

**EUROCONTROL SAFETY REGULATORY REQUIREMENT  
(ESARR)**

**ESARR 1**

**SAFETY OVERSIGHT IN ATM**

<b>Edition</b>	<b>:</b>	<b>2.0</b>
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<b>Abstract</b>		
ESARR 1 was developed to ensure effective and harmonised safety oversight processes and capabilities as part of the ATM safety regulatory frameworks operated in the ECAC region. ESARR 1 supports a process approach to the safety oversight of ATM service providers and defines the minimum elements that must exist in the safety oversight processes operated by a National Supervisory Authority (NSA).		
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<b>Contact Person(s)</b>	<b>Tel</b>	<b>Unit</b>
Agnieszka DYBOWSKA	+32 2 729 51 52	DG/SRU

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Safety Regulation Unit EUROCONTROL Rue de la Fusée, 96 B-1130 Bruxelles	Tel: +32 2 729 51 38 Fax: +32 2 729 47 87 E-mail: <a href="mailto:sru@eurocontrol.int">sru@eurocontrol.int</a> Website: <a href="http://www.eurocontrol.int/src">www.eurocontrol.int/src</a>

## F.3 DOCUMENT APPROVAL

### EUROPEAN ORGANISATION FOR THE SAFETY OF AIR NAVIGATION

#### "EUROCONTROL"

- Decisions of the Permanent Commission -

#### DECISION No. 114

**approving the EUROCONTROL Safety Regulatory Requirement – ESARR 1, Edition 2.0  
- 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, Edition 2.0 – entitled "Safety Oversight in ATM", as attached.

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

Done at Brussels on 02.12.2009

For the President of the Commission,

  
Mr Kamen KITCHEV  
Vice-President of the Commission



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## F.4 AMENDMENT RECORD

The following table records the complete history of this document.

Edition No.	Date	Reason for Change	Pages Affected
0.01	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. Appendices included addressing 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
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

<b>Edition No.</b>	<b>Date</b>	<b>Reason for Change</b>	<b>Pages Affected</b>
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
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
1.01	13-May-08	Document re-drafted to take into consideration the DRAHG recommendations on the alignment of ESARRs with EC text. Document submitted to SRCCG10 for discussion.	All
1.02	14-May-08	SRU quality review.	All
1.03	12-Jun-08	Document updated after SRCCG consultation. Inclusion of the expression "or other equivalent provisions wherever applicable" where other EC rules are referenced. Executive Summary added. Inclusion of a new paragraph in Section A (Rational) to explain the need for the expression.	F.6, Section A, Attachment A
1.1	12-Jun-08	SRU quality review. Document sent for SRC consultation.	-
1.2	15-Jul-08	Document amended following SRC consultation. Inclusion of 2 new sentences in Section A.8 explaining the alignment of the text with Commission Regulation (EC) No. 1315/2007. Inclusion of new Section A.11 explaining the applicability date of the amended ESARR1.	Sections A.8 & A.11
1.3	22-Sep-08	Changes made as a result of EUROCONTROL-wide consultation (RFC No. 0805). Modification of text in Objective B.1b).  Document status amended to 'Proposed Issue' and sent to SRC33 for formal approval.	10
1.4	06-Oct-08	Incorporation of comments from SRC33.	Sections 1, 3 & Attachment A
1.5	24-Nov-08	Incorporation of comments from the Provisional Council's 30 <sup>th</sup> session and Ad-Hoc session of the EUROCONTROL Permanent Commission.	Sections F.6, B1.1, 1.1, 3.1, Attachment A (Arts. 2, 5 & 12)
1.6	28-Nov-08	Proposal made by Turkey following the discussions at the Provisional Council's 30 <sup>th</sup> session and Ad-Hoc session of the EUROCONTROL Permanent Commission.	All
1.7	01-Jul-09	Incorporation of changes intended to address the issues raised at the Provisional Council's 30 <sup>th</sup> session and Ad-Hoc session of the EUROCONTROL Permanent Commission.	All. In particular inclusion of Attachment B
1.8	18-Sep-09	Version resulting from the discussions held with Turkey in order to address the issues raised at the Provisional council 30 <sup>th</sup> session and Ad-Hoc session of the EUROCONTROL Permanent Commission. Edition submitted to SRC for consultation.	All
1.9	16-Oct-09	Version after SRC consultation. Minor editorial changes	All
2.0	02-Dec-09	Released Issue after approval by Provisional Council and EUROCONTROL Commission.	-

