

EUROPEAN ORGANISATION FOR THE SAFETY OF AIR NAVIGATION

“EUROCONTROL”

- Decisions of the Permanent Commission -

DECISION No. 103

approving the EUROCONTROL Safety Regulatory Requirement - ESARR 1 - entitled “Safety Oversight in ATM”

THE PERMANENT COMMISSION FOR THE SAFETY OF AIR NAVIGATION,

Having regard to the EUROCONTROL International Convention relating to Co-operation for the Safety of Air Navigation, amended by the Protocol signed at Brussels on 12 February 1981, and in particular Articles 1(c), 2.1(j), 6.1 and 7.1 thereof;

Having regard to the Protocol consolidating the EUROCONTROL International Convention relating to Co-operation for the Safety of Air Navigation, which was opened for signature on 27 June 1997, and in particular Article 2.1(R) of the consolidated version of the Convention annexed thereto;

Having regard to Decisions No. 71 and No. 72 of 9 December 1997 on early implementation of certain provisions in the revised Convention, and in particular paragraph 5 of Decision No. 72;

On the proposal of the Provisional Council,


HEREBY TAKES THE FOLLOWING DECISION:

The Commission approves, for incorporation and implementation in ATM regulatory frameworks of EUROCONTROL Contracting Parties, the EUROCONTROL Safety Regulatory Requirement - ESARR 1 - entitled “Safety Oversight in ATM”, as attached.

The present Decision will come into effect on the day of its signature.

Done at Brussels on 5.11.04

For the President of the Commission,



S. SCIACCHITANO
Vice-President of the Commission



EUROCONTROL SAFETY REGULATORY REQUIREMENT
(ESARR)

ESARR 1

SAFETY OVERSIGHT IN ATM

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<p>ESARR 1 provides a set of safety regulatory requirements for the implementation of an effective ATM safety oversight function in EUROCONTROL Member States. Its provisions support a process approach to the safety oversight of ATM service providers and define the minimum elements that must exist in the safety oversight processes operated by a National Supervisory Authority.</p> <p>The document is designed to support the implementation of the Single European Sky initiative by allowing the development of ATM safety oversight within the functions of the National Supervisory Authorities and the regulatory framework defined in the Single European Sky regulations.</p> <p>ESARR 1 also provides the means to ensure the implementation of an appropriate ATM safety oversight function in the EUROCONTROL Member States who are not members of the EU. The National Supervisory Authority function denotes an existing regulatory task that applies to the relevant authorities of any State that has accepted the responsibility for regulating and providing air navigation services functions over its territory and associated areas.</p>		
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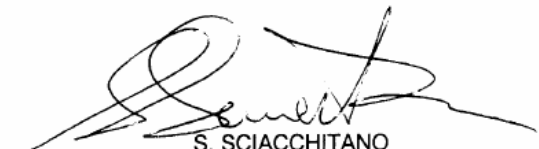
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F.3 DOCUMENT APPROVAL

