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FOR THE SAFETY OF AIR NAVIGATION

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EXPLANATORY MATERIAL ON ESARR 1 REQUIREMENTS

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Abstract :

This deliverable has been prepared by the Safety Regulation Commission to provide guidance to support the implementation of ESARR 1. The main purpose of this document is to describe the provisions of ESARR 1 and to facilitate their interpretation.

The document describes the mandatory provisions of ESARR 1 by explaining their rationale and the most significant implications related to their implementation. The document also includes advice, recommendations and information on further guidance which is available or under development.

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F.3 DOCUMENT APPROVAL

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

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Head Safety Regulation Unit (SRU)	***signed by Peter Stastny*** (Peter STASTNY)	19-Apr-05
Chairman Safety Regulation Commission (SRC)	***signed by Ron Elder*** (Ron ELDER)	19-Apr-05

Note: For security reasons and to reduce the size of files placed on our website, this document does not contain signatures. However, all management authorities have signed the master copy of this document which is held by the SRU. Requests for copies of this document should be e-mailed to: sru@eurocontrol.int.

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F.4 DOCUMENT CHANGE RECORD

The following table records the complete history of this document.

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0.02	15-Sep-04	Amendments following discussions at RTF27. Document circulated to SRC for information together with ESARR 1, Proposed Issue, Edition 0.3.	All
0.03	08-Oct-04	SRU quality check and revision prior to circulation to RTF for formal consultation. Various editorial changes introduced to ensure consistency with ESARR 1, Edition 0.3. Further elaboration of Section 3.20.	All
0.1	17-Jan-05	Draft after RTF consultation. Editorial changes introduced for clarification with regards to some sections in the light of feedback received.	All
1.0	19-Apr-05	Document released following SRC consultation/approval. Editorial changes and clarification of certain sections as a result of feedback received.	All

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F.5 CONTENTS

Section	Title	Page
FOREWORD		
F.1	**Title Page**	**1**
F.2	**Document Characteristics**	**2**
F.3	**Document Approval**	**3**
F.4	**Document Change Record**	**4**
F.5	**Contents**	**5**
F.6	**Executive Summary**	**7**
CONTENTS		
1.	**Introduction**	**8**
1.1	Purpose of this Document	8
1.2	Development of ESARR 1	8
1.2.1	*Background*	*8*
1.2.2	*Introductory and Mandatory Provisions*	*9*
1.2.3	*Contents and Approach*	*9*
2.	**ESARR 1 Safety Oversight Model**	**11**
3.	**Explanation of Requirements**	**14**
3.1	Rationale and Objective – Introductory Material (ESARR 1, Sections A and B)	14
3.1.1	*Rationale*	*14*
3.1.2	*Objective*	*14*
3.2	Definitions (ESARR 1, Section 1)	15
3.2.1	*Requirement*	*15*
3.2.2	*Rationale and Implications*	*15*
3.2.3	*Definitions of Significance in ESARR 1*	*16*
3.3	Applicability (ESARR 1, Section 2)	17
3.3.1	*Requirements*	*17*
3.3.2	*Rationale and Implications*	*18*
3.3.3	*Specific Related Issues*	*18*
3.4	Safety Oversight Function – Establishment and Roles (ESARR 1, Section 3.1)	20
3.4.1	*Requirements*	*20*
3.4.2	*Rationale and Implications*	*20*
3.4.3	*Specific Related Issues*	*20*
3.5	Safety Oversight Function – Functional Block of Airspace (ESARR 1, Section 3.2)	22
3.5.1	*Requirements*	*22*
3.5.2	*Rationale and Implications*	*22*
3.5.3	*Specific Related Issues*	*23*
3.6	Monitoring of Safety Performance (ESARR 1, Section 4)	24
3.6.1	*Requirements*	*24*
3.6.2	*Rationale and Implications*	*24*

Section **Title** **Page**

3.

3.7 Verification of Compliance – Situations to be Addressed (ESARR 1, Section 5.1) 25
3.7.1 Requirements *25*
3.7.2 Rationale and Implications *26*

3.8 Verification of Compliance – Elements of the Process (ESARR 1, Section 5.2) 29
3.8.1 Requirements *29*
3.8.2 Rationale and Implications *30*

3.9 Safety Regulatory Auditing – General Principles (ESARR 1, Sections 6.1 and 6.2) .. 33
3.9.1 Requirements *33*
3.9.2 Rationale and Implications *33*
3.9.3 Further Specific Guidance *35*
3.9.4 Specific Related Issues *35*

3.10 Safety Regulatory Auditing – Programme of Audits (ESARR 1, Sections 6.3, 6.4 and 6.5) 36
3.10.1 Requirements *36*
3.10.2 Rationale and Implications *37*
3.10.3 Further Specific Guidance *39*

3.11 Safety Regulatory Auditing – Management of the Findings (ESARR 1, Section 6.6) . 39
3.11.1 Requirements *39*
3.11.2 Rationale and Implications *40*

3.12 Safety Oversight of Changes – Types of Changes 41
3.12.1 Requirements *41*
3.12.2 Rationale and Implications *41*
3.12.3 Further Specific Guidance *43*

3.13 Safety Oversight of Changes – General Approach (ESARR 1, Sections 7.3, 7.4 and 7.5) 43
3.13.1 Requirements *43*
3.13.2 Rationale and Implications *44*
3.13.3 Further Specific Guidance *45*

3.14 Safety Oversight of Changes – Review of Changes (ESARR 1, Section 7.6) 46
3.14.1 Requirements *46*
3.14.2 Rationale and Implications *47*
3.14.3 Further Specific Guidance *49*

3.15 Recognised Organisations and Notified Bodies (ESARR 1, Section 8) 49
3.15.1 Requirements *49*
3.15.2 Rationale and Implications *50*

3.16 Safety Oversight Capabilities – General Principles (ESARR 1, Sections 9.1, 9.2 and 9.3) 52
3.16.1 Requirements *52*
3.16.2 Rationale and Implications *53*
3.16.3 Specific Related Issues *54*

3.17 Safety Oversight Capabilities – Personnel Competency (ESARR 1, Section 9.4) 54
3.17.1 Requirements *54*
3.17.2 Rationale and Implications *55*

3.18 Safety Directives (ESARR 1, Section 10) 57
3.18.1 Requirements *57*
3.18.2 Rationale and Implications *57*

3.19 Safety Oversight Records (ESARR 1, Section 11) 58
3.19.1 Requirements *58*
3.19.2 Rationale and Implications *58*

3.20 Safety Oversight Annual Report (ESARR 1, Section 12) 59
3.20.1 Requirements *59*
3.20.2 Rationale and Implications *60*
3.20.3 Specific Related Issues *61*

F.6 EXECUTIVE SUMMARY

This deliverable has been prepared by the Safety Regulation Commission (SRC) to provide guidance and support in the implementation of ESARR 1. It is the first deliverable in the series of ESARR 1 Advisory Material (EAM 1) documents to be developed by SRC.

The main purpose of this document is to explain the provisions of ESARR 1 and facilitate their interpretation.

The document describes the mandatory provisions of ESARR 1 by describing their rationale and the most significant implications related to their implementation. It also includes advice, recommendations and information on further guidance which is available or under development.

ESARR 1 has been developed to support a process-based approach to the safety oversight of ATM service providers. The requirement establishes the principles and minimum elements which must exist in the safety oversight processes operated by a National Supervisory Authority (NSA).

This approach is based upon a model built around two core processes:

- Safety regulatory auditing to obtain objective evidence of compliance; and
- The safety oversight of new systems and changes to ATM based on a review of safety arguments produced by service providers.

The conduct of safety regulatory audits is required, in line with the most advanced audit techniques, in order to provide the NSAs with the most powerful means available to obtain confirmation of compliance wherever the supervision of safety is concerned.

The document also addresses the monitoring of safety performance, the harmonisation of the capabilities of the safety oversight function, the issuance of safety directives and the implementation of means to ensure visibility of the safety oversight process and facilitate the auditing of the ATM safety oversight frameworks.

These processes, capabilities and means form a process model that supports the development of an efficient safety oversight function as part of the generic supervision of requirements applicable to ATM services.

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1. INTRODUCTION

1.1. PURPOSE OF THIS DOCUMENT

This deliverable has been prepared by the Safety Regulation Commission (SRC) to provide guidance and support in the implementation of ESARR 1. It is the first deliverable in the series of ESARR 1 Advisory Material (EAM 1) documents to be developed by SRC.

The main purpose of this document is to describe the provisions of ESARR 1 and facilitate its interpretation.

After a brief overview of the safety oversight process established in ESARR 1, the document describes the mandatory provisions of ESARR 1 by explaining their rationale and the most significant implications related to their implementation. Advice and recommendations are also provided, as well as information on additional guidance which is available or under development.

Similar clarifications are also provided for all other sections of ESARR 1 to facilitate their understanding and uniform implementation across States.

1.2 DEVELOPMENT OF ESARR 1

1.2.1 Background

In February 2002, the SRC decided to undertake the development of an EUROCONTROL Safety Regulatory Requirement, namely ESARR 1, to harmonise the national ATM safety regulatory frameworks in the ECAC region.

The initial development considered the whole ATM safety regulatory process. However, various reasons indicated the need for reconsidering the scope of ESARR 1.

The new Single European Sky (SES) legislation[1] came into force in April 2004 and introduced an ATM regulatory framework applicable to European Union (EU) Member States. This legislation not only established the notion of a 'National Supervisory Authority (NSA)', but also provided the basis for a common rulemaking process for EU Member States based around the development of common requirements and various implementing rules[2].

The implementation of this new framework raised the need for provisions to ensure that robust capabilities and harmonised processes were implemented by National Supervisory Authorities (NSAs) to supervise safety.

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[1] *This legislation, adopted by the European Parliament and Council consists of Regulation (EC) 549/2004 (the framework Regulation), Regulation (EC) 550/2004 (the service provision Regulation), Regulation (EC) 551/2004 (the airspace regulation) and Regulation (EC) 552/2004 (the interoperability Regulation).*

[2] *Including the interoperability implementing rules.*

That essential need was consistent with the evidences and findings from the EUROCONTROL ESARR Implementation Monitoring and Support (ESIMS) Programme, as well as from other inputs such as the conclusions from the High Level Action Group for ATM Safety (AGAS) and the lessons learnt from the ICAO Universal Safety Oversight Audit Programme (USOAP). Those findings confirmed the urgent need for effective safety oversight mechanisms in Europe.

Consequently, it was agreed to focus the scope of ESARR 1 on safety oversight in order to address these critical needs and support the implementation of the SES as regards the supervision of ATM safety by NSAs.

1.2.2 Introductory and Mandatory Provisions

ESARR 1 has adopted significant changes to the approach, terminology, format and level of detail to that used in previous ESARRs. These changes will facilitate the alignment of ESARR 1 with EC law.

A clear distinction has been made between mandatory and non-mandatory provisions. The mandatory part comprises those sections that use the term “shall” to express an obligation.

The structure of the non-mandatory part has been simplified. More particularly:

a) Section A “Rationale”, adopts a central role in the non-mandatory part. It intends to introduce ESARR 1 and provides guidance for its interpretation.

b) The Section “Scope” (formally Section 2 in other ESARRs) has been omitted to prevent issues in relation to the use of the term ‘scope’ under EC law. Its purpose is covered in other parts of the document, notably the rationale and the mandatory provisions related to the applicability of the requirement.

c) The Section “Safety Objective” (formally Section 4 in other ESARRs) has been re-named “Objective” (Section B) in order to differentiate it from the term “safety objective” which is defined and used in accordance with previous ESARR 4-related definitions.

The mandatory part starts with a list of definitions and includes a requirement addressing the applicability of ESARR 1 and ten requirements (Sections 2 to 12) which form the core of the ESARR 1 mandatory provisions.

1.2.3 Contents and Approach

The structure of ESARR 1 relies on various links between its sections. This ensures that ESARR 1 appropriately addresses the following issues:

a) **Compatibility with the SES regulations**, building the ESARR on the generic features established in the SES legislation (NSAs, certification, designation, proper inspections/surveys, common requirements, recognised organisations, etc.) in order to support its implementation in EU Member States;

b) The development of ATM safety oversight as **a specific part** of the generic supervisory role established in the SES regulations;

c) The need to support the development of ATM safety oversight, not only within the SES framework, **but also in non-EU States** who are Members of EUROCONTROL;

d) The assumption that **"applicable safety regulatory requirements**" will exist in each country. In that regard, it should be noted that:

(i) ESARR 1 confines itself to providing requirements on processes and basic principles for the supervision of safety. ESARR 1 does not address the rulemaking aspects of ATM safety regulation;

(ii) The applicable safety regulatory framework will vary depending on the country. Within the EU, a common regulatory framework will be built around the four SES regulations (in force since April 2004) and their implementing rules. In particular, Common Requirements and Interoperability Implementing Rules will be developed;

(iii) In non-EU States who are Members of EUROCONTROL, the regulatory framework will primarily continue being of a national nature and developed consistently with various international obligations binding on those States (e.g. ICAO, EUROCONTROL);

(iv) The ESARR 1 definition of "applicable safety regulatory requirements" is carefully tailored to cover all possible scenarios.

e) The introduction by means of Regulation (EC) 551/2004 (the interoperability Regulation) of:

(i) The EC verification of technical systems; and

(ii) The EC assessment of conformity or suitability for use of constituents of technical systems.

ESARR 1 does not specify any links between these processes and the risk assessment and mitigation activities conducted in accordance with ESARR 4. The approach adopted for the safety oversight of changes to the ATM system is focused on considering the outputs of all the processes required.

f) A change to the **level of detail and prescription**[3] in comparison with previous ESARRs. The text is not only more accurate, but also more detailed. This approach complements and supports the high-level SES regulations by focusing on the details of how the NSAs processes should work.

g) The introduction of some **features taken from the airworthiness domain** (e.g. the notion of safety directives). The procedures for authorities established under the EASA regulations, Part 21 (formerly JAR-21) have been used as a major input to the development of ESARR 1. As a result, the level of prescription more closely adopts the approach taken by EASA.