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## F.6 EXECUTIVE SUMMARY

ESARR 1 was developed to ensure effective and harmonised safety oversight processes and capabilities as part of the ATM safety regulatory frameworks operated in the ECAC region. It supports a process approach to the safety oversight of ATM service providers and defines the minimum elements that must exist in the safety oversight processes operated by a National Supervisory Authority (NSA).

The critical elements of the safety oversight process were addressed to ensure a robust supervision of safety. Two major processes form the core of ESARR 1: the safety regulatory audit process and the safety oversight of changes. The requirements also include 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.

Pursuant to Regulation (EC) No. 550/2004, the European Commission shall identify and adopt the ESARRs that shall be made mandatory under Community law. Accordingly, Commission Regulation (EC) No. 1315/2007 was developed to transpose the provisions of ESARR 1, Edition 1.0, into Community law.

The EUROCONTROL Provisional Council and the Single Sky Committee (SSC) recognised the need to ensure an identical text between the ESARR safety requirements and their corresponding EC legislation and agreed on the recommendations of the joint SRC/EC Double Regulation Ad-Hoc Group's (DRAHG) 'Report on the Resolution of Double ATM Safety Regulation in Single European Sky States', dated 23 November 2007. Following that agreement, the SRC decided in February 2008 to initiate the application of the DRAHG recommendations to ESARR 1 and developed a proposal for the amendment of ESARR 1, Edition 1.0.

According to those recommendations, the proposed amendment is exclusively intended to adopt the text of the rules transposing the relevant safety requirements into Community law, whilst maintaining the existing ESARR 1-related obligations on EUROCONTROL Contracting Parties and the scope of those obligations.

Being that the two texts are equivalent, their full alignment does not modify the previously agreed requirements. Nevertheless, the amendment brings the benefit of removing potential double regulation issues with regard to safety oversight in EUROCONTROL Member States where EC regulations are directly applicable. It also provides a platform to take advantage of the synergies between the EC and EUROCONTROL frameworks and support the implementation of SES across the ECAC region. In particular, ESARR 1 provides the means to ensure the implementation of an appropriate ATM safety oversight function in EUROCONTROL Member States and facilitates implementation in the military domain. This requirement also supports such implementation in those ECAC States outside the scope of both organisations.

The obligations of the EUROCONTROL Member States where EC law is not directly applicable will not be automatically modified by the amendment of the EC rules referred to in Commission Regulation (EC) No. 1315/2007. Nevertheless, the amendments introduced by the second package of single European sky legislation have already been taken into consideration in the ESARR 1 text approved by the EUROCONTROL Permanent Commission in December 2009.

