes.

The NAA **may define criteria which can be used for the establishment of a predetermined classification of the change**, which should be associated with specific procedures of the ANSP/Organisation which have been accepted at the time of certification and which are periodically assessed (through on-going oversight and the audit process).

Once the procedure has been agreed by the NAA, the ANSP/Organisation may undertake changes using the accepted procedure. This agreement is usually put in place for certain types of safety-related changes, for instance if those changes:

- Can be considered as routine by the ANSP/Organisation;
- That are conducted are the same as changes that have previously been carried out and if the methods for controlling and implementing the changes have been shown by the previous change to achieve the safety requirements placed on the system;
- Have been previously carried out with procedures and standards already validated by the service provider and accepted by regulatory authorities in a comparable environment;
- Replace parts of the original equipment strictly according to the specification (including performances) made by the manufacturer.
- Use procedures and standards which have been shown to be adequate in a prior application, and if the ANSP/Organisation has been certified, when it applies the same procedure for a new change the NAA can have high confidence that the change will meet the safety requirements.

To ensure that the NAA can identify, through certification and on-going oversight, processes, procedures and standards that are considered appropriate, it may be recommended to include their references within the Safety Management System (SMS) or to clearly identify them within the ANSP/Organisation's rulemaking process.

2.2 Options for the Notification of Changes

According to ESARR 1, Edition 2.0, Attachment A, Article 8.2 and Commission Implementing Regulation (EU) No. 1034/2011, Article 9.2, the organisation shall notify the NAA of all planned safety-related changes. In order to start the safety oversight process, the NAA should establish appropriate procedures to ensure the notification of the changes by the organisation to the NAA[1]. Two different options are proposed in this guidance and the options for notification of change by the ANSP/Organisation to the NAA should be documented in a procedure.

Option 1	***Option 2***
The NAA may consider that the maturity of the ANSP/Organisation's safety assessment process has to be improved (e.g. additional procedures for changes).	The NAA has confidence in the ANSP/Organisation for classifying the changes (completeness of the list of hazards, determination of correct level of severity of the effects, compliance with the classification rules).
The ANSP/Organisation notifies **all planned safety-related changes** to the NAA prior to their implementation within a timescale agreed with the NAA.	The ANSP/Organisation notifies **all planned safety-related changes** to the NAA prior to their implementation within a timescale agreed with the NAA.
The ANSP/Organisation proposes a classification and provides the associated justification material.	The **ANSP/Organisation undertakes an internal classification of all changes according to the criteria that has been defined by the NAA** and maintains records of the associated justification.
The NAA assesses the justification material, records and accept of not the classification of the change. It provides its responses within a timescale agreed with the ANSP.	The ANSP/Organisation communicates to the NAA the proposed changes **for review** in accordance with those criteria and the changes which **cannot be classified with the initial criteria and which necessitate a specific agreement** on their classification.
It is recommended that the procedures associated with the management of all changes include their records in a database or any kind of repository material accessible by the NAA which allows access to: • information about changes which are on going, without waiting for the implementation of the change, • checking of the correctness of the classification of the changes without waiting regulatory auditing activities.	It is recommended that the procedures associated with the management of all changes include their records in a database or any kind of repository accessible by the NAA which allows access to: • information about changes which are on going, without waiting for the implementation of the change, • checking of the correctness of the classification of the changes without waiting regulatory auditing activities.

[1] *The ANSP/Organisation should explicitly inform the NAA if the change under consideration is submitted to conformity assessment process and declaration of verification according to Regulation (EC) N° 552/2004.*

Option 1	*Option 2*
The NAA decides on the basis of the arguments provided by the ANSP/Organisation if the change has to be reviewed.	As soon as at least one of the criteria for review of change has been identified during the preliminary assessment made by the ANSP/Organisation, the process for review of change should be applied.

2.3 Classification of Changes

In all cases, the introduction of the classification should only take place after a period where the service provider demonstrates, through a number of safety assessments, that they have a safety management system in place which ensures a competent and well managed safety assessment process.

The classification of the severity of the change is under the responsibility of the ANSP who proposes a classification of the change to the NAA. However, the NAA decides what changes are subject, or not, to a review of the safety arguments. This NAA's decision may be based on the classification provided by the ANSP/Organisation by other conditions related to safety may lead the NAA to decide the need for review.

As a minimum, ESARR 1, Edition 2.0 and Commission Implementing Regulation (EU) No. 1034/2011 requires the review of changes when the:

1) Safety assessment determines a severity class 1 or 2 for the potential effect of the identified hazards (worse credible scenario),
2) Implementation introduces a new aircraft standard,
3) NAA decides to use other criteria in addition to 1) and 2) to determine if a change is submitted to review.

The ANSP/Organisation is responsible *for notifying* the *planned safety-related change* to the NAA. The NAA should decide on the type of oversight to perform. With regard to the NAA's safety oversight of the change, several possibilities may be considered, depending on the type of change:

- The severity class of the change identified by the ANSP, and additional safety related conditions identified by the NAA as per Commission Implementing Regulation (EU) No. 1034/2011, would be inputs to confirm or not the review of the change.
- The **ANSP/Organisation drafts a preliminary safety assessment (c.f.** infra §2.3.2**) of the change** and proposes a classification to the NAA, who may or may not accept this classification after reviewing the proposed **preliminary safety assessment.**
- On one hand, the NAA should accept a certified ANSP/Organisation to use specific procedures to undertake the safety assessment of certain categories of changes. On the other hand, the ANSP/Organisation should apply the procedures for those categories of change. Therefore, the NAA's oversight of changes should be defined by a specific NAA procedure dealing with categories of changes agreed by the NAA and ANSPs. Depending on the agreed categories of change, it could be an audit or a review of the **results of those procedures** applied to changes.

2.3.1 Criteria to Assist in the Classification of Changes

Some changes do not need to be reviewed. However, depending on ad-hoc criteria established by the NAA, a review may be necessary.

This list of criteria in the table below provides some examples of the key elements to be considered by the NAA, on the basis of the arguments provided by the ANSP/Organisation, before deciding that a change should be reviewed.

It should be noted that most of wide range changes do not belong to a single category. They could address more complex combinations of categories. It is advised that the NAA should draft a procedure which identifies simple categories or combinations of change to identify the type of relevant oversight to be conducted.

Category of Changes	Examples	Advised Processes
Severity of the Effect of the Hazard Caused by the System	Risk Assessment and Mitigation indicates a Hazard with an effect classified at 1 or 2.	Review.
	Risk Assessment and Mitigation indicates a Hazard with an effect classified 3 to 5.	Audit.
Verification of Safety Requirements	• Need to use assurance level approach. • Difficulties of verifying validity safety requirements (software, people or procedures). • Need to be submitted to Human Factor validation. • Have an impact on the operational working methods. • Have an impact on operational procedures. • Contingency Plan. • Letter of agreement.	Review.
Novelty	• Routine.	Audit (ANSP/organisation procedures)
	• Introduces recognised novelty into the ATM system (technical, operational).	Review.
Complexity	• Systems which require the allocation of safety requirements across several service providers. • Several ATM segments concerned by the change (satellites, air, ground systems). • Have a significant geographical extent, numerous locations of implementation. • Imply organisational changes within several operational centres (foreign or not). • Changes which impact all organisations involved in a FAB.	Review. The NAA could decide that the more organisations involved in a change, the more likely for the safety requirements could be difficult to be achieved. It is advised that any change requiring the coordination of more than three organisations should be submitted to review. The complexity of the change may be combined with other category of changes. For instance a change can required a low novelty but an important complexity.

Category of Change	Examples	Advised Process
Alteration of Configuration Data	User configuration settings which affect the operational functionality.	Audit (ANSP/Organisation procedure). It often concerns software components, the same re-configurability can occur within hardware systems.
Modifications to Change System Performance	To change the performance of the system or to a function of the system.	Review. This could indicate a change to the safety objectives of the system as a result of increased safety risk. Such a change could then require a new risk assessment and mitigation.
Replacement Parts	• Have direct impact on some ATM safety-related operational equipment (ILS, radio, radar, telephone, etc.). • Imply a modification of AIS as a risk mitigation. • Imply a request for exemption (rules, service provision). • Large software development. • Transfer of the ATM function under a new operating system. • Important change of equipment. • Upgrade of a system: change of obsolete equipment to a limited extend, upgrade of equipment or re-hosting software.	Review: the NAA could consider that the repair / upgrade of a system with a component that is not as specified by the original manufacturer could require a new ESARR 4 assessment. Audit: if the ANSP / Organisation conducts a safety assessment to show that the part does not alter / impact the ATM operational functions, the operating characteristics or performance characteristics of the system. Audit : the NAA on the basis of the ANSP arguments could consider that any replacement part that is part of the original equipment and is as specified by the manufacturer could be fitted without requiring an acceptance to the change.
Changes Controlled by Procedures and Standards Already Validated by Other Agencies	• Change to aircraft standards/equipment. • ICAO standards and recommended practices. • International Telecommunication Union standards. • EUROCONTROL specifications. • EUROCAE standards. • Technical standards for equipment. • Operational phraseology. • Design of ATC procedures such as SID/STAR. • Airspace management (sectors, routes, areas).	Review: there may be no specific safety analysis conducted in the standard. The change needs a safety assessment in the existing local environment. Many standards relate to the technical details of the interoperability of systems without consideration of the operational, procedural and people aspects of the use of the system. Audit : with ANSP/organisation procedures.

Category of Change	Examples	Advised Process
Temporary measures	• can be considered any safety related temporary measures (airspace, procedures, technical aspect).	Audit: if the temporary measure is supported by an accepted procedure of the ANSP. In other cases, the classification should be done case-by-case, on the basis of safety-related arguments provided by the ANSP and the duration of the temporary measure.
Changes Controlled by Procedures and Standards Already Validated at the Service Provider	In everyday life an ATM service provider faces all kinds of activities, which are well defined and documented as part of the existing system that could be considered as "changes" in the sense of ESARR 4. These changes are captured by ANSP's procedures which are part of the documentation of operational system or SMS.	Audit: if the ANSP's procedures and standards have been certified by the NAA. Review: the NAA should make sure that the "change" is any activity or alteration that 1) is NOT included in, or described as being part of, the "existing system" and 2) that has a safety impact on the ATM system.

The criteria for the classification of changes can be different for each ANSP/Organisation, according to the nature and extent of its service provision, the maturity of its SMS and the number of changes which are forecast.

If during the safety assessment process, potential impacts of severity 1 or 2 or any other criteria are identified which could lead to the need for a review (e.g. limitation or lack of internal procedure of the ANSP, specific environment, safety-related consequences which have not been foreseen, etc.), the ANSP/Organisation should inform the NAA. The NAA should then modify the initial classification and proceed to the review of the change.

The reverse situation is possible; if a change has been identified to be submitted to a review process and if during the safety assessment and mitigation process it does not satisfy the criteria for review, this change can be de-classified by the NAA based on a proposition from the reviewer.

All the criteria on which the classification of the change is performed should be recorded.

2.3.2 Preliminary Assessment Before Classification

Sometimes the classification of the change could not be identified by an accepted procedure, or the ANSP/Organisation identifies a change classification which leads directly to a review. Therefore, the NAA should assess the preliminary safety assessment provided by the ANSP before identifying and confirming the need for a review of the change.

It is advised that the ANSP/Organisation and the NAA should agree on a minimum list of documented arguments to support the classification. This would help to have a common understanding of the importance of some safety impacts of the change to be taken into account before reviewing the safety arguments. Those arguments should be consistent with the extent and impact of the change (i.e. its potential impact on the continued safe operation of the service, e.g. the safety assessment and analysis of routine changes or maintenance activities on site should be classified on the basis of agreed procedures with the NAA). The severity is associated with the effect of the hazard identified for this type of change.

This list could include the:

- Identification of an ANSP/Organisation focal point for that change;
- Identification of regulations related to the change;
- Reference of the ANSP/Organisation's procedures dealing with the change;
- Description of the change (perimeter, environment, extend and location, timescale for intended implementation, resources);
- Initial list of hazards and their potential effects on each part of the ATM system (controller / aircraft / aircrew);
- ESARR 4 severities of the effects of hazards for the specific change under consideration;
- Need or not for new aircraft standards;
- Novelty of the change, or experience gained in this kind of change within the ANSP/Organisation;
- Need for co-ordination with other segments, e.g. airborne, satellite, or with different type of providers;
- Results of a safety impact analysis on the ATM system on:
  - Operations,
  - Interfaces with other systems and equipments,
  - Different stages of the life cycle, including system integration, level of tests, installation and deployment stages,
  - Human factor and operational methods,
  - AIS as possible mitigation mean or external/aircraft information,
  - External coordination, letter of agreement,
  - Operational functions or services, communication,
  - Airspace management.

2.3.3 Decision of the Review Made by the NAA

Using past experience in classifying changes and lessons drawn from similar changes, the NAA assesses the safety arguments and justification material provided by the ANSP/Organisation. More specifically, they should;

- examine the provided documentation and justification material,
- determine if the change is within its legal scope of competence,
- determine if the documentation provided is sufficient to classify the change,
- ask for additional material if necessary,
- acknowledge the classification proposed by the ANSP/Organisation, or indicate a need to modify the classification,
- update its planned actions for the review of changes as necessary,

On the basis of the information provided, the NAA agrees -or not- the **proposed classification of the change** to the ANSP/Organisation within the timeframe defined in the procedure describing its oversight of changes.

The NAA should either accept or reject the proposed classification.

It is advised that **if the NAA does not agree the proposed classification of the change** the NAA should provide arguments, including the:

- presentation of the change;
- regulatory framework, need for coordinating safety with conformity assessment process;
- feed back on the initial safety assessment;
- reservations and/or limitations;
- revised proposal of classification in compliance with NAA's criteria.

It is advised that **if the NAA agrees the proposed classification of the change** they should not provide specific arguments.

If a review is decided, the NAA will provide proposals related to the conditions of the review: level of rigour, salient elements to be analysed in depth, initial milestones, resources needed, etc.The NAA will provide as well the identification of the material to be reviewed.

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3. PART 2: THE AUDIT OF THE CHANGE

3.1 Responsibilities of the NAA

The audit of the changes provides the NAA with a means to obtain objective evidences of compliance, or lacks of compliance, with specified requirements relating to the initial or continued operation of the ATM service provider, as far as changes are considered. This process is partly covered by Article 6 of ESARR 1, Edition 2.0, Attachment A and Article 7 of Commission Implementing Regulation (EU) No. 1034/2011.

The NAA should put in place adequate procedures in order to ensure safety regulatory audits of changes. The activities of the NAA described in this document are the:

- **Audit of the results of the ANSP's processes applied to the specific changes**. In the course of "on-going safety oversight", this audit should consist in the selection of a sample of changes and the assessment of their safety arguments,
- **Verification of the continued compliance** of changes with the safety requirements and other safety conditions associated to the change which has been implemented.

The assumption is made that the formal acceptance of the procedures used by the service provider for the risk assessment and mitigation of changes is covered by the certification process. Therefore, the procedures in use by the service provider have already been identified and accepted by the certification process.

To facilitate the audit of the change by the NAA, it should be ensured that procedures dealing with the following items should be drafted at ANSP level and provided as evidences for the NAA audit of change process:

- The risk assessment and mitigation processes in compliance with the relevant requirements;
- The ANSP/Organisation's procedures related to the change management process ;
- Arrangements related to the final decision taken by the ANSP/Organisation's management in the light of the conclusions obtained from the various service providers' procedures.
- Identification of the inputs to be provided to the NAA's "audit of changes" process ;
  - list of implemented changes,
  - list of safety requirements,
  - other safety-related conditions which are outputs of the review of changes process.

These procedures are subject to safety regulatory auditing to verify their compliance with applicable safety regulatory requirements and any arrangements needed to implement them (regulatory audits).

3.2 Audits of the Results of ANSP's Processes Applied to Specific Changes

In order to avoid duplication of work during the "review of changes" process, it is advised that the sample of Safety Arguments to be considered during the on-going oversight of changes (audit of changes) should only be those related to the changes which have not been reviewed.

The audit of change process should apply to the individual parts of the ATM system, as well as the integration of such parts. As such:

- audits should verify the overall consistency of numerous safety arguments and their consistent implementation in the ATM system within tolerable safety levels;
- audits should equally assess the effectiveness of the interface of the ATM system under the managerial control of the service provider with other external systems with which it interfaces (such as MET systems, AIS, aircraft systems, externally supplied systems);
- the audit should ensure that the safety assessment of the change is performed in accordance with the ANSP's procedures which have been accepted by the NAA.
- some ANSP/Organisations and ATS units may have opted to develop and maintain a **"Unit Safety Argument",** which shows that the on-going, day-to-day operations of a given ATS Unit are safe and will remain so when changes are implemented;
- Unit Safety Arguments would typically include arguments and evidences that processes are in place to ensure that all changes to the ATM system are managed safely;
- in that case, the safety regulatory audits would assess the continuous consistency of the **Unit Safety Argument through a sample of changes** and their impact on the overall Unit Safety Argument. The audit should also consider how the changes have been integrated into the ATS Unit Safety Argument, if any.

This process should also determine the capacity of the ANSP/Organisation to conduct those risk assessment and mitigation processes as documented, in a manner compliant with the relevant requirements. This includes, where applicable, the arrangements put in place to ensure the verification of technical systems as required by Regulation (EC) No. 552/2004 (Interoperability Regulation).

This verification can be based on any type of change. It is advised to apply the process to a sample of changes. In addition, this process should verify that any changes to the applicable national regulations are timely reflected in the documented risk assessment and mitigation procedures of the ATM service provider.

The process should also include the determination of the adequacy of resources, the allocation of responsibilities, existence and adequacy of internal instructions, information dissemination process and of all other means necessary to conduct risk assessment.