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

<p style="text-align: center;"><u>EUROPEAN ORGANISATION FOR THE SAFETY OF AIR NAVIGATION</u></p> <p style="text-align: center;"><u>“EUROCONTROL”</u></p> <p style="text-align: center;">- Decisions of the Permanent Commission -</p> <p style="text-align: center;"><u>DECISION No. 103</u></p> <p><i>approving the EUROCONTROL Safety Regulatory Requirement - ESARR 1 - entitled “Safety Oversight in ATM”</i></p> <p>THE PERMANENT COMMISSION FOR THE SAFETY OF AIR NAVIGATION,</p> <p>Having regard to the EUROCONTROL International Convention relating to Co-operation for the Safety of Air Navigation, amended by the Protocol signed at Brussels on 12 February 1981, and in particular Articles 1(c), 2.1(j), 6.1 and 7.1 thereof;</p> <p>Having regard to the Protocol consolidating the EUROCONTROL International Convention relating to Co-operation for the Safety of Air Navigation, which was opened for signature on 27 June 1997, and in particular Article 2.1(R) of the consolidated version of the Convention annexed thereto;</p> <p>Having regard to Decisions No. 71 and No. 72 of 9 December 1997 on early implementation of certain provisions in the revised Convention, and in particular paragraph 5 of Decision No. 72;</p> <p>On the proposal of the Provisional Council,</p> <p>HEREBY TAKES THE FOLLOWING DECISION:</p> <p>The Commission approves, for incorporation and implementation in ATM regulatory frameworks of EUROCONTROL Contracting Parties, the EUROCONTROL Safety Regulatory Requirement - ESARR 1 - entitled “Safety Oversight in ATM”, as attached.</p> <p>The present Decision will come into effect on the day of its signature.</p> <p>Done at Brussels on 5.11.04</p> <p style="text-align: right;">For the President of the Commission,</p> <p style="text-align: center;"> S. SCIACCHITANO Vice-President of the Commission</p>
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F.4 DOCUMENT CHANGE RECORD

The following table records the complete history of this document.

EDITION NUMBER	EDITION DATE	REASON FOR CHANGE	PAGES AFFECTED
0.01	29-Apr-02	Creation – Proposal for an initial working draft circulated to AGC/RTF as an attachment to WP AGC8.7. The document took various inputs from SRC POL DOC 3 and the draft Single European Sky Regulations available at SRU in April 2002.	All
0.02	11-Jul-02	Working draft incorporating comments from the discussion held at AGC/RTF. Additional comments from GS.2 (Legal Service) taken into account. Comment/Response Document initiated.	All
0.03	11-Nov-02	Working draft for discussion at RTF. It incorporates comments from RTF and SRU review.	All
0.04	05-Dec-02	Further modifications and additions included after RTF 17 to reflect the discussions held at the meeting. Appendixes included to address the safety regulation of multinational airspace blocks and recognised organisations. It incorporates UK inputs regarding the oversight of external services. Besides, the non-mandatory sections of the document have also been developed in detail.	All
0.041	06-Mar-03	Working draft produced at RTF 19. The RTF review covered the Executive Summary, Scope, Rationale, Applicability, Safety Objective and sections 5.1, 5.2, 5.3 and 5.4, using comments provided by GS.1. Comments not discussed were kept as forwarded by GS.1 for discussion at RTF 20. Appendix B removed.	All

EDITION NUMBER	EDITION DATE	REASON FOR CHANGE	PAGES AFFECTED
0.05	10-Mar-03	Document re-formatted to include comments from RTF 19 and sections covering 'Introductory Material' and 'Obligatory Provisions'.	All
0.06	26-Mar-03	Comments included from RTF 20.	Sections 5, 6, 7 & 8
0.07	22-Apr-03	Comments included from RTF 21.	Sections 3 to 12
0.08	28-May-03	Comments included from RTF 22.	All
0.09	04-Mar-04	Working draft completely revised to confine the scope of ESARR 1 to ATM safety oversight as agreed at SPG, and ensuring consistency with the Single European Sky regulatory framework. Significant changes were therefore introduced in terms of approach, format and terminology.	All
0.010	11-May-04	Comments included from RTF consultation.	All
0.1	28-May-04	Draft issue incorporating comments from RTF consultation after discussion at RTF26. Edition sent for formal SRC consultation.	All
0.2	02-Jul-04	Addition of Foreword pages. Changes included addressing comments from SRC consultation and quality check from SRU. Sent for formal EUROCONTROL-wide consultation.	All
0.3	07-Sep-04	Changes made as a result of EUROCONTROL-wide consultation (RFC No. 0409). Document status amended to 'Proposed Issue' and sent to SRC for formal approval.	All

EDITION NUMBER	EDITION DATE	REASON FOR CHANGE	PAGES AFFECTED
1.0	05-Nov-04	Document approved by the EUROCONTROL Permanent Commission with minor amendments to Sections 8.1, 9.3 and 12.1 (h).	20, 21 & 23