[3] *The high-level objective-based approach used in other ESARRs has been effective in addressing the case of service-providers. However, from the findings of the ESIMS visits, it can be concluded that the non-prescriptive approach needed to be reconsidered when requirements apply to ATM safety regulators. A more prescriptive approach is necessary.*

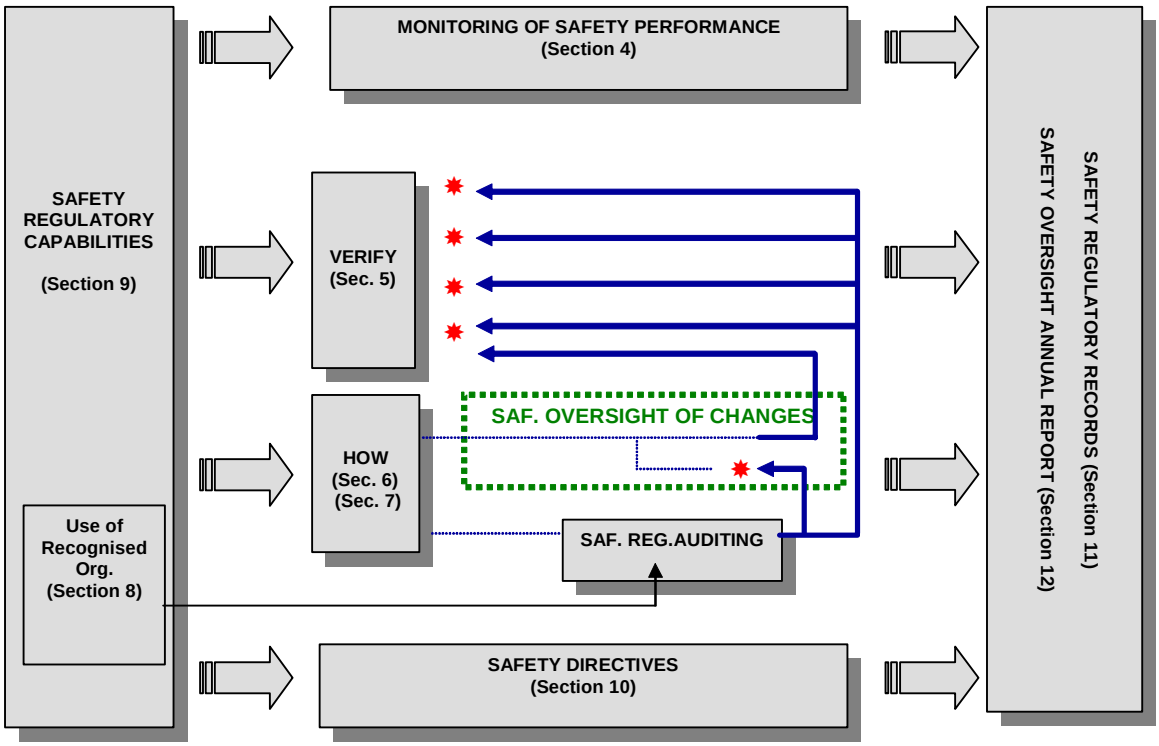
2. ESARR 1 SAFETY OVERSIGHT MODEL

ESARR 1 has been developed to support a process-based approach to the safety oversight of ATM service providers. The requirement defines the minimum elements that must exist in the safety oversight processes operated by a NSA.

Any activity or set of activities, such as the ATM safety oversight function, which uses resources to transform inputs to outputs, can be considered as a process.

For NSAs to function effectively, they have to identify and manage numerous interrelated and interacting processes. In most cases, the output from one process will directly form the input to the next process.

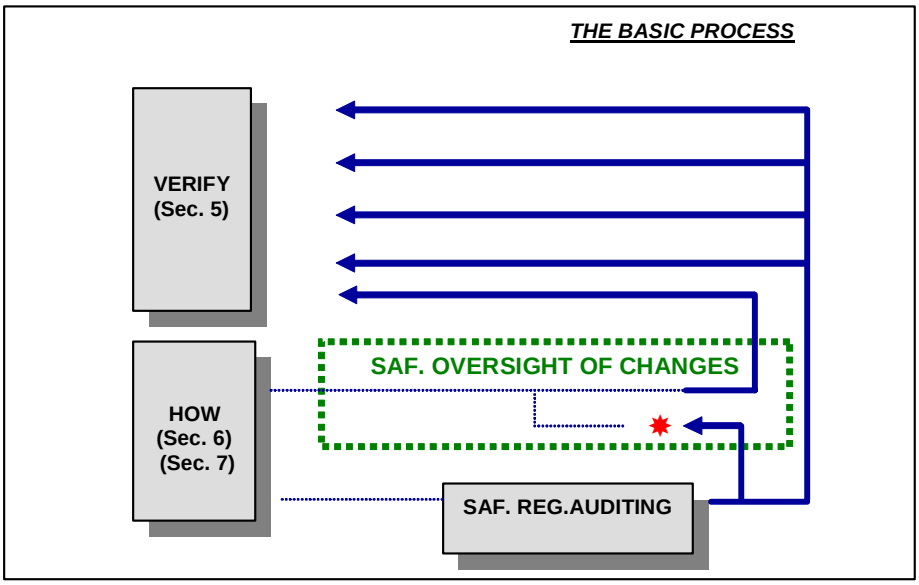
ESARR 1 provides NSAs with a model to develop their safety oversight arrangements in a harmonised manner across the ECAC region. Figure 1 below summarises this model and describes the ESARR 1 safety oversight process:



(Figure 1 – The ESARR 1 Safety Oversight Model)

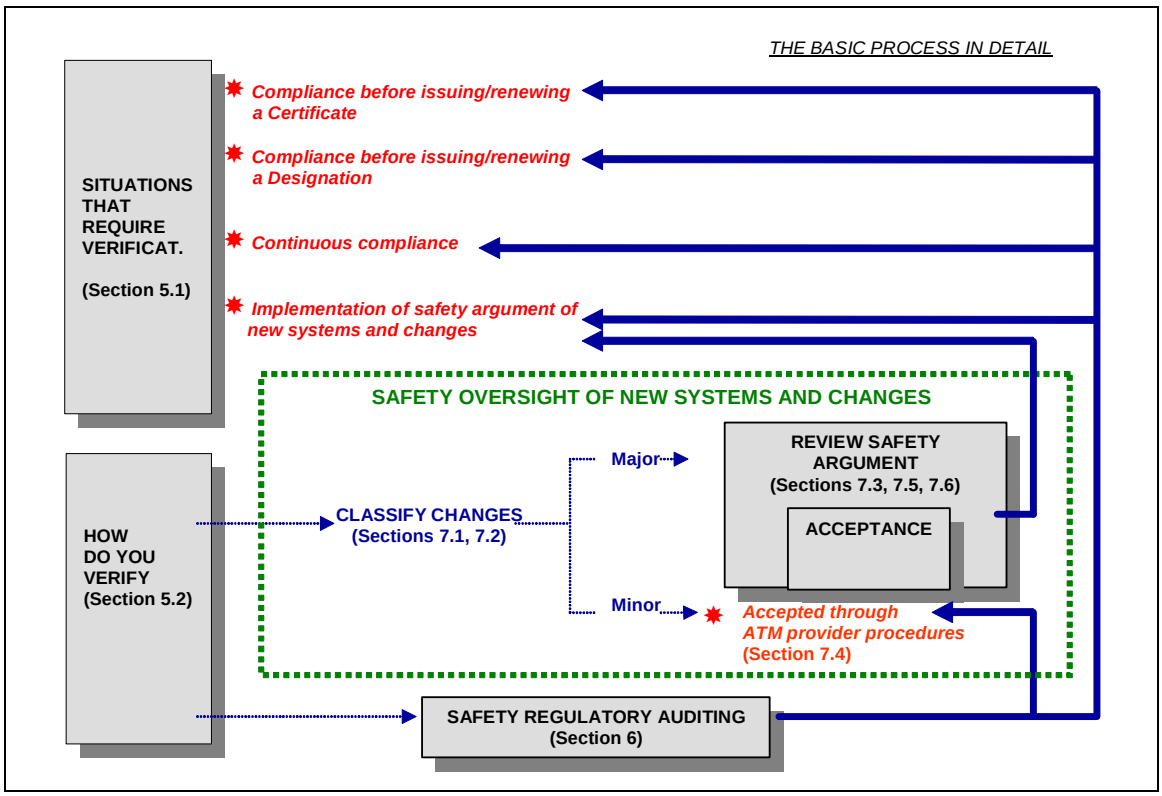
The left part of the diagram includes the **MEANS**. The central area describes the main **ACTIONS**. The right part of the figure illustrates the **DOCUMENTED RESULTS** of the safety oversight process.

At the core of this model there is a *"basic process"*, which is represented in the following diagram:



(Figure 2 – The "basic process" of the ESARR 1 Safety Oversight Model)

This diagram can then be expanded to describe the *"basic process"* in more detail:



(Figure 3 – The "basic process" of the ESARR 1 Safety Oversight Model in detail)

These diagrams illustrate the various processes required in ESARR 1 and the most basic interrelationships between their elements.

IN PARTICULAR WE MAY NOTE THAT:

a) There are four basic situations which may require verification of compliance:

- The **CERTIFICATION** of service providers[4] to signify their capability to provide specified services;
- The **DESIGNATION** of service providers to operate in specific airspace blocks;
- The **CONTINUOUS COMPLIANCE** with the applicable safety regulatory requirements and any arrangements needed to implement them;
- The implementation of safety-related conditions (forming part of the "safety argument") of **NEW SYSTEMS AND CHANGES TO THE ATM SYSTEM.**

b) Two major processes provide the tools to address these situations:

- The **SAFETY REGULATORY AUDITING PROCESS** which provides the NSA with a means to obtain objective evidence of compliance, or lack of compliance, with specified requirements;
- The **SAFETY OVERSIGHT OF NEW SYSTEMS AND CHANGES** which is specifically intended to address the introduction of new systems and changes, and is based upon:
  - A classification of the changes depending upon their significance;
  - A review of the safety arguments produced by the service provider for the changes proposed. The review concerns those changes classified as 'major' from a safety perspective. These major changes are subject to **ACCEPTANCE** by the NSA prior to their implementation;
  - Acceptance and auditing of the procedures used by the service provider to deal with the changes not subject to acceptance by the NSA.

c) The **MONITORING OF SAFETY PERFORMANCE** supports all the processes operated by the NSA.

d) The NSA may issue **SAFETY DIRECTIVES** if any of the above processes identify that an unsafe condition exists in a system.

[4] *Only wherever certification is required by the existing regulatory framework against a certification regulatory reference that should have also been determined in that framework. ESARR 1 does not require the establishment of a certification process. ESARR 1 only addresses the NSA safety oversight actions that would exist in any certification process established by the applicable regulatory framework.*

3. EXPLANATION OF REQUIREMENTS

This section identifies each mandatory requirement of ESARR 1 and provides explanatory material to address the rationale of the provisions, the most significant implications related to its implementation, advice, recommendations, and information on additional guidance which is available or under development.

In order to facilitate its understanding and uniform implementation across States, similar clarifications are also provided for all other sections of ESARR 1.

3.1 RATIONALE AND OBJECTIVE – INTRODUCTORY MATERIAL (ESARR 1, SECTIONS A AND B)

These two sections are not mandatory. They do not make use of the term “shall” to express an obligation when referring to actions or other arrangements.

3.1.1 Rationale

The rationale is an introduction of the requirements and their context. It includes information about the reasons for developing ESARR 1 and the types of provisions included to address the needs identified. It also provides elements for the interpretation of the requirements.

Each paragraph addresses a specific aspect. This includes the description of:

- The general context of the work developed by the SRC;
- The urgent needs identified by the SRC as regards the implementation of an effective safety oversight function of ATM services;
- The Single European Sky (SES) regulatory framework;
- ESARR 1 as an enabler for the implementation of the supervision of safety, or safety oversight, within the generic supervisory role established in SES;
- ESARR 1 as an enabler for EUROCONTROL Member States who are not covered by the SES regulatory framework;
- The supervision function in the context of the State’s responsibilities for regulating and providing air navigation services functions.

3.1.2 Objective

In the context of ESARR 1, the objective is not considered as a mandatory provision.

The overall objectives of ESARR 1 are defined within the three possible institutional arrangements:

a) In relation to EUROCONTROL Contracting Parties, the objective is to ensure the implementation of effective ATM safety oversight in the public interest;

b) In respect of ECAC States who are not Members of EUROCONTROL, the objective is to support them in that implementation.

c) As regards the implementation of the Single European Sky, the objective of ESARR 1 is to **support its implementation** by allowing the development of ATM safety oversight within the functions of NSAs and the regulatory framework defined in the SES legislation; and more particularly:

- Harmonising the actions (processes) undertaken by NSAs in overseeing safety. These harmonised processes **will be part of** the procedures established in the existing regulatory framework with regard to the certification and designation of service providers. Furthermore, they will always cover the on-going supervision of service providers, irrespective of the existence or not of a certification scheme;
- Enabling joint civil-military initiatives with regard to ATM safety oversight in accordance with the existing regulatory framework. ESARR 1 contains references to General Air Traffic (GAT), carefully included[5] to scope the provisions in a manner that covers the safety oversight of all services provided to GAT, irrespective of the military or civil nature of the organisation providing the services.

3.2 DEFINITIONS (ESARR 1, SECTION 1)

3.2.1 Requirement

"1.1. For the purpose of this Requirement, the following definitions shall apply: ..."

3.2.2 Rationale and Implications

ESARR 1, Section 1 includes twenty-six specific definitions. They are part of the mandatory provisions and therefore provide an exact and agreed meaning for each term used.

The ESARR 1 definitions have been aligned, as far as is possible, with the set of definitions included in Regulation (EC) 549/2004 (the framework Regulation). Two differences remain due to various reasons:

- The use of the term 'ATM' instead of 'ANS'; and
- The use of the term 'system'.