## **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 In that context, ESARR 1 was developed to ensure effective and harmonised safety oversight processes and capabilities as part of the ATM safety regulatory frameworks operated in the ECAC region. ESARR 1 supports a process approach to the safety oversight of ATM service providers and defines the minimum elements that must exist in the safety oversight processes operated by a National Supervisory Authority (NSA). ESARR 1, Edition 1.0 was issued on 5 November 2004.
- 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) No. 549/2004 (the Framework Regulation), Regulation (EC) No. 550/2004 (the Service Provision Regulation), Regulation (EC) No. 551/2004 (the Airspace Regulation) and Regulation (EC) No. 552/2004 (the Interoperability Regulation).
- A.4 Pursuant to Regulation (EC) No. 550/2004, the European Commission shall identify and adopt the EUROCONTROL ESARRs and subsequent amendments to those requirements that shall be made mandatory under Community law. Accordingly, Commission Regulation (EC) No. 1315/2007 was developed to transpose the provisions of ESARR 1, Edition 1.0, into Community law.
- A.5 The EUROCONTROL Provisional Council and the Single Sky Committee (SSC) recognised the need to ensure an identical text between the ESARR safety requirements and their corresponding EC legislation and agreed on the recommendations of the joint SRC/EC Double Regulation Ad-Hoc Group's (DRAHG) Report on the Resolution of Double ATM Safety Regulation in Single European Sky States, dated 23 November 2007.



- A.6 Following that agreement, SRC decided in February 2008 to initiate the application of the DRAHG recommendations to ESARR 1 and developed a proposal of amendment to Edition 1.0.
- A.7 According to the recommendations of DRAHG, such an amendment should be exclusively intended to adopt the text of the rules transposing the relevant safety requirements into Community law while maintaining the existing ESARR 1 related obligations on the EUROCONTROL Contracting Parties and the scope of those obligations.
- A.8 The result of this alignment is that the text of the safety requirements in Section 3 has been entirely replaced by the relevant Community text. The relevant provisions of Commission Regulation (EC) No. 1315/2007 are therefore adopted and presented in Attachment A to this Requirement. The only modifications introduced are related to the references to other provisions included in Commission Regulation (EC) No. 1315/2007. In particular, the expression 'relevant requirements' has been introduced wherever EC rules were referenced. The exact meaning of that expression is provided in Attachment B for each article concerned, establishing its correspondence with the EC references which are exclusively valid in the EUROCONTROL Member States where EC legislation is applicable.
- A.9 Being that the two texts are equivalent, their full alignment does not modify the previously agreed requirements. Nevertheless, the amendment brings the benefit of removing potential double-regulation issues with regard to safety oversight in EUROCONTROL Member States where EC regulations are directly applicable. It also provides a platform to take advantage of the synergies between the EC and EUROCONTROL frameworks and support the implementation of SES across the ECAC region. In particular, ESARR 1 provides the means to ensure the implementation of an appropriate ATM safety oversight function in EUROCONTROL Member States. This requirement also supports such implementation in those ECAC States outside the scope of both organisations.
- A.10 In that regard, it should be noted that the National Supervisory Authority (NSA) function denotes an existing supervisory task which applies to the competent authorities of any State that 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.
- A.11 ESARR 1, Edition 1.0, became effective in November 2007 for all EUROCONTROL Member States. Commission Regulation (EC) No. 1315/2007 also became effective in November 2007, with the exception of Article 9(3) whose entry into force could be delayed by EU States until 1<sup>st</sup> November 2008. Taking into consideration the alignment of both texts and that no new obligations have been introduced by means of this new edition of ESARR 1, the applicability date does not need to be extended beyond the date of its original approval by the EUROCONTROL Permanent Commission. The requirements will already be implemented in Member States either by means of Commission Regulation (EC) No. 1315/2007, or national provisions wherever EC legislation is not applicable.

A.12 As explained in A.8 above, this Requirement has been drafted in a manner which ensures that the obligations of the EUROCONTROL Member States where EC law is not directly applicable are not automatically modified by the amendment of the EC rules referred to in Commission Regulation (EC) No. 1315/2007. Further amendments to those EC rules will require a review of ESARR 1 to ensure consistency between both texts. Nevertheless, the amendments to Regulation (EC) No. 549/2004 and Regulation (EC) No. 550/2004 adopted in the second package of Single European Sky legislation have already been taken into consideration in the text of ESARR 1 as approved by the EUROCONTROL Permanent Commission in December 2009.