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F.5 CONTENTS

<u>Section</u>	<u>Title</u>	<u>Page</u>
<u>FOREWORD</u>		
F.1	Title Page	1
F.2	Document Characteristics	2
F.3	Document Approval	3
F.4	Document Change Record	4
F.5	Contents	7
F.6	Executive Summary	8
<u>INTRODUCTORY MATERIAL</u>		
A.	Rationale	9
B.	Objective	10
<u>MANDATORY PROVISIONS</u>		
1.	Definitions	11
2.	Applicability	13
3.	Safety Oversight Function	13
4.	Monitoring Safety Performance	14
5.	Verification of Compliance with Safety Regulatory Requirements	14
6.	Safety Regulatory Auditing	16
7.	Safety Oversight of Changes to the ATM System	18
8.	Recognised Organisations and Notified Bodies	20
9.	Safety Oversight Capabilities	21
10.	Safety Directives	22
11.	Safety Oversight Records	23
12.	Safety Oversight Annual Report	23

F.6 EXECUTIVE SUMMARY

This EUROCONTROL Safety Regulatory Requirement (ESARR) has been prepared by the Safety Regulation Commission.

The purpose of ESARR 1 is to provide a set of safety regulatory requirements for the implementation of an effective ATM safety oversight function in EUROCONTROL Member States. Its provisions support a process approach to the safety oversight of ATM service providers and define the minimum elements that must exist in the safety oversight processes operated by a National Supervisory Authority (NSA).

ESARR 1 is designed to support the implementation of the Single European Sky (SES) by allowing the development of ATM safety oversight within the functions of the NSAs and the regulatory framework defined in the SES regulations.

This requirement also provides the means to ensure the implementation of an appropriate ATM safety oversight function in EUROCONTROL Member States who are not members of the European Union (EU). In that regard, it should be noted that the NSA 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 service 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 EU Member States nor is it limited to the tasks of the NSA under the SES regulations.

The critical elements of the safety oversight process have been addressed to ensure a robust supervision of safety. Two major processes form the core of ESARR 1. Firstly, a safety regulatory audit process provides means to obtain objective evidences on the compliance with the applicable safety regulatory requirements established by the rule-maker and other safety-related arrangements needed to implement them. Secondly, the safety oversight of new systems and changes to the ATM system is built around the review of safety arguments proposed by service-providers consistently with the safety regulatory framework in which they operate.

It should be noted that ESARR 1 addresses the safety oversight processes, their principles and interrelated elements and outputs without identifying the set of applicable safety regulatory requirements which constitutes the regulatory reference for verification. That regulatory reference will depend on the existing regulatory framework. In the countries under the Single European Sky, the applicable safety regulatory requirements will be established around the common rulemaking activities foreseen in that framework. In the case of those EUROCONTROL Member States who are not members of the EU, the existing regulatory framework will continue being primarily of national nature. ESARRs and other rules and standards related to international obligations will provide common elements to all frameworks.

This requirement includes provisions intended to harmonise the capabilities of the safety oversight function, notably those related to the levels of resources available and the qualification of safety oversight personnel. Additionally, specific processes are required to address the resolution of safety issues and the implementation of means to ensure the transparency of all safety oversight processes and ease the auditing of safety oversight frameworks operated in the ECAC region.