Even in these two cases, the overall approach and the careful wording used ensures consistency between the provisions of the two regulatory packages.

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[5] *See definition of NSA and ESARR 1, Section 3.1.*

3.2.3 Definitions of Significance in ESARR 1

3.2.3.1 Applicable Safety Regulatory Requirements

The set of applicable safety regulatory requirements will depend upon the existing regulatory framework. Within the SES framework, a common regulatory system will exist, based around the common requirements, the interoperability implementing rules and other implementing rules. In non-EU States who are Members of EUROCONTROL, the regulatory framework will primarily continue being of a national nature.

The ESARR 1 definition is further discussed in Section 3.4.5.3 of this document.

3.2.3.2 Air Traffic Management (ATM)

ESARR 1 has adopted the SES definition. This is also fully compatible with the definition used in other SRC documents. 'ATM' means the aggregation of ground-based (comprising variously of ATS, ASM, ATFM) and airborne functions to ensure the safe and efficient movement of aircraft during the appropriate phases of flight.

The use of the term 'ATM' throughout the document scopes the requirements in a manner consistent with the SRC's Terms of Reference.

It should be noted that the SES legislation scopes its provisions in relation to air navigation services (ANS). This implies that some minimum adjustments in the scope may be needed to transpose ESARR 1 into Community law. For example, SES might decide to expand the applicability of the ESARR 1 processes to AIS or MET.

ESARR 1 adopts several SES definitions verbatim, except for the replacement of the term "ANS" with "ATM". Examples of this are the definitions for "airspace block", "ATM service provider", "certificate", "constituents" and "functional airspace block".

3.2.3.3 National Supervisory Authority (NSA)

The notion of an NSA is not explicitly defined in Regulation (EC) 549/2004 (the Framework Regulation). The ESARR 1 definition has been worded by considering the SES article requiring States to nominate or establish NSAs. It also includes a reference to the "existing regulatory framework" to make it compatible with SES and any other situation that could exist outside SES.

It should also be noted that the wording of this definition is key to ensuring that the NSAs are independent of service providers in those countries which are outside the SES framework.

Additionally, the definition includes an explicit reference to General Aviation traffic (GAT) in order to clarify the scope of ATM safety oversight as regards military activities.

In conjunction with the other references to GAT included throughout the document[6], its specific inclusion makes it clear that the scope of the ESARR 1 provisions encompasses any NSA established or nominated by States which, irrespective of its civil or military nature, supervises service providers, civil or military, providing services to GAT.

[6] *See ESARR 1, Section 3.1.*

3.2.3.4 Safety Argument

A safety argument is the demonstration and evidence that a proposed change can be implemented within the applicable tolerable levels of safety.

The safety argument is to be reviewed by the NSA at least in those cases where changes are classified as needing NSA acceptance prior to their implementation. Such safety arguments are produced by the service provider.

The ESARR 1 definition is further discussed in Section 3.13.2.1 of this document.

3.2.3.5 Safety Regulatory Audit

Is the means identified in ESARR 1 to implement the "proper inspections and surveys" required in Regulation (EC) 550/2004 (the service provision Regulation) wherever safety is the subject to be verified.

This aspect is further discussed in Section 3.9.4.1 of this document.

3.2.3.6 System and Technical System

The ESARR 1 definition for "technical system" matches the SES definition for "systems" (except for the term ATM instead of ANS). Within their respective contexts, both terms can therefore be considered as synonyms.

The expression "system" has been replaced by "technical system" in all those definitions taken from the SES framework.

The reason for the differences is the need to keep the notion of "system" as used in previous ESARRs, notably ESARR 4, and which is referred to in the provisions for the safety oversight of changes.

A "system" is defined in ESARR 1 as a combination of technical systems (equipment), procedures and human resources to perform a function.

3.3 APPLICABILITY (ESARR 1, SECTION 2)

3.3.1 Requirements

"2.1. This Requirement shall apply to all EUROCONTROL Contracting Parties with regards to the operation of all National Supervisory Authorities nominated or established by them.

2.2. The provisions of this Requirement are to become effective within three years from the date of its approval by the EUROCONTROL Commission."

3.3.2 Rationale and Implications

The EUROCONTROL Contracting Parties are bound[7] to implement in their regulatory frameworks the provisions of ESARR 1 with regard to the operation of their National Supervisory Authorities.

A National Supervisory Authority (NSA) is a body nominated or established by the States that:

- Is independent of service providers; and
- According to the existing regulatory framework, supervises the implementation of requirements applicable to the provision of ATM services to GAT.

ESARR 1 establishes requirements as regards all National Supervisory Authorities operating under the regulatory frameworks of all EUROCONTROL Contracting Parties.

Within EU Member States, the existing regulatory framework and requirements applicable to the provision of ATM services are based on the SES legislation which came into force in April 2004. This legislation, adopted by the European Parliament and Council consists of four Regulations (EC); 549/2004 (the framework Regulation), 550/2004 (the service provision Regulation), 551/2004 (the airspace Regulation) and 552/2004 (the interoperability Regulation).

Regulation (EC) 549/2004 requires EU Member States to nominate or establish National Supervisory Authorities.

In non-EU countries who are Members of EUROCONTROL, the existing regulatory framework and requirements applicable to the provision of ATM services will primarily be of a national nature and developed consistently with the various international obligations binding on those States, such as those contained in the Chicago Convention and the EUROCONTROL Convention. In particular, the national regulatory framework will address[8] the notion of National Supervisory Authority established in ESARR 1.

In order to facilitate the full implementation of ESARR 1, its provisions will be in force three years after their approval by the EUROCONTROL Permanent Commission.

3.3.3 Specific Related Issues

3.3.3.1 NSA's Arrangements

The supervision function of a NSA has traditionally been performed by the national civil aviation administration of each country. However, within the SES framework, nothing prevents States from considering alternative arrangements when nominating or establishing such an entity, provided that the existing applicable provisions, notably ESARR 1, are met.

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[7] Decision 103 of the EUROCONTROL Commission, dated 5th November 2004, approves ESARR 1 Edition 1.0 for incorporation and implementation in the ATM regulatory frameworks of the EUROCONTROL Contracting Parties.

[8] See Section 3.4.3 about the existence of NSAs in non-EU States who are Members of EUROCONTROL.

The SES regulations have notably introduced possibilities for a joint implementation of the NSA functions by States or other entities.

The SES regulations do not contain any specific requirements or restrictions regarding the status of the NSAs (public or private entity, intergovernmental body, etc.). They leave a certain amount of discretion to States with regards the nomination or establishment of NSAs. The nominated or established entities would undertake those tasks on behalf of the States.

For example, NSAs can be civil, military or joint civil-military organisations, depending upon the nature of the ATM services subject to supervision.

In non-EU States, the existing national regulatory framework will define the possible arrangements which could exist as regards to their NSAs.

ESARR 1 does not introduce constraints to these possibilities. It only establishes requirements as regards the safety oversight processes to be conducted by any NSA established or nominated by EUROCONTROL Member States.

3.3.3.2 Implementation Approach

ESARR 1 establishes the minimum safety oversight arrangements to be implemented by a NSA. As a result, the NSA is the addressee of most of the provisions included in ESARR 1.

The incorporation and implementation of these provisions in the regulatory frameworks of the EUROCONTROL Contracting Parties may be addressed by means of internal NSA arrangements, provided that:

- These internal NSA arrangements are mandatory, documented and effectively implemented;
- They emanate from, and are consistent with, the provisions[9] enabling the NSA to supervise the provision of ATM services; and

On the other hand, it should be noted that the implementation of the ESARR 1 provisions addressed to States[10] cannot be implemented by means of internal NSA arrangements.

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[9] According with ICAO Document 9734, Part A ('The Establishment and Management of a State's Safety Oversight System'. First Edition, 1999) the establishment of the authority and the extent of its functions and empowerment must be based on the solid foundation of a legal document. It should be noted that ICAO Document 9734 describes the critical elements of a safety oversight system as considered by USOAP in order to audit the capabilities of a State to implement appropriate safety oversight. A revised version encompassing ATM was being developed by ICAO at the time of this writing.

[10] This concerns ESARR 1 Section 3.1 (Establishment by States of safety oversight function within the NSAs); ESARR 1, Section 3.2 (as regards the agreements between States for the supervision of functional airspace blocks); Section 9.1 (States to ensure that NSAs have organisational and functional capability and sufficient resources); and ESARR 1 Section 9.2 (States to ensure that NSAs and recognised organisations have access to the service provider's organisation, facilities and documentation).

3.4 SAFETY OVERSIGHT FUNCTION – ESTABLISHMENT AND ROLES (ESARR 1, SECTION 3.1)

3.4.1 Requirements

"3.1. States shall ensure that safety oversight is specifically exercised by National Supervisory Authorities as part of the supervision of regulatory requirements applicable to the provision of ATM services to general air traffic, in order to:

a) Monitor the safe provision of ATM services, and

b) Verify that the applicable safety regulatory requirements and any arrangements needed to implement them are effectively met."

3.4.2 Rationale and Implications

Within the applicable regulatory framework of each country, supervision exists with regards to the implementation of requirements established in relation to various aspects, such as safety, financial matters, environmental issues, etc.

Amongst those aspects, safety constitutes a primary concern in aviation. It is widely recognised that the operation of aviation and other safety-related industries must be undertaken on the basis of achieving levels of safety which are both publicly and politically acceptable and this too has to be demonstrated to all parties.

The need is therefore accepted for addressing the safety oversight of ATM services in a **specific and explicit manner** as part of the generic supervisory functions established by the existing regulatory framework. The aim of this approach, based on addressing safety in a central and differentiated matter, is to facilitate the implementation, in the public interest, of the most effective forms of supervision in the case of safety.

3.4.3 Specific Related Issues

3.4.3.1 Existence of National Supervisory Authorities

Within the SES framework, States are required to nominate or establish National Supervisory Authorities.

In those EUROCONTROL Member States who are not included in the SES framework, ESARR 1 makes it clear that **States shall ensure** ATM safety oversight is exercised by National Supervisory Authorities.

It should be noted that the rationale of ESARR 1 (Section A.6) gives some explanations directly related to this subject:

"A.6. In that regard, it should be noted that the National Supervisory Authority function denotes an existing regulatory task which applies to the relevant authorities of any State who has accepted the responsibility for regulating and providing air navigation services functions over its territory and associated areas, and that, consequently, the term National Supervisory Authority used in the context of ESARR 1 is not limited to the European Union Member States nor is it limited to the tasks of the National Supervisory Authorities under the Single European Sky regulations."

This paragraph provides the basis for any interpretation of the ESARR 1 provisions with regards to their applicability to States who are outside the SES framework.

3.4.3.2 Functional Separation

Regulation (EC) 549/2004 requires the NSAs of all EU Member States to be independent of service providers. This independence shall be achieved through adequate separation (at least at a functional level) between NSAs and service providers.

In those EUROCONTROL Member States, who are not included in the SES framework, the ESARR 1 definition of an NSA, when considered in conjunction with Section 3.1, makes clear that **States shall ensure** ATM safety oversight is exercised by National Supervisory Authorities that are independent (at least at a functional level) of the service providers.

3.4.3.3 Monitoring and Verification

Two major safety oversight roles are identified in ESARR 1: monitoring safety in the provision of ATM services and verifying compliance with applicable safety regulatory requirements.

The term 'monitoring' refers to the need to watch and follow-up the safe provision of ATM services. On the other hand, 'verification' is defined in ESARR 1 as the confirmation through the provision of objective evidence that specified requirements have been fulfilled. Verification of compliance normally implies taking specific action to obtain evidences.

The *monitoring* of safety normally makes use of various indicators and levels, qualitative or quantitative, depending upon the situation. On the other hand, the *verification* of compliance is conducted against a set of specified requirements.

3.4.3.4 Applicable Safety Regulatory Requirements

ESARR 1 defines the "applicable safety regulatory requirements" as the requirements for the provision of ATM services applicable to the specific situation under consideration, and established through the **existing rulemaking framework**, concerning, inter alia:

i) Technical and operational competence and suitability to provide ATM services,

ii) Systems and processes for safety management,

iii) Technical systems, their constituents and associated procedures.

In EU Member States, the "existing rulemaking framework" will be built on the four Single European Sky Regulations in force since April 2004. In non-EU countries who are Members of EUROCONTROL, the "existing rulemaking framework" will primarily be of a national nature.

The two first bullets of the definition reproduce the wording used in Regulation (EC) 550/2004 to define two out of the nine categories of SES Common Requirements. This implies that within EU Member States the SES common requirements established for those two categories are necessarily identified as "applicable safety regulatory requirements" and subject to verification by means of the processes required in ESARR 1.

The third bullet of the definition **covers the interoperability implementing rules** that will be developed within the SES framework and which will be applicable within EU Member States, or the equivalent existing rules in the case of non-EU countries.

3.5 SAFETY OVERSIGHT FUNCTION – FUNCTIONAL AIRSPACE BLOCKS (ESARR 1, SECTION 3.2)

3.5.1 Requirements

"3.2. In cases of functional airspace blocks which extend across the airspace falling under the responsibility of more than one State, agreements between States on the supervision of the ATM services relating to those blocks, shall specifically ensure that responsibilities for ATM safety oversight are identified and allocated in a manner which ensures that:

a) Clear points of responsibility exist to implement each requirement that ESARR 1 imposes on National Supervisory Authorities;

b) The States concerned have visibility of the safety oversight mechanisms operated as a result of the agreement, and their results;

c) A means to regularly review the agreement and its practical implementation in the light of safety performance measurements is established. All States concerned shall have visibility of that means and its results."

3.5.2 Rationale and Implications

The creation of functional airspace blocks (FABs) is central to the SES legislation. FBAs will be established based on operational requirements reflecting the need to ensure a more integrated airspace management regardless of national boundaries.

