



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, XXX

Draft

**COMMISSION REGULATION (EU) No .../2010**

**of [...]**

**on safety oversight in air traffic management and air navigation services**

**(Text with EEA relevance)**

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**of [...]**

**on safety oversight in air traffic management and air navigation services**

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC<sup>1</sup> as amended by Regulation (EC) No 1108/2009 of the European Parliament and of the Council of 21 October 2009 in the field of aerodromes, air traffic management and air navigation services and repealing Directive 2006/23/EC<sup>2</sup>, and in particular Article 8b thereof,

Having regard to Regulation (EC) No 550/2004 of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the Single European Sky<sup>3</sup> (the service provision Regulation) as amended by Regulation (EC) No 1070/2009 of the European Parliament and of the Council of 21 October 2009 in order to improve the performance and sustainability of the European aviation system<sup>4</sup>, and in particular Article 4 thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 216/2008, the Commission, assisted by the European Aviation Safety Agency (hereinafter referred to as ‘the Agency’), is required to adopt the relevant implementing rules to provide a set of safety regulatory requirements for the implementation of an effective air traffic management (ATM) safety oversight function. Article 8b of Regulation 216/2008 requires these implementing rules to be developed based on the regulations adopted under the Single European Sky I. This regulation is based on Regulation (EC) No 1315/2007 of 8 November 2007 on safety oversight in air traffic management<sup>5</sup> and amending Regulation (EC) No 2096/2005<sup>6</sup>.
- (2) There is a need to further define the role and functions of competent authorities based on the provisions of Regulation (EC) No 216/2008, Regulation (EC) No 549/2004 of

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<sup>1</sup> OJ L 79, 19.3.2008, p. 1.

<sup>2</sup> OJ L 309, 24.11.2009, p. 51.

<sup>3</sup> OJ L 96, 31.3.2004, p. 10.

<sup>4</sup> OJ L 300, 14.11.2009, p. 34.

<sup>5</sup> OJ L 291, 9.11.2007, p. 16.

<sup>6</sup> OJ L 335, 21.12.2005, p. 13.

the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky<sup>7</sup> (the framework Regulation), Regulation (EC) No 550/2004 and Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network<sup>8</sup> (the interoperability Regulation). These regulations include requirements on the safety of air navigation services. While the responsibility for the safe provision of service lies with the provider, the Member States should ensure effective supervision through competent authorities.

- (3) This Regulation does not cover military operations and training, as provided for in Article 1(2) of Regulation (EC) No 549/2004 and Article 1(2)(c) of Regulation (EC) No 216/2008.
- (4) Competent authorities should conduct safety regulatory audits and reviews in accordance with this Regulation as part of the proper inspections and surveys required by Regulation (EC) No 216/2008 and Regulation (EC) No 550/2004.
- (5) Competent authorities should consider using the safety oversight approach of this Regulation in other areas of oversight as appropriate in order to develop efficient and coherent supervision.
- (6) All air navigation services, as well as air traffic flow management and airspace management, use functional systems that enable the management of air traffic. Therefore any changes to functional systems should be subject to a safety oversight.
- (7) Competent authorities shall take all necessary measures in case a system or a constituent of a system does not comply with the relevant requirements. In this context and in particular when a safety directive has to be issued, the competent authority should consider instructing the notified bodies involved in issuing the Declaration referred to in Article 6 or Article 5 of the Regulation (EC) No 552/2004 to conduct specific investigations with regard to that technical system.
- (8) Annual safety oversight reporting by the competent authorities should contribute to the transparency and accountability of the safety oversight. The reports should be addressed to the Commission, the Agency and the Member State nominating or establishing the authority. Furthermore, they should be used in the context of regional cooperation, standardisation inspections under Regulation (EC) No 216/2008 and international safety oversight monitoring. The actions to be reported should include relevant information with regard to the monitoring of safety performance, the compliance with applicable safety regulatory requirements by the organisations supervised, the programme of safety regulatory audits, the review of the safety arguments, the changes to functional systems implemented by the organisations in accordance with procedures accepted by the authority and the safety directives issued by the competent authority.
- (9) Pursuant to Article 10(1) of Regulation (EC) No 216/2008 and Article 2(4) of Regulation (EC) No 550/2004, competent authorities should make appropriate arrangements for close cooperation with each other to ensure adequate supervision of

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<sup>7</sup> OJ L 96, 31.3.2004, p. 1.