INTRODUCTORY MATERIAL

*The provisions in this section are **not** mandatory*

A. RATIONALE

- A.1. Under the early implementation of the EUROCONTROL Revised Convention, the Safety Regulation Commission (SRC) has been established within the EUROCONTROL Organisation as an independent body that provides advice in order to ensure consistent high levels of safety in air traffic management (ATM) within the ECAC area. SRC is responsible for the development of harmonised safety regulatory requirements for the ATM system, namely EUROCONTROL Safety Regulatory Requirements (ESARRs), for implementation by the EUROCONTROL Contracting Parties, after approval by the EUROCONTROL Permanent Commission.
- A.2. The scope of those measures includes the uniform application of European ATM safety regulatory requirements. In that context, the SRC's work has identified the need for specific regulatory action to ensure effective and harmonised safety oversight processes and capabilities as part of the ATM safety regulatory frameworks operated in the ECAC region. The findings from the ESARR Implementation Monitoring and Support (ESIMS) Programme undertaken by SRC have confirmed that significant need.
- A.3. As part of the Single European Sky (SES) initiative, a generic framework for the regulation of ATM in the European Union (EU) has been established through the adoption by the Council of Ministers and the European Parliament 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).
- A.4. Within the safety domain, this framework needs to be further developed with provisions which ensure the necessary processes and capabilities are in place for National Supervisory Authorities (NSAs) to supervise safety. The development of ESARR 1 provides the means to ensure the specific implementation of safety oversight by NSAs as part of the supervision of the requirements applicable to the provision of ATM services within the Single European Sky.
- A.5. ESARR 1 provides the means to ensure the implementation of an appropriate ATM safety oversight function in the EUROCONTROL Member States who are not members of the EU. This requirement also supports such implementation in those ECAC States outside the scope of both organisations. In all these cases, applicable safety regulatory requirements, determined at national level, will provide the reference for safety oversight.

- A.6. In that regard, it should be noted that the NSA 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 service 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 EU Member States nor is it limited to the tasks of the NSAs under the SES regulations.
- A.7. The processes and capabilities required in ESARR 1 are essential to develop an effective safety oversight function as part of the supervision of requirements applicable to ATM services. The findings of the ESIMS Programme confirm the need to mandate and specify their implementation. Consequently, ESARR 1 requires them, within a specific ATM safety oversight function, to be operated as part of the generic supervision of requirements applicable to ATM services.

B. OBJECTIVE

- B.1. The objectives of ESARR 1 are to:
- a) Ensure the implementation of a harmonised and effective ATM safety oversight function by the EUROCONTROL Contracting Parties in order to ensure safety in the public interest with regard to the provision of ATM services to general air traffic;
 - b) Support that implementation in other ECAC States; and
 - c) Support the implementation of the Single European Sky by:
 - i) Allowing the development of ATM safety oversight within the functions of National Supervisory Authorities and the framework defined in the Single European Sky regulations,
 - ii) Harmonising the actions undertaken by the National Supervisory Authorities to oversee safety within the certification, designation and on-going supervision of ATM service providers, and
 - iii) Enabling joint civil / military initiatives with regard to ATM safety oversight in accordance with the existing regulatory framework.

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MANDATORY PROVISIONS

1. DEFINITIONS

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

- a) **“Airspace block”** means an airspace of defined dimensions, in space and time, within which ATM services are provided.
- b) **“Applicable safety regulatory requirements”** means 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.
- c) **“Air Traffic Management (ATM)”** means the aggregation of the airborne and ground-based functions (air traffic services, airspace management and air traffic flow management) required to ensure the safe and efficient movement of aircraft during all phases of operations.
- d) **“ATM service”** means a service for the purpose of ATM.
- e) **“ATM service provider”** means any public or private entity providing ATM services for general air traffic.
- f) **“ATM system”** means the part of the ANS system composed of a ground based ATM component and an airborne ATM component. The ATM system includes human, technical systems and procedures, and assumes the existence of a supporting CNS system.
- g) **“Certificate”** means a document issued by a Member State in any form complying with national law, which confirms that an ATM service provider meets the requirements for providing a specific service.
- h) **“Constituents”** means tangible objects such as hardware and intangible objects such as software upon which the interoperability of the European ATM network depends.
- i) **“Corrective action”** means action to eliminate the cause of a detected non-conformity or other undesirable situation.