Regulation (EC) 550/2004 establishes that, in respect of functional blocks of airspace falling under the responsibility of more than one State, the States concerned shall conclude an agreement on the supervision of the service providers providing services related to those FABs. The text adds that States may conclude an agreement on the supervision of service providers operating in a State other than that in which the provider has its principal place of operation. No other details are provided in the regulation about the possible contents of such agreements.

ESARR 1 refers to those agreements and identifies some minimum elements to be necessarily covered in them in order to ensure safety.

3.5.2.1 Clear Allocation of Responsibilities

Regulation (EC) 549/2004 does not constrain the types of practical arrangements which can be established as a result of those agreements. For example, under the SES legal framework, arrangements could be established to apportion the supervisory responsibilities between different NSAs.

In the safety domain, it is crucial to ensure the clear identification of safety oversight responsibilities within those agreements to **prevent a dilution of responsibilities** between the different entities involved in the supervision of ATM services within a functional airspace block. ESARR 1 explicitly requires that any agreement between States ensures clear points of responsibility for implementing each requirement that ESARR 1 imposes on a NSA.

3.5.2.2 Means for Visibility and Safety Performance Review

In addition, ESARR 1 explicitly requires that those agreements shall ensure all States concerned have full visibility of the safety oversight mechanisms established and their results.

ESARR 1, Section 12 provides a basic tool to achieve that visibility. The provisions of Section 12 require a NSA to produce an Annual Safety Oversight Report and establishes that this document shall be made available to all States concerned in the case of a FAB.

Additionally, the agreements shall have specific means to permit the States concerned to review the agreement and its practical implementation in the light of safety performance measurement.

Various arrangements can be conceived in order to meet that requirement. By way of illustration, a safety review committee or group could be established with participation from each State concerned. Such a group should:

- Have access to the data available on ATM-related safety occurrences in the FAB, as well as to the Annual Safety Oversight Report produced by each NSA involved in the supervision of safety at the FAB,
- Meet at planned intervals to review the suitability and efficiency of the safety oversight mechanisms in place in the light of the safety performance obtained and the safety issues identified
- If required, identify measures to improve the safety oversight arrangements and the agreements upon which they are based, and follow up the implementation of the agreed measures for improving safety oversight in the FAB.

3.5.3 Specific Related Issues

3.5.3.1 Recommendation for a Single Point of Responsibility

Consistently with the wide range of options allowed by the SES legislation, ESARR 1 cannot impose additional constraints on the type of safety oversight arrangements established. ESARR 1 only requires that such agreements between States ensure clear points of responsibility.

However, although not required in ESARR 1, it appears advisable from a safety perspective to recommend the establishment of a single point of responsibility for all ATM safety oversight functions related to a particular FAB. Such an option would provide further safety barriers to prevent a dilution of responsibilities in complex situations.

3.6 MONITORING OF SAFETY PERFORMANCE (ESARR 1, SECTION 4)

3.6.1 Requirements

"4.1. National Supervisory Authorities shall provide regular monitoring and assessment of the levels of safety achieved against the tolerable levels of safety determined for the airspace blocks under their jurisdiction responsibility."

"4.2. National Supervisory Authorities shall use the results of the monitoring of safety to determine areas where the verification of compliance with safety regulatory requirements is necessary as a matter of priority."

3.6.2 Rationale and Implications

ESARR 1, Section 1 defines a "tolerable level of safety" as a quantified target, qualitative target or standards identified in relation to the safe provision of ATM services within airspace blocks, and established through the existing regulatory framework consistently with applicable safety regulatory requirements.

Some aspects should be noted as regards the determination of tolerable levels of safety and their monitoring by NSAs:

a) ICAO Annex 11, Section 2.26 states that the acceptable level of safety and safety objectives applicable to the provision of ATS services within airspaces and at aerodromes shall be established by the State or States concerned. In addition, Annex 11 explicitly recognises that the levels of safety can be determined by means of regional agreements.

b) ESARR 1 does not require the NSAs to define the "tolerable levels of safety" for the provision of services within the airspace blocks subject to their supervision. Within ESARR 1, NSAs are only required to monitor them and assess their achievement.

c) The "tolerable levels of safety" for the provision of services in an airspace block will be established **through the "existing regulatory framework"**, that is to say:

- In EU Member States that regulatory framework will be based upon the SES legislation in force since April 2004. In particular, Common Requirements for the provision of services shall be established. The tolerable levels of safety also apply to the provision of services. Therefore, their determination may be expected to take place within that context, or in relation to it.
- In non-EU States who are Members of EUROCONTROL, the State will probably continue defining the levels of safety applicable to the provision of services in the airspaces under its jurisdiction.

3.6.2.1 Results from Monitoring to Determine the Need for Verification

Section 4.2 establishes a direct link between the actions required to verify compliance and the applicable safety regulatory requirements. The results from the monitoring actions must be considered in order to identify those areas where verification of compliance is needed.

In practical terms, the monitoring process should feed information into the planning of safety regulatory audits identifying areas of safety concern.

3.7 VERIFICATION OF COMPLIANCE – SITUATIONS TO BE ADDRESSED (ESARR 1, SECTION 5.1)

3.7.1 Requirements

"5.1. National Supervisory Authorities shall establish a process in order to verify:

a) Compliance with applicable safety regulatory requirements prior to the issue or renewal of a certificate by the National Supervisory Authority recognising the capability of an organisation to provide ATM services.

b) Compliance with applicable safety regulatory requirements prior to the designation, or the renewal of a designation, of an organisation holding a certificate to provide ATM services within specific airspace blocks.

c) Continuous compliance of ATM service providers with applicable safety regulatory requirements.

d) In relation to the three previous points, the implementation of additional safety-related conditions associated to the certificates or the designations referred to, such as those related to tolerable levels of safety in the ATM services provided within specific airspace blocks.

e) The implementation of safety objectives, safety requirements and other safety-related conditions identified in;

i) EC declarations of verification of technical systems,

ii) EC declarations of conformity or suitability for use of constituents of technical systems; and

iii) Risk assessment and mitigation documentation, related or not to those declarations,

to allow the proposed operation of new ATM systems, including transition into operational use, or proposed changes to the operation of existing ATM systems in the form of new developments or modifications.

f) The implementation of safety directives issued by the National Supervisory Authority."

3.7.2 Rationale and Implications

Section 5.1 identifies the situations where specific actions are required to verify the compliance with applicable safety regulatory requirements and any arrangements needed to implement them.

Verification of compliance is required in respect of:

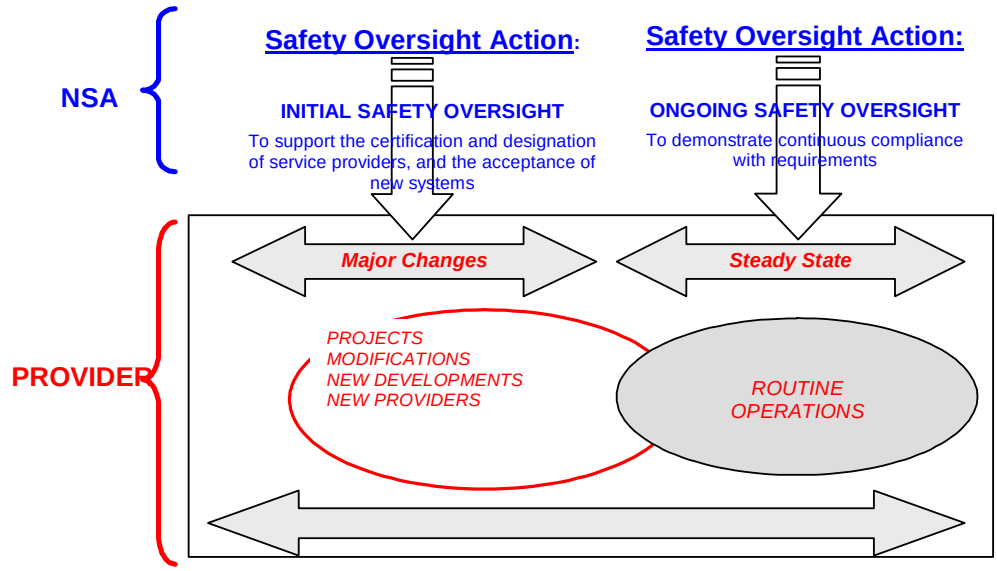
- Any certification process established to signify the capability of a service provider to provide specified services;
- Any process established to designate the ATM service providers which will operate in a particular airspace block;
- The demonstration of continuous compliance with all applicable safety regulatory requirements;
- The implementation of safety-related conditions derived from the application of the existing rules in the introduction of a new system or change;
- The implementation of safety-related conditions contained in safety directives that may be issued by NSAs.

The certification, designation and verification of new systems and changes are related to the notion of **initial safety oversight**.

Initial safety oversight addresses the proposed operation of ATM organisations and systems, or the proposed changes to the operation of existing ATM systems or organisations.

Continuous compliance is related to the **on-going safety oversight** of the continuous operations of in-service ATM systems.

Figure 4 below illustrates the safety oversight actions to be developed in relation to the ATM service provision activities:



(Figure 4 – Initial and Ongoing Safety Oversight)

3.7.2.1 Certification and Designation

The two first bullets of Section 5.1 concern those situations where a service provider is to be certified as being capable of providing services, or designated to provide services in a particular airspace block. In that context it should be noted that:

a) Within the EU, a certificate for the provision of services issued to a suitably assessed applicant is to be recognised across the Community. The certificate will signify the capability of the service provider organisation to provide specific services. A service provider holding such certification may then be designated by any EU Member State to provide the specified services in a particular airspace block.

b) Verification of compliance is required before issuing or renewing a certificate. In EU Member States, the "applicable safety regulatory requirements" to be verified will be identified in the Common Requirements defined within the SES framework.

c) According to ESARR 1, verification of compliance is also required prior to the designation, or the renewal of a designation, of an organisation holding a certificate to provide ATM services within specific airspace blocks. In this case it should be noted that:

- ESARR 1 Section 5.2 bullet (e) requires the verification process to assume compliance with the specific provisions already verified by a NSA for the issuance or renewal of a certificate, wherever verification relates to the designation of the holder of that certificate. That assumption is required in the light of the mutual recognition of certificates established by the SES legislation.

d) As referred to in Section 5.2 bullet (d), the certification and designation processes may involve the identification of additional safety-related conditions which are to be met by the service provider. In these situations, any additional safety-related conditions will also have to be verified. This situation may take place as a result of:

- The SES legislation[11] establishing that there can be "additional conditions" attached to the certificates including "required levels of performance of such services, including safety and interoperability".
- Article 8 of the SES Service Provision Regulation stating that States shall define the "rights and obligations" to be met by the designated service providers. The application of this article could result in the existence of specific requirements beyond the SES Common Requirements. If that were the case, those specific requirements would form part of the "applicable safety regulatory requirements" to be verified in conjunction with the designation step.

[11] *See Regulation (EC) 550/2004 (the service provision regulation), Annex II (Conditions to be attached to certificates), bullet 2.*

It should be noted that the provisions of ESARR 1 do not depend upon the interpretation of the expression “rights and obligations” as used in the SES legislation, or the level of detail and development of the SES Common Requirements. If safety-related conditions are identified in relation to the certification or designation, or if additional safety regulatory requirements existed in relation to the designation step, they would simply have to be verified.

e) In the case of non-EU States who are members of EUROCONTROL, the need to verify compliance with regards to the certification and designation of service providers will **only apply in those cases** where the applicable (national) regulatory framework establishes certification and/or designation schemes equivalent to those established in the SES legislation.

3.7.2.2 On-going Safety Oversight

Section 5.1, bullet (c) requires NSAs to establish a process to verify the continuous compliance with applicable safety regulatory requirements by service providers.

In addition, according to Section 5.2 bullet (d), any safety-related condition associated to the certification or designation steps will also be subject to the continuous verification of compliance process.

Verification of continuous compliance is required **irrespective** of the existence, or not, of certification and designation schemes. These provisions are therefore sufficient to adequately **cover the cases of non-EU states** where no certification/designation schemes exist.

3.7.2.3 Safety-related Conditions Related to Specific Systems or Changes

According to Section 3.1 bullet (b), NSAs verify compliance, not only with applicable safety regulatory requirements, but also with any arrangements needed to implement them. Section 5.1 bullet (e) addresses this issue in relation to the introduction of new systems.

The implementation of safety-related conditions identified in the process to allow the proposed operation of new systems needs to be verified. Those safety-related conditions will always be developed as part of the implementation of “applicable safety regulatory requirements”.

A case in point is the application of ESARR 4 by service-providers. ESARR 4 is part of the “applicable safety regulatory requirements” in all EUROCONTROL Member States. It requires service providers to conduct risk assessment and mitigation in relation to new systems and changes to the ATM system.

The ESARR 4 risk assessment and mitigation process provides for a set of safety objectives and safety requirements (also known as ‘mitigation measures’). These are safety-related conditions pertaining to the implementation of ESARR 4. In accordance with ESARR 1, Section 5.1 bullet (e), their implementation needs to be verified.

Another significant case stems from the application of Regulation (EC) 552/2004 which is applicable in EU Member States. It establishes a framework in which:

- Technical systems are subject to "EC verification" by service providers in accordance with the relevant implementing rules for interoperability developed under the SES framework. An "EC declaration of verification" signifies the result of that verification.

- Constituents of technical systems need to be accompanied by an 'EC declaration of conformity' or suitability for use. This declaration is normally produced by the manufacturer after the appropriate conformity assessment has taken place in accordance with the relevant implementing rules for interoperability developed under the SES framework.

According to Regulation (EC) 552/2004, both types of declarations must contain all the necessary information about the "conditions and limits of use". These constitute arrangements needed to implement the provisions of the interoperability implementing rules and, as such, their implementation needs to be verified.

ESARR 1 does not require a particular link between the ESARR 4 risk assessment and mitigation process and the EC verification/conformity assessment processes. It is therefore assumed that the risk assessment and mitigation documentation resulting from the application of ESARR 4 can, or cannot, be directly related to the EC declarations. That is the reason for the inclusion of the expression "related or not to those declarations" in Section 5.1 (f) (iii).