Finally, the objectives and scope of the safety regulatory audits should be determined taking into account the outcome of previous safety regulatory audits and identified issues and their identified issues leading to corrective actions.

3.3 Activities Associated with the Audit of Changes

This section will not develop all auditing techniques, but aims to highlight the type of information which is audited. For detailed information on undertaking audits of changes, it is advised to refer to the check lists presented in §5.8 below.

Whereas EAM 1 / GUI 3 addresses the overall audit activities in the ESARR 1 framework, this chapter only addresses the activities related to the audit of changes.

The NAA's acceptance of the ANSP/Organisation's procedures related to the implementation of the change is based on the compliance of the risk assessment and mitigation procedures with the relevant regulatory requirements.

The implementation of a change is notified to the NAA by the ANSP. The NAA should record them, thereby allowing it to keep a global view of the changes implemented by the ANSP/Organisation and to define a sample of changes which may be audited. Several types of non-reviewed changes should be selected (for example, in relation with the level of risk).

Within the framework of regular auditing, the processes used for the risk assessment and mitigation of changes should be audited. Therefore, the results of these processes, such as the safety arguments, should be available for the audit.

Consideration should be given to performing a documentation review (of safety arguments) during the preparation phase of the audit, as this would allow the use of specific expertise without the pressure of time. The audit can be used to verify that the safety-related conditions have been met.

In practice, regarding the audit of change, the following activities should be undertaken by the NAA:

- The verification of the compliance of ANSP/Organisation to the implemented procedures with applicable safety regulatory requirements. It should imply an assessment of the changes implementation procedures against ESARR 4 or, where applicable, Commission Implementing Regulation (EU) No. 1035/2011;
- If any, and if agreed by the NAA, verification of the outcomes of the ANSP's procedures regarding the management of specific changes;
- Regarding the procedures applied by the ANSP's; identification of any non-conformities and/or deficiencies;
- The verification of evidences; all safety arguments should be recorded and maintained (e.g. database or equivalent repository system) by the ANSP/Organisation and made available to the NAA for the audit of changes.
- If the change under consideration is submitted to a declaration of verification by the ANSP/Organisation, the documents related to the declaration of verification and declaration of conformity, as well the technical file should be verified by the NAA during the audit process.
- The audit should also verify whether some changes have not been underestimated (especially those related to level 3). The rationale for classifying some changes should be requested during an audit and examined.

A sample checklist is provided in §5.8 of this document. The checklist identifies two levels of rigor for the audit of changes (for the definition of levels of rigor see §4.5). The choice of level and the number and nature of changes to consider in the sample, is made according to the maturity in safety of the ANSP/Organisation and the availability of resources.

3.4 Verification of Continued Compliance

The NAA should establish procedures to ensure the verification of the continued compliance of changes which have been reviewed. The verification is performed by mean of audits.

The verification of continued compliance is to ensure that the ATM system meets the safety-related conditions[1] identified during the review of changes. This includes examining the evidence claimed in the safety argument, the risk assessment and mitigation applicable to the ANSP/Organisation, the implementation of safety objectives or requirements identified in EC declarations of verification of systems, including the EC declaration and suitability for use of the constituents of the system.

Safety-related conditions can address all the phases of project's development, from its definition to decommissioning. The implementation phase, in particular, may introduce specific hazards.

All safety requirements and other safety-related conditions cannot be verified to the necessary extent before the implementation of a change.

Such requirements and conditions may therefore need to be identified as outputs of the review of changes process. They also form inputs to the NAA's ongoing oversight activities, including safety performance monitoring.

More generally, the acceptance of a change before its implementation does not allow an ATM system to be operational without further review. The verification of continued compliance should ensure the:

- continued validity of assumptions,
- continued implementation of safety requirements and other safety-related conditions,
- effectiveness of the implemented mitigation measures,
- ATM system is operated within tolerable safety minima.

It is advised that the NAA should undertake **a risk-based approach**, which includes the provision made in safety arguments along the life cycle of the change (i.e. identification of risky situation at deployment phase) but which may include information issued by current safety analysis or any other safety related information related to the change which may be available at the time of the audit.

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[1] *Refer to ESARR 1, Edition 2.0 for the definition of "safety requirement", "safety-related conditions" and "safety regulatory requirement".*

4. PART 3 : REVIEW OF CHANGES

4.1 Responsibilities and Procedures of the NAA

Once a change has been selected for review, t**he NAA should start its review as early as possible in the life cycle** of the development of that change. A specific process is required in relation to changes to the ATM system that are subject to NAA review. This process:

- Includes the review of the "safety arguments" associated with the changes under consideration;
- Provides the rationale to support the NAA's decision on the acceptance of the system to go into operational use.

The safety arguments[1] are developed by the ANSP/Organisation to provide evidence that the change can be implemented safely.

The ANSP/Organisation carries on procedures to produce that demonstration, notably a full risk assessment and mitigation process is conducted in accordance with ESARR 4. The outputs of the risk assessment and mitigation process are:

- Lists of hazards that are used within the process to derive safety-related conditions;
- Demonstration and evidence that those safety-related conditions have been properly derived in a **process compliant** with ESARR 4;
- **Demonstration and evidence that the safety-related conditions are effective** to meet the safety objectives identified in the risk assessment and mitigation process, and that they will continue to be met;
- Demonstration that the safety-related conditions are **effectively implemented**, and will continue to be implemented.

All these aspects form the safety argument to be reviewed and assessed by the NAA. Various aspects must be underlined as regards the implementation of this review:

- The review is required for changes which necessarily require acceptance by the NAA before their implementation. Nothing prevents NAAs undertaking the review of a change, subject or not to acceptance[2], if necessary.
- The review must provide the **rationale to support the NAA's decision** about the acceptance, or not, of the change.
- In order to eliminate discrepancies in the application of the review, it is required to use documented procedures. In addition, specific documentation is required to provide safety oversight personnel involved in the review with guidance on how to perform their functions[3].
- The review involves auditing to verify the processes used by service providers in relation to new systems and changes. Depending upon the case, such auditing may be specific or part of the on-going safety oversight of the continuous compliance with requirements.

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1 *The terms "safety argument" and "safety-related condition" are defined in ESARR 1, Edition 2.0, Article 2. In addition, the definitions for "safety requirement" and "safety objective" correspond with those included in ESARR 4 and, therefore, identify the outputs of the risk assessment and mitigation process conducted in accordance with ESARR 4.*

2 *Acceptance is required, as a minimum, for reviewed safety-related changes. Nothing prevents NAAs from requiring the acceptance of any other changes if that option is consistent with the existing regulatory framework applicable to the case.*

3 *The considerations made in Sections 3.8.2.1 and 3.8.2.2 of this document, with regard to the documentation and guidance material related to the verification process, are fully applicable to the review process as well.*

- The review process must identify the situations related to the implementation of new systems and changes that will need verification of compliance. That is to say, the review process will normally **feed into the auditing programme** information concerning the safety-related conditions[1] whose effective implementation will need to be verified.

Aviation is no longer a puzzle built out of autonomous elements, but **inter-related ground and airborne** parts and elements. The authority for enforcing safety requirements bearing on aircraft design and flight operations is usually vested in a specific authority. When developing safety requirements and standards for new airborne systems, it is essential that due account is given to the safety constraints arising from the ground ATM systems, in addition to the traditional airworthiness and flight operations requirements. Co-ordination with the safety oversight authorities dealing with airworthiness and flight operations is therefore essential, notably wherever the implementation of the change introduces a need for new airworthiness or flight operations standards.

The review focuses on the safety arguments associated with the change under consideration:

- As already mentioned[2], the safety argument is the demonstration and evidence that a change can be implemented safely; i.e. within tolerable levels of safety.
- Amongst other elements, the safety argument includes a set of specific objectives and measures, identified consistently with the applicable safety regulatory requirements, whose implementation is found necessary to ensure safety.
- The review should check that the service provider has considered any interrelationships and that any assumptions placed on elements of the aviation system outside its managerial control have been validated.
- It is also essential to check whether the **documented outcome** of the risk assessment and mitigation process is acceptable. In that regard, ESARR 1, Edition 2.0 and Commission Implementing Regulation (EU) No. 1034/2011 explicitly refer to several interrelated points which need to be checked with regards to the steps and outputs of a risk assessment and mitigation process:
  - **All the ESARR 4 or Commission Implementing Regulation (EU) No. 1035/2011 steps** intended to **identify hazards and determine safety objectives;**
  - The "validity, effectiveness and feasibility of safety requirements and any other safety-related conditions identified". This includes the links between **the safety requirements and safety objectives that have to be achieved**;
  - The need to implement the results of the process. This aspect implies **checking that there are means to ensure that the safety requirements and other safety-related conditions are met and will continue to be met**;

[1] *Notably, the safety objectives and safety requirements identified in the ESARR 4 risk assessment and mitigation process, and the safety-related conditions that could be contained in EC declarations of verification of technical systems or conformity/suitability of technical systems.*

[2] *See also 3.13.2.1 about the meaning and scope of the term "safety argument".*

- **The process and its compliance with applicable safety regulatory requirements.** The demonstration provided may be sufficient or may prompt, if necessary, the use of audits as foreseen in ESARR 1, Edition 2.0, Attachment A, Article 6 and Commission Implementing Regulation (EU) No. 1034/2011, Article 7.2 to check its consistency.

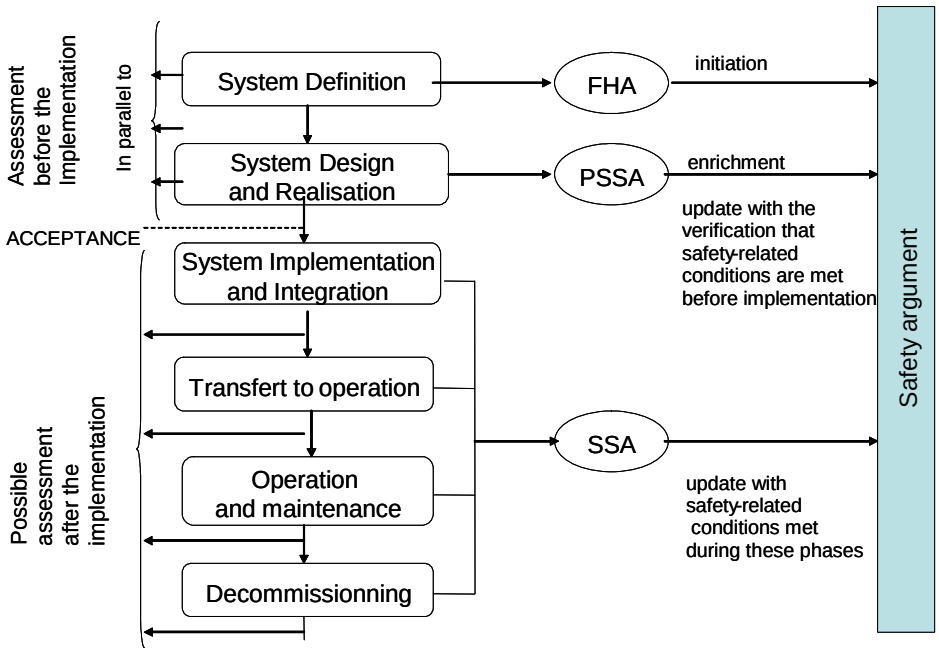
4.2 Link with the Life Cycle of the Development of the Change

For a review of change, the assessment takes place before the implementation of the change in the framework of the review process. The review is made in parallel with the system definition, design and realisation (where the ANSP/Organisation deploys the FHA and the PSSA steps of the SAM methodology if this one as been used).

Considering that new hazards or effects can be identified during the design and realisation phases, the safety assessment can be updated throughout the development of the change (e.g. after the FHA and after the PSSA).

Part of the assessment (verification that the safety-related conditions are met) can also take place after this implementation, during or after each possible phase if it has been decided to do so:

- either in the framework of the review process
- or, if the change has been selected in the sample for the audit process. This assessment takes place most of time after the implementation of the change if it has been selected in the sample of changes.



Changes can be selected to be audited until the corresponding part of the system is decommissioned. A same change can be assessed several times as it is necessary to check if the safety-related conditions remain valid and because the system can be in a new phase of the life-cycle with new safety-related conditions.

In each case, the purpose of the assessment is to check that the risk is acceptable and to verify that the safety-related conditions are met and will continue to be met, (the safety criteria are sufficient to achieve the required level of safety). An assessment of the change after decommissioning would check that the safety-related conditions have been met as expected during the decommissioning.

4.3 Summary of a Review Process

In order to perform a successful review, checklists should be used to:

- Address safety deliverables in accordance of the criteria of ESARR 1, Edition 2.0 or, where applicable, Commission Implementing Regulation (EU) No. 1034/2011;
- Be specific, all safety recommendations and advices would address the deliverable under review and its environment;
- Give an unambiguous position with regard the provided safety arguments from a regulatory point of view;
- Give practical recommendations for next stages, if necessary;
- Identify the compliance with applicable regulations.

Filtering the Review Activities at Different Levels of the Scope/Impact

During the review process, from its early planning stages to its detailed activity, it is necessary to put in place effective practices to ensure that the review gives adequate results in a timely manner, having regard to the next stages of development and within the required resources and costs.

Selection and Priority of the Deliverable to be Reviewed

This activity is performed by the review manager and should be done in close co-ordination with the ANSP when the review programme is developed.

The deliverables identified within the framework of the change would to be assessed with regard to their safety regulatory aspects along their developments and before their operational implementation. However, the number of deliverables might be important and the safety regulatory impact should be considered in the short, medium and long term. Consequently, the anticipation of the regulatory impact should be done at a period which allows the most effective decision making. Actions accruing too early or too late in the SES development process could be ineffective and increase costs.

The review process is a sampling and iterative process which cannot be applied for all deliverables of all changes.

To ensure this selection, the review manager should take into account:

- SES implementation priorities;
- Innovative aspects of the project (operational, technical);
- Complexity of the programme;
- The types of change which may be submitted to the review processes of ESARR 1, Edition 2.0 and Commission Implementing Regulation (EU) No. 1034/2011;
- Operational and Safety impact of the programmes;
- Industry maturity with regard the programme;
- Deadline for implementation;
- Extension of the implementation;
- Proposition for priorities.

The result of the filtering should be established on an agreed basis. The outcome of the impact analysis of each filtering criterion should be justified.

Strategy, Scope and Limitation of the Review

This activity is performed by the reviewer with the support of the review manager. The objective is to limit the scope and the extent of the review of a particular deliverable. This limitation should ensure that the review will be effectively done in the maximum time frame of a review cycle.

This activity is the main part of the preparation phase.

The type of deliverable and the phase of the development of the programme shall be considered for identifying the impact on regulation (existing elements, need for new or amended regulation).

The **strategy** is determined by the maturity of the deliverable, for instance the place of the deliverable in the life cycle, and the deliverable is:

- a safety case for local implementation, the review should give a position on the capability and the need before to implementation of the change;
- a very innovative development, the review should give a position on the actual regulatory coverage and should propose to amend or to develop new rules and standards;
- very complex, it can necessitate several cycles of review. The decision of the number of cycle of review is part of the strategy process;
- a preliminary safety assessment : not all regulatory safety requirements could be verified;

The **scope** is identified by the type of deliverable (which may not necessary be a safety case, but a user manual or any type of deliverable) and its development status with regard the life cycle of the system. The review process should be performed at any stage of the life cycle of a programme. Depending of its development phase, it is proposed that the Review should address the:

- Overall Safety Impact Analysis (regulations, organisations, qualification of personnel, needs for guidance, etc.), or;
- Regulatory Aspect of Safety Arguments provided for the system functional architecture or the system design (confidence, robustness and compliance with regulatory requirements).

The definition of the scope consists of choosing pertinent aspects to be reviewed. All the topics identified in this chapter should not be part of all reviews and different types of deliverables, not only safety cases, are dealing with those safety topics.

With regard the ***Overall Safety Regulatory Impact***, the reviewers would address the following topic (non exhaustive list):

- Organisational aspects linked to the implementation of the programme;
- Qualification of personnel and licensing issues (ATCO, ATSEP, etc.);
- Aircraft Impact;
- Certification (airborne, other);
- Modification of the functional system (ATM, other);
- Airspace (mandates) linked to equipage and airspace definition;
- Controller Training;
- Development of Guidance;
- Oversight arrangements;
- Authorisations / acceptance (as airspace changes, separation);

- Existing safety regulatory framework (change, new regulation, etc.); Specific / further verification;
- Safety monitoring;
- Publication of information to users;
- Involvement of different regulatory bodies (States, NAAs, EASA);
- Documents for next stages of implementation (Implementer);
- Safety documentation;
- Safety requirements for next stage of implementation.

With regard the ***Regulatory and Standards Aspects of Safety Arguments***, the reviewers would address the following topics (non exhaustive list):

- With regard the system safe design aspects:
  - Technology maturity;
  - Types of Redundancies;
  - Impact on workload;
  - Quality of system interface;
  - Robustness of safety barriers;
  - Single mode of failure;
  - Degraded mode;
  - Fault containments and tolerance;
  - Recovery methods.
- With regard the safe implementation at functional level:
  - Data shared with other system;
  - Redundancies at functional level;
  - Network impact;
  - External provision (Power, …);
  - Transition period;
  - Maintenance;
  - Withdraw of the previous system;
  - Operational restrictions;
  - Off line work;
  - Parameters;
  - Number of location / extension of system;
  - Contingency.

The Limitation of the Review

The limitation of the review is the level of rigor to be applied to the review activity. This level of rigor may be stronger or lighter, in accordance of the proposal of this advisory document. Several criteria should be taken into consideration, including the:

- Maturity of the deliverable,
- Innovative aspect of the deliverable,
- Result of previous reviews made in the domain under consideration,
- Priority given to the deliverable.