<sup>8</sup> OJ L 96, 31.3.2004, p. 26.

air navigation service providers which provide services relating to the airspace falling under the responsibility of a Member State different from the Member State which issued the certificate. Pursuant to Article 15 of Regulation (EC) No 216/2008 authorities should exchange in particular appropriate information about the safety oversight of organisations.

- (10) The Agency should further evaluate the provisions of this Regulation, in particular those related to the safety oversight of changes, and issue an Opinion to adapt them towards a total system approach, taking into account the integration of these provisions into the common regulatory structure for civil aviation safety and the experience gained by stakeholders and competent authorities. The Agency's Opinion should further aim at facilitating the implementation of the ICAO State Safety Programme (SSP) within the European Union and as part of this total system approach.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Single Sky Committee,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

#### **Subject matter and scope**

1. This Regulation establishes requirements to be applied to the exercise of the safety oversight function by competent authorities concerning air navigation services, air traffic flow management (ATFM) and airspace management (ASM) for general air traffic.
2. This Regulation shall apply to the activities of competent authorities and qualified entities acting on their behalf regarding the safety oversight of air navigation services, ATFM and ASM.

#### *Article 2*

#### **Definitions**

For the purposes of this Regulation the definitions established by Regulation (EC) No 216/2008 and Regulation (EC) No 549/2004 shall apply, except the definition in Article 2(15) of Regulation 549/2004.

The following definitions shall also apply:

- (a) 'corrective action' means an action to eliminate the cause of a detected non-conformity;
- (b) 'functional system' means a combination of systems, procedures and human resources organised to perform a function within the context of ATM;
- (c) 'organisation' means either an air navigation service provider or an entity providing ATFM or ASM;
- (d) 'process' mean a set of interrelated or interacting activities which transforms inputs into outputs;

- (e) ‘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;
- (f) ‘safety directive’ means a document issued or adopted by a competent authority which mandates actions to be performed on a functional system to restore safety, when evidence shows that aviation safety may otherwise be compromised;
- (g) ‘safety objective’ means a qualitative or quantitative statement that defines the maximum frequency or probability at which a hazard can be expected to occur;
- (h) ‘safety regulatory audit’ means a systematic and independent examination conducted by, or on behalf of, a competent 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;
- (i) ‘safety regulatory requirements’ means the requirements established by the European Union or national regulations for the provision of air navigation 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;
- (j) ‘safety requirement’ means a risk mitigation, defined from the risk mitigation strategy that achieves a particular safety objective, including organisational, operational, procedural, functional, performance and interoperability requirements or environmental characteristics;
- (k) ‘verification’ means confirmation through the provision of objective evidence that specified requirements have been fulfilled;
- (l) ‘Pan-European service’ means a service which is designed and established for users within most or all Member States.

*Article 3*  
**Competent authority**

For the purpose of this Regulation, the competent authority shall be:

- (a) for organisations having their principal place of operation and, if any, its registered office located in a Member State, the national supervisory authority nominated or established by that Member State;
- (b) for air navigation service providers offering services within a Functional Airspace Block (FAB) where under the agreement between States the responsibilities for safety oversight have been allocated differently from paragraph (a), the national supervisory authority(ies) nominated or established under that agreement;
- (c) for organisations providing services in the airspace of the territory to which the Treaty applies and having their principal place of operation and, if any, its registered office located outside the territory subject to the provisions of the Treaty, the Agency;

- (d) for organisations providing Pan-European services, the Agency.

#### *Article 4*

### **Safety oversight function**

1. The competent authority shall exercise safety oversight as part of their supervision of requirements applicable to air navigation 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 Regulation;
- (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 5*

### **Monitoring of safety performance**

1. The competent 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. The competent 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 6*

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

1. The competent 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 navigation services including safety-related conditions attached to it;
- (b) compliance with any safety-related obligations in the designation act issued in accordance with Article 8 of Regulation (EC) No 550/2004;
- (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) declarations of verification of systems, including any relevant declaration of conformity or suitability for use of constituents of systems issued in accordance with Regulation (EC) No 552/2004;
    - (ii) risk assessment and mitigation procedures required by safety regulatory requirements applicable to air navigation services, ATFM and ASM;
  - (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 7, 9 and 10;
  - (e) provide the competent authority with the evidence needed to support further action, including measures foreseen by Article 9 of Regulation (EC) No 549/2004, Article 7(7) of Regulation (EC) No 550/2004 and by Articles 10, 25 and 68 of Regulation (EC) No 216/2008 in situations where safety regulatory requirements are not being complied with.