Finally, it should be noted that Section 5.2 bullet (f) further specifies the context in which the verification of the implementation of those safety-related conditions takes place:

- In the context of the review of changes to the ATM system (process established in ESARR 1, Section 7);

- As part of safety regulatory auditing conducted to verify continuous compliance with applicable safety regulatory requirements.

3.8 VERIFICATION OF COMPLIANCE – ELEMENTS OF THE PROCESS (ESARR 1, SECTION 5.2)

3.8.1 Requirements

"5.2. That process shall:

a) Use documented procedures to eliminate discrepancies in its application;

b) Be supported by documentation specifically intended to provide safety oversight personnel with guidance to perform their functions;

c) Provide the ATM service provider concerned with an indication of the results of the safety oversight activity;

d) Base the verification of compliance on the use of safety regulatory audits conducted in accordance with the requirements of Section 6 below;

e) *Wherever required by the existing regulatory framework, assume compliance with the specific provisions already verified by a National Supervisory Authority for the issuance or renewal of a certificate, if verification relates to the designation of the holder of that certificate;*

f) *Undertake the verification referred to in 5.1. bullet e) above:*

i) *In the context of the review of safety arguments conducted in accordance with the requirements of Section 7 in relation to systems or changes under consideration.*

ii) *As a part of safety regulatory auditing conducted to verify continuous compliance of ATM services with applicable safety regulatory requirements.*

g) *Provide the National Supervisory Authority with the evidence needed to support further action in situations where safety regulatory requirements are not being complied with, or where successful compliance cannot be expected."*

3.8.2 Rationale and Implications

ESARR 1 does not establish requirements on how the NSA should internally organise itself to establish the process. The requirement only identifies various principles which need to be addressed in the process.

3.8.2.1 Documented Procedures

In order to eliminate discrepancies in the application of the verification processes, it is required to use documented procedures. These procedures should describe in practical and actionable terms what has to be done. Each procedure should be understandable, actionable, auditable and mandatory.

All the procedures can be bound together and all concerned staff given access to the complete set, forming a manual. An alternative approach is for departments to have available just those procedures, which are relevant to their own work and this may be the better approach in larger organisations.

Different records will be created throughout the safety oversight process. The procedures should determine their format and whose responsibility it is to produce them[12].

[12] *See also ESARR 1, Section 11 regarding safety oversight records.*

3.8.2.2 Guidance for Use by Safety Oversight Personnel

ESARR 1 requires that the process is supported with specific documentation intended to provide the safety oversight personnel involved in the process with guidance on how to perform their functions.

It should be noted that this aspect has been identified as a critical element of a safety oversight system in ICAO Doc.9734-A[13].

NSAs may use, amongst other documentation, the ESARR Advisory Material (EAM) and other guidance deliverables produced by the EUROCONTROL Safety Regulation Commission to support the implementation of ESARRs.

3.8.2.3 Use of Safety Regulatory Auditing

Safety regulatory auditing is a technique which provides NSAs with means for obtaining objective evidences to support conclusions and decisions about a claimed compliance, or lack of compliance, with specified requirements.

The verification processes operated by the NSAs should be supported by the use of this powerful tool, most notably **wherever objective evidences are needed**, or where safety issues have been identified in the monitoring of safety performance.

The use of safety regulatory audits, and its overall planning, must meet the requirements contained in Section 6.

3.8.2.4 Assumption of Compliance with Provisions Verified in the Certification Step

As already mentioned, ESARR 1, Section 5.2, bullet (e) requires the verification process to assume compliance with the specific provisions already verified by a NSA for the issuance or renewal of a certificate:

- wherever verification relates to the designation of the holder of that certificate, and
- if this assumption is required in the existing regulatory framework.

This assumption is required in the light of the mutual recognition of certificates established by the SES legislation.

It is important to note that ESARR 1 only provides requirements as regards the safety processes operated by NSAs. The SES framework, not ESARR 1, will provide for a set of common rules applicable in those countries within the SES framework.

However, the regulatory reference will be different outside the SES framework. As a result, mutual recognition between SES and non-SES countries cannot be assured without additional arrangements. This is the main reason for the inclusion of the expression **"wherever required in the existing regulatory framework"** in the text of ESARR 1.

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[13] *See ICAO Document 9734, Part A 'The Establishment and Management of a State's Safety Oversight System'. First Edition, 1999. This document describes the critical elements of a safety oversight system as considered by USOAP in order to audit the capabilities of a State to implement appropriate safety oversight. A revised version encompassing ATM was being developed by ICAO at the time of this writing.*

It is important to emphasise that the assumption of compliance can only exist as regards **specified provisions** already verified by a NSA when issuing or renewing a certificate. Wherever the designation step involves other specified requirements or conditions, compliance cannot be assumed and verification will be needed.

This implies a need for **traceability** between the results of the verification activities conducted in the certification and its specified requirements.

3.8.2.5 Contexts of the Verification Related to New Systems and Changes

As already mentioned, Section 5.2 bullet (f) specifies the context in which the verification of the implementation of those safety-related conditions takes place:

- In the context of the review of changes to the ATM system in accordance with the requirements of section 7. This is to say, wherever the need for auditing is raised as a result of the review of a change[14].

- As part of safety regulatory auditing conducted to verify continuous compliance with applicable safety regulatory requirements.

The need for this differentiation is necessary in order to make totally clear the two contexts in which the verification process will normally be undertaken in relation to the introduction of new systems and changes.

The other situations in which the verification mechanisms are triggered are evident and do not need to be further specified (e.g. wherever someone applies for a certification, or wherever a State considers designating a provider, etc.).

3.8.2.6 Supporting Further Action in Cases of Lack of Compliance

The process of safety oversight may present situations where requirements are not being complied with, or where successful compliance cannot be expected.

In these situations, further regulatory action may be required, and it is essential to support any measures taken with a **clear rationale and objective evidences**. The verification mechanisms operated by NSAs must be capable of supporting that rational and provide for those evidences, notably by using the auditing process, wherever needed.

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[14] *That need would notably concern the demonstration included in the safety argument to show that the risk assessment and mitigation process is compliant with the requirements, wherever that demonstration needs to be checked. See Sections 3.13 and 3.14 of this document for more details.*

3.9 SAFETY REGULATORY AUDITING – GENERAL PRINCIPLES (ESARR 1, SECTIONS 6.1 and 6.2)

3.9.1 Requirements

"6.1. National Supervisory Authorities, or recognised organisations acting on their behalf, shall conduct the safety regulatory audits foreseen in Section 5.2 d)."

"6.2. Those safety regulatory audits shall:

a) Provide National Supervisory Authorities with evidence of compliance with applicable safety regulatory requirements and related arrangements by evaluating the need for improvement or corrective action;

b) Be undertaken under the managerial responsibility and overall control of the National Supervisory Authority independently of the internal auditing activities undertaken by ATM service-providers as part of their safety management arrangements;

c) Be conducted by qualified auditors of the National Supervisory Authorities, or recognised organisations acting on behalf of them, in accordance with the requirements of Sections 8 and 9.4 c) below;

d) Depending upon the case, apply to, but not be limited to, complete arrangements or elements thereof, to processes, products or services;

e) Be used to determine the conformity or non-conformity of:

i) Established arrangements against required arrangements;

ii) The implemented arrangements and their results against the established arrangements and their expected results.

f) Provide the auditee with an opportunity to correct non-conformities and improve the safety of the area under consideration.

3.9.2 Rationale and Implications

The safety regulatory audits are the basic means by which NSAs may obtain objective evidences as regards the compliance with specified requirements. They shall be conducted by the NSAs, or recognised organisations acting on their behalf, in order to support the whole safety oversight process.

ESARR 1, Section 6.2 establishes the principles to be meet by the safety regulatory audits organised by the NSAs. Some basic points to note are:

a) The main objective of the audits is to provide NSAs with **objective evidences** on the compliance, or lack of compliance, with applicable safety regulatory requirements and any arrangements needed to implement them. Their approach is focused on evaluating the need for improvement or corrective action;

b) Safety regulatory auditing is a process arranged and organised by the NSAs under their managerial responsibility and overall control. Wherever NSAs decide to delegate the conduction of safety regulatory audits to recognised organisations, the **responsibility** still rests with the NSA;

Accordingly, any arrangements established between NSAs and recognised organisations should ensure[15] that the:

- Audits fulfil the objectives of the NSA, address any issues and areas of concern specifically identified by the NSA, and are consistent with the programme of safety regulatory audits established by the NSA;
- NSA is the organisation responsible for requesting corrective actions in the light of the findings obtained by the recognised organisation.

c) The safety regulatory audits are not a possible means of compliance to implement the ESARR 3 requirements establishing the need for safety surveys in the Safety Management Systems operated by service-providers;

d) Nothing prevents the use of ESARR 1 compliant **cross-auditing arrangements** between NSAs to undertake the safety regulatory audits required in ESARR 1. Wherever that approach is implemented, the NSA with jurisdiction over the audited service provider will remain responsible for the audit, notably as regards the responsibilities, for requesting corrective actions wherever they are needed;

e) Depending upon the case, the audits address the processes and/or products/services[16]. ESARR 1, Section 5.1 requires the verification of compliance with applicable safety regulatory requirements and any arrangements needed to implement them. Accordingly, two complementary levels of verification and their related references are defined in Section 6.2, bullet (e):

i. Established arrangements against required arrangements;

ii. Implemented arrangements and their results against established arrangements and their expected results

A case in point is the implementation of Safety Management Systems (SMS) in accordance with ESARR 3, where those points may correspond with:

i. The SMS Manual against ESARR 3

ii. What actually happens against the SMS Manual

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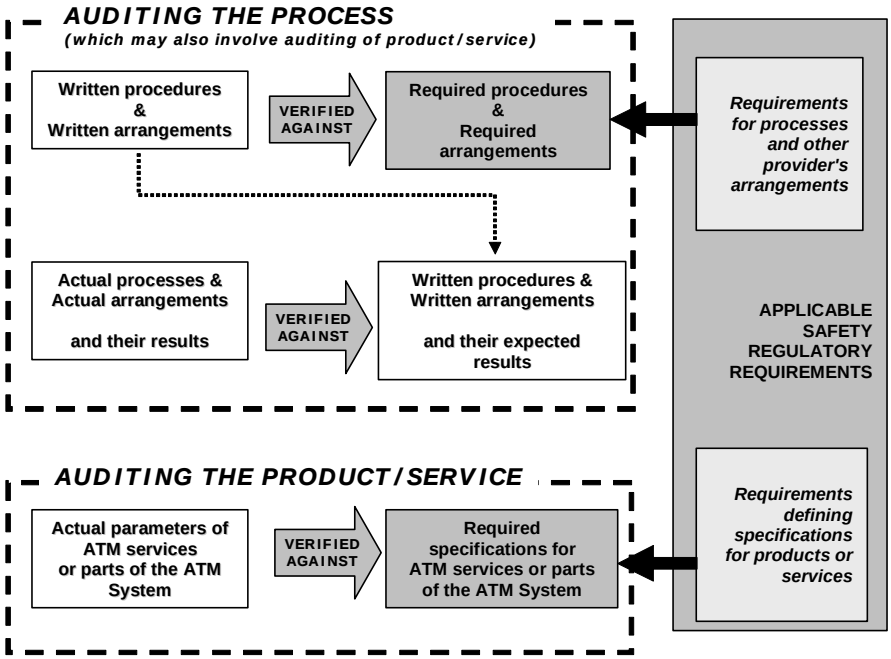
[15] *See also the guidance provided in relation to ESARR 1, Section 6.5 (included in Section 3.10 of this document).*

[16] *Irrespective of their nature, the "products" are the final outputs of a process. Within the ATM environment, and for the purpose of ESARR 1, the "ATM services" are normally the "products" under consideration.*

Figure 5 below may be useful to illustrate these notions:



(Figure 5 – Safety regulatory auditing of processes/products and references used)

3.9.3 Further Specific Guidance

A specific EAM 1 deliverable providing guidelines on ATM safety regulatory auditing (EAM 1 / GUI 3) is being developed by SRC to provide NSAs with further guidance on the use of safety regulatory audits.

That material will focus its attention on specific aspects related to the application of auditing to ATM organisations, and provide guidance on situations involving the use of recognised organisations or cross-border arrangements.

The safety regulatory audits required in ESARR 1 are considered compatible with the ISO-19011 auditing methodology.

3.9.4 Specific Related Issues

3.9.4.1 Safety Auditing as the Means to Perform Inspections

Regulation (EC) 550/2004 establishes that National Supervisory Authorities shall organise *"**proper inspections and surveys"*** to verify compliance with the requirements of the Regulation. These requirements cover a wide range of areas apart from safety.

Safety oversight is established as a specific part of the generic supervisory role of a NSA. In that context, ESARR 1 identifies safety regulatory auditing as the means to implement those *"proper"* inspections[17] and surveys wherever safety is the aspect subject to verification.

[17] *It should be noted that across the European ATM industry the term "inspection" does not represent an establish methodology and may have different meanings and implications depending on the country. On the other hand the term "audit" is commonly known and understood in relation to the application of ISO standards.*

The rationale for this is that the most advanced methods are needed to support the NSA's verification processes wherever safety is under supervision. Such methods also need to be well-established and used in a harmonised manner by all NSAs.

Consistent with the **priority given to safety** in the public interest, the conduct of safety regulatory audits is required in line with the most advanced safety auditing techniques to provide the NSAs with the most powerful means available to verify the compliance with applicable safety regulatory requirements.

Other specific methodologies might be used to carry out "proper inspections and surveys" in relation to non-safety related requirements.