The limitation of the review is neither a decision of the reviewer nor a result of a standardised process. The limitation should be examined on a case-by-case basis. It is the result of a co-ordinated activity (meetings, brainstorming) and agreed with all parties interested in the review.

4.4 The Regulatory Review of Changes

The main objective of the NAA is to assess whether the safety arguments presented demonstrate that the proposed change to the ATM system can be implemented within the applicable acceptable levels of safety. The NAA should provide its rationale for the acceptance, or non-acceptance, of such changes.

For a given change, the review of the safety arguments could be done with different levels of scrutiny: from the compliance of the ANSP/Organisation's procedures for risk assessment and mitigation to the examination of the technical **results**.

Some pre-requisites are necessary before the review of a change. The ANSP/Organisation should be informed of the procedure defining the NAA's oversight of changes. This should include details of the organisation of the NAA, responsibilities and planning and the definition of the levels of rigour (levels of scrutiny of the NAA) when considering a change.

4.5 Nomination of an NAA Reviewer

The implementation of a safety regulatory process by an NAA requires the establishment of clear responsibilities as regards programming, management of resources, conducting and following up of reviews, as well as safety regulatory audits.

The NAA management has the overall responsibility for the review activities and should provide sufficient resources to conduct the reviews. The NAA should designate a Reviewer for the review of the safety arguments. It is the Reviewer's responsibility to conduct the review and to produce a report on the results of the review which can support the decision of acceptance by the NAA.

When nominating the reviewer, consideration should be given to the expertise required, the availability of competent resources and the strategy which has been defined by the NAA.

If necessary, the reviewer defines the additional competences necessary to conduct the review. These should cover the technical competences relevant to the system change, the applicable international national and local regulations, as well as competences in safety assurance and safety auditing techniques. In practice, this may be difficult to achieve and it is the responsibility of the NAA to recognise the limits of its competences and not to establish conclusions beyond their capabilities. Accordingly, it is the responsibility of the NAA to ensure that the key areas of competence required for safety are appropriately covered.

4.6 NAA Review Plan

The review of the safety arguments should be distributed throughout their development. Coordination with the ANSP/Organisation is essential to define the milestones and the activities at different stages of the development of the change. Therefore, the process should consider a phase during which the review is defined and planned. The NAA should comment on the safety arguments according to agreed milestones, with acceptance only being given at the end prior to implementation.

The NAA should define a Review Plan defining how all the activities will be managed. This plan should be communicated to the ANSP/Organisation. It should be updated during the review in case of important modifications.

The NAA reviewer responsible for the review should draft this plan which should contain the:

- Definition of the stages and methods that will be used and the corresponding planning according to the chosen level(s) of rigour,
- Timeframe for the review and the key milestones,
- Definition of responsibilities and authorities for conducting the review and related expertises, in particular the identification of the review team,
- Identification of a focal point for the ANSP/Organisation,
- Key records required to provide evidence that the ANSP/Organisation's risk assessment and mitigation meets the requirements (including the safety argument),
- Schedule of meetings foreseen between the NAA and the ANSP/Organisation,
- Recognised Organisations involved in the review and their role.

The timeframe for a review may be fixed by a procedure or by agreement between the NAA and the ANSP/Organisation. The delay should be sufficient to allow an effective review of the change, according to the level of rigour which has been defined.

Some changes could imply the involvement of several NAAs. The safety review of a change involving several NAAs could be shared between these NAAs. The Review Plan(s) should indicate the actions under the responsibility of each NAA and the coordination which must be achieved with the other NAAs, in particular concerning the information relative to the results of safety oversight.

4.7 Definition of the Level of Rigour of NAA Reviews

The term 'level of rigour' means the depth of the NAA's involvement and the accuracy of the verifications they intend to perform during the review of the safety arguments developed by an ANSP/Organisation.

A higher level of rigour means that an NAA will need to commit more resources (time and/or staff/recognised organisation) to the review and pay closer attention to the detail of the safety arguments and supporting evidence.

An NAA should define the different levels of rigour to be applied to the review of safety arguments and supporting evidence covering a reviewed change. The table below proposes a scheme of four levels of rigour that may be used, although NAAs are free to define their own scheme.

The following criteria should be considered when deciding the level of rigour to be applied to the review of safety arguments and supporting evidence:

- The safety impact (severity) of the change identified after the preliminary safety assessment made by the ANSP,
- The novelty of the change,
- The complexity of the change: geographical extent, number of locations, need for co-ordination, impact on several ATM systems or functions.

The criteria used to support the decision of the review have to be taken into consideration. For instance, the novelty of the change could be taken into account in such a way: for a change of severity 1 or 2 with new concepts of operation, the NAA could decide to use a level of rigour L3 or L4 where, if the change is severity 3 without any new concept, the NAA could decide to use a level of rigour L1 or L2.

- *Content of the safety plan (if available).*

  When a safety plan is provided by the ANSP/Organisation, the methods and tests considered in this plan can influence the reviewer in deciding whether or not it will be necessary to look carefully at these tests.
- *The experience of the NAA with similar changes.*
- *The experience of the application of safety regulatory requirements by the ANSP/Organisation.*
- *The experience and knowledge of the ANSP/Organisation team in charge of the safety argument.*

Depending on the experience and knowledge of this team in technical/operational domains (when appropriate) and in safety argument making, the reviewer can decide whether or not to look carefully at the proposed safety argument.

The amount of resource that the NAA can commit to the review could have an impact on the level of rigor, but the role of qualified entities should be taken into account when necessary.

This guidance proposes four levels of rigour. The NAA may choose to follow these levels or can define its own number of levels and the definition of each level.

L1	The NAA assesses the comprehensiveness, consistency, relevance and completeness of the risk assessment and mitigation process used in the given change and of its result (safety argument).
L2	(minimum best recommended practice to add value) In addition, the NAA assesses the operational and technical contents of the safety argument from its own expertise, from specific experts or helped with data coming from similar changes, other areas or from other Recognised Organisations.
L3	In addition, the Reviewer can attend to Safety Assessment meeting or witness simulations or tests undertaken as part of the Safety Requirement validation phase. The purpose is to audit the actual evidence to supply additional assurance as to the process used. *NB: It is essential for the NAA to be clear as to the role of the reviewers at such meetings. It is very easy to be used by the ANSP/Organisation as an "interim certifier" where there attendance at a meeting is taken as de-facto endorsement of the results of that meeting. Hence an NAA must clearly state the reasons for the attendance.*
L4	NAA asks for external and independent provisions for risk assessment and mitigation activities in parallel to the ones done by the ANSP/Organisation to be able to compare alternative findings with those of the ANSP/Organisation. This independent verification could be performed by specific test laboratories, specialised in certain critical domains. In the context of single sky regulation this could be done by qualified entities.

In order to ease or guide the review, the reviewer may compare the safety argument with other relevant accepted safety arguments. This should be done with extreme care as the validity and conclusions of a safety argument are dependent on the context and local implementation. Thus, it is recommended when using the comparison method to apply a stringent analysis structure and procedure.

There is a great variety of detailed technical methods for the development of safety arguments by ANSPs which are chosen according to the type of system to which they are applied, to the context and to the competence of the applicant. In some cases[1], it may be necessary to apply specific validation methods tailored to the subject and method used to demonstrate the safety of the change (e.g. formal protocol validation, validation of probabilistic studies or Monte Carlo simulation as far as software is concerned). The reviewer should have sufficient knowledge and expertise of such methods or can ask for expert assistance.

The level of rigour can be modulated according to the different steps of the risk assessment and mitigation, and also according to the different parts of the system impacted by the effect of the hazards. The NAA should focus its review on key risk areas which are essential for the integrity and the validity of the conclusions. For example, the level L4 can be applied only to a part of the oversight activities.

4.8 Feedback on the ANSP Safety Plan (Optional)

After the notification of a change and if the change is considered to be reviewed, the ANSP/Organisation should provide to the NAA with its Safety Plan, and the planning of the development of the change. The Safety Plan specifies the ANSP/Organisation's safety activities to be conducted throughout the project lifecycle and the responsibilities for their execution. This document is a guideline for the ANSP/Organisation to drive the safety argument.

While the provision of a Safety Plan is not required, this type of document could be identified in the safety management system of ANSPs. This document is of interest as it shows the foresight of the ANSP/Organisation and can help to give confidence with the safety practices of the ANSP/Organisation. NAAs should therefore encourage the ANSP/Organisation to produce Safety Plans for their projects (information about existing "safety plans" can be found in MOC SAM V2). A preliminary draft of a Safety Plan of ANSP's change(s) could be provided with the initial safety arguments at the time of the notification.

The Safety Plan should contain:

- The purpose and scope of the change to the ATM system that is being considered (considering equipment, procedures and people, perimeter of the change),
- The purpose and scope of the safety argument (what does it intends to demonstrate),
- The safety activities planned to be carried in the different phases of the project throughout its lifecycle,
- An outline of how it is intended to argue the safety of the system e.g. identifying the level of safety assurance evidence that may be required,
- A description of the methods to be used;
  - to realise the safety assessment,
  - to obtain the safety objectives,
  - to evaluate the safety,

[1] *These cases happen for reviewed changes and/or stringent levels of rigor.*

  - Analyses, tests and simulations to be processed.
- Identification of the technical part of the EATMN system submitted to Conformity Assessment process (if any),
- When, or at what stage in the project, the safety activities will be carried out e.g. linked to dates or specific project milestones,
- Expected planning with target implementation dates,
- Any International and National safety regulatory requirements that are applicable e.g. ICAO SARPs, ESARRs, EC regulations and Implementing Rules, EASA rules, EUROCAE standards, etc.
- The staff responsible for contributing to the safety activities.

Where an ANSP/Organisation has produced a Safety Plan, it should be encouraged to supply it to the NAA early in the project lifecycle for review and feedback. This is to enable any concerns that the NAA identifies to be raised at the earliest stage in the project when it is easier to modify options or decisions. The NAA review can also increase confidence in the ability of the ANSP/Organisation to undertake the safety activities. This may lead to adapting the level of rigor accordingly and to improve the coordination between the NAA and the ANSP.

As part of the NAA review of the Safety Plan, the reviewer should:

- Request more information or detail where this is lacking;
- Identify any omissions or other concerns with the planned activities; or
- Indicate that the NAA has no issues or concerns regarding the Safety Plan;
- Examine the Safety Plan and requests supplementary information if needed;
- Comment the Safety Plan.

The Safety Plan is a living document and may change as the project matures. Where this is the case the ANSP/Organisation should supply the revised Safety Plan, identifying the changes, to the NAA for further review and feedback.

4.9 Review of Safety Arguments

This step is carried out **before** the implementation of the change. The review is supported by checklists (as defined in Part 4), but requires experience and methodology to assess the arguments

The aim of this step is to give **rationale** for the acceptance (or eventually rejection) of a reviewed change, or the limitation to implementation by preparing a report to the NAA. The review should assess whether the safety arguments and associated procedures demonstrate that the proposed change (with a complete and correct description) can be implemented within the applicable acceptable levels of safety. When necessary, some **added safety-related conditions** for the implementation of the change could be identified.

The verification of the effective implementation of safety related conditions is part of the post acceptance activities of the NAA. The number of safety-related conditions could increase; therefore the NAA should define a specific strategy to select the way by which the safety related conditions are controlled.

According to its Review Plan, the NAA checks the deliverable produced by the ANSP/Organisation (safety argument and associated documents and products) and proceeds also to the interview of the staff/specialists in charge of the change.

According to the level of rigour chosen for the review, several cases could be considered;

- L1 : this review is formal;
- L2 : the advices of experts competent in the relevant domain are requested;
- L3 : the NAA reviewer (or a member of his team) participates as observer to key ANSP/Organisation meetings;
- L4 : the NAA reviewer launches actions aimed at corroborating (part of) the conclusions of the safety argument.

The assessment of the safety argument and the processes used to develop it against safety regulatory requirements is conducted according to the principles described by checklists of questions and recommendations.

During the review of the safety argument, the NAA checks the safety requirements and other safety-related conditions that have been identified by the ANSP/Organisation before the implementation of the change.

The verification that the safety-related conditions are met should include the examination of the ATM system and constituents parts and the operational and technical documentation. In addition to the safety-related conditions that have already been identified by the ANSP/Organisation, the NAA can suggest others to the ANSP/Organisation.

Some of them can be under the responsibility of the NAA (e.g. proposal for amendment of the regulation). Some safety-related conditions could be issued from ICAO Annex 11, §2.20.2 and §2.20.3 and should be published in the AIS through the AIRAC cycle (refer to EAM 1 / GUI 7 '*Guidance on the Criteria for the Assessment of Compliance with the Standards of ICAO Annex 11'*).

4.10 Issuing the Report

The objective of the Safety Review Report is to enable the NAA to make a decision regarding the acceptance of a change and the rationale for its decision.

The report, and its conclusion, is established under the responsibility of the reviewer. Parts of the report can be written by other persons, but the report must be accepted by the Reviewer prior to its release.

Before finishing the review, in order to avoid any misunderstanding or misinterpretation, the reviewer should present the review conclusions to the ANSP/Organisation.

The review of a safety argument may suffer some limitations regarding the comprehensiveness, depth of verifications or even their feasibility. These limitations should be clearly identified in the review report. It is the responsibility of the reviewer to ensure that the limitations in one area of the review do not weaken the conclusions in another and to ensure the coherence and consistency of the conclusion at system level.

Before issuing the report, it is recommended to verify its; accuracy, completeness, correct integration of expert contributions, readability, clear identification of the issues, hypothesis and assumptions related to the safety argument and to the review itself and the identification of the contributors. This verification should be done preferably by somebody else other than the review team leader.

The review report should clearly state the decisions and subsequent actions proposed to the NAA, with the reasons for them in a specific and stand alone chapter. This may result in some repetition of some points, but it is necessary to summarise in a single place the decisions and the reasons so that the accountabilities and responsibilities are clearly set for the decision maker.

The reviewer should include the updated checklist as an annex to the final review report.

4.11 Acceptance and Non-Acceptance

Considering the NAA reviewer report where there is a justified advice on the safety arguments, the NAA gives their final decision and has the possibility to address four different decisions:

- Final acceptance,
- Final acceptance with safety-related conditions and/or limitations,
- No decision with a request for additional information and authorisation to pursue,
- Refusal.

As soon as the acceptance is notified to the ANSP/Organisation, it is allowed to implement the change. Some safety-related conditions and/or limitations may be added to the Report and these should be verified after the implementation of the change.

In case of a request for additional information, the safety argument must be revised and resubmitted to the safety argument reviewer for a second safety argument oversight.

In case of refusal, the reviewed change is cancelled and not implemented.

4.12 Post Acceptance / Checking of Safety-Related Conditions

During or after the implementation of the change, the NAA verifies that the safety-related conditions that can be tested only during or after the implementation of the change are met by the system.

For this purpose, the ANSP/Organisation provides the necessary data, possibly through an update of the safety argument or other related documents.

The NAA verifies the data provided and proceeds to specific verifications if necessary.

In order to verify that the defined level of safety continues to be met (post-implementation monitoring), the reviewer prepares a list of safety requirements and other safety-related conditions that cannot be verified before the implementation of the change but which have to be checked:

- by direct inspection during the latter phases of the project (post implementation safety argument), and/or
- according to safety performance monitoring, and/or
- during safety regulatory auditing.

The criteria to select one of these three options are the severity of the risk, the nature and importance of the safety-related conditions and risk mitigation and the availability of the reviewers. A new concept has probably to be followed very carefully just after its implementation with specific measures (e.g. RVSM).

As the verification of safety-related conditions could be carried out at different periods of the life of the implemented system, it is strongly recommended to keep full traceability of safety-related conditions to be taken into consideration by the NAA by recording their nature and the means used to verify their implementation.

4.13 Recording Activities

All the data and correspondence between the NAA and the ANSP/Organisation should be recorded. They concern the steps before the implementation of the change, as well as the checking made after its implementation.

The data to be recorded and archived for each change concerns, as the minimum, the following documents:

- The internal mails within the NAA,
- Results of the ANSP/organisation's preliminary safety assessment
- Remarks / comments / answers / correspondences between the ANSP / Organisation and the NAA's reviewer,
- The name and references of the ANSP/Organisation focal points,
- The notification of the change from the ANSP/Organisation (individual or through the Review Plan) associated to the preliminary safety assessment ,
- The nomination of the NAA reviewer,
- The ANSP/Organisation's Safety Plan, at least in its final version,
- The Review Plan,
- The Review Report,
- The final decision of acceptance by the NAA's Management,
- The reference of external documents that have been used in the review (e.g. reference to similar changes oversight documentation),
- The results of safety-related conditions checked during or after the implementation of the change,
- The ANSP/Organisation declaration of verification (where applicable),
- The manufacturers' declaration of conformity and suitability for use (where applicable),
- The ANSP/Organisation conformity assessment technical file (where applicable).

If the number of records associated to changes increase, it is recommended to implement a configuration management control of those records. It is recommended to use those records and eventually to draft a summary of the lessons learnt during the review actions in order to improve the learning process of the NAA.

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5. PART 4: CHECKLISTS

The assessment of safety arguments and associated procedures is the core of the review of changes and audit of changes processes. This chapter provides recommendations and a checklist for such assessments.

5.1 Objectives of the Assessment

The objective of the assessment is to verify the compliance of the ANSP/Organisation risk assessment and mitigation process and its results with the safety regulatory requirements and any arrangements needed to implement them.