## **B. OBJECTIVES**

B.1 The objectives of ESARR 1 are to:

- a) Ensure the implementation of an effective ATM safety oversight function by the EUROCONTROL Contracting Parties in a manner harmonised with SES to ensure safety in the public interest with regard to the provision of ATM services to general air traffic;
- b) Ensure the applicability of the ESARR 1 requirements to general air traffic in the Member States of EUROCONTROL;
- c) Support that implementation in other ECAC States;
- d) Support the implementation of the SES by:
  - i) Allowing the development of ATM safety oversight within the functions of NSAs and the framework defined in the SES regulations,
  - ii) Harmonising the actions undertaken by the NSAs to oversee safety within the certification, designation and on-going supervision of ATM service providers,
  - 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, applicable definitions are included in Attachments A and B.

### **2. APPLICABILITY**

- 2.1 This requirement shall apply to all EUROCONTROL Contracting Parties with regards to the operation of their NSAs nominated or established by them to supervise the provision of Air Traffic Services (ATS), Air Traffic Flow Management (ATFM) and Airspace Management (ASM) to General Air Traffic (GAT).
- 2.2 The provisions of this requirement become effective on the day of its approval by the EUROCONTROL Permanent Commission.

### **3. SAFETY REQUIREMENTS**

- 3.1 For the purpose of this Requirement, all applicable provisions are included in Attachment A.

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# **ATTACHMENT A**

## *Article 1*

### **Subject matter and scope**

1. This Requirement establishes a safety oversight function concerning air traffic services, air traffic flow management (ATFM) and air space management (ASM) for general air traffic.
2. This Requirement shall apply to the activities of national supervisory authorities and qualified entities acting on their behalf regarding the safety oversight of air traffic services, ATFM and ASM.

## *Article 2*

### **Definitions**

For the purposes of this Requirement, the following definitions shall apply:

1. 'airspace block' means an airspace of defined dimensions, in space and time, within which air navigation services are provided;
2. 'air traffic flow management' means a function established with the objective of contributing to a safe, orderly and expeditious flow of air traffic by ensuring that ATC capacity is utilised to the maximum extent possible, and that the traffic volume is compatible with the capacities declared by the appropriate air traffic service providers;
3. 'air traffic management' 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;
4. 'air traffic services' means the various flight information services, alerting services, air traffic advisory services and ATC services (area, approach and aerodrome control services);
5. 'airspace management' means a planning function with the primary objective of maximising the utilisation of available airspace by dynamic time-sharing and, at times, the segregation of airspace among various categories of airspace users on the basis of short-term needs;
6. 'certificate' means a document issued by a national supervisory authority in any form complying with national law, which confirms that an air navigation service provider meets the requirements for providing a specific service;
7. 'constituents' means tangible objects such as hardware and intangible objects such as software upon which the interoperability of the EUROCONTROL ATM Network depends;
8. 'corrective action' means action to eliminate the cause of a detected non-conformity;
9. 'functional airspace block' means an airspace block based on operational requirements, and established regardless of State boundaries, where the provision of air navigation services and related functions are performance-driven and optimised with a view to introducing, in each functional airspace block, enhanced cooperation among air navigation service providers or, where appropriate, an integrated provider;
10. 'functional system' means a combination of systems, procedures and human resources organised to perform a function within the context of ATM;

11. '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 ICAO;
12. "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 traffic.
13. 'organisation' means either an air traffic service provider or an entity providing ATFM or ASM;
14. 'process' means a set of interrelated or interacting activities which transforms inputs into outputs;
15. 'safety argument' means the demonstration and evidence that a proposed change to a functional system can be implemented within the targets or standards established through the existing regulatory framework consistently with the safety regulatory requirements;
16. 'safety directive' means a document issued or adopted by a national supervisory authority which mandates actions to be performed on a functional system to restore safety, when evidence shows that aviation safety may otherwise be compromised;
17. 'safety objective' means a qualitative or quantitative statement that defines the maximum frequency or probability at which a hazard can be expected to occur;
18. '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, related 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;
19. 'safety regulatory requirements' means the requirements established for the provision of air traffic services or ATFM and ASM functions concerning the technical and operational competence and suitability to provide these services and functions, their safety management, as well as systems, their constituents and associated procedures;
20. '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 environmental characteristics;
21. 'system' means the aggregation of airborne and ground-based constituents, as well as space-based equipment, that provides support for air navigation services for all phases of flight;
22. 'verification' means confirmation through the provision of objective evidence that specified requirements have been fulfilled.