3.10 SAFETY REGULATORY AUDITING – PROGRAMME OF AUDITS (ESARR 1, SECTIONS 6.3, 6.4 and 6.5)

3.10.1 Requirements

"6.3. National Supervisory Authorities shall establish an annual programme of safety regulatory audits to:

a) Cover all the areas of potential safety concern.

b) Focus, but not exclusively, on those areas where problems have been identified as a result of monitoring safety performance

c) Conduct audits to address all the ATM service-providers and the different ATM services operating under their responsibility;

d) Conduct sufficient audits, at least once every two years, to check the compliance of all ATM service-providers under their responsibility with applicable safety regulatory requirements in all the functional areas of relevance; and

e) Follow up the implementation of corrective actions intended to address non-conformities found in previous audits

6.4. The programme shall be designed to allow for the modification of the objectives of pre-planned audits, and the inclusion of additional audits to those originally programmed, wherever that need is identified in the safety oversight activities of the National Supervisory Authority.

6.5. National Supervisory Authorities shall decide which arrangements, elements, services, products, physical locations and organisational activities are to be audited within a specified timeframe."

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3.10.2 Rationale and Implications

The conduct of audits relies on the use of specific resources. Notably, this includes the use of personnel with auditor qualifications as defined in ESARR 1. These resources, provided by the NSAs or recognised organisations, need to be efficiently managed to achieve the objectives of the safety oversight process.

The resources committed to an audit should be sufficient to meet its intended scope and depth. Consequently, planning is crucial to make proper use of the available resources.

ESARR 1 requires NSAs to establish an annual programme to address this necessity.

The annual programme should be sufficiently flexible so that it can be improved throughout its implementation by considering unexpected auditing priorities which may be raised as a result of, inter alia, the:

a) Findings of audits already conducted;

b) **Monitoring of safety performance**, notably wherever serious safety occurrences occur;

c) Need to **follow-up** the implementation of corrective actions to address non-conformities found in previous audits;

d) Implementation of new systems and changes to the ATM system (including changes in the organisational service provider arrangements, etc.);

e) New organisations applying for a Certificate, etc.

3.10.2.1 Minimum Timeframe and Scope Required

As a general principle, NSAs should concentrate their audit resources in verifying those areas where problems have been identified, in a manner which meets the following minimums established in ESARR 1:

The programme of audits must include audits to cover:

- All ATM service provider organisations operating under the jurisdiction of the NSA. Consequently, **each organisation** must be addressed in the programme.
- The different types of ATM services provided by those service provider organisations operating under the NSA's jurisdiction. This means that the scope of the audits must target **all the different ATM services** (e.g. area control, approach control, aerodrome control, AFIS, etc.) being provided.

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According to ESARR 1, audits must be conducted to check the compliance of **all service providers** with the applicable safety regulatory requirements in all areas of functional relevance **at least once every two years.** This means that compliance needs to be completely reviewed **over a period of two years**.

In meeting these minimums it should be noted that:

a) The two year period required is consistent with equivalent EASA mandatory provisions[19] requiring auditing every 24 months in the airworthiness domain.

b) The programme is established on an **annual basis** and, therefore, needs to be **reviewed and updated** at least annually.

c) The scope of a specific audit does not necessarily have to involve the whole organisation and can be confined to a particular facility or area of functional relevance.

d) All service providers should be **completely reviewed for compliance** with all the applicable safety regulatory requirements **over a period of 24 months**.

e) The number of audits conducted will normally be related, amongst several aspects, to the size of the organisation, its complexity and number of facilities and the safety criticality of its activities.

f) All service providers shall be subject to **auditing at least once every two years**.

g) The expression “areas of functional relevance” should be interpreted as meaning the technical, operational and managerial functions needed by the service provider organisation to provide a safe operational ATM service and related to the requirements under consideration.

3.10.2.2 Responsibility for the Auditing Programme

Being responsible for the organisation and overall control of the auditing activity, the NSAs remains responsible for the establishment of the auditing programme, even in those cases where recognised organisations are commissioned to conduct the audits. This responsibility includes the decisions concerning the scope and timeframe of the audits as established in Section 6.5.

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[19] *See Part 21, Section 21B.235 (Continued Surveillance) included in the annexes to Commission Regulation (EC) 1702/2003 dated 24 September 2003.*

3.10.3 Further Specific Guidance

Apart from the development of a specific EAM 1 deliverable to provide NSAs with further guidance on the use of safety regulatory audits, the SRC is assessing the possibility of developing further specific guidance on the methods to determine the resources needed by a NSA to implement appropriate safety regulatory auditing under its jurisdiction.

Such methods could perhaps be based on existing guidance material developed in relation to ISO standards[20].

3.11 SAFETY REGULATORY AUDITING – MANAGEMENT OF THE FINDINGS (ESARR 1, SECTION 6.6)

3.11.1 Requirements

"6.6. In a safety regulatory audit:

a) Audit observations and identified non-conformities shall be documented, supported by evidence, and identified in terms of the applicable safety regulatory requirements or related arrangements against which the audit has been conducted;

b) An audit report, including the details of the non-conformities, shall be forwarded to a designated point of responsibility within the National Supervisory Authority;

c) The point of responsibility within the National Supervisory Authority shall

i) Ensure that the audit findings are communicated to the senior management of the organisation audited;

ii) Request corrective actions to address the non-conformities identified, and;

iii) Undertake additional actions as required.

d) Auditors shall only be responsible for identifying the need for corrective actions. The auditee shall be responsible for determining and initiating the corrective actions needed to correct a non-conformity or to correct the cause of a non-conformity;

e) The National Supervisory Authority shall assess the corrective actions determined by the auditee and accept them if the assessment concludes that they are sufficient to address the non-conformities found in the audit;

f) Corrective actions and subsequent follow-up audits shall be completed within a time period agreed by the National Supervisory Authority."

[20] *For further information see IAF Guidance on the Application of ISO/IEC Guide 62:1996, dated December 2001. Amongst several topics, the document includes guidance for the determination of the auditor-time needed to complete an initial or ongoing assessment of an organisation depending on the size of the organisation and other factors. At the time of this writing, this material had not been assessed by SRC in relation to its possible use in ATM safety oversight.*

3.11.2 Rationale and Implications

Section 6.6 addresses some basic points to be met in any audit conducted by the NSAs or the recognised organisations acting on their behalf. More particularly, these provisions are primarily focused on critical aspects related to **the outputs** of an audit, their management and the various roles involved.

The audit report is prepared by the audit team, formed by personnel from the NSA or the recognised organisation acting on its behalf, under the direction of the lead auditor who should be responsible for its accuracy and completeness. Auditors are only responsible for identifying the need for corrective action. The auditors **never** define the corrective measures[21].

The full report, including the details of non-conformities shall be forwarded to a **designated point of responsibility within the NSA**. That point of responsibility should not be involved in the conduct of the audit. He/she shall play a key role as regards the management of the outputs from the audit, by:

a) Ensuring that the audit findings are communicated **to the senior management** of the organisation audited. It should be noted that this does not necessarily mean the forwarding of the full report produced by the audit team;

b) Requesting the audited organisation to define and implement **corrective action** to address the non-conformities identified in the findings;

c) Undertaking **additional actions** if required, particularly when an unsafe condition has been determined to exist. The term “undertaking” should not be interpreted as taking responsibility for these additional actions. It only means that he/she provides appropriate inputs to the NSA’s internal arrangements established to deal with this sort of situation.

   The types of actions which might need to be taken by a NSA will depend upon the situation and the existing regulatory framework in place, but may include, inter alia:

   - The issuance of a safety directive to address a detected unsafe condition;
   - Placing restrictions on the service provider or, in extreme cases, initiating the process to withdraw permission to provide the service or impose other punitive measures on the organisation or its individuals, as dictated by the situation. This must always be done within the established rules of the existing regulatory framework.

[21] *Correctives actions are defined by the auditee and proposed to the NSA’s designated point of responsibility. The NSA assesses the proposed corrective actions and, if appropriate, accepts them as an appropriate means to address the non-conformities detected. This assessment should ensure that the auditee has the opportunity to provide comments within agreed timescales. Once accepted by the NSA, the corrective actions must be implemented within a period agreed by the NSA.*

3.12 SAFETY OVERSIGHT OF CHANGES – TYPES OF CHANGES (ESARR 1, SECTIONS 7.1 and 7.2)

3.12.1 Requirements

"7.1. For the purposes of this Requirement, National Supervisory Authorities shall classify the new systems or changes to the ATM system proposed by ATM service-providers into two main categories:' major' and 'minor' changes.

7.2. The category of 'major changes' shall include, as a minimum, any new system or change whose;

a) Assessment of the potential effects of hazards on the safety of aircraft, conducted in accordance with ESARR 4, identifies hazards with potential to lead to an accident or serious incident; or,

b) Implementation introduces a need for new aircraft standards."

3.12.2 Rationale and Implications

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

The existing regulatory frameworks have addressed this major issue by requiring the service providers to implement specific processes, such as risk assessment and mitigation as required in ESARR 4, or the EC verification of technical systems as required in Regulation (EC) 552/2004 to ensure the safe implementation of changes.

The implementation of new systems and changes, and the arrangements required around them, need particular attention within the ATM safety oversight process due to the safety significance of this implementation.

A National Supervisory Authority cannot dedicate the same level of safety oversight resources to all changes in the ATM system. The degree of the NSA's involvement may also be different. For example, some changes and operations/systems may be subject to the acceptance of the NSA, others not.

The criteria and conditions driving the level of safety oversight effort, the degree of the NSA's involvement and related procedures must be explicitly specified.

In that context, ESARR 1 establishes specific safety oversight actions depending upon the type of change under consideration. Initial safety oversight, based on a specific review, will be conducted on particular systems selected by virtue of their significance. These systems will be subject to **acceptance by the NSA**.

In order to harmonise the implementation of this approach, ESARR 1 defines the minimum boundaries for each category of change which must be addressed through the review and acceptance mechanisms.

3.12.2.1 Classification of New Systems and Changes to the ATM System

For the purposes of ESARR 1, the National Supervisory Authorities shall classify new systems and changes to the ATM system proposed by service providers into:

- Major changes; or
- Minor changes.

The major changes shall include, **as a minimum**, any new system or change:

- Whose assessment of the potential effects of hazards on the safety of aircraft conducted in accordance with ESARR 4, identifies hazards with potential to lead to an accident or serious incident; **or**
- Whose implementation introduces a need for new aircraft standards.

The introduction of new operational units, equipment, operational procedures or airspace structure design are some clear examples of possible major changes.

Various aspects must be underlined with regards to these requirements:

a) The text includes the expression **"For the purposes of this Requirement"**. This means that the classification required in ESARR 1 does not necessarily need to be used in other contexts. The terms "major" and "minor" are merely names used as titles for the two categories of changes that the process needs to take into consideration;

b) The Requirement includes the term "as a minimum" which implies that a NSA may, at its discretion, decide to consider other changes as 'major' if necessary;

c) The ultimate rationale for the two bullets is to cover the situations with safety significance in the light of two factors:

   - The first bullet implicitly relates to the safety significance of a proposed change and the **potential effects**[22] of its implementation;
   - The second bullet considers that a complex integration of the change into the **total aviation system**, and the complexity of the interfaces in that case, imply a significant hazard source.

d) The assessment of the potential effects of hazards referred to in the first bullet is conducted in accordance[23] with ESARR 4. This means that the service provider is the **organisation responsible for the assessment** which will be obtained from the application of the risk assessment and mitigation process required in ESARR 4;

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[22] *Using criteria focused on the potential "effects" appears consistent with the approach adopted by EASA in Part 21 (former JAR-21). That approach is based on classifying as major any change that could bring "appreciable effects" to the physical characteristics related to the airworthiness of the aircraft (e.g. mass, balance, structural strength, etc).*

[23] *It should be noted that ESARR 4 is applicable within all the existing regulatory frameworks of the EUROCONTROL Contracting Parties.*

e) Indeed, the assessment of the potential effects of hazards is conducted in the first steps of the ESARR 4 risk assessment and mitigation process which is developed, normally, in parallel to any project or programme;

f) The expression "potential effects of hazards on the safety of aircraft with potential to lead to an accident or serious incident" matches the severity classes 1 and 2 as defined in ESARR 4. The severity classification scheme included in ESARR 4 is at the core of the criteria proposed to classify the changes in ESARR 1.

3.12.3 Further Specific Guidance

ESARR 4 describes the risk assessment and mitigation process which must be conducted by service providers and includes a severity classification scheme with five categories and examples of the effects on operations for category.

There is a series of guidance deliverables (EAM 4) associated with ESARR 4. The document 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.

Apart from the minimum categories identified in ESARR 1, EAM 4 / GUI 2 includes advice on the criteria to identify additional categories of changes which could be subject to review and acceptance.

3.13 SAFETY OVERSIGHT OF CHANGES – GENERAL APPROACH (ESARR 1, SECTIONS 7.3, 7.4 and 7.5)

3.13.1 Requirements

"7.3. The implementation of major changes shall be subject to acceptance by the National Supervisory Authority;

7.4. The use of procedures conducted by ATM service providers to decide the implementation of minor changes shall be subject to:

a) Acceptance of such procedures by the National Supervisory Authority;

b) The inclusion in such procedures of a step to notify the National Supervisory Authority of any minor changes implemented; and

c) Regular safety regulatory auditing conducted as part of the verification of continuous compliance of ATM services with applicable safety regulatory requirements.

7.5. The National Supervisory Authority shall review, as a minimum, those safety arguments associated with new systems or changes to the ATM system which are classified as a major change."

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3.13.2 Rationale and Implications

The decisions on the introduction of new systems and changes into operational service are either:

- Made directly by the service-provider's management for those changes classified as 'minor'; or
- Subject to prior acceptance by the NSA for changes classified as 'major'.

In both cases, specific procedures operated by the service provider, notably those intended to implement ESARR 4 and Regulation (EC) 552/2004, will provide the rationale to support a final decision on the implementation of the system or change under consideration.