As required by ESARR 1, Edition 2.0 and, where applicable, Commission Implementing Regulation (EU) No. 1034/2011, the checklist addresses the:

- verification of **established** procedures and arrangements against **required** procedures and arrangements,
- verification of **implemented** procedures and arrangements and their results (such as the safety arguments) against **established** and **required** procedures and arrangements and their expected results,
- **assessment of the ATM system** (verification that the ATM system and related elements in its final implementation meet allocated safety-related conditions as well as the safety regulatory requirements, whether or not published in specifications and standards).

The verification of established procedures and arrangements against all applicable requirements only needs to be undertaken once, with continuous compliance being verified over time through periodic audits, unless the applicable regulation or the ANSP/Organisation arrangements are being significantly modified. Therefore, this checking is more a part of the audit activity.

The initial verification/acceptance of the procedures relative to risk assessment and mitigation implies not only the verification of the established procedures but also to verify through a sample of changes the implemented procedures and their results (safety arguments) and possibly that the safety-related conditions are met.

5.2 Purpose of the Checklist

The checklist can be used in the framework of the requirements of ESARR 1, Edition 2.0 or, where applicable, Commission Implementing Regulation (EU) No. 1034/2011, related to the oversight of changes:

- for the review of a safety argument and associated procedures related to **the review of change** , before its implementation,
- for **the initial acceptance** of the ANSP/Organisation procedures when considering the processes used for the risk assessment and mitigation,
- in **auditing changes** during the corresponding continuous regulatory auditing activities.

In the first case, the checklist is to be used when considering the **specific change during the review process**; in the two last cases, when considering **a sample of changes,** usually once they have been implemented.

The safety arguments considered in the continuous regulatory auditing activities are mainly related to changes which have not been reviewed (to avoid duplication of work). However, the verification that safety-related conditions are met after the implementation of the change can be part of the audit for a sample of former **reviewed** changes.

For the validation/acceptance of the procedures, if the changes under review have not yet been formally accepted, the sample should consider **any type** of changes.

The checklist **is a tool common to the two processes** "Review of changes" and "Audit of changes" and uses the same methods, with possibly a different weighting between them and a different level of rigour in verification.

All changes do not need of course the same level of risk assessment and mitigation. In some cases, no mitigation is necessary and the process is limited to the first steps. The audit should be adapted to this situation.

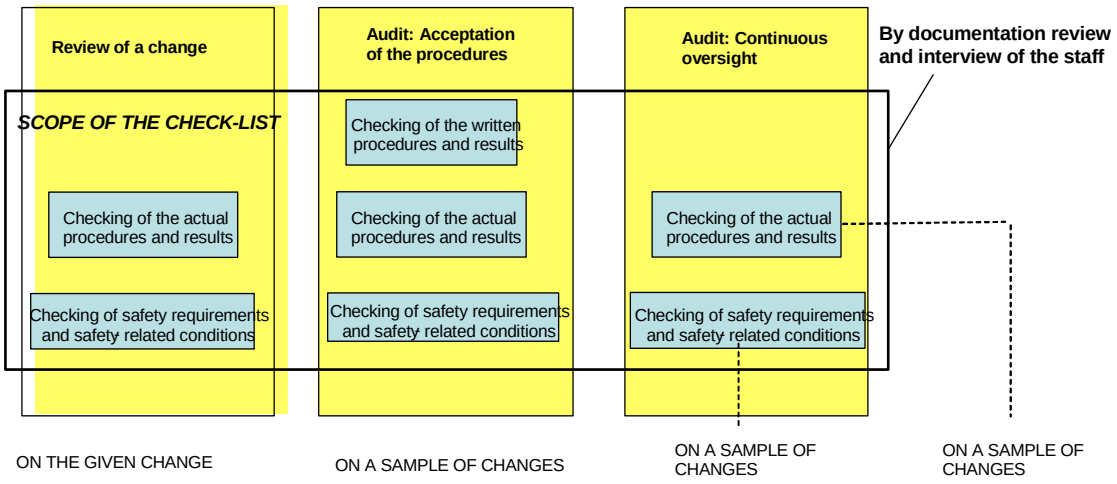
When a selection of changes should be operated, the NAA should consider the list of the new systems and changes to existing system within the managerial control of the ANSP/Organisation and selects enough changes to cover:

- different stages of their lifecycle,
- airborne and ground components,
- human, procedures and equipment,
- different ATM operational units and different types of ATM services provided by the ANSP/Organisation.

The checklist is intended to be used for any type of change.

5.3 Scope of the Checklist

The scope of the common checklist for the review and the audit of changes processes is given below.



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5.4 Structure of the Checklist

The checklist is divided in sections which correspond to the successive steps of a risk assessment and mitigation process.

The following table gives the correspondence between the assessment of the safety arguments defined by ESARR 1, Edition 2.0, the development of the safety assessment process defined in ESARR 4 and the different sections of the checklist: sections 1 to 7 correspond to seven logical steps that could be defined for safety assessment.

ESARR 1 Requirements for the NAA Safety Review	**ESARR 4 Requirements for the ANSP/Organisation Risk Assessment and Mitigation Process**
The assessment of the safety argument addresses the: • identification of hazards (Article 9e), • consistency of the allocation of severity classes (Article 9e), • validity of the safety objectives (Article 9e), • validity, effectiveness and feasibility of safety requirements and any other safety-related conditions identified (Article 9e), • demonstration that the safety objectives, safety requirements and other safety-related conditions are continuously met (Article 9e),	• General consideration (ESARR 4, §5.1) and Documenting risk assessment and mitigation processes and results (ESARR 4, §5.3), • System description (ESARR 4, §5.2 a), • Hazards and consequence identification (ESARR 4, §5.2 b (i)), • Estimation of the severity of the consequences of the hazards occurring (ESARR 4, §5.2 b (ii)), • Estimation / assessment of the likelihood of the hazards consequences occurring (ESARR 4, §5.2 b (iii) 2nd part of the item),
• demonstration that the process used meets the applicable safety regulatory requirements (Article 9e).	• Evaluation of the risk (ESARR 4, §5.2 b (iii) 1st part of the item) , • Identification of risk mitigation measures (ESARR 4, §5.2 c (i)) and safety requirements (ESARR 4, §5.2 c (ii)) and assurance of their feasibility and effectiveness (ESARR 4, §5.2 c (iii) , • Claims, arguments and evidence that the safety objectives and safety requirements have been met and will continue to be met (ESARR 4, §5.2 d).

In each section of the checklist, the process is assessed as well as its results. A specific section (Section 0) is devoted to **general considerations** relative to “the demonstration that the process used meets the applicable safety regulatory requirements”. The oversight of ESARR 4 requirements concerning the documentation is explicitly taken into account in Section 0 and implicitly in the other sections.

ESARR 1, Edition 2.0, Attachment A, Article 6 and Commission Implementing Regulation (EU) No. 1034/2011, Article 7 have to be interpreted as follows: for specific reviewed changes a part of the verifications has to be done before the implementation of the change, a part after this implementation. For the other type of change the verification is done during the audit, most of time after the implementation of the change.

The seven steps of the safety assessment could be iterated on the successive phases of the life-cycle of the systems, with a different weighting. The check-list could take into account such consideration.

For example, some new hazards could be identified during the design. The identification of safety requirements from safety objectives is a core part of the design. Only some of the safety requirements can be verified before the implementation.

5.5 Detailed Contents of Each Section

Each section contents the following items:

- Name of the section,
- Reference to the applicable regulatory requirements relative to the section (specific ESARR requirements),
- Objective of the section,
- Specific applicable safety regulatory requirements that the ANSP/Organisation should comply with for the section is indicated, (in the first place ESARR 4 requirements[1]). This should be adapted and completed for any other applicable safety regulation (ICAO SARPs, implementing rules, national regulation, etc.) as necessary,
- List of checks to be done on the documentation related to the verification of the established written procedures and expected results against the applicable safety regulatory requirements,
- List of questions to be asked to staff when checking the actual procedures and results against established written procedures and against applicable safety regulatory requirements,
- List of checks to be done on the documentation for the same purpose.

The levels of rigor 1 and 2 which have been defined for the review of the safety argument can be extended for the audit of changes. Each check has been associated with a level of rigour. Only levels 1 and 2 are indicated in the checklist. Due to the nature of the activities required by level 3, it should not have supplementary questions to the review of the change.

Specific questions can be issued during the specific studies of level 4. Getting more detail from the experts of the ANSP/organisation has been considered as a level 2 activity.

The checklist does not address the quality of the safety argument (that should be complete, clear, rational, accurate, objective, appropriate, etc.).

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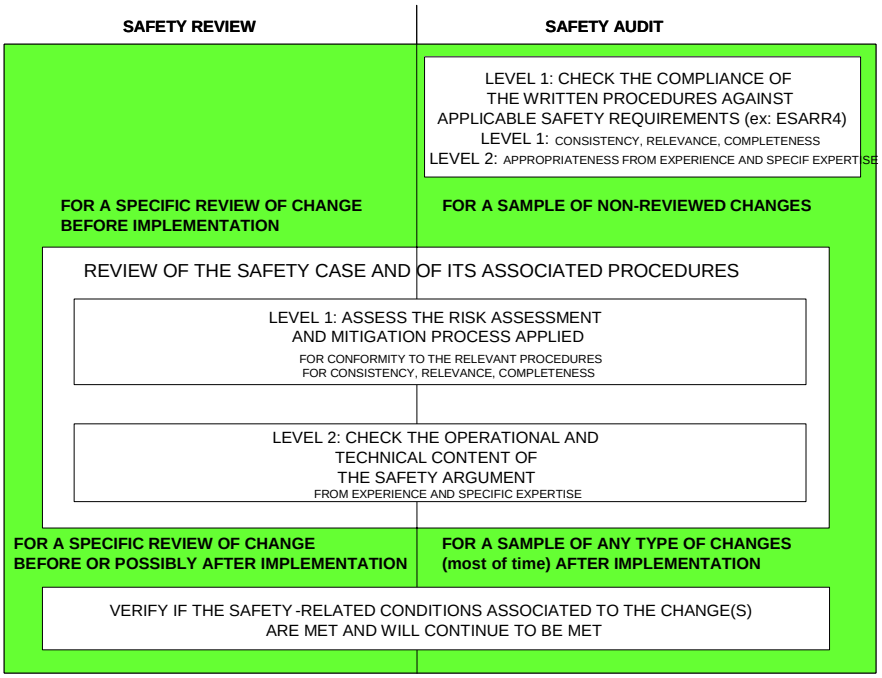
[1] *ICAO Annex 11, Sections 2.27.3, 2.27.4 provisions do not need to be mentioned as they are covered by the requirements of ESARRs 3 and 4.*



5.6 Recommendations for the Review of the Safety Arguments

The safety arguments of a change is often a complex set of documents and one may easily waste a lot of time to deal with this complexity. To prevent this waste it is recommended to identify the minimum core of the subject of the safety argument and to focus the work on it in a first stage. In a second stage the other aspects may be considered either to be dismissed if not relevant or to complement the review if useful.

In most cases findings and conclusions can be derived from previous safety arguments on similar cases or other experiences. The reviewer should take the most advantage of the existing experience to ease the assessment work. The review should focus on key elements of the safety assessment process and its usual description in the ANSP/Organisation deliverable:

- System definition and context,
- Identification of the proposed change,
- Regulatory requirements
- Safety objectives and safety directives identification
- Safety requirement issued by the implementing rules
- Risk assessment
- Validation criteria for the mitigation measures
- ANSP/Organisation conclusion of safety assessment

The examination of those topics should be done with the accuracy requested by the chosen level of rigor, taking into account the possible common pitfalls.

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System definition and context

Whatever the change is, it is always related to a defined part of the existing ATM system. The change can be the implementation of the new system itself, a change in the existing system, a change in the manner it is operated, or a change of its context (new location, change of regulation, new hazards identification, etc.). The precise and consistent definition of the system in question is fundamental for the elaboration of further steps of the safety assessments and hence for the review of the safety arguments. The reviewer should check that the scope of the change and the identification of the corresponding system are correctly done.

The description of the system and its context should, as far as practicable, be cohesive, complete and homogeneous for all parts, in order to ensure the integrity of the reasoning and to avoid discrepancies in the conclusions. For example, it is particularly recommended to avoid mixing functional descriptions and some local implementation means as the thorough safety assessment methods are not of the same nature. The reviewer should check that the description of the system is correct.

The reviewer should check that the references, reference dates and possibly version numbers of the system and context elements are clearly identified. This applies not only to the elements themselves but also to the documents produced in relation with them. In other words, the system configuration should be completely identified.

Identification of the proposed change

The description of the change should be comprehensive, complete and consistent with the system description. It should also indicate the reason(s) for the change which may imply or impose the regulatory requirements, the risks, the validation criteria and the assessment methods to be taken into account. The reviewer should as far as practicable establish that all the elements, or consequential elements of the change, within the limits of the system and according to the lifecycle phase, are adequately identified.

Regulatory requirements

The reviewer should verify that all the international, national and local regulatory requirements which are potentially applicable or impacted by the system change are clearly identified. The reviewer should identify which of these regulatory requirements are quoted and referenced by the ANSP/Organisation in the safety argument, check their correctness, identify the implication of the absence of the regulatory requirements which are not included in the safety argument, and eventually document the rejection of the regulatory requirements presented by the ANSP/Organisation which are not relevant either in absolute or in the context of the review.

Safety objectives and safety directives identification

The reviewer should verify that the safety objectives and safety directives cover the whole range of issues implied by the system change, and that they are compliant or consistent with the regulatory requirements. The review should identify separately on one hand the safety objectives and directives which are derived from the NAA, the implementing rules of the system impacted by the change and other international provisions and on the other hand the safety objectives and directives proposed by the ANSP/Organisation in the framework of its own SMS. The review should clearly state whether these latter safety objectives and directives are acceptable for the case and under which conditions if any.

Risk assessment

The review should clearly establish if all the potential hazards have been identified within the limits of the knowledge available to the reviewer[1] and their corresponding risks adequately assessed. Consequently it is necessary to document in the safety argument or in the supporting documentation how these limits have been determined.

It is also reminded that hazards can be related to the change implementation, to the entry into service procedure, and eventually to the back up procedure, if the change has to be removed after the entry into service. Consequently the time limit after which a back up is impracticable need be determined.

Validation criteria for the mitigation measures

The safety argument includes mitigation measures for the identified risks. The validity of these measures can generally be demonstrated by evidence of compliance with safety objectives and directives. This evidence is derived from argumentation and adequate demonstration. There are cases where the validation criterion can only be based on expert judgement substantiated by his technical experience or by proven efficiency and harmlessness of the measures.[2] Thus the validation criteria should be clearly stated in the safety argument, even if it is "best we can do". The mitigation measures should be submitted to the testing process of the ANSP/Organisation. The level of tests should take into consideration the severity of the change as identified in the change classification.

ANSP/Organisation Conclusion of the safety assessment

Particular attention should be paid to the review of the conclusions of the safety argument. They should list the decisions and actions submitted to the NAA. They should clearly indicate the assumptions on which they are based and the limits of the assumptions and conclusions, as regard the system itself, the regulatory requirements and their applicability. The technical documents of the ANSP/Organisation should be updated with the different declaration

5.7 Possible Pitfalls in the Safety Arguments

There are numerous examples of inappropriate safety arguments produced. The reviewer needs to be aware of the most common pitfalls at the root of these inappropriate safety arguments. This will prevent them from initiating a consuming review process which will result in a rejection of the safety argument, or help in advising the ANSP/Organisation on how to improve its safety argument before re-submitting it. The identified pitfalls are as follows:

- Too few samples to guarantee credible statistics;
- Comparison of the future situation and the current situation without demonstrating that the current situation is acceptable;
- Insufficient analysis of human factors;
- No assessment of the global consistency of the system;
- Bad identification or even no identification of the interfaces of the subsystem considered in the safety argument;

[1] *On the basis of international bibliography or expertise: international or national guidance or reference documentation, available studies on the subject, expert panel reports. A list of references should be included in the review report. If there is no reference outside the references made by the ANSP/Organisation, this should be stated.*

[2] *This often corresponds to best practices which are known effective without proper demonstration. The most prominent example lies with the 5NM radar separation to mitigate the in-flight collision risk which had been chosen by expert judgement before being far later substantiated by mathematical methods.*

- Having used accurate quantitative arguments without any sensitivity analysis to assess the impact of errors on the figures;
- Developing a safety argument to attempt to justify a decision that has already been made;
- Using a generic assessment when a site-specific assessment is needed;
- Carrying out a detailed quantified risk assessment without first considering whether any relevant good practice was applicable, or when relevant good practice exists;
- Carrying out a risk assessment using inappropriate good practice;
- Only considering the risk from one activity;
- Not involving in the assessment a team of people with practical knowledge of the process/activity being assessed;
- Ineffective use of consultants;
- Failure to identify all hazards;
- Logical errors or fallacious arguments
- Failure to fully consider all possible outcomes;
- Inappropriate use of data;
- Inappropriate definition of a representative sample of events;
- Inappropriate use of risk criteria;
- Inappropriate use of cost benefit analysis;
- Not doing anything with the results of the assessment;
- Not linking hazards with risk controls.