### *Article 3*

#### **Safety oversight function**

1. National supervisory authorities shall exercise safety oversight as part of their supervision of requirements applicable to air traffic services as well as to ATFM and ASM, in order to monitor the safe provision of these activities and to verify that the applicable safety regulatory requirements and their implementing arrangements are met.

2. When concluding an agreement on the supervision of organisations active in functional airspace blocks which extend across the airspace falling under the responsibility of more than one Member State, Member States concerned shall identify and allocate the responsibilities for safety oversight in a manner which ensures that:
  - (a) specific points of responsibility exist to implement each provision of this Requirement;
  - (b) the Member States have visibility of the safety oversight mechanisms and their results.

Member States shall regularly review the agreement and its practical implementation in particular in the light of achieved safety performance.

#### *Article 4*

#### **Monitoring of safety performance**

1. National supervisory authorities shall provide regular monitoring and assessment of the levels of safety achieved in order to determine whether they comply with the safety regulatory requirements applicable in the airspace blocks under their responsibility.
2. National supervisory authorities shall use the results of the monitoring of safety in particular to determine areas in which the verification of compliance with safety regulatory requirements is necessary as a matter of priority.

#### *Article 5*

#### **Verification of compliance with safety regulatory requirements**

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 necessary to provide air traffic services including safety-related conditions attached to it;
  - (b) compliance with any safety-related obligations in the designation act issued in accordance with relevant requirements;
  - (c) ongoing compliance of the organisations with applicable safety regulatory requirements;
  - (d) implementation of safety objectives, safety requirements and other safety-related conditions identified in:
    - (i) risk assessment and mitigation procedures required by safety regulatory requirements applicable to air traffic services, ATFM and ASM; and
    - (ii) where applicable, EC declarations of verification of systems, including any relevant EC declaration of conformity or suitability for use of constituents of systems;
  - (e) the implementation of safety directives.
2. The process referred to in paragraph 1 shall:
  - (a) be based on documented procedures;
  - (b) be supported by documentation specifically intended to provide safety oversight personnel with guidance to perform their functions;

- (c) provide the organisation concerned with an indication of the results of the safety oversight activity;
- (d) be based on safety regulatory audits and reviews conducted in accordance with Articles 6, 8 and 9;
- (e) provide the national supervisory authority with the evidence needed to support further action, including measures foreseen by relevant requirements in situations where safety regulatory requirements are not being complied with.

#### *Article 6*

#### **Safety regulatory audits**

1. National supervisory authorities, or qualified entities as delegated by them, shall conduct safety regulatory audits.
2. The safety regulatory audits referred to in paragraph 1 shall:
  - (a) provide national supervisory authorities with evidence of compliance with applicable safety regulatory requirements and with implementing arrangements by evaluating the need for improvement or corrective action;
  - (b) be independent of internal auditing activities undertaken by the organisation concerned as part of its safety or quality management systems;
  - (c) be conducted by auditors qualified in accordance with the requirements of Article 11;
  - (d) apply to complete implementing arrangements or elements thereof, and to processes, products or services;
  - (e) determine whether:
    - (i) implementing arrangements comply with safety regulatory requirements;
    - (ii) actions taken comply with the implementing arrangements;
    - (iii) the results of actions taken match the results expected from the implementing arrangements;
  - (f) lead to the correction of any identified non-conformities in accordance with Article 7.
3. Within the inspection programme required by relevant requirements, national supervisory authorities shall establish and update at least annually a programme of safety regulatory audits in order to:
  - (a) cover all the areas of potential safety concern, with a focus on those areas where problems have been identified;
  - (b) cover all the organisations and services operating under the supervision of the national supervisory authority;
  - (c) ensure that audits are conducted in a manner commensurate to the level of risk posed by the organisations' activities;
  - (d) ensure that sufficient audits are conducted over a period of two years to check the compliance of all these organisations with applicable safety regulatory requirements in all the relevant areas of the functional system;