In the first case:

a) The procedures used by the service provider need to be known and accepted by the NSA;

b) These procedures may depend upon the existing regulatory framework, but should normally encompass, inter alia:

- The risk assessment and mitigation processes complaint with ESARR 4 in all EUROCONTROL Member States;
- The EC verification of technical systems required in Regulation (EC) 552/2004 in the case of EU Member States;
- Arrangements related to the final decision-making step[24] taken by the organisation's management in the light of the conclusions obtained from the various service providers' procedures

c) No specific integration is required between the various procedures that may be required by the existing regulatory framework (e.g. links between ESARR 4 and EC verification of technical systems);

d) These procedures are subject to safety regulatory auditing implemented to verify continuous compliance with applicable safety regulatory requirements and any arrangements needed to implement them.

In the second case:

a) The NSAs shall review the "safety arguments" associated with the new systems or changes under consideration;

b) That review provides the rationale to support the NSA's decision on the acceptance of the system to go into operational use.

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[24] *It is important to establish clear arrangements to identify who, within the service provider's management, makes the final decision to implement a system in the light of all the information available.*

[26] *The terms "safety argument" and "safety-related condition" are defined in ESARR 1, Section 1. 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.*

3.13.2.1 Safety Argument

The safety argument[26] is developed by the service provider to **demonstrate** and to provide evidence that a proposed change can be implemented safely, i.e. within tolerable levels of safety.

The service provider conducts specific procedures to produce that demonstration, notably a full risk assessment and mitigation process is conducted in accordance with ESARR 4.

The safety argument is formed by:

a) 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;

This collection of safety-related conditions is identified[27] 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'.

b) Other outputs of the risk assessment and mitigation process, such as lists of hazards that are used within the process to derive safety-related conditions;

c) Demonstration and evidence that those safety-related conditions have been properly derived in a **process compliant** with ESARR 4;

d) 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;

e) Demonstration that the safety-related conditions are **effectively implemented**, and will continue to be implemented.

All these aspects form the safety argument,[28] to be reviewed and assessed by the NSA.

3.13.3 Further Specific Guidance

Within the series of guidance deliverables associated with ESARR 4, 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.

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

[28] *Sometimes known as "safety case".*

3.14 SAFETY OVERSIGHT OF CHANGES – REVIEW OF CHANGES (ESARR 1, SECTION 7.6)

3.14.1 Requirements

"7.6. That review shall:

a) Use documented procedures to eliminate discrepancies in its application.

b) Be supported by documentation specifically intended to provide safety oversight personnel with guidance to perform their functions.

c) Consider the safety objectives, safety requirements and other safety-related conditions that are related to the change under consideration which have been identified in:

i) EC declarations of verification of technical systems;

ii) EC declarations of conformity or suitability for use of constituents of technical systems; and

iii) Risk assessment and mitigation documentation, related or not to those declarations.

d) Provide the rationale for the acceptance, or non-acceptance, of major safety-related changes referred to in Section 7.3 above.

e) Wherever needed, identify additional safety-related conditions associated to the implementation of the change.

f) Assess whether the safety arguments presented demonstrate that the proposed changes can be implemented within the applicable tolerable levels of safety. Such assessment shall address:

i) The completeness and correctness of the list of hazards;

ii) The consistency of the allocation of severity classes;

iii) The validity of the safety objectives;

iv) The validity, effectiveness and feasibility of safety requirements and any other safety-related conditions identified;

v) The demonstration that the safety objectives, safety requirements and other safety-related conditions are met and will continue to be met;

vi) The demonstration that the process used meet the applicable safety regulatory requirements.

g) Involve auditing to verify the processes used by ATM service providers in relation to the new system or change under consideration.

h) Identify the need for the verification of compliance referred to in Section 5.2, bullet f) above.

i) Involve any necessary co-ordination activities with the authorities responsible for the safety oversight of airworthiness and flight operations."

3.14.2 Rationale and Implications

A specific review process is required in relation to new systems and changes to the ATM system that are classified as major safety-related changes.

Various aspects must be underlined as regards the implementation of this review:

a) The review is required, as a minimum, for all major changes. These changes necessarily require acceptance by the NSA before being implemented. Nothing prevents NSAs undertaking the review of a minor change, subject or not to acceptance[29], if necessary and possible within the existing regulatory framework.

b) The review must provide the **rationale to support the NSA's decision** about the acceptance, or not, of major safety-related changes.

c) 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 process with guidance on how to perform their functions[30].

d) 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.

e) 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[32] whose effective implementation will need to be verified.

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[29] *Acceptance is required, as a minimum, for major safety-related changes. Nothing prevents NSAs from requiring the acceptance of minor changes if that option is consistent with the existing regulatory framework applicable to the case.*

[30] *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.*

[32] *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.*

3.14.2.1 Co-ordination with Airworthiness and Flight Operations Authorities

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.

Aviation is no longer a puzzle built out of autonomous elements, but a mosaic of **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.

3.14.2.2 Specific Aspects to be Reviewed

The review is focused on the "safety argument" associated with the new system and change under consideration.

As already mentioned[33], 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 explicitly refers to six interrelated points which need to be checked with regards to the steps and outputs of a risk assessment and mitigation process:

a) The three first points are related to the ESARR 4 steps intended to identify hazards and determine safety objectives;

b) The fourth point concerns 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;

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

c) The fifth point is about 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;

d) The sixth point concerns **the process and its compliance** with applicable safety regulatory requirements. The demonstration provided may be sufficient or may prompt if necessary, the use of auditing as foreseen in Section 7.6 (g) to check its consistency.

3.14.3 Further Specific Guidance

There is a series of guidance deliverables associated with ESARR 4 (EAM 4). 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.

3.15 RECOGNISED ORGANISATIONS AND NOTIFIED BODIES (ESARR 1, SECTION 8)

3.15.1 Requirements

"8.1. Subject to the conditions in the regulatory framework for the delegation of supervisory tasks, a National Supervisory Authority may decide to commission recognised organisations to conduct safety regulatory audits on their behalf. Such a decision shall be based upon a specific demonstration provided by the recognised organisation as to their suitability to perform the required safety oversight activities.

8.2. Such demonstrations shall satisfy the National Supervisory Authority that:

a) The recognised organisation is competent, having regard to any prior experience in assessing safety in aviation entities, in particular ATM service-providers, to produce adequate auditing results in relation to ATM safety aspects.

b) The recognised organisation is not involved in safety surveys or any other safety-related verification activities implemented internally by the audited ATM service-provider within its Safety Management System.

c) All personnel concerned with the conduct of safety regulatory audits are adequately trained and qualified for their job functions and meet the qualification criteria established by the National Supervisory Authority in accordance with Section 9.4 c) of this Requirement.

d) The recognised organisation provides the National Supervisory Authority with full visibility of its planning, procedures and working methods to conduct safety regulatory audits and their results, and accepts the possibility of being audited by the National Supervisory Authority or any organisation acting on its behalf.

8.3. National Supervisory Authorities shall maintain a record of the recognised organisations commissioned to conduct safety regulatory audits on their behalf. The records shall document compliance with the requirements contained in Section 8.2 above

8.4. When considering the appointment of a notified body to carry out tasks related to the EC assessment of conformity or suitability of constituents of technical systems and/or EC verification of technical systems, the National Supervisory Authorities shall require the notified body to accept the conduct of investigations if that need arises in accordance with Section 10.3 below."

3.15.2 Rationale and Implications

Within the SES legislation applicable to EU Member States, Regulation (EC) 550/2004 establishes that:

a) NSAs **may decide** to delegate, in full or in part, the inspections and surveys needed to recognise organisations which fulfil a set of requirements included in a specific annex of the Regulation;

b) A recognition granted by a NSA is valid within the Community for a three years renewable period. NSAs **may instruct** any of the recognised organisations located in the Community to undertake these inspections and surveys.

These provisions are complemented by the annex, including generic requirements, which are to be met by an organisation in order for it to be recognised as capable of conducting inspections and surveys **should a NSA decide** to select it for such tasks.

These provisions imply that:

- Within the EU, there will be a "list" of **organisations eligible** to conduct inspections and surveys on behalf of a NSA. Within the EU, no other organisations will be eligible to act as recognised organisations;

- In order to be added to that "list", an organisation must fulfil the requirements included in the annex of the Regulation, and this needs to be formally recognised by an NSA of an EU Member State.

The tasks and activities that can be delegated, as well as the requirements established in the annex of the Regulation, concern the generic supervision which must be implemented by NSAs and does not address safety oversight in a specific manner.

Subject to this generic regulatory framework, ESARR 1 addresses the case of the supervisory tasks specifically related to safety.

Various key aspects must be underlined in the provisions of ESARR 1 Section 8:

a) Wherever safety is the issue under consideration, any decision on the delegation of tasks to a recognised organisation should specifically ensure that the safety implications have been appropriately considered;

b) It is important to note that the ESARR 1 requirement only refers to **the decision** which is made internally by the NSA with regards the delegation of tasks to a particular recognised organisation. ESARR 1 does not interfere with the SES regime of formal recognition. Eligible organisations will be determined on the basis of the requirements of the SES Regulations, not by ESARR 1;

c) ESARR 1 only requires the NSA to take some actions to support its decision-making process wherever a decision is to be made with regard to a possible delegation of tasks to a formally recognised organisation;

d) The ESARR 1 provisions are only applicable in the cases of inspections or surveys intended to supervise safety; i.e. to the safety regulatory audits identified by ESARR 1 as the means to implement the "proper inspections and surveys" needed as regards safety[34];

e) Any delegation of tasks is confined to the conduct of safety regulatory audits (or non safety-related inspections and surveys) organised by the NSA. As a general principle, no other tasks (e.g. the monitoring of safety performance, the review of new systems and changes, etc.) can be delegated unless specific provisions exist in the applicable regulatory framework to allow it.

3.15.2.1 Specific Safety-related Aspects to be Considered

The decision of the NSA will be based on a specific demonstration provided by the recognised organisation as to their suitability to perform the specific safety oversight activities that the NSA may wish to delegate.

Such demonstrations shall satisfy the NSA that four criteria related to the suitability of the organisation to specifically deal with safety are covered:

- Competence in **specifically assessing safety** in aviation and producing adequate results when auditing safety;
- Lack of any involvement by the organisation in the safety management activities implemented internally by the service provider to be audited;
- The personnel designated to conduct safety regulatory audits meets the **specific qualification criteria established for safety auditors** in accordance with ESARR 1, Section 9.4;
- Visibility of the methods, planning and procedures **specifically** related to the conduct of safety regulatory requirements, and the acceptance by the organisation that it can be audited by the NSA, or an organisation acting on its behalf.

It should be noted that a demonstration accepted by another NSA could be a valid demonstration to satisfy the NSA that the criteria are covered.

[34] *See also Section 3.9.4.1 of this document (safety regulatory audits as the means to perform inspections).*

3.15.2.2 Notified Bodies

Regulation (EC) 552/2004 establishes that EU Member States shall appoint bodies, called "Notified Bodies"[35], to carry out tasks related to the:

- EC assessment of conformity or suitability for use of constituents of technical systems;
- EC verification of technical systems for which service-providers are responsible.

In the SES framework "notified bodies" and "recognised organisations" are different concepts. However, an organisation can simultaneously act as a "notified body" and "recognised organisation" if it meets all the applicable requirements related to both concepts.

ESARR 1 establishes that, before considering the possible appointment of a notified body, the NSA will require them to accept the conduct of specific investigations relating to the technical systems or constituents of technical systems on which the notified body has worked, wherever a safety directive has to be issued in relation to those technical systems or constituents[36].

3.15.2.3 Recognised Organisations Outside the European Union

The notion of recognised organisations is based on the SES legislation applicable to EU Member States.

In EUROCONTROL Member States who are not members of the EU, the conduct of safety regulatory audits by a recognised organisation on behalf of the NSA can only be possible if:

a) That option is allowed under the existing regulatory framework;

b) A regime of recognition or accreditation is established to determine which organisations are eligible to act as a recognised organisation, and

c) The requirements established in ESARR 1 are met.

3.16 SAFETY OVERSIGHT CAPABILITIES – GENERAL PRINCIPLES (ESARR 1, SECTIONS 9.1, 9.2 and 9.3)

3.16.1 Requirements

> *"9.1. States shall ensure that National Supervisory Authorities have the organisational and functional capability to undertake the safety oversight of all ATM service providers operating under their supervision, including sufficient resources to carry out the actions identified in this Requirement.*

[35] *They are called "notified bodies" as EU Member States are obliged to notify the European Commission and other EU Member States of the bodies appointed.*

[36] *See also Section 3.18.2.1 of this document with regards to the links between safety directives and notified bodies.*

9.2. Within their area of responsibility, States shall ensure that National Supervisory Authorities and recognised organisations acting on their behalf have access to the ATM service provider's organisation, facilities and documentation when safety regulatory audits are conducted.

9.3. National Supervisory Authorities shall every two years produce and/or update an assessment of the human resources needed to perform their safety oversight functions, based on the analysis of the processes required by ESARR 1, their sequence and interaction, and their application throughout the organisation. The assessment shall also compare its results with the actual staffing levels of the organisation."

3.16.2 Rationale and Implications

The implementation and operation of ATM safety oversight is **critically dependent upon the capabilities of the NSA**, notably those related to obtaining and maintaining the resources needed to perform its functions. NSAs should have capabilities to recruit, train and maintain the competent personnel needed to carry out its tasks at the desired levels of quality. If needed, NSAs should also be in a position to delegate tasks to adequately experienced recognised organisations.

It should also be noted that ICAO Document 9734[37] identifies the establishment of an appropriate and practical organisation and the provision of the necessary qualified personnel as a critical element at the core of all safety oversight activities.

From the findings of the ESIMS Programme, it can be concluded that the level of resources given to the ATM safety oversight function is inadequate in many ECAC States. Amongst the various causes of that situation, it appears that a lack of political will in the States is a major underlying reason in many cases.

Experience shows that a mandatory provision requiring States to be responsible for providing sufficient resources, without further qualitative indications of what is meant by 'sufficient resources', is not enough.