- j) “**Designation**” means the process by which States designate ATM service providers to provide ATM services within specific airspace blocks in respect of the airspace under their responsibility.
- k) “**Functional airspace block**” means an airspace block based on operational requirements reflecting the need to ensure more integrated management of the airspace regardless of existing boundaries.
- l) “**General air traffic**” means all movements of civil aircraft, as well as all movements of State aircraft (including military, customs and police aircraft) when these movements are carried out in conformity with the procedures of the International Civil Aviation Organisation.
- m) “**National Supervisory Authority**” means a body nominated or established by States which is independent of service providers at least at a functional level and according to the existing regulatory framework, supervises the implementation of requirements applicable to the provision of ATM services to general air traffic.
- n) “**Process**” means a set of interrelated or interacting activities which transforms inputs into outputs.
- o) “**Safety argument**” means the demonstration and evidence that a proposed change can be implemented within the applicable tolerable levels of safety.
- p) “**Safety directive**” means a document issued or adopted by a National Supervisory Authority which mandates actions to be performed on a system to restore a tolerable level of safety, when evidence shows that aviation safety may otherwise be compromised.
- q) “**Safety objective**” means a quantitative or qualitative statement that defines the maximum probability at which a hazard can be expected to occur.
- r) “**Safety regulatory audit**” means a systematic and independent examination conducted by, or on behalf of, a National Supervisory Authority to determine whether complete safety-related arrangements or elements thereof, to processes and their results, products or services, comply with required safety-related arrangements and whether they are implemented effectively and are suitable to achieve expected results.
- s) “**Safety regulatory requirement**” means the formal stipulation by the regulator of a safety-related specification.
- t) “**Safety-related condition**” means a specific objective or measure, identified consistently with safety regulatory requirements, whose implementation is found necessary to ensure safety.

- u) **“Safety requirement”** means a risk mitigation means, defined from the risk mitigation strategy that achieves a particular safety objective, including organisational, operational, procedural, functional, performance, and interoperability requirements or environment characteristics.
- v) **“Serious incident”** means an incident involving circumstances indicating that an accident nearly occurred.
- w) **“System”** means a combination of technical systems, procedures and human resources organised to perform a function.
- x) **“Technical system”** means the aggregation of airborne and ground-based constituents, as well as space-based equipment that provides support for ATM services for all phases of flight.
- y) **“Tolerable level of safety”** means either a quantified target, qualitative target or standard 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.
- z) **“Verification”** means confirmation through the provision of objective evidence that specified requirements have been fulfilled.

2. APPLICABILITY

- 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. SAFETY OVERSIGHT FUNCTION

- 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.

- 3.2. 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.

4. MONITORING OF SAFETY PERFORMANCE

- 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 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.

5. VERIFICATION OF COMPLIANCE WITH SAFETY REGULATORY 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.

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.

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- 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.

6. SAFETY REGULATORY AUDITING

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.

- 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.
- 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.

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- 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.

7. SAFETY OVERSIGHT OF CHANGES TO THE ATM SYSTEM

- 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 change' 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.
- 7.3. The implementation of major changes shall be subject to the acceptance by the National Supervisory Authority.
- 7.4. The use of procedures conducted by ATM service providers to decide the implementation of a 'minor change' 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.
- 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 a rationale for the acceptance, or non-acceptance, of major changes referred to in Section 7.3 above.
 - e) Wherever needed, identify additional safety-related conditions associated to the implementation of the change.

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- 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 meets 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.

8. RECOGNISED ORGANISATIONS AND NOTIFIED BODIES

- 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.

9. SAFETY OVERSIGHT CAPABILITIES

- 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.
- 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.
- 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.

- 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.

10. SAFETY DIRECTIVES

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.

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11. SAFETY OVERSIGHT RECORDS

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 changes, and accreditation of recognised organisations or notified bodies.

12. SAFETY OVERSIGHT ANNUAL REPORT

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 responsibility;
- 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 airspace blocks which extend across the airspace falling under the responsibility of more than one State.

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