- (e) ensure follow up of the implementation of corrective actions.
4. National supervisory authorities may decide to modify the scope of pre-planned audits, and to include additional audits, wherever that need arises.
  5. National supervisory authorities shall decide which arrangements, elements, services, products, physical locations and activities are to be audited within a specified time frame.
  6. Audit observations and identified non-conformities shall be documented. The latter shall be supported by evidence, and identified in terms of the applicable safety regulatory requirements and their implementing arrangements against which the audit has been conducted.

An audit report, including the details of the non-conformities, shall be drawn up.

#### *Article 7*

#### **Corrective actions**

1. The national supervisory authority shall communicate the audit findings to the audited organisation and shall simultaneously request corrective actions to address the nonconformities identified without prejudice to any additional action required by the applicable safety regulatory requirements.
2. The audited organisation shall determine the corrective actions deemed necessary to correct non-conformity and the time frame for their implementation.
3. The national supervisory authority shall assess the corrective actions and the implementation determined by the audited organisation and accept them if the assessment concludes that they are sufficient to address the nonconformities.
4. The audited organisation shall initiate the corrective actions accepted by the national supervisory authority. These corrective actions and the subsequent follow-up process shall be completed within the time period accepted by the national supervisory authority

#### *Article 8*

#### **Safety oversight of changes to functional systems**

1. Organisations shall only use procedures accepted by their national supervisory authority when deciding whether to introduce a safety-related change to their functional systems. In case of providers of air traffic services the national supervisory authority shall accept these procedures in the framework of relevant requirements.
2. Organisations shall notify their national supervisory authority of all planned safety related changes. To this effect, the national supervisory authorities shall establish appropriate administrative procedures in accordance with national law.
3. Unless Article 9 applies, the organisations may implement the notified change following the procedures referred to in paragraph 1 of this Article.

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*Article 9***Review procedure of the proposed changes**

1. The national supervisory authority shall review the safety arguments associated with new functional systems or changes to existing functional systems proposed by an organisation when:
  - (a) the severity assessment conducted in accordance with relevant requirements, determines a severity class 1 or a severity class 2 for the potential effects of the hazards identified; or
  - (b) the implementation of the changes requires the introduction of new aviation standards.

When the national supervisory authority determines the need for a review in situations other than those referred to in points (a) and (b), it shall notify the organisation that it will undertake a safety review of the change notified.

2. The review shall be conducted in a manner commensurate with the level of risk posed by the new functional system or change to existing functional systems.

It shall:

- (a) use documented procedures;
- (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) risk assessment and mitigation documentation established in accordance with applicable safety regulatory requirements;
  - (ii) where applicable, EC declarations of verification of systems; or
  - (iii) EC declarations of conformity or suitability for use of constituents of systems
- (d) identify additional safety-related conditions associated to the implementation of the change, wherever needed;
- (e) assess the acceptability of safety arguments presented, taking account of:
  - (i) the identification 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 continuously met;
  - (vi) the demonstration that the process used to produce the safety arguments meets the applicable safety regulatory requirements;

- (f) verify the processes used by the organisations to produce the safety arguments in relation to the new functional system or changes to existing functional systems under consideration;
  - (g) identify the need for the verification of ongoing compliance;
  - (h) include any necessary coordination activities with the authorities responsible for the safety oversight of airworthiness and flight operations;
  - (i) provide notification of the acceptance, with conditions where applicable, or the non-acceptance, with supporting reasons, of the change under consideration.
3. The introduction into service of the change under consideration in the review shall be subject to acceptance by the national supervisory authority.