5.8 Detailed Checklists

0. General	**ESARR 1**: no specific reference **ESARR 3**
Objective: To gain confidence that the process used for the risk assessment meets the applicable safety regulatory requirements (general considerations). *Note: the verifications of this section are applied during the auditing process only. In this phase, all types of changes should be considered.*	

ANSP/Organisation Applicable Regulatory Requirements
ESARR 4, §5.1 *An ATM service shall ensure that hazard identification as well as risk assessment are systematically conducted for any changes to those parts of the ATM system and supporting services within its managerial control in a manner which:* - *addresses the complete life-cycle of the constituent part of the ATM system under consideration (…),* - *addresses the airborne and ground components of the ATM system, through the co-operation with responsible parties,* - *addresses the three types of ATM elements (human, procedures, equipment), the interactions between these elements and the interactions between the constituent part under consideration and the remainder of the ATM system*

ANSP/Organisation Applicable Regulatory Requirements
ESARR 4, §5.3 (documentation) *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:* - *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[1]including, as appropriate, specifications of any predictive, monitoring or survey techniques being used;* - *that all safety requirements related to the implementation of a change are traceable to the intended operations/functions.* ICAO Annex 11, §2.20.2 and §2.20.3 (coordination with AIS) ICAO Annex 11, §2.26.4 (safety assessment including consultation of users)

Level of Rigour	Written Procedures and Expected Results Checking
1, 2	Check the existence of documented procedure(s) in place for hazards identification and risk assessment and mitigation relatively to reviewed changes and other changes.
1, 2	Check that the procedure(s) relative to non-reviewed changes include(s) a step to notify the NAA of any type of changes to be implemented.
1, 2	Check that the procedure(s) describe(s) which part of the classification of changes is delegated to the ANSP/Organisation if any.
1, 2	Check that the process described in the procedure(s) applies to any changes to those parts of the ATM system and supporting services within the managerial control of the ANSP/Organisation.
1, 2	Check that the process described in the procedure(s) address(es) the complete life-cycle of the constituent part of the ATM system under consideration, from initial planning to decommissioning.
1, 2	Check that the process described in the procedure(s) address(es) the airborne, spatial and ground components of the ATM system concerned by the change. Check that the process includes steps for cooperation with responsible parties wherever a change concerns components (airborne and/or ground) of the ATM system outside the managerial control of the ANSP/Organisation.
1, 2	Check the existence of co-operation arrangements agreed with relevant responsible parties as regards changes concerning components (airborne and/or ground) of the ATM system outside the managerial control of the ANSP/Organisation.
1, 2	In particular, check the coordination arrangements with AIS according to ICAO Annex 11, §2.20.2 and §2.20.3.
1, 2	Check that the process described in the procedure(s) address(es) the: o Human; o Procedures; and o Equipment, which are related to the change.
1, 2	Check that the process described in the procedure(s) address(es) the interactions as described in ESARR 4 §5.1 c

[1] *i.e. meeting allocated safety objectives and requirements.*

Level of Rigour	Written Procedures and Expected Results Checking
1, 2	Check that the procedure(s) include(s) specific requirements defined by/with the NAA relative to the risk assessment and mitigation process and to the Safety argument such as: o a step of internal verification, o a defined Safety Argument structure (with a configuration control page, an executive summary, etc.), o the use of a diagrammatic representation for the Safety Argument (ex: GSN: Goal Structured Notation)
1, 2	Check that the procedure(s) establish(es) the means to collate and document the results, associated rationales and evidence from the: o Determination of scope, boundaries and interfaces required in ESARR 4, §5.2 a), o Identification of hazards required in ESARR 4, §5.2 a) i), o Determination of severities required in ESARR 4, §5.2 a) ii), o Determination of hazards tolerability required in ESARR 4, §5.2 a) iii), o Derivation of a risk mitigation strategy as required in ESARR 4, §5.2 c), o Verification that all identified safety objectives and safety requirements have been met as required in ESARR 4, §5.2 d. Check that an appropriate set of risk assessment and mitigation documentation is defined in the procedure(s).
1, 2	Check that the procedure(s) establish the means to articulate the results, associated rationales and evidences into a safety argument for each change considered.
2	Check that the procedure(s) establish the means to keep traceability of all safety requirements and other safety-related conditions to the intended operations/functions. Notably when: o The safety requirements are defined as a result of ESARR 4, §5.2 c) ii), o Assurance is provided to show that safety requirements and other safety-related conditions in the context of ESARR 4, §5.2 d).
1, 2	Check that the process plans a consultation of the users when appropriate.
2	Check if the ANSP/Organisation has sufficient and appropriate resources to conduct the risk assessment of changes.
2	Check that the ANSP/Organisation has defined an organisation and allocated responsibilities regarding the risk assessment of changes.
2	Check that the ANSP/Organisation risk assessment and mitigation procedures and associated guidance have been disseminated to its concerned staff.
2	Check that the ANSP/Organisation has provided the sufficient training concerning these procedures.
2	Check that the ANSP/Organisation has verified that the procedures and other documentation are known and applied by the concerned staff.
2	Check that the ANSP/Organisation has developed a learning process concerning the risk assessment of changes.
2	Check that the ANSP/Organisation learning process concerning the risk assessment of changes is really implemented.
2	Check that the improvements defined are brought into play.

Level of Rigour	Written Procedures and Expected Results Checking	
2	Check that any modifications to the applicable national safety regulations are timely reflected in the ANSP/Organisation documented procedures.	
2	Check that the risk assessment of changes process is part of the ANSP/Organisation Safety Management system.	
2	Check that the ANSP/Organisation risk assessment and mitigation process is internally audited.	
2	Check that the ANSP/Organisation procedures are modified according to the experience gained.	
	Actual Procedures and Results Checking	
	Interview Questions	**Judgement Call guidance**
2	What are the changes that you have considered in the last x months? How many audited changes?	Confirm that all changes are considered including all types of changes
2	Show me that you have applied or are applying a risk assessment and mitigation procedure on these changes (existence of a safety argument)	Confirm that a risk assessment and mitigation process has been applied on these changes
	List of Changes - Safety Argument and Associated Documentation	
1, 2	Considering the list of changes that have been addressed, check if all types of changes have been addressed: o Changes submitted to reviews or to audits, o changes concerning: o airborne and ground components, o human, procedures and equipment, o different ATM operational units and different types of ATM services provided by the ANSP/Organisation	
2	From your knowledge of the system, and considering the list of changes that have been addressed, check if all changes have been recorded.	
1, 2	Considering a sample of changes, verify that a risk assessment and mitigation process has been applied for these changes.	
1, 2	Verify on a sample of audited changes that the NAA has been notified of their implementation.	
2	Check on a sample of audited change, that the classification is justified (if this classification is delegated to the ANSP/Organisation for all or parts of the changes)	
1, 2	Check on a sample of reviewed changes that they have all been accepted before their implementation.	
1, 2	Check that a data base of audited changes is maintained if the procedure plans to do so.	

Level of rigour	Actual Procedures and Results Checking
	The following items should be verified on the given change (review process) or on a sample of changes (audit process) during each step of the safety risk assessment and mitigation process if deemed convenient. They are presented here to ease the presentation
1, 2	Check that all the life-cycles phases were addressed, or are planned to be addressed.
1, 2	Check that the Safety Argument shows evidence of appropriate cooperation with parties responsible for developing and/or implementing the safety requirements and other safety-related conditions bearing on the constituent part under consideration or on other parts of the ATM system or the environment of operations. Ex: letter of agreement with aircraft manufacturer, airport operator, MET, AIS…
2	Check that the consistency of the safety argument with the other safety arguments is assured and in particular when a Unit safety argument exists. Ex: Assess the consistency of the change documentation with the existing hazard classifications, operational description, existing mitigations and local Safety Management processes
1, 2	Check: o The assessment of the impact on airborne of spatial component is performed , o It has been identified whether the change concerns components (airborne, spatial and/or ground) of the ATM system outside the managerial control of the ANSP/Organisation , o The components concerned are identified, o The parties responsible for these components are identified, o Co-operation has taken place or is planned. o Wherever cooperation was completed, results from that cooperation can be shown in terms of appropriate measures related to the implementation of the change by all the parties involved and AIS (notifying required to equipage or to given airspace block).
1, 2	Check: o Human, procedure and equipment elements are considered if they are concerned, o Interactions between them are identified and subsequently addressed according to the procedures, o Interactions between the part under consideration and the remainder of the ATM system are identified and subsequently addressed according to the procedures.
2	When a change requires publication of AIS material (including changes that effect charts and computer-based navigation systems), check that: o Coordination between ANSP/Organisation and AIS took place following the agreed arrangements, o Actions were conducted to allow the preparation, production and issue of relevant material by AIS, o The interval between the communication to AIS and the introduction of the change observed the agreed effective dates in addition to 14 days. o No change was introduced before relevant AIS information was published Cross check the records provided by the ANSP/Organisation with those kept by AIS.

Level of rigour	Actual Procedures and Results Checking
	The following items should be verified for each safety argument. They are presented here to ease the presentation.
1, 2	Check if the safety argument has been verified before its sending to the NAA if this action is planned in the procedure.
1, 2	Check if the safety argument has been accepted by the ANSP/Organisation management if this action is planned in the procedure.
1, 2	Check if the safety argument contains the sections defined in the procedure.
1, 2	Check if the safety argument provides a log with the different versions of the document (including those produced avec the implementation of the change) with an identification of what has changed at each up-issue.

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1. System Description	**ESARR 1**: no specific ref.
Objective: To gain confidence that the safety assessment process has been carried out considering the full extent of the system concerned, its environment and its interaction with other systems: the system description is complete and correct.	

ANSP/Organisation Applicable Regulatory Requirements
ESARR 4, §5.3 (documentation) ESARR 4, §5.2 a): *The hazard identification, risk assessment and mitigation processes shall include a. 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.*

Level of Rigour	**Written Procedures and Expected Results Checking**	
1, 2	Check that the procedures(s) define(s) actions to provide guidance and how to determine: o The scope, o Boundaries, and o Interfaces of the constituent part being considered, as well as the: o functions that the constituent part is to perform, o Environment of operations in which it is intended to operate.	
1, 2	Check that the procedure(s) include(s) appropriate cooperation with parties responsible for developing/implementation of safety requirements and other safety-related conditions.	
1, 2	Check that the procedures(s) define(s) means to collate the results from these actions.	
2	From your experience, verify that the procedure(s) is/are appropriate.	
	Actual Procedures and Results Checking	
	Interview Questions	**Judgement Call guidance**
2	Show me the documentation that describes the system/concept/procedure.	Confirm documentation exists.
2	Describe the system/concept/procedure.	Assess whether the interviewee understands the system.
2	Describe the environment in which this system is installed.	Assess whether the interviewee understands the environment.
2	Describe the interfaces this system etc has with other systems.	Assess whether the interviewee understands the interfaces.
	Safety Argument and associated documentation Checks	
1, 2	Confirm that the System description process has been carried out in accordance with the relevant procedure.	

Level of rigour	Actual Procedures and Results Checking
1, 2	Assess whether the 'System Description" documentation contains all the sections you would expect to see and with sufficient details, allowing you to understand the functions of the system and how they interact internally and externally, e.g. o overview, o scope, boundaries, interfaces, functions, environment of operations for the constituent part under consideration, o reference to applicable regulatory requirements, o coordination with other parties (The functions of interest are the safety-related functions necessary for the planned operation)
2	Assess any diagrams or figures used. Are they complete, appropriate, clear? (To further aid in understanding the system a configuration diagram showing the main functional elements should have been included in the System description)
2	Read the system description text. Does it make sense? Is it complete? Is it precise? Is it clear? Is it appropriate? Does is contain sufficient detail?
2	Check if the description of the environment matches expectations.
2	Check if all the expected interfaces to other systems have been described.
2	Check that the Safety Argument shows evidence of appropriate cooperation with parties responsible for developing/implementing the safety regulatory requirements bearing on the constituent part under consideration or on other parts of the ATM system or the environment of operations.
1, 2	Check if the references, reference dates and possibly version numbers of the system and context elements, including corresponding documentation are clearly identified.
2	Where a system already exists, is part built or delivered, inspect it against the documented system description: o Can you see all of the system components described? o Are there any extra components not shown in the documentation? o Is the environment for the system as described? o Are the interfaces as described?
1, 2	Check if the description of the change is comprehensive, complete and consistent with the system description, in particular as regard the phase of the system lifecycle.
1, 2	Check if the reason(s) for the change is/are indicated.
1, 2	Check if the applicable regulatory requirements are identified.
2	Check if all the identified applicable safety regulatory requirements are relevant for the change. Check if any relevant safety regulatory requirement is missing.
1, 2	Check if the system description remains complete and correct whatever are the modifications which have been introduced during the successive phases of the system life-cycle (ex: identification of new hazards)

2. Completeness and correctness of the list of hazards and of their effects	**ESARR 1**: Article 9 (e), (i)
Objective: To gain confidence that a rigorous hazards identification process has been carried out on the system and that the range of consequences of the hazards have been identified and documented: all hazards and hazards effects have been identified completely and correctly.	

ANSP/Organisation Applicable Regulatory Requirements
ESARR 4, §5.3 (documentation) ESARR 4, §5.2 b) (i): hazard and consequence identification *The hazard identification, risk assessment and mitigation processes shall include a determination of the safety objectives to be placed on the constituent part incorporating an identification of ATM-related credible hazards and failure conditions, together with their combined effects.*

Level of rigour	**Written Procedures and Expected Results Checking**	
1, 2	Check that the procedure defines a systematic process to identify ATM related credible hazards and failure conditions (ex: functional hazards, brainstorming, databases, other risk assessments, trials, simulation, operational data…)	
1, 2	Check that the procedure(s) define(s) a systematic process to assess the effects of hazards and failure conditions on operations including: o Effects on the ability to provide or maintain safe services, o Effects on the performance of the ATM system, o Effects on the functional capabilities of the airborne and ground parts of the ATM system, o Effects on ATCO and/or aircrew, o Effects on the environmental mitigation means (which are not part of the constituent under consideration).	
1, 2	Check that the procedure(s) define(s) means to collate the results.	
1, 2	Check that the procedure(s) define(s) the update of the hazard log if the list of hazards or failure conditions must be modified (for example, if new hazards are identified during the phases which follow the definition phase of the system).	
1, 2	Check criteria exist to define people qualified to contribute to the identification of hazards or failure conditions and of their effects.	
2	From your experience, verify that the procedure(s) is/are appropriate.	
	Actual Procedures and Results Checking	
	Interview Questions	**Judgement Call guidance**
2	Show me records of your hazards identification process?	Confirm that the documentation exists.
2	Who were the people involved in the process and why were they chosen?	Judge whether the people chosen have the necessary experience and competence to do this well.
2	Which method or methods did you use for hazards identification and why do you think they were appropriate?	Judge whether the hazards identification processes were appropriate for the system concerned.

Level of Rigour	Written Procedures and Expected Results Checking	
2	What gives you confidence that you have addressed all the hazards with the system?	
	Safety Argument and associated documentation	
1, 2	Confirm that the Hazards Identification process was carried out in accordance with the relevant procedure (ex: all types of effects have been considered; new hazards identified during post-definition phases have been integrated).	
1, 2	Check that the Safety Argument identifies ATM related credible hazards, failure conditions and their combined effects.	
1,2	Check if the hazards identified are traceable to the functions of the subject system (for functional hazards).	
2	Check if hazards are identified at a same level. For example: During the Functional Hazard Assessment (conducted early during the development of a system), all relevant hazards are identified at the boundary of the system.)	
1, 2	Check that the operationally non credible hazards are listed to allow further analysis in case of change of the environment (or in case of actual occurrence).	
1, 2	Check that the hazards are independent.	
1, 2	Check that a clear and complete description of the effects (ex: what ATCO and/or aircrew have to do or cannot do anymore) is provided. (Any reviewer that did not take part to the assessment will be able to objectively understand and support the severity assignment in the next step)	
2	Check if all interactions with the operational environment are accounted for (hazards affecting a service may have an adverse effect on external services).	
1, 2	Check that the operationally non credible effects of hazards are listed to allow further analysis in case of change of the environment (or in case of actual occurrence).	
2	Check that the hazards log has been updated if the list of hazards or failure conditions was modified during the process and these hazards completely integrated in the process (for example, if new hazards are identified during the phases which follow the definition phase of the system).	
2	Check specifically if the identification of hazards is conducted before risks are assessed.	
2	Check the Safety Argument contains proof that people were qualified to contribute to the identification of hazards or failure conditions and in particular verified the criteria which have been defined. (ex: controllers validated and with appropriate ratings for the type of operation which is considered: approach, aerodrome, en route ; pilot flying in this airspace)	
2	Assess whether the obvious hazards (that you are aware of through experience or previous assessments of similar work) have been identified.	
2	For a small randomly selected set of hazards, trace them through the documentation to their consequences. Some may have a range of consequences and this needs to be reflected in the documentation.	
2	Assess from the documentation whether you believe that sufficient effort has been expended identifying and documenting the hazards.	

3. Consistency of the Allocation of Severity Classes	**ESARR 1**: Article 9 (e), (i)
Objective: To gain confidence that the severity of the hazards consequences identified has been assigned completely, correctly and with a clear statement.	

ANSP/Organisation Applicable Regulatory Requirements
ESARR 4, §5.3 (documentation)
ESARR 4, §5.2 b) (ii): Estimation of the severity of the consequences of the hazard occurring
The hazard identification, risk assessment and mitigation processes shall include a determination of the safety objectives to be placed on the constituent part incorporating 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.

Level of Rigour	**Written Procedures and Expected Results Checking**	
1, 2	Check that the procedure(s) define(s) a systematic process to address all hazards identified.	
1, 2	Check that the procedure(s) define(s) a systematic process to assign a severity to each effect identified.	
1, 2	Check that the procedure(s) define(s) a systematic process to use a Severity Classification Scheme when assigning the severity	
1,2	Check the documentation for a Severity Classification Scheme (this may be in the form of a severity table or a list of different severity levels).	
2	From your experience and other similar safety arguments, assess whether the Severity Classification Scheme which has been defined looks reasonable (if different from ESARR 4).	
1, 2	Check that the procedure(s) define(s) means to collate the results.	
1, 2	Check criteria exist to define people qualified to contribute to the severity assessment	
2	Check the rationale described or the procedure used to qualify the “probable effect under the worst case scenario” to assess if statistically sound.	
2	From your experience, verify that the procedures are appropriate	
	Actual Procedures and Results Checking	
	Interview Questions	**Judgement Call guidance**
2	Show me the severity scheme (or severity categories) you used to classify the severity of the consequences?	Compare this to the one in Fig A-1 ESARR 4 Appendix A. Is it similar? If different, what is the rationale for using a different one; is it consistent with ESARR 4; is the rationale clear, sound and documented?
2	Show me how you recorded the severity for each consequence?	