*Article 7*  
**Safety regulatory audits**

1. Competent 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 competent 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 12;
  - (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 8.
3. Within the inspection programme required by Article 8 of Commission Regulation (EU) No XXXX/2010, competent 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 competent 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. Competent authorities may decide to modify the scope of pre-planned audits and to include additional audits, wherever that need arises.
5. Competent 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 8*

#### **Corrective actions**

1. The competent authority shall communicate the audit findings to the audited organisation and shall simultaneously request corrective actions to address the non-conformities 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 competent 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 non-conformities.



4. The audited organisation shall initiate the corrective actions accepted by the competent authority. These corrective actions and the subsequent follow-up process shall be completed within the time period accepted by the competent authority.

#### *Article 9*

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

1. Organisations shall only use procedures accepted by their competent authority when deciding whether to introduce a safety-related change to their functional systems. In case of providers of air traffic services and providers of communication, navigation or surveillance services, the competent authority shall accept these procedures in the framework of Regulation (EU) No XXXX/2010.

2. Organisations shall notify their competent authority of all planned safety-related changes. To this effect, the competent authorities shall establish appropriate administrative procedures in accordance with national law.

3. Unless Article 10 applies, the organisations may implement the notified change following the procedures referred to in paragraph 1 of this Article.

#### *Article 10*

### **Review procedure of the proposed changes**

1. The competent 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 Annex II, point 3.2.4 of Regulation (EU) No XXXX/2010 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 competent 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) declarations of verification of systems referred to in Article 6 of Regulation (EC) No 552/2004;
  - (ii) declarations of conformity or suitability for use of constituents of systems referred to in Article 5 of Regulation (EC) No 552/2004; or
  - (iii) risk assessment and mitigation documentation established in accordance with applicable safety regulatory requirements;
- (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 competent authority.

#### *Article 11* **Qualified entities**

1. When a competent authority decides to delegate to a qualified entity the conduct of safety regulatory audits or reviews in accordance with this Regulation, it shall ensure that the criteria used to select an entity amongst those qualified in accordance with Article 3 of

Regulation (EC) No 550/2004 and Article 13 of Regulation (EC) No 216/2008 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 12(3) of this Regulation.
2. The qualified entity shall accept the possibility of being audited by the competent authority or any body acting on its behalf.
3. Competent 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 12*

#### **Safety Oversight capabilities**

1. Member States and the Commission shall ensure that competent 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 Regulation.
2. Competent 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 Regulation and their application.
3. Competent 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 competent authority. The criteria shall address:
    - (i) the knowledge and understanding of the requirements related to air navigation 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 13*  
**Safety directives**

1. The competent 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 competent authority shall forward a copy of the safety directive to the Agency and any other competent authorities concerned, in particular those involved in the safety oversight of the functional system, and to the Commission.
4. The competent authority shall verify the compliance with applicable safety directives.

*Article 14*  
**Safety oversight records**

Competent 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 15*  
**Safety oversight reporting**

1. The competent authority shall produce an annual safety oversight report of the actions pursuant to this Regulation. The report shall also include information on the following:
  - (a) organisational structure and procedures of the competent authority;
  - (b) airspace falling under the responsibility of the Member States which established or nominated the competent authority, if applicable, and organisations falling under the supervision of the competent 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 competent authority.

2. Member States shall use the reports produced by their competent authorities when producing their annual reports to the Commission required by Article 12 of Regulation (EC) No 549/2004.

The annual safety oversight report shall be made available to the Member States concerned in the case of functional airspace blocks, to the Agency and to the programmes or activities conducted under agreed international arrangements to monitor or audit the implementation of the safety oversight of air navigation services, ATFM and ASM.

#### *Article 16*

### **Information exchange between competent authorities**

Competent authorities shall make arrangements for close cooperation in accordance with Articles 10 and 15 of Regulation (EC) No 216/2008 and Article 2(4) of Regulation (EC) No 550/2004 and exchange any appropriate information to ensure the safety oversight of all organisations providing cross-border services or functions.

#### *Article 17*

### **Transitional provisions**

1. Actions which are initiated before the entry into force of this Regulation on the basis of Commission Regulation (EC) No 1315/2007 shall be administered in conformity with the provisions of this Regulation.

2. The authority of a Member State which has had the responsibility for the safety oversight of organisations for which the Agency is the competent authority in accordance with article 3 shall transfer to the Agency the safety oversight function of these organisations 6 months after the date of entry into force of this Regulation.

#### *Article 18*

### **Repeal provisions**

1. Commission Regulation (EC) No 1315/2007 is hereby repealed.

#### *Article 19*

### **Entry into force**

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, ...

*For the Commission*

*The President*