*Article 10*  
**Qualified entities**

1. When a national supervisory authority decides to delegate to a qualified entity the conduct of safety regulatory audits or reviews in accordance with Article 9(2), it shall ensure that the criteria used to select an organisation amongst those qualified in accordance with relevant requirements include the following:
  - (a) the qualified entity has prior experience in assessing safety in aviation entities;
  - (b) the qualified entity is not simultaneously involved in internal activities within the safety or quality management systems of the organisation concerned;
  - (c) all personnel concerned with the conduct of safety regulatory audits or reviews are adequately trained and qualified and meet the qualification criteria of Article 11(3) of this Requirement.
2. The qualified entity shall accept the possibility of being audited by the national supervisory authority or any body acting on its behalf.
3. National supervisory authorities shall maintain a record of the qualified entities commissioned to conduct safety regulatory audits or reviews on their behalf. The records shall document compliance with the requirements contained in paragraph 1.

*Article 11*  
**Safety oversight capabilities**

1. Member States shall ensure that national supervisory authorities have the necessary capability to ensure the safety oversight of all organisations operating under their supervision, including sufficient resources to carry out the actions identified in this Requirement.
2. National supervisory authorities shall produce and update every two years, an assessment of the human resources needed to perform their safety oversight functions, based on the analysis of the processes required by this Requirement and their application.
3. 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 operational knowledge, experience and qualifications relevant to the duties of each position involved in safety oversight activities within their structure;

- (b) ensure specific training for those involved in safety oversight activities within their structure;
- (c) ensure that personnel designated to conduct safety regulatory audits, including auditing personnel from qualified entities, meet specific qualification criteria defined by the national supervisory authority. The criteria shall address:
  - (i) the knowledge and understanding of the requirements related to air traffic services, ATFM and ASM 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.

*Article 12*  
**Safety directives**

1. The national supervisory authority shall issue a safety directive when it has determined the existence of an unsafe condition in a functional system requiring immediate action.
2. A safety directive shall be forwarded to the organisations concerned and contain, as a minimum, the following information:
  - (a) the identification of the unsafe condition;
  - (b) the identification of the affected functional system;
  - (c) the actions required and their rationale;
  - (d) the time limit for compliance of the required actions with the safety directive;
  - (e) its date of entry into force.
3. The national supervisory authority shall forward a copy of the safety directive to other national supervisory authorities concerned, in particular those involved in the safety oversight of the functional system, and where appropriate to EUROCONTROL and other concerned parties required by the provisions specified in Attachment B where applicable.
4. The national supervisory authority shall verify the compliance with applicable safety directives.

*Article 13*  
**Safety oversight records**

National supervisory authorities shall keep and 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, the safety oversight of changes, safety directives and the use of qualified entities.

*Article 14*

**Safety oversight reporting**

1. The national supervisory authority shall produce an annual safety oversight report of the actions taken pursuant to this Requirement. The report shall also include information on the following:
  - (a) organisational structure and procedures of the national supervisory authority;
  - (b) airspace falling under the responsibility of the Member States which established or nominated the national supervisory authority and organisations falling under the supervision of the national supervisory authority;
  - (c) qualified entities commissioned to conduct safety regulatory audits;
  - (d) existing levels of resources of the authority;
  - (e) any safety issues identified through the safety oversight processes operated by the national supervisory authority.
2. Member States shall use the reports produced by their national supervisory authorities when producing their annual reports required by the relevant requirements.
3. The annual safety oversight report shall be made available to the Member States concerned in the case of functional airspace blocks and to the programmes or activities conducted under agreed international arrangements to monitor or audit the implementation of the safety oversight of air traffic services, ATFM and ASM.