Level of rigour	Actual Procedures and Results Checking	
2	Who was involved in the severity assessment and why where they chosen?	Judge whether these people had the necessary experience and competence to do this well
	Safety Argument and associated documentation	
1, 2	Check that the Severity Classification process was carried out in accordance with the relevant procedure (including for hazards detected after the definition phase).	
2	Check the Safety Argument contains proof that people were qualified to contribute to the severity assessment.	
1, 2	Check that all hazards identified have been considered.	
2	Check that all potential effects on operations have been considered.	
1, 2	Confirm that the Severity Scheme used is the same as any Severity Classification Scheme documented in the Safety Management System of the organisation.	
1, 2	Check that at least for a sample of hazards that a severity level of their effects has been allocated consistently with the Severity Classification Scheme and recorded.	
1, 2	Check that a rationale for the severity assignment is stated and recorded for this sample of hazards.	
2	From your experience, check that the rationale is acceptable.	

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4. Validity of the Safety Objectives **a) Estimation/Assessment of the Likelihood of the Hazard Consequences Occurring**	**ESARR 1, EDITION 2.0**: Article 9 (e), (i)
Objective: To gain confidence that the likelihood of hazards consequences identified have been correctly estimated	

ANSP/Organisation Applicable Regulatory Requirements
ESARR 4, §5.3 (documentation) ESARR 4, §5.2 b) (iii) last part of the item: estimation/assessment of the likelihood of the hazard consequences occurring *The hazard identification, risk assessment and mitigation processes shall include:* - *[a determination of the safety objectives to be placed on the constituent part, incorporating 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.* *Note: The term "probability" has to be understood as "rate" or "frequency".*

Level of Rigour	**Written Procedures and Expected Results Checking**	
1, 2	Check that the procedure defines a systematic process to assign a probability (rate, frequency) to each effect identified	
1, 2	Check that the procedure defines a systematic process to use the likelihood (or probability) classification scheme when assigning the probability (rate, frequency).	
1, 2	Check the documentation for a likelihood or probability classification scheme.	
2	From your experience and other similar safety arguments, assess whether the Likelihood Classification Scheme which has been defined looks reasonable.	
1, 2	Check criteria exist to define people qualified to contribute to the likelihood assessment.	
2	From your experience, verify that the procedure is appropriate.	
	Actual Procedures and Results Checking	
	Interview Questions	**Judgement Call guidance**
2	Show me the likelihood (or probability) classification scheme you used.	
2	Show me how you recorded each likelihood for each hazard – consequence sequence.	
2	Who was involved in assessing the likelihood and why were they chosen?	Judge whether these people had the necessary experience and competence to do this well.
2	What methods did you use to assess the likelihood?	

Level of rigour	Actual Procedures and Results Checking
	Safety Argument and associated documentation
1, 2	Check that the likelihood assignation process was carried out in accordance with the relevant procedure (including for hazards identified after the definition phase).
2	Check the Safety Argument contains proof that people were qualified to contribute to the likelihood assessment.
1, 2	Check that all hazards and all their effects identified have been considered and a probability assigned to each effect.
1, 2	Confirm that the Likelihood or Probability Classification scheme used is the same as any Likelihood or Probability Classification scheme documented in the Safety Management System of the organisation.
2	Choose a sample of hazards consequences and trace them through to their likelihood classification. From your experience, do the classifications look reasonable?
2	Check for evidence of fault tree, event trees, reliability analysis or any other techniques that help establish the likelihood of hazards consequence occurring.
2	Where event or fault trees have been used, check through a sample of the trees and ensure that the events/fault and/or any assumptions are credible and that the associated probabilities (rates) are reasonable.

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5. Validity of the Safety Objectives **b) Estimation of the Risks**	**ESARR 1**: Article 9, 1 (a) (b) and (e) (ii) ,(iii)
Objective: To gain confidence in the classification of the tolerability of the risks identified.	

ANSP/Organisation Applicable Regulatory Requirements
ESARR 4, §5.3 (documentation) ESARR 4, §5.2 b (iii) first part of the item: evaluation of the risks *The hazard identification, risk assessment and mitigation processes shall include:- a determination of the safety objectives to be placed on the constituent part, incorporating 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.* *Note: The term "probability" has to be understood as "rate" or "frequency".*

Level of Rigour	**Written Procedures and Expected Results Checking**
	Note: A Risk Classification Scheme (RCS) sets the maximum acceptable rate of occurrence of hazards effect (Safety Target) for a corresponding severity class of the hazards effect. *The ANSP/Organisation RCS should be derived from the NAA RCS taking into account the contribution of the ANSP/Organisation to overall national ATM risk and an ambition factor (or safety margin factor) which represents the ratio between regulatory minimum and what the ANSP/Organisation accepts to face as a risk* *A Safety Objective Classification Scheme (SOCS) specifies the maximum acceptable frequency of occurrence of a hazard per reference unit (flight hour, operational hour, per sector, etc.) taking into account the severity of the worst credible hazard effect (amongst all hazard effects).* *A Safety Objective Classification Scheme can be defined either at ANS/ATM Organisation level or at Programme or Functional level. Consequently, an ANSP/Organisation can have many SOCS. Each SOCS is defined for the purpose of a specific (sub-) system under safety assessment and is applicable only for this specific (sub-)system.* *Safety Objectives (qualitative or quantitative statements that define the maximum frequency at which a hazard can be accepted to occur) should be derived from the Safety Targets set in the ANSP/Organisation RCS. The combination of Safety Objectives and mitigation means (external to the system under assessment) should satisfy the Safety Target per severity class.*
1, 2	Check that a Risk Classification Scheme (RCS) (ex: tolerability matrix) has been defined and is documented.
1, 2	Check that the RCS is consistent with the NAA RCS.
2	From your experience, check that the ANSP/Organisation RCS reflects the contribution of the ANSP/Organisation to overall national ATM risk and looks reasonable.
1, 2	Check that the procedure(s) define(s) a systematic process which derives the Safety Objectives Classification Scheme from the ANSP/Organisation Risk Classification Scheme.
2	Check the Safety Argument contains proof that people were qualified to contribute in setting the tolerability criteria.
2	Check if the SOCSs are consistent with the ANSP/Organisation RCS.

Level of Rigour	Written Procedures and Expected Results Checking	
2	From your experience, check if the SOCSs look reasonable.	
1, 2	Check that the procedures(s) define(s) a systematic process which: o Addresses all the hazards identified, o Obtains safety objectives expressing the tolerability of the hazards in terms of maximum rate of occurrence, o Derives the hazard's tolerability from the severity of the effect of the hazard and the maximum rate of the occurrence of the hazard, o Derives the hazard's tolerability by using a Risk Classification Scheme or Safety Objective Scheme consistent with ESARR 4 Appendix A (when checking these points, consider the provisions mentioned on this table regarding ESARR 4 Appendix A).	
1, 2	Check that the procedure(s) define(s) means to collate the results.	
1, 2	Check criteria exist to define people qualified to contribute to the tolerability assessment.	
2	From your experience, verify if the procedure(s) is/are appropriate.	
	Actual Procedures and Results Checking	
	Interview Questions	**Judgement Call guidance**
2	Show me your Safety Objective Classification Scheme on what basis you measured the acceptability of any risk	NB: A specific SOCS can have been generated on the occasion of the change or not.
2	How did you generate the Safety Objective Classification Scheme?	
2	Who was involved in setting the tolerability criteria of your Safety Objective Classification Scheme and why were they chosen?	
	Safety Argument and associated documentation	
1, 2	Check that the evaluation of the tolerability of risk process was carried out according to the relevant procedure (including for the hazards or changes to their consequences detected after the definition phase).	
2	Check the Safety Argument contains proof that people were qualified to contribute in setting the classification of the risks.	
1, 2	Confirm that the ANSP/Organisation Risk Classification Scheme used is the same that the Risk Classification Scheme documented in the Safety Management System of the organisation.	
1, 2	(if a specific SOCS has not been defined at the occasion of the change) Confirm that the Safety Objective Classification Scheme used is the same that the Safety Objective Classification Scheme documented in the Safety Management System of the organisation.	
2	If a specific SOCS has been defined at the occasion of the change, check if the SOCS is consistent with the organisation RCS and has been made by qualified people and consistently with the relevant procedure.	
2	For at least a selected sample of hazard, check to see whether the SOCS has been used to assess the hazard's tolerability.	

Level of Rigour	Actual Procedures and Results Checking
2	Check that the safety related assumptions (system, environmental, regulatory requirements assumptions) used to derive the safety objectives are credible, appropriately justified and documented.
2	Check that distribution of risk among safety objectives is justified. For example: In some cases the ANSP/Organisation can assume to allocate the same weight to each hazard leading to one particular effect.
2	Check that the probability that the hazard generates an effect is justified. For example: In some cases the ANSP/Organisation can assume to allocate a probability that the hazards generate an effect is equal to 1 to remain conservative.
1, 2	Check to ensure that for a sample of effects found to be unacceptable, that these have been recorded and addressed in the next step.
1, 2	Check that the output of these actions is a set of safety objectives traceable to identified hazards and expressing the tolerability of hazards in terms of maximum acceptable rate of occurrence.

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6. Validity, effectiveness and feasibility of safety requirements and any other safety-related conditions identified	**ESARR 1**: Article 9, (e) (iv) (v)
Objective: To gain confidence that reasonable risk mitigation measures have been identified where necessary and that associated appropriate safety-related conditions have been generated.	

ANSP/Organisation Applicable Regulatory Requirements
ESARR 4, §5.3 (documentation) ESARR 4, §5.2 c (i),(ii) (iii) : *The hazard identification, risk assessment and mitigation processes shall include the derivation, as appropriate, of a risk mitigation strategy which:* • *specifies the mitigation measures to be implemented to protect against the risk bearing hazards,* • *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.* • *presents an assurance of its feasibility and effectiveness.*

Level of rigour	**Written Procedures and Expected Results Checking**
1, 2	Check that the procedures(s) define(s) a systematic process to produce a risk mitigation strategy which: o Addresses all the safety objectives; o Specifies the mitigation measures (defences) to be implemented, and Check that these mitigation measures are intended to meet the safety objectives obtained from the application of ESARR 4, §5.2 b) and, consequently, reduce and/or eliminate the risks induced by the identified hazards.
1, 2	Check that the procedures(s) define(s) actions forming a systematic process which: o Addresses the safety objectives as necessary; o Includes the development, as necessary, of safety requirements; o Includes appropriate cooperation with parties responsible for developing / implementing safety requirements and other safety-related conditions. Check that these safety-related conditions bear, as necessary, on: o The constituent part under consideration; o Other parts of the ATM system; o The environment of operations.
1, 2	Check that the procedures(s) define(s) a systematic process to produce a risk mitigation strategy which includes assurances of its feasibility and effectiveness, by showing that it is: o Comprehensive (addressing both potential causes and potential consequences of identified hazards), o Able to reduce the risk to a tolerable level in an environment assumed, o Testable when implemented, o Feasible.

Level of rigour	Written Procedures and Expected Results Checking	
1, 2	Check that the procedures(s) define(s) means to collate the results.	
1, 2	Check that the procedure(s) allocate responsibilities with regard to the implementation of safety requirements and other safety-related conditions.	
1, 2	Check the Safety Argument contains proof that people were qualified to contribute to the definition of safety requirements and other safety-related conditions.	
2	From your experience, verify if the procedure(s) is(are) appropriate.	
	Actual Procedures and Results Checking	
	Interview Questions	**Judgement Call guidance**
2	Show me where you have recorded the safety requirements and other safety-related conditions for the system.	
2	Who was involved in deriving the safety requirements and other safety-related conditions and why were they chosen?	
2	(Choose a safety requirement that introduces a mitigation measure) Show me how you have assessed the impact of this measure on the safety of the system.	
2	(Choose a safety requirement) Show me how this safety requirement traces back to an identified hazard.	
	Safety Argument and associated documentation	
1, 2	Check that the identification, feasibility and effectiveness checking of Risk mitigation and safety-related conditions were carried out according to the relevant procedure.	
2	Check the Safety Argument contains proof that people were qualified to contribute to the risk mitigation process.	
1, 2	Check that mitigation measures were defined and recorded.	
2	Check that the mitigation measures are traceable to the safety objectives and consequently to the identified hazards.	
1, 2	Check that the safety requirements and other safety-related conditions for the system have been defined as necessary and recorded.	
2	Review the range of safety safety-related conditions. From your experience of similar systems, assess whether the range of the safety-related conditions are typical for a system of this type.	
2	For a sample of the safety-related conditions, attempt to trace back how they were derived. Assess whether there is a logical progression from hazard to safety requirement.	
2	Check that the safety requirements and other safety-related conditions are traceable to the intended operations/functions.	

Level of rigour	Actual Procedures and Results Checking
2	Check that : o All Safety Objectives are apportioned into Safety Requirements, o All Safety Requirements have been identified for all system elements, o Any additional Safety Requirements to meet regulations or standards are identified, o All assumptions are listed, o The Safety Requirements apportionment is credible, o The Safety Requirements are unambiguous, o Safety Requirements are quantified, when possible, o Assurance Level of requirement satisfaction demonstration is allocated to the system element.
2	For a safety requirement concerning a system mitigation (such as the provision of additional equipment or procedures), assess whether the impact of the proposed mitigation on the overall system has been assessed and recorded.
1, 2	Check that for each change the development of safety-related conditions was addressed as necessary in cooperation with parties responsible.
2	Check that the ANSP/Organisation produced a risk mitigation strategy which includes assurances of its feasibility and effectiveness, based on an analysis and detailed arguments, at the appropriate level
2	Check that risk mitigation strategy is: o Comprehensive (addressing both potential causes and potential consequences of identified hazards), o Able to reduce the risk to an acceptable level in an environment assumed, o Testable when implemented, o Credible (this can be proven, for example, by stakeholder endorsement of the process and conclusions).
1, 2	Check that assurances of feasibility and effectiveness cover all identified hazards.
1, 2	Check that the validation criteria have been defined for each mitigation measure (even if it is only “best practises”).
1, 2	Check that the Safety Argument allocates responsibilities with regard to the implementation of safety-related conditions and to the verification that safety-related conditions are met.

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7. Demonstration that the safety objectives, safety requirements and other safety-related conditions are met and will continue to be met	**ESARR 1**: Article 9, (e) (v) (vi)
Objective: To gain confidence that the safety objectives, safety requirements and other safety-related conditions are met and will continue to be met.	

ANSP/Organisation Applicable Regulatory Requirements
ESARR 4, §5.3 (documentation) ESARR 4, §5.2 d)*:* Claims, arguments and evidence that the safety-related conditions have been met and will continue to be met. *The hazard identification, risk assessment and mitigation processes shall include:* • *verification that all identified safety objectives and safety requirements have been met:* o *prior to its implementation of the change,* o *during any transition phase into operational service,* o *during its operational life, and* o *during any transition phase till decommissioning.* *ICAO Annex 11, §2.26.4 (consultation of users)* *ICAO Annex 11, §2.20.2 and §2.20.3 (coordination with AIS)*

Level of Rigour	**Written Procedures and Expected Results Checking**
1, 2	Check that the procedures(s) define(s) a systematic process to take appropriate measures, prior to the implementation of the change, to provide assurance that: o Assumptions on which the safety objectives or safety requirements were founded are satisfied, o Safety objectives are satisfied, o Safety requirements are satisfied as planned, o New hazards or effects of hazards detected during this phase (for example during the system design) are properly integrated in the risk assessment and mitigation process.
1, 2	Check that the procedures(s) define(s) a systematic process to take appropriate measures, during any transition phase into operational service (such as implementation, integration), to provide assurance that: o Assumptions on which the safety objectives or safety requirements were founded are satisfied, o Safety objectives are satisfied, o Safety requirements are satisfied as planned, o Hazards specific to transition are identified, o Specific back up plans exist, o New hazards or effects of hazards detected during this phase are properly integrated in the risk assessment and mitigation process (update of the safety argument, reiteration of the design). Such new hazards can be relative to any phase of the life-cycle of the system.

Level of Rigour	Written Procedures and Expected Results Checking	
1, 2	Check that the procedures(s) define(s) a systematic process to take appropriate measures during operational life, including safety monitoring, to provide assurance that: o Assumptions on which the safety objectives or safety requirements were founded are satisfied, o Safety objectives are satisfied, o Safety requirements are satisfied as planned, o New hazards or effects of hazards detected during this phase are properly integrated in the risk assessment and mitigation process.	
2	Check that these measures form a "post implementation" monitoring of assumptions and safety performance and follow-up incidents in order to verify compliance to safety-related conditions.	
	Check that the procedures(s) define(s) a systematic process to take appropriate measures, during any transition till decommissioning, to provide assurance that: o Assumptions on which the safety objectives or safety requirements were founded are satisfied, o Safety objectives are satisfied, o Safety requirements are satisfied as planned, o New hazards or effects of hazards detected during this phase are properly integrated in the risk assessment and mitigation process.	
1, 2	Check that in each case the procedure(s) plan(s) to consider the safety requirements and other safety-related conditions which are identified in the hazard analysis process and those applicable from regulatory material and other standards.	
1, 2	Check that the procedures(s) define(s) means to collate the results.	
1, 2	Check the Safety Argument contains proof that people were qualified to contribute to the demonstration that the safety objectives, safety requirements and other safety-related conditions are met and continue to be met.	
2	From your experience, verify if the procedure(s) is(are) appropriate.	
	Actual Procedures and Results Checking	
	Note: this checking should be done for reviewed changes in two steps: o *before the implementation of the change,* o *during of after this implementation, for each phase of the life-cycle considered.* *For audited changes, the checking should verify that the safety-related conditions have been met in due time (according to the system life-cycle and the nature of the conditions), as described in the safety argument.*	
	Interview Questions	**Judgement Call guidance**
2	(Before the implementation of the change) Are you confident that the safety argument is sound and that the system can be safely put into service? If confident, please explain why?	

