

COMMISSION REGULATION (EC) No 1315/2007

of 8 November 2007

on safety oversight in air traffic management and amending Regulation (EC) No 2096/2005

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

(3) This Regulation should not cover military operations and training as referred to in Article 1(2) of Regulation (EC) No 549/2004.

Having regard to the Treaty establishing the European Community,

(4) National supervisory 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 550/2004.

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 (the service provision Regulation) (1), and in particular Article 4 thereof,

(5) National supervisory 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.

Whereas:

(6) In line with Annex 11, Section 2.26 of the Convention on International Civil Aviation, ESARR 1 requires the monitoring and assessment of the levels of safety achieved against the tolerable levels of safety determined for specific airspace blocks. However, those tolerable levels of safety still need to be completely established at Community level and therefore they should be taken into consideration in this Regulation at a later stage.

(1) Pursuant to Regulation (EC) No 550/2004, the Commission is required to identify and adopt the relevant provisions of the Eurocontrol Safety Regulatory Requirements (ESARRs), taking into account existing Community legislation. ESARR 1 provides a set of safety regulatory requirements for the implementation of an effective air traffic management (ATM) safety oversight function.

(7) All air navigation services, as well as air traffic flow management and air space management use functional systems that enable the management of air traffic. Therefore any changes to functional systems should be subject to a safety oversight.

(2) The role and functions of national supervisory authorities have been established in Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) (2), Regulation (EC) No 550/2004, 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 (the interoperability Regulation) (3) and Commission Regulation (EC) No 2096/2005 of 20 December 2005 laying down common requirements for the provision of air navigation services (4). 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 national supervisory authorities.

(8) Article 7 of Regulation (EC) No 552/2004 requires a national supervisory authority to 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 national supervisory authority should consider instructing the notified bodies involved in issuing the EC Declaration to conduct specific investigations with regard to that technical system.

(1) OJ L 96, 31.3.2004, p. 10.

(2) OJ L 96, 31.3.2004, p. 1.

(3) OJ L 96, 31.3.2004, p. 26.

(4) OJ L 335, 21.12.2005, p. 13.

(9) National supervisory authorities should be given a sufficient period of time to prepare for the safety oversight of changes, notably as regards the identification of the targets and standards. The identification should be supported by appropriate Community specifications and other guidance material.

(10) Annual safety oversight reporting by the national supervisory authorities should contribute to the transparency and accountability of the safety oversight. The reports should be addressed to the Member State nominating or establishing the authority. Furthermore, they should be used in the context of regional cooperation 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 national supervisory authority.

(11) Pursuant to Article 2(4) of Regulation (EC) No 550/2004, national supervisory authorities should make appropriate arrangements for close cooperation with each other to ensure adequate supervision of 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. Authorities should exchange in particular appropriate information about the safety oversight of organisations.

(12) Regulation (EC) No 2096/2005 should be amended accordingly, in order to ensure consistency in the implementation of the Single European Sky.

(13) 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 a safety oversight function concerning air navigation services, air traffic flow management (ATFM) and air space management (ASM) for general air traffic by identifying and adopting the relevant mandatory provisions of the Eurocontrol Safety Regulatory Requirement on safety oversight in air traffic management (ATM) (ESARR 1) issued on 5 November 2004.
2. This Regulation shall apply to the activities of national supervisory authorities and recognised organisations 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 549/2004 shall apply.

The following definitions shall also apply:

1. 'corrective action' means action to eliminate the cause of a detected non-conformity;
2. 'functional system' means a combination of systems, procedures and human resources organised to perform a function within the context of ATM;
3. 'organisation' means either an air navigation service provider or an entity providing ATFM or ASM;
4. 'process' means a set of interrelated or interacting activities which transforms inputs into outputs;
5. '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;
6. '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;
7. 'safety objective' means a qualitative or quantitative statement that defines the maximum frequency or probability at which a hazard can be expected to occur;
8. '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;
9. 'safety regulatory requirements' means the requirements established by Community 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;

10. '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;
11. '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 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 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 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) EC declarations of verification of systems, including any relevant EC declaration of conformity or suitability for use of constituents of systems;
 - (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 6, 8 and 9;
 - (e) provide the national supervisory authority with the evidence needed to support further action, including measures foreseen by Article 9 of Regulation (EC) No 549/2004 and by Article 7(7) of Regulation (EC) No 550/2004 in situations where safety regulatory requirements are not being complied with.

Article 6**Safety regulatory audits**

1. National supervisory authorities, or recognised organisations 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 Article 7 of Regulation (EC) No 2096/2005, 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 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 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 non-conformities.

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 and providers of communication, navigation or surveillance services, the national supervisory authority shall accept these procedures in the framework of Regulation (EC) No 2096/2005.

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.

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 Annex II, point 3.2.4 of Regulation (EC) No 2096/2005 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) EC declarations of verification of systems;
- (ii) EC declarations of conformity or suitability for use of constituents of systems; 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 national supervisory authority.

Article 10

Recognised organisations

1. When a national supervisory authority decides to delegate to a recognised organisation 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 recognised in accordance with Article 3 of Regulation (EC) No 550/2004 include the following:

- (a) the recognised organisation has prior experience in assessing safety in aviation entities;
- (b) the recognised organisation 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 Regulation.

2. The recognised organisation 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 recognised organisations 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 Regulation.

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 Regulation 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 recognised organisations, 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 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 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 to the Commission, the European Aviation Safety Agency (EASA) and Eurocontrol as far as appropriate.

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 recognised organisations.

Article 14

Safety oversight reporting

1. The national supervisory authority shall produce an annual safety oversight report of the actions taken pursuant to this Regulation. 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) recognised organisations 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 to the Commission required by Article 12 of Regulation (EC) No 549/2004.

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 navigation services, ATFM and ASM.

Article 15

Information exchange between national supervisory authorities

National supervisory authorities shall make arrangements for close cooperation in accordance with 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 16

Amendment to Regulation (EC) No 2096/2005

Article 5(3) of Regulation (EC) No 2096/2005 is deleted.

Article 17

Transitional provision

Member States may defer the application of Article 9(3) until 1 November 2008. They shall forthwith inform the Commission thereof.

Article 18

Entry into force

This Regulation shall enter into force on the day following 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, 8 November 2007.

For the Commission

Jacques BARROT

Vice-President