*Article 15*

**Information exchange between national supervisory authorities**

National supervisory authorities shall make arrangements for close cooperation in accordance with relevant requirements and exchange any appropriate information to ensure the safety oversight of all organisations providing cross border services or functions.

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## ATTACHMENT B

**B.1** For the purpose of this Requirement, ‘relevant requirements’ mean:

<b>Article in Attachment A</b>	<b>In general</b>	<b>Wherever EC law is directly applicable</b>
In Article 5, Point 1, bullet b	What it is determined in the rules the State is bound to, as regards the designation of service providers.	Article 8 of Regulation (EC) No. 550/2004 of 10 March 2004, as amended by Regulation (EC) No. 1070/2009 of 21 October 2009, published in the Official Journal of the European Union L 300/34 on 14.11.2009.
In Article 5, Point 2, bullet e	What it is determined in the rules the State is bound to, as regards measures to be taken in situations where safety regulatory requirements are not being complied with.	Article 9 of Regulation (EC) No. 549/2004 of 10 March 2004, and Article 7(7) of Regulation (EC) No. 550/2004 of 10 March 2004, both as amended by Regulation (EC) No. 1070/2009 of 21 October 2009, published in the Official Journal of the European Union L 300/34 on 14.11.2009,
In Article 6, Point 3	What it is determined in the rules the State is bound to, as regards the overall oversight of service providers.	Article 7 of Commission Regulation (EC) No. 2096/2005 of 20 December 2005, published in The Official Journal of the European Union L 335/13 on 21.12.2005.
In Article 8, Point 1	What it is determined in the rules the State is bound to, as regards the certification of service providers.	Commission Regulation (EC) No. 2096/2005 of 20 December 2005, published in The Official Journal of the European Union L 335/13 on 21.12.2005.
In Article 9, Point 1, bullet a	ESARR 4, Appendix A, Section A-1 (Hazard Identification and Severity Assessment in ATM).	Annex II, point 3.2.4 of Commission Regulation (EC) No. 2096/2005 of 20 December 2005, published in The Official Journal of the European Union L 335/13 on 21.12.2005.
In Article 10, Point 1	What it is determined in the rules the State is bound to, as regards requirements to be met by an organisation in order to delegate, fully or partially, oversight activities to that organisation.	Article 3 of Regulation (EC) No. 550/2004 of 10 March 2004, as amended by Regulation (EC) No. 1070/2009 of 21 October 2009, published in the Official Journal of the European Union L 300/34 on 14.11.2009
In Article 14, Point 2	What it is determined in the rules the State is bound to, as regards the production of annual reports to the relevant bodies.	Article 12 of Regulation (EC) No. 549/2004 of 10 March 2004, as amended by Regulation (EC) No. 1070/2009 of 21 October 2009, published in the Official Journal of the European Union L 300/34 on 14.11.2009

Article in Attachment A	In general	Wherever EC law is directly applicable
In Article 15	What it is determined in the rules the State is bound to, as regards the oversight of service providers from a Member State that also provide services relating to the airspace falling under the responsibility of another Member State.	Articles 2(4) and 2(5) of Regulation (EC) No. 550/2004 of 10 March 2004, as amended by Regulation (EC) No. 1070/2009 of 21 October 2009, published in the Official Journal of the European Union L 300/34 on 14.11.2009.

**B.2** For the purpose of this Requirement, ‘concerned parties’ mean:

Article in Attachment A	In general	Wherever EC law is directly applicable
In Article 12, Point 3	What it is determined in the rules the State is bound to, as regards the distribution of safety directives to international organisations.	The European Commission and EASA, as specified in Article 12(3) of Commission Regulation (EC) No. 1315/2007 of 8 November, published in the Official Journal of the European Union L 291/16 on 09.11.2007.

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