Level of Rigour	Actual Procedures and Results Checking
	Safety Argument and associated / referenced documentation
1, 2	Review the conclusions of the Safety Argument. Check if they list the decisions and actions submitted to the NAA and indicate clearly the assumptions on which they are based and the limits of the assumptions and conclusions, as regard the system itself, the regulatory requirements and their applicability.
1, 2	Check that the evidence shows that at the end of the pre-implementation phases, as far it is relevant, the: o verification measures have been implemented, o assumptions have been verified, o safety objectives have been satisfied, o safety requirements have been met. (see examples here after)
1, 2	In case of a review before the implementation: Check that a plan is defined to meet all the safety requirements and other safety-related conditions relative to the following phases (ex: measures to be implemented in the implementation, integration, operational, decommissioning phases are identified and managed).
1, 2	Check that the users have been consulted if appropriate before the implementation of the change: the stakeholders have validated and accepted the methodology, assumptions and conclusions
1, 2	Review the conclusions of the safety argument and ensure that the conclusion states that the system is fit to be put in service.
1, 2	Check that the evidence shows that for any transition phase into operational service, as far it is relevant, the: o verification measures have been implemented, o assumptions have been verified, o safety objectives have been satisfied, o safety requirements have been met. (see examples here after) More specifically check that: o Arrangements have been made to ensure that safety performance is verified in the operational environment, o New safety problems raised during the transition have been addressed.
1, 2	Check that the evidence shows that for operational life, and in particular during maintenance interventions, as far it is relevant, the: o verification measures have been implemented, o assumptions have been verified, o safety objectives have been satisfied, o safety requirements have been met. More specifically check that the verification measures implemented included, as appropriate. o Continuous safety monitoring, o Continuous safety occurrences reporting and assessment.

Level of Rigour	Actual Procedures and Results Checking
1, 2	Check that the evidence shows that for any transition phase till decommissioning, as far it is relevant, the: o verification measures have been implemented, o assumptions have been verified, o safety objectives have been satisfied, o safety requirements have been met. More specifically check that: o The safety impact on ATM operations due to withdrawing from operations has been assessed. o Within the ”post implementation”, there was sufficient monitoring of assumptions and safety performance, and follow-up of incidents
1, 2	Check that in each case the safety requirements and other safety-related conditions considered are those identified in the hazard analysis process and those applicable from regulatory material and other standards (ICAO SARPs; CAA regulation; SES Interoperability Rules, etc.).
2	Check that in each case the evidence is associated with a claim being made and an argument that explains how the evidence demonstrates that the safety requirement has been met.
2	Check if the level of evidence provided to demonstrate that a Safety Requirement has been achieved is commensurate with the criticality of the Safety Requirement.
1,2	Check if : o The interactions within the system and interaction between the system and its environment are satisfied, o Assurance & Evidence is available showing that transfer phase Safety Requirements for the installation of different equipment or change of procedure are met, o Assurance & Evidence is available showing that risks induced by transfer phase on on-going ANS operations are acceptable, o There are a definition of safety performance indicators, o The constraints when interfacing other systems are identified and documented, o Some limitations are proposed if new safety related problems are highlighted, o There is a monitoring of performance of the transfer into operation phase, o A continuous safety monitoring is performed to ensure that Safety Requirements are met, the Safety Objectives are satisfied and the assumptions are correct while the system is in operation, o A continuous safety occurrence reporting and assessment is performed, o The risk is continuously monitored for acceptability, o A use is made of "lessons learned", to complement formal safety occurrence reporting & assessment, o Safety surveys are conducted, o Safety assessment of maintenance intervention is performed, o Assurance and Evidence are correct and complete to show that Personnel conducting the safety assurance are suitably qualified.

Examples of checking that safety requirements and other safety-related conditions are met that can be done before the implementation of the change:

- Examination of a prototype or trial implementation against allocated safety-related conditions, and
- Examination of the test coverage for a software,
- Verification that the designed Human Machine Interface is acceptable,
- Examination that the operational documentation reflects the outcome of the safety argument (i.e. AIP, Operational, maintenance, engineering and training manuals updated according to outcome of safety argument),
- Examination of letters of agreement between FIRs,
- Examination of a contract with a third party (agreement on the principles and procedures by which the contractor operates a system in interface to minimise the risk of unscheduled impacts),
- Verification that Head of Operations and Head of Maintenance are committed to implementing documented safety-related conditions,
- Examination of the “Reporting Manual” or equivalent to determine to verify the requirements for safety performance monitoring have been included into the internal safety occurrence reporting and analysis process,
- Verification that the safety-related conditions bearing on the airborne segment are indeed reflected in up to date airborne standards and that compliance with these is being verified by appropriate authorities,
- Verification that the safety-related conditions bearing on the airborne segment are promulgated via AIS,
- Identification for areas for research.

Examples of checking that safety requirements and other safety-related conditions are met that can be done during or after the implementation of the change:

- Verification that claimed performances for a system are met (i.e. reliability, availability),
- Verification of the continuous validity of assumptions made in the safety argument with examination of evidence (ex: through incident reports),
- Verification of continuous validity of safety regulatory requirements, with examination of evidence,
- Verification of effectiveness of implemented mitigation measures, with examination of evidence (ex: training records),
- Verification that acceptable safety minima are met, with examination of evidence.

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APPENDIX A: NAA'S MANAGEMENT OF THE OVERSIGHT OF CHANGES

A1.1 NAA's Management Tasks

The NAA should manage the oversight of changes process.

This process is highly dependent on the organisation of the NAA and on the integration of this process into the more general oversight management process dealing with other functions related to oversight (such as performance monitoring), or other domains (airfields, aircraft, …) which can share common resources.

The considerations developed for the management of safety regulatory auditing activities in EAM 1 / GUI 3, §5.2 and §5.8 are in particular applicable for the management of the audit of changes process and will not be repeated here. They can be transposed for the management of the review of changes process.

For the part related to the review of changes, the operational management process undertakes as a minimum the:

- coordination with other NAAs and Aviation Authorities and with the SRC,
- planning of the reviews at a high level,
- evaluation of the resources necessary (human resources and budget),

A1.2 Arrangements with Other Authorities

The review of a safety argument shall be performed according to, and within the limits of, the institutional competences of the NAA, of the ANSP/Organisation and of the reviewer. These institutional competences depend on the national and local regulatory regime, and on the contractual or conventional relationship between them. There are various situations amongst States which can be illustrated with the following examples.

The NAA is responsible for the supervision of the ANSP/Organisation whereas local authorities are responsible for the supervision of aerodromes. For consistency, the safety argument relative to the entry into operational service of the A-SMGCS should be unique. However, the review under the supervision of the NAA, and its conclusions should, in principle, be limited to the area of competence of the NAA. If the ANSP/Organisation is a subcontractor of the aerodrome operator, the global responsibility for the safety argument will rely with the aerodrome operator and the final acceptance with the local authority. In practice for such complex situations it is recommended to coordinate the actions of the two operators and of the supervisory bodies in the co-ordination plan to ensure the full coherence and consistency of the safety argument, the review and its conclusions, and to avoid duplication and pitfalls.

The actual implementation of a data-link application requires changes implemented by the ANSP/Organisation and the aircraft operators. Thus the implementation requires acceptance by the NAA and the OPS authorities, the institutional and geographical competences of which may differ.

The ANSP/Organisation may be either its own operator for ground communications and surveillance or have placed a contract for these services to a national or an international provider. This will have an impact on the form and content of the safety argument, on the review and on the conclusions. Another example is the case of an ANSP/Organisation providing the service for a combination of States, or on a portion of an adjacent State.

Other variability of institutional competences may derive from the certification, continuous oversight and punctual safety audits regimes and responsibilities: for example the certification of the ANSP/Organisation is the responsibility of the central office of the NAA, while the continuous oversight of the local ANSP/Organisation bodies is delegated to the local offices of the NAA with full responsibility for audited changes whereas acceptance of reviewed changes requires an audit by a qualified entity.

Therefore, the NAA should identify the interfaces it needs to exert its safety oversight in general and when reviewing a safety argument. A typical interface to be established includes the airport and aircraft certification Authorities.

It is essential that adequate mechanisms and interfaces are established to ensure that consistent safety regulatory and certification activities are conducted in a co-ordinated manner with regards to ATM/CNS.

Co-ordination with EASA or other NAAs is also required to establish respective responsibilities regarding general provisions as well as specific provisions concerning a given change (e.g. cross border service provisions).

The EUROCONTROL Agency co-ordinates the definition and implementation of a number of changes to the European ATM/CNS system with its Member States, service providers and other stakeholders. As such, a number of core safety activities are also co-ordinated at European level, within the EUROCONTROL Agency. Those safety activities aim at demonstrating that the proposed operational concepts can be implemented within tolerable safety minima, subject to a number of conditions to be met.

The SRC is tasked with the development of a harmonised safety regulatory views of a number of proposed European changes (refer to SRC Document 6) which is intended to be provided to the EUROCONTROL Permanent Commission. As such, the SRC;

- will assess the risk assessment and mitigation processes proposed by the Agency against applicable regulations and provide a SRC position paper which represents the harmonised opinion of the SRC,
- will assess safety deliverables against existing regulatory requirements and provides position paper providing harmonised opinion of the SRC,
- will co-ordinate, as necessary, with aircraft safety regulatory authorities regarding the acceptability of safety requirements and other safety-related conditions bearing on the aircraft segment,
- may also assess some national safety deliverables, should issues in that area impact the overall safety of the proposed European change, hence of other ECAC States.

Therefore, it would be advisable for a given NAA to contribute to the review of pan-European changes by providing national views on the acceptability of related safety deliverables and ultimately, of the proposed change.

This would also imply making use of the SRC harmonised view in the national safety oversight process when times come for the national implementation of a change previously assessed by the SRC, and providing feed back to SRC on implementation issues.

A1.3 Planning and Scheduling the Reviews

The NAA should plan and schedule its review activities utilising the available resources in the most effective manner to ensure the acceptance of reviewed changes implementation and the audit of the other changes.

The annual programme of safety regulatory audits (refer to EAM 1 / GUI 3) defines the planning of audits.

The NAA should develop and maintain a Review Programme and be responsible for its implementation in relation to all ANSP/Organisation operating under the responsibility of the NAA.

The Review Programme is deduced from the identification of changes and from the dates corresponding to the probable notification of changes and presentation of the safety arguments. Provisions are made to allow the inclusion of additional reviews to those originally programmed? The Review programme should be periodically updated.

Such a programme should be based on sound considerations included identified key risks areas, confidence in the service provider, experience from previous reviews and audits results and **not** on the limitations of review resources available to the NAA.

The Review Programme should contain every change to the ATM system planned by the ANSP/Organisation for the next years. The ANSP/Organisation data should be as precise as possible for short-term changes but may be less precise for medium and long-term changes. Different projects will be at different phases, some of them being merely thoughts, some others already covered by a preliminary safety assessment.

To ease the coordination of the Authorities dealing with ATM services, aircraft and airfield, in particular when a change involves several of these actors, depending on the State organisation, the participation of these Authorities to the Review Programme definition and periodic updating could be investigated.

A1.4 Evaluation of the Resources Necessary

Generic requirements related to the safety oversight capacity are given in ESARR 1, Edition 2.0 and, where applicable, Commission Implementing Regulation (EU) No. 1034/2011. The need to assess the human resources needed to perform the safety oversight functions and ensure the NAA is staffed accordingly should be a matter of priority for the NAA to guarantee ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011 application.

Considering the review process, NAA top management will need to ensure that there are sufficient, adequate and competent resources to undertake the reviews. Besides the biennial assessment of human resources required by ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011, the effective use of such resources should be planned as far as possible. As an example, the Review Programme should help defining says every 6 months the resources needed for the next 12 to 18 months.

In case of lack of internal resources or expertise, the NAA can turn to a Qualified Entity provided that this is authorised by the applicable regulatory framework for the review activity. The acceptance of reviewed changes remains the responsibility of the NAA.

The size of the budget, structure and level of staffing are dependent upon the volume of work to be handled, and more specifically the:

- number of ANSP/Organisation under safety oversight as per ESARR 1, Edition 2.0 and/or Commission Implementing Regulation (EU) No. 1034/2011,
- frequency and scope of changes being submitted to safety regulatory acceptance,
- safety oversight processes and procedures in place, these procedures being tailored to the maturity of the ANSP/Organisation and the NAA in safety oversight management (see EAM 1 / GUI 3[1]),
- global staffing strategy,
- existence of multi-national/pan European changes which may lead to a European coordination and synergy of resources among NAA for the review of safety arguments.

It could be more efficient to define the budget for the whole safety oversight activity, a lack of resources in the reviewing activity being possibly counterbalanced by more effort in the auditing activity.

A1.5 Ensuring the Competency of Staff

The NAA should ensure that reviews are conducted by appropriately qualified and competent reviewers of the NAA or Qualified Entities commissioned by the NAA. The quality of an assessment depends on the professional competence, independence and integrity of the experts.

Generic requirements are given in ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011. These include:

- selecting the reviewing staff (or accept it wherever Qualified Entities are involved),
- identifying qualification criteria for reviewers and supplying the required levels of training for the reviewers of the NAA and the Qualified Entities working on its behalf.

The NAA should possess competence criteria and rules for selection, recruitment, role adaptation, empowerment and monitoring of the competence of its personnel: experts and persons responsible in conducting the assessment. It should determine and provide the resources needed to maintain and improve its professional competence and efficiency in its expertise work.

EAM1 / GUI3 provides generic qualification criteria for auditors. These criteria are equally true for the staff performing the reviewing activity (which includes specific audits).The criteria are classified along four categories (refer to the above reference) of knowledge and skills relating to ATM, auditing/reviewing, safety oversight and other regulatory processes and interpersonal skills.

The provisions given in EAM1 / GUI3 for suitable auditor training are completely valid for reviewer training:

- In order to implement the requirements of ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011 as regards the training and qualification of reviewers, an NAA should recognise specific training courses as acceptable means to train its auditors and the auditors from Qualified Entities who conduct audits on behalf of the NAA.

[1] *These considerations will also have an impact on the oversight strategy that will need to be adopted (level of rigour of the review).*

- Such recognition should only take place after the NAA is satisfied that a training programme meets criteria previously defined by the NAA in order to meet the minimum requirements established in ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011.
- A list of such criteria is given in EAM 1 / GUI 3 (Appendix J).

The means used to maintain the reviewer competence are the same that those used for maintaining the competence of the auditors (see EAM1 / GUI3, §5.6.5). It is recommended that the competency of reviewers/auditors is maintained by means of a combination of routine performance monitoring and periodic recurrent training, together with providing for variation in the reviewers/auditors undertaking reviews/ audits relative to particular ATM service providers and the composition of review/ audit teams.

To assure their independence, the experts shall not undertake work likely to compromise their neutrality or likely to lead them to assess their own work. Particularly, persons conducting a review should not have participated directly in the development of the change being reviewed (for example, in case of movement of staff).

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APPENDIX B: OVERSIGHT OF CHANGES AND CONFORMITY ASSESSMENT ACTIVITIES

Note: This Appendix is only applicable for those EUROCONTROL Members States where EC legislation is directly applicable.

B1.1 Consideration Addressing the Changes Within the Interoperability Regulation

Within the European Union, the SES Interoperability Regulation (EC) No. 552/2004 introduces the requirements for the conformity assessment of **technical** systems[1] and constituents. The Essential Requirements (ERs) of the Interoperability Regulation[2] are applicable to any part or procedure of the European Air Traffic Management Network (EATMN) system which consist of:

- Airspace Management,
- Flow Management,
- Air Traffic Services,
- Communication, Navigation and Surveillance,
- Flight Data Processing,
- Aeronautical Information Services,
- Meteorological Information.

Safety requirements may apply to human operators, operational procedures, (technical) systems or equipment. The conformity assessment introduced by the Interoperability Regulation (IR) only applies to EATMN constituents and technical systems. The EC declaration cannot be associated to an operational procedure implemented by an ANSP/Organisation. However, the safety of technical systems has an impact on the systems in operation. Therefore, as the ANSP/Organisation is responsible for the safety of the technical system in operation, the ANSP/Organisation should ensure that all the requirements addressing safety are implemented within the ATM functional system, as defined in Commission Implementing Regulation (EU) No. 1035/2011. Technical components and procedures are part of the ATM functional system.

Where an Implementing Rule dealing with a part of the EATMN system is published, the safety requirements identified in the Essential Requirements have to be verified in accordance with safety assessment and mitigation practices.