ESARR 1, Section 9 maintains the approach of identifying the States' responsibilities for resourcing the safety oversight function, but includes a basic qualitative indication to support the interpretation of the term 'sufficient resources'. The States are responsible for ensuring that the NSAs have:

- Organisational and functional capability to undertake the safety oversight **of all ATM service providers operating under their supervision**;
- Sufficient resources to carry out **all the actions identified in ESARR 1**.

[37] *See ICAO Document 9734-A, "The Establishment and Management of a State's Safety Oversight System", First Edition, 1999". This document describes the critical elements of a safety oversight system considered by USOAP in order to audit the capabilities of a State to implement appropriate safety oversight. A revised version encompassing ATM was being developed by ICAO at the time of this writing.*

Consequently, there is a basic reference that ultimately determines the resources needed in a NSA. That reference is implicitly related to the number of service providers being supervised, their size, and the effective conduct of all ESARR 1 processes with regards to them.

3.16.2.1 Assessment of the Human Resources Required

ESARR 1, Section 9.3 establishes the obligation to regularly evaluate the levels of human resources needed to perform the safety oversight function. More specifically, an assessment has to be produced and/or updated every two years. It should be based on an analysis of the processes required in ESARR 1 with regards to all the service providers operating under the NSA's jurisdiction.

It should be noted that ESARR 1 only establishes an obligation as regard the production or update of such assessment. The intent is to ensure the **visibility** of the situation and provide a **documented rationale** which may, if necessary, be useful to prompt corrective actions at the appropriate level.

Information from the assessment should normally be included in the Safety Oversight Annual Report to be produced by the NSA in accordance with ESARR 1, Section 12, in order to meet the requirement of presenting relevant information on the existing levels of resources in the organisation[38].

3.16.3 Specific Related Issues

3.16.3.1 Organisational Structures in the NSAs

ESARR 1 **does not require** a specific organisational structure within the NSAs. There are no requirements with regards to the reporting line within the organisation, the different levels of management needed, the departments or units required, the sizing of the units, the adoption of a centralised or de-centralised structure, or any other internal organisational arrangements.

ESARR 1 only requires the implementation of a consistent set of processes with some basic principles irrespective of the internal organisational arrangements chosen by the NSA.

3.17 SAFETY OVERSIGHT CAPABILITIES – PERSONNEL COMPETENCY (ESARR 1, SECTION 9.4)

3.17.1 Requirements

"9.4. National Supervisory Authorities shall ensure that all persons involved in safety oversight activities are competent to perform the required function. In that regard they shall:

a) Define and document the education, training, technical and/or operational knowledge, experience and qualifications relevant to the duties of each position involved in safety oversight activities within their organisation.

[38] *See ESARR 1, Section 12.1, bullet h)*

b) Ensure specific training for those involved in safety oversight activities within their organisation.

c) Ensure that personnel designated to conduct safety regulatory audits, including auditing personnel from recognised organisations, meet specific qualification criteria defined by the National Supervisory Authority. The criteria shall address:

i) The knowledge and understanding of the ATM environment and the requirements against which safety regulatory audits may be performed;

ii) The use of assessment techniques;

iii) The skills required for managing an audit;

iv) The demonstration of competence of auditors through evaluation or other acceptable means.

3.17.2 Rationale and Implications

All persons involved in safety oversight activities, including management activities, should have the appropriate education, training, technical and/or operational knowledge, experience and qualifications relevant to the specific duties they perform.

The provisions in Section 9.4 (a) and (b) concern the NSA's personnel working on safety oversight matters. These requirements mean that a NSA should normally establish processes to:

- Define job descriptions for safety oversight-related functions, to specify the minimum levels of education for the job, the amount, type and diversity of required experience;
- Set up staff selection criteria derived from those job descriptions;
- Implement associated training programmes, specifically intended to cover the needs of the safety oversight functions to be performed.

It is highly desirable that the personnel tasked with safety oversight have consistent technical and/or operational experience and specific training matching the experience and training of the ATM service provider organisations (i.e. personnel with extensive operational experience within the service provider organisation).

It should also be noted that ICAO Document 9734[39] identifies the qualification and training of safety oversight personnel as a critical element at the core of all safety oversight activities.

[39] *See ICAO Document 9734-A, "The Establishment and Management of a State's Safety Oversight System", First Edition, 1999". This document describes the critical elements of a safety oversight system considered by USOAP in order to audit the capabilities of a State to implement appropriate safety oversight. A revised version encompassing ATM was being developed by ICAO at the time of this writing.*

3.17.2.1 Qualification Criteria for Safety Auditors

ESARR 1 includes specific provisions as regards the qualifications of personnel designated to conduct safety regulatory audits in the NSA or the recognised organisations acting on its behalf.[40]

NSAs must define the qualification criteria to be met by audit personnel. Those qualification criteria must, at least, cover the following aspects:

a) The knowledge and understanding of the ATM environment and the requirements against which safety regulatory audits are performed. In that regard it should be noted that:

- The need for an **understanding of the ATM environment** implies that being an expert on auditing techniques is not sufficient to deal with ATM safety.
- The requirements against which safety regulatory audits are to be performed may depend on the existing regulatory framework applicable to the situation.

b) The use of assessment techniques including examining, questioning, evaluating and reporting;

c) Additional skills required for managing an audit, e.g. planning, organising, communicating and directing;

d) The **demonstration of the competence** of auditors through examinations or other acceptable means

Safety auditors should have undergone **specific training** to the extent necessary to ensure their competence in the skills required for performing and managing audits. Such competence should be demonstrated through written or oral examinations, or other acceptable means.

NSAs may therefore decide to recognise the training provided by a particular organisation as an acceptable means to demonstrate the competence to conduct and manage safety audits, provided that the training given:

a) Meets all the specific criteria established by the NSA in order to ensure the qualification criteria established in ESARR 1, Section 9, and

b) Includes an evaluation which must be successfully passed by the candidate auditor and whose result must be documented by the organisation.

[40] *See also ESARR 1, Section 8.2 as regards the qualification of audit personnel in recognised organisations.*

3.18 SAFETY DIRECTIVES (ESARR 1, SECTION 10)

3.18.1 Requirements

"10.1. National Supervisory Authorities shall issue safety directives when an unsafe condition has been determined by the National Supervisory Authority to exist in a system.

10.2. A safety directive shall contain, as a minimum, the following information:

a) The identification of the unsafe condition;

b) The identification of the affected system;

c) The actions required and their rationale;

d) The compliance time for the required actions; and

e) The date of entry into force.

10.3. When a safety directive has to be issued to correct an unsafe condition relating to a technical system for which an EC Declaration of Verification or EC Declaration of Conformity or Suitability exists, the National Supervisory Authority may instruct the notified bodies involved in relation to the issuance of the EC Declarations to conduct specific investigations with regard to that technical system."

3.18.2 Rationale and Implications

Situations exist where urgent action needs to be taken in the interest of safety. For example, pursuant to an investigation of an accident or serious incident in which ATM was found to be a contributory factor, it might be necessary to urgently react without recourse to the regular rulemaking process.

ICAO Document 9734-A[41] has identified the resolution of safety issues as a critical element at the core of all safety oversight activities.

The approach adopted in ESARR 1 is inspired by the existing practices for airworthiness and flight operations. The wording of ESARR 1 is based on the provisions for issuing **"airworthiness directives"** currently included in EASA, Part-21 with regard to the obligations of aircraft certification authorities[42].

Any safety directive issued by a NSA should be supported by a **clear rationale** justifying the need for the NSA's intervention in the interest of safety. The safety directive should make clear that rationale in the identification of the unsafe condition detected and the definition of actions required by the NSA.

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[41] *See ICAO Document 9734-A, "The Establishment and Management of a State's Safety Oversight System", First Edition, 1999". This document describes the critical elements of a safety oversight system considered by USOAP in order to audit the capabilities of a State to implement appropriate safety oversight. A revised version encompassing ATM was being developed by ICAO at the time of this writing.*

[42] *See Part 21, Section 21A.3B (Airworthiness Directives) included in the annexes to Commission Regulation (EC) 1702/2003 of 24 September 2003.*

3.18.2.1 Safety Directives in the Case of Technical Systems

An unsafe condition can be related to a particular technical system or constituent of a technical system.

Within the EU regulatory framework, the technical systems and their constituents are respectively subject to EC verification or EC assessment of conformity/suitability in accordance with Regulation (EC) 552/2004. The tasks needed for those activities are normally conducted by "notified bodies"[43].

If a safety directive has to be issued with regards to a technical system or a constituent on which a notified body developed its tasks, the NSA may instruct that notified body to conduct specific investigations in relation to the technical system or constituent under consideration.

3.19 SAFETY OVERSIGHT RECORDS (ESARR 1, SECTION 11)

3.19.1 Requirement

"11.1. National Supervisory Authorities shall keep, or maintain access to, the appropriate records related to their safety oversight processes, including the reports of all safety regulatory audits and other safety-related records related to certificates, designations, acceptance of major safety-related changes, and accreditation of recognised organisations or notified bodies."

3.19.2 Rationale and Implications

NSAs should keep, or maintain access to, documented records resulting from the safety oversight process. The records, their format and contents are normally defined in the procedures defining the safety oversight processes operated by the NSA.

ESARR 1 identifies various key records that need to be kept or maintained access to. This includes the reports from all safety regulatory audits organised and conducted by the NSA or the recognised organisation acting on its behalf.

The records should be easily accessible. They should be made available, if requested, whenever the NSA is audited or monitored regarding the implementation of ATM safety oversight.

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[43] *See also Section 3.15.2.1 of this document in relation to the notified bodies and the safety directives.*

3.20 SAFETY OVERSIGHT ANNUAL REPORT (ESARR 1, SECTION 12)

3.20.1 Requirements

"12.1. A National Supervisory Authority shall produce an annual safety oversight report to present relevant information on the status of the following issues:

a) Airspace and service providers under its responsibility;

b) Organisation, structure and procedures of the National Supervisory Authority;

c) Monitoring of tolerable levels of safety as regards the airspace blocks under its jurisdiction;

d) Compliance with applicable safety regulatory requirements by those organisations providing ATM services in its area of responsibility;

e) Programme of safety regulatory audits, including information about the audits conducted and/or planned, and their scope;

f) Review of safety arguments for new systems and changes to the ATM system, including information about the new systems and changes accepted by the National Supervisory Authority and those accepted by the ATM service providers following the procedures referred to in Section 7.4.above;

g) Recognised organisations commissioned to conduct safety regulatory audits, listing them and documenting the basis under which they decided to delegate the conduct of safety regulatory audits;

h) Existing levels of resources within the organisation;

i) Safety issues identified through the safety oversight processes operated by the National Supervisory Authority;

j) Safety directives issued by the National Supervisory Authority.

12.2. The Safety Oversight Annual Report shall be made available to the:

a) Programmes or activities conducted under international agreed arrangements to monitor or audit the implementation of ATM safety oversight frameworks established by States;

b) State(s) who established or nominated the National Supervisory Authority;

c) States concerned in the case of functional blocks of airspace that extend across the airspace falling under the responsibility of more than one State."

3.20.2 Rationale and Implications

The Safety Oversight Annual Report will provide NSAs with a managerial tool to support the continuous improvement of the ATM safety oversight function.

Within the ESARR 1 process-based approach, the report will be a significant means to:

a) Ensure the visibility of the actual situation of the ATM safety oversight function;

b) Ensure overall traceability of the safety oversight actions taken by the NSA;

c) Support the identification and follow-up of measures for the continuous improvement of safety oversight.

It should be noted that ESARR 1 imposes the obligation of making the Safety Oversight Annual Report available, if requested, to:

a) Any programme or activity conducted under internationally agreed arrangements to monitor or audit the implementation of ATM safety oversight frameworks by States. This certainly includes the:

- ICAO Universal Safety Oversight Audit Programme (IUSOAP);
- EUROCONTROL ESARR Implementation Monitoring and Support (ESIMS) Programme; and
- EC monitoring mechanisms that may be established under the SES framework (e.g. “peer reviews” related to the implementation of Common Requirements, once established[44]).

b) The State(s)[45] which established or nominated the NSA;

c) The States concerned in the case of functional airspace blocks which extend across the airspace falling under the responsibility of more than one State. This facilitates the establishment of means to ensure the visibility and safety performance review of the safety oversight arrangements established in a functional airspace block[46].

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[44] *The draft Common Requirements being developed at the time of writing this document included provisions to establish a “peer review” mechanism organised by the European Commission and implemented with national experts. The scope of such mechanism would go beyond safety in order to cover all the supervisory tasks allocated to NSAs in the Common Requirements.*

[45] *See also Section 3.3.3.1 of this document for further details about possible NSA arrangements.*

[46] *See also Section 3.5 of this document about the ATM safety oversight function in the case of a functional blocks of airspace.*

3.20.3 Specific Related Issues

3.20.3.1 Links with SES Monitoring Obligations

Within the SES framework, Regulation (EC) 549/2004, Article 12.1 establishes that:

> *"The supervision, monitoring and methods of impact assessment shall be based on the submission of annual reports by the Member States on implementation of the actions taken pursuant to this Regulation and the measures referred to in Article 3."*

In that regard, it should be noted that:

a) SES requires States to report, whilst ESARR 1 requires the NSAs to produce a report. **This difference is crucial**. Situations may exist where several NSAs operate in the same State or multinational NSAs are established with regards to specific airspace blocks;

b) The State **may certainly use** the contents of the annual safety oversight reports developed by the NSAs to produce its own report(s) and meet its obligations under the SES framework. In principle, nothing prevents the State from using a NSA report, totally or partially, as part of the annual reports required under the SES regulations;

c) The Safety Oversight Annual Report is **specifically focused on ATM safety oversight.** In contrast, the reports referred to in the SES Framework Regulation are generic and cover several aspects beyond safety oversight;

d) In that context, the need for reports specifically focused on ATM safety oversight stems from the priority given to safety and the notion of ATM safety oversight as a specific and differentiated function within the generic supervision of ATM services as required in ESARR 1, Section 3.1.

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