The conformity assessment activities are triggered by the ANSP/Organisation's decision to develop and install a new technical system or to upgrade an existing technical system. This process identified some salient elements to be taken into consideration when the NAA carries on the audit or review process, which are the:

- **Declaration of Verification:** This is a document put together by the Service Provider.
- **Technical File:** This is a document put together by the Service Provider. A Technical File (TF) will normally support the declaration of verification

[1] *The difference between a system and a technical system is given in ESARR 1, Edition 2.0, Attachment A, Article 1.*
[2] *The Essential Requirements can be found in Annex II of the Interoperability Regulation (Regulation No (EC) N° 552/2004).*

The contents of the Technical File, must as a minimum contain the following:

- indication of the relevant parts of the technical specifications used for procurement that ensure compliance with the applicable ER and IR for interoperability and, where appropriate, the Community Specification (CS) or Standard (e.g. EUROCAE),
- list of constituents (Hardware and/or Software) covered by the TF,
- copies of the *Declaration of Conformity* or *Suitability for Use* with which the above mentioned constituents accompanied, where appropriate, by a copy of the records of the tests and examinations carried out by the *Notified Bodies,*
- where a *Notified Body* has been involved in the verification of the system(s), a certificate countersigned by itself, stating that the system complies with this Regulation and mentioning any reservations recorded during performance of activities and not withdrawn,
- where there has not been involvement of a *Notified Body*, a record of the tests and installation configurations made with a view to ensuring compliance with essential requirements and any particular requirements contained in the relevant IRs or CSs for interoperability.

According to ESARR 4[1], any changes are submitted to risk assessment and mitigation process. The development and installation of a new technical system, procedure or the upgrade of an existing system are to be considered as changes to existing system. Therefore, those changes are submitted to safety assessment and mitigation which should be adapted to the nature of the change, depending on its impact of safety.

Before the putting into service of a technical system, an ANSP/Organisation shall have completed the conformity assessment of the system installed in its operational environment. This includes that **safety**:

- is implemented as required by the essential requirements (safety being one of them) and by the IRs[2] related to the system and its constituents; and,
- as being under the responsibility of the ANSP/Organisation, safety is submitted to the requirements[3] of ESARRs 1 and 4.

In compliance with Article 3 of Regulation (EC) No. 552/2004, the verification must show that the part of EATMN system complies with their essential requirement throughout its life-cycle. After a successful completion of the on-site technical system integration and conformity assessment verification activities, the ANSP/Organisation shall issue the EC declaration of conformity and suitability for use of constituents, and the EC declaration of verification of systems. The putting into service of the EATMN systems is only allowed once these files and their conclusions have been sent to the NAA. The NAA may require additional information to supervise the compliance of the systems.

Although the SES Interoperability Regulation does not clearly state whether the NAA must give an explicit acceptance for the putting into service, nevertheless, for safety reasons, according to ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011, the NAA shall give its acceptance before putting the changes into service of.

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1 *and Commission Implementing Regulation (EU) N° 1035/2011.*

2 *An implementing rule focused on a given interoperability target contains safety requirements relating to this interoperability target. These safety requirements contribute to the mitigation of safety hazards stemming from misbehaviour of the interoperability target.*

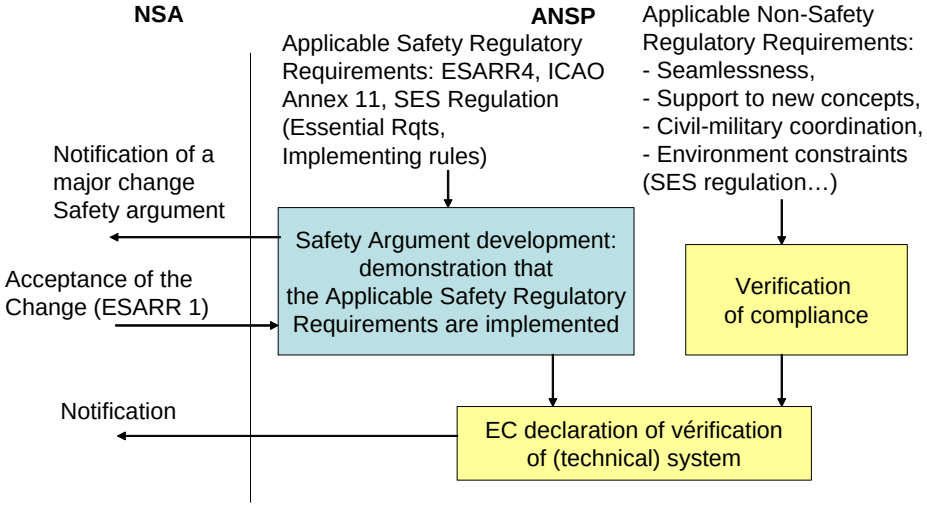
Therefore the EC declaration of conformity and suitability for use of constituents, and the EC declaration of verification of systems should be provided by the ANSP/Organisation by means of its safety arguments, and according to ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011, could be submitted to review or to audit process. However all systems/changes subject to Declaration of Verification or Compliance *or* Suitability for Use should not require such an acceptance as per Commission Implementing Regulation (EU) No. 1034/2011.

These requirements only deal with the reviewed changes, other changes are submitted to another process and do not require NAA acceptance. Therefore the classification of changes is a key activity which should rely on an agreed baseline between the NAA and the ANSP/Organisation.

SES Requirements include a step where the safety of the implementation of the change in an environment of operation is demonstrated through the assessment of the safety argument and associated documentation. This assessment takes into account all the applicable safety regulatory requirements; this should include the ones of the implementing rule related to the change. As per ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011, when reviewing the safety argument the NAA is expected to request relevant evidences, including testing records potentially undertaken by notified bodies.

With regard changes which are submitted to conformity assessment process, when the compliance with safety requirements of the change (as stated in the implementing rule) is accepted by the NAA in accordance with ESARR 1, Edition 2.0 and Commission Implementing Regulation (EU) No. 1034/2011, and when the verification of compliance with non safety requirements have been demonstrated, the ANSP/Organisation can send an EC declaration of verification to the NAA.

The overall mechanism described above is summarised in the following chart.



B1.2 Integration of the Safety Assessment of Changes and Conformity Assessment

The NAA has to establish a process which is aimed at verifying the implementation of safety objectives, safety requirements and other safety related conditions identified in the EC declaration of verification of systems and the EC declaration of conformity and suitability for use of constituents.

According to ESARR 1, Edition 2.0 / Commission Implementing Regulation (EU) No. 1034/2011, the NAA undertakes a review of the safety arguments or a safety audit. Therefore the changes related to the conformity assessment process are classified and, as such, can be submitted to the review of change process.

Despite the differences in the legal framework between the Interoperability Regulation (Regulation (EC) No. 552/2004) and the Service Provision Regulation (Regulation (EC) No. 550/2004), the conformity assessment and risk assessment and mitigation processes are required as part of the change process. In a practical way, these processes could be integrated into a common process.

The NAA safety oversight of changes process and the NAA conformity assessment process could benefit from being integrated. Whilst this document specifically considers the safety oversight of changes processes, it proposes some guidance on integrating both processes in order to avoid duplicating effort in the verification process.

The verifications concerning the safety assessment that could be done by the NAA during the life-cycle of the system developed by the service provider will be considered independently of those realised for the conformity assessment process.

The risk assessment and mitigation activities related to the change, irrespective of the EC declarations and verification activities, have to be undertaken by the ANSP/Organisation in order to ensure that the safety requirements and other safety-related conditions are met.

It is proposed by the conformity assessment methodology to develop a conformity assessment plan. This plan describes the verifications activities and methods made by the ANSP/Organisation in order to provide a framework to verification activities.

Consideration should be given to demonstrating compliance with all requirements within the standards and documenting the results in the Safety Argument. This saves having to go through the process of differentiating between safety and non-safety requirements with the possibility of making errors leading to some safety requirements to be overlooked. It is acceptable for a Safety Argument to include such aviation-related requirements.

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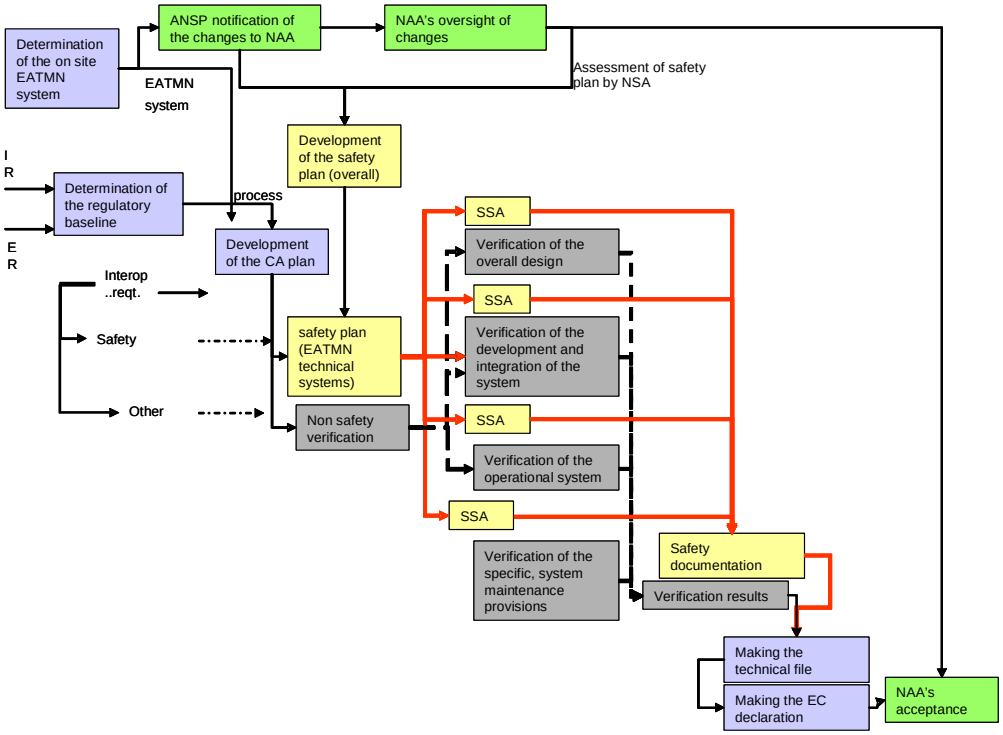

It is proposed that the ANSP/Organisation should develop a **safety plan**. The safety plan should identify the verification stages of safety process, usually the SSA activities. The safety plan addresses the safety assessment and mitigation process which is performed by the ANSP/Organisation in parallel to the conformity assessment process. The safety verification activities of the EATMN technical system are normally part of the safety plan and they could be addressed through the Conformity Assessment plan. The results of the verifications of the EATMN system address safety are safety arguments which are identified in the Conformity Assessment technical file.

In both cases, specific procedures operated by the service provider, notably those intended to implement ESARR 4 and, where applicable, Regulation (EC) No. 552/2004, will provide the rationale to support a final decision on the implementation of the system or change under consideration. Co-ordination arrangements must exist, where necessary due to the nature of the change, with the authorities responsible for the safety oversight of airworthiness and flight operations. The type of arrangements will depend on the significance of the change and its links with the airborne systems.

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APPENDIX C: STRUCTURE OF A NAA REVIEW REPORT

Summary

This section clearly states the decisions and subsequent actions proposed to the NAA, with the reasons for.

1. Introduction

1.1 Report Purpose

- Refer to the notification of the change
- Identify the organisation (ANSP/Organisation) whishing to implement the change, identify the organisation submitting the safety argument (organisation responsible for the safety argument development).
- Describe briefly the nature of the change, what it relates to, its extent: what general ATM function is concerned, what global system is modified, what kind of procedure is amended, on what site, etc.
- Describe briefly the context, the motives for the proposed change, the objectives searched by the ANSP/Organisation.
- Give information concerning the planning of the change: target implementation date, key dates for the ANSP/Organisation project, phases, etc.
- Indicate the report purpose (acceptance of the change but also possible re-use of the study in other contexts, list of actions for the NAA…).

1.2 Report Contents

- Guidelines used for the writing of the report
- Presentation of the different chapters of the document

2. Applicable Safety Regulatory Requirements

- List rules, laws, safety directives and other regulatory level material that is applicable for this change at an international or national level: Common Requirements, EUROCONTROL requirements, ICAO convention, national regulation, etc.
- Identify safety requirement under interoperability regulation: essential requirements and implementing rules.
- Specify, if necessary, the versions of these texts that are applicable (amendments, ESARR version, etc.).

3. Reference Documents

3.1 ANSP/Organisation Documents

- List documents submitted by the ANSP/Organisation (safety argument and associated documents) for this change.
- The EC declaration of verification of systems.
- The EC declaration of conformity and suitability for use of constituents.

3.2 NAA Inputs

- List NAA documents that have been used for the review: previous reports, audits reports, internal procedures documents, etc.

3.3 Others

- List the other documents possibly used for the review: standards, third party study reports, technical guides, etc.

4. People Involved in the Safety Argument Review

4.1 People from the NAA/Involved on Behalf of NAA

- Make out a list of the people involved in the safety review for the NAA, and specify:
- The organisation/company they belong to, and their position in this organisation/company (indicate in particular if a recognised organisation has been used);

- Their role and responsibility within the review;
- Their level/domain of competence (if necessary, for experts for instance);
- Their intervention frame: institutional, contractual, etc.;
- Clearly identify: the reviewer (the person who commands the review and takes the final decision on the basis of the review report), and the Lead reviewer (the person in charge of the conduct of the review and for elaborating the report conclusion).

4.2 People Involved in the Oversight Activity on Behalf of the ANSP/Organisation

- Indicate the focal point of the ANSP/Organisation for this change.

4.3 Other People Involved

- List organisations (possibly persons) who took part in the review, or with whom a coordination has been made for this review, and the scope of their intervention: punctual consultation of EUROCONTROL, aircraft certification authorities, other ANSP/Organisation, other NAA, etc.
- Identification of notified bodies

5. Change Classification

- Indicate the classification given to the change by the NAA, and when this classification has been made.
- Specify the arguments for this classification (ANSP/Organisation and NAA arguments).
- Explain how this classification has been made: ANSP/Organisation proposal, NAA agreement, possible discussions, etc.

6. Main Features of the Safety Argument

- The review report should sum up the main points of the safety argument:
  - definition/perimeter of the change: what are the modified, added or removed elements, according to the successive phases of the change, on what sites, etc.
  - definition of the safety assessment perimeter: starting from the previous point, what are the functions/services/systems/procedures impacted from safety point of view, and, therefore, what perimeter must be studied.
  - assumptions made: hypothesis taken concerning some functions/services/ systems/procedure located outside of the safety assessment perimeter, context (operational environment) assumptions, etc.
  - identification of the hazards (high level), and the assessment of the severity of their effects.
  - identification of the safety objectives related to these hazards.
  - determination of the safety requirements stemming from the safety objectives,
  - demonstration that the safety requirements and other safety-related conditions are met.
  - verification of the validity of the risk mitigation means.
  - cover of the complete life cycle for the concerned perimeter: upstream phases, transition phases, operational service, maintenance, decommissioning (if adequate).
  - cover of the three components of the ATM: equipments, procedures, human factors (knowing that, depending on the nature of the change, some of these components may not be dealt with for this particular change. However, the safety argument should then justify it).
  - appropriate cooperation with parties responsible for developing and/or implementing the safety requirements and other safety-related conditions bearing on the constituent part under consideration or on other parts of the ATM system or the environment of operations.

7. Strategy and Review Plan for the Safety Argument

- Resume the strategy chosen for the review (and the underlying coordination strategy between NAA and ANSP/Organisation: continuous overview during the whole change lifecycle, review of a complete safety argument file submitted by the ANSP/Organisation at the end of the conception phase, gather of experts panels for some particular points, strategy consisting in relying on the ANSP/Organisation competence, for some particular aspects only, etc.
- In particular, indicate which level of rigour has been chosen and if the review strategy includes auditing techniques (formal interview of the staff).
- Indicate the main domains that have been verified by the NAA.
- Mention the limitations of the review: constraints in terms of technical competence, of human resources, of budget, of planning; recognized competence of the ANSP/Organisation, limitations in terms of responsibility on the institutional/legal level; innovative aspects of the methods/tools used by the ANSP/Organisation or of the nature of the change, etc.
- Refer to the Review Plan and indicate the differences with what has been planned.

8. Results of the Verification

- For each step of the risk assessment and mitigation process, the report should show:
  - If the process used to establish what the safety argument states has been audited (as part of the review strategy/review plan), the results of this audit.
  - The reviewer analysis of the results of each step: consistency, coherence, problematic points, points to be verified, missing elements, validity conditions of the arguments presented in the file, etc.
  - The cover (or not) of the whole applicable requirements set.
  - The points the reviewer considers that should possibly be treated in addition to the review itself: regulation modification, regulation interpretation, etc.
- The report should/must also show if the safety argument is consistent with the ANSP/Organisation Safety Plan.

9. Safety-related Conditions

- The report should identify the:
  - safety measures, requirements and other condition to put in place for the implementation of the change.
  - means used by the NAA verify the effective implementation of those safety-related conditions.

10. Rationale for the decision proposal

- List the main points identified during the analysis that lead to the decision proposal: summary of the analysis report, through the key points. These key points may be a list of the highest residual risks (with their severity and occurrence frequency, as well as their corresponding mitigation means).
- The rationale should also establish the review findings concerning the non compliance against the applicable requirements
- The rationale should make it possible to justify, briefly, the points appearing in the report conclusion.

11. Report Conclusion

11.1 Proposal for the Decision

- Indicate the proposal made for the supervisor concerning the decision to take as regards to the acceptance of the change:
  - Acceptance;
  - Acceptance with reserves or conditions;
  - Refusal;
  - Refusal pending further information.

- List, if necessary, the reserves and conditions applicable to the proposal: time limits, perimeter limits, coordination with other supervisory entities (foreign entities, airworthiness authorities...), safety-related conditions that should be verified in a further step of the review, during audits or as elements of the performance monitoring.

11.2 Other Proposals

List the actions the person responsible for the review proposes to carry out, according to the experience gained at the occasion of this review, in all domains: regulation, regulation interpretation, acceptable means of compliance, review procedure, ANSP/Organisation safety management procedure, review strategy, safety argument presentation, etc.

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