



Director General of Civil Aviation Authority of Kosovo,

Pursuant to articles 3.5 item (ii), 15.1 item (a) and (c), 21.2, 78, 79 and 80 item (a) and (b) of Law No. 03/L-051 on Civil Aviation ("Official Gazette of the Republic of Kosovo", Year III, No. 28, of 4 June 2008),

Taking into consideration,

International obligations of the Republic of Kosovo towards Multilateral Agreement on Establishing the European Common Aviation Area (hereinafter "ECAA Agreement") since its provisional entry into force for Kosovo on 10 October 2006,

Commission Regulation (EC) No. 1315/2007 of 8 November 2007 on safety oversight in air traffic management, which became part of the internal legal order of the Republic of Kosovo in implementation of the ECAA Agreement through CAA Regulation No. 13/2009 on safety oversight of air traffic management, dated 29 December 2009,

CAA Regulation No. 3/2009, dated 30 October 2009, CAA Regulations No. 8/2009, No. 9/2009, No. 10/2009, No. 11/2009 of 15 November 2009, No. 12/2009 and 13/2009 of 24 December 2009, and No. 12/2010 of 18 November 2010, all issued for the implementation of ECAA Agreement,

With the aim of implementing "Commission Implementing Regulation (EU) No. 1034/2011 on safety oversight in air traffic management and air navigation services and amending Regulation (EU) No. 691/2010" of 17 October 2011, within the internal legal order of the Republic of Kosovo,

Upon completion of the process of public consultation of interested parties, in accordance with the Administrative Instruction No. 01/2012 on procedures for public consultation of interested parties,

Hereby issues:

**REGULATION No. 6/2012
ON SAFETY OVERSIGHT IN AIR TRAFFIC MANAGEMENT AND AIR
NAVIGATION SERVICES**

Article 1

Implementing Regulation of the Commission of the European Union (EU) Nr. 1034/2011, of 17 October 2011 on safety oversight in air traffic management and air navigation services and amending Regulation (EU) No. 691/2010 (hereinafter "Commission Regulation") is declared applicable in the Republic of Kosovo. Commission Regulation is attached to the present Regulation as an Annex and forms its integral part.

Article 2

2.1 Provisions of Articles 1 to 18 of the Commission Regulation are applicable in the Republic of Kosovo.

2.2 Any provision of the future amendments of the Commission Regulation, except provisions pursuant or referring to the Commission Regulation No. 691/2010 of 29 July 2010, upon its becoming part of the Annex I or II of the ECAA Agreement shall become directly applicable in the Republic of Kosovo.

Article 3

3.1 Definitions of terms and expressions used in this Regulation are those contained in Article 2 of Commission Regulation.

3.2 Notwithstanding paragraph 1, terms "Community", "Community law", "Community legislation", "Community instruments", "EC Treaty", "Community airport", "Official Journal of the European Communities", "Official Journal of the European Union", "Community air carrier" and "Member State(s)", if referred to directly or indirectly in the Commission Regulation, shall be read in accordance with Points 2 and 3 of Annex II to the ECAA Agreement.

Article 4

In case of interpretation of the Commission Regulation the original version in the English language as published on the Official Journal of the European Union shall be used.

Article 5

This Regulation repeals CAA Regulation No. 13/2009 on safety oversight air traffic management, dated 24 December 2009.

Article 6

In the text of the Regulation No. 12/2010 of 18 November 2010 the reference to Commission Regulation No. 1315/2007 shall be deleted and replaced with “CAA Regulation No. 6/2012” of 10 December 2012.

Article 7

This Regulation shall enter into on 21 December 2012.

Dritan Gjonbalaj
Director General

COMMISSION IMPLEMENTING REGULATION (EU) No 1034/2011**of 17 October 2011****on safety oversight in air traffic management and air navigation services and amending Regulation (EU) No 691/2010****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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,

Having regard to Regulation (EC) No 551/2004 of the European Parliament and of the Council of 10 March 2004 on the organisation and use of the airspace in the single European sky ('the airspace Regulation') ⁽²⁾, and in particular Article 6 thereof,

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 ⁽³⁾, and in particular Article 8b thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 216/2008, the Commission, assisted by the European Aviation Safety Agency ('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 (EC) No 216/2008 requires these implementing rules to be developed based on the regulations adopted pursuant to Article 5(3) of 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') ⁽⁴⁾. This Regulation is based on Commission Regulation (EC) No 1315/2007 of 8 November 2007 on safety oversight in air traffic management and amending Regulation (EC) No 2096/2005 ⁽⁵⁾.

(2) There is a need to further define the role and functions of competent authorities based on the provisions of Regulations (EC) No 216/2008, (EC) No 549/2004, (EC) No

550/2004, and (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') ⁽⁶⁾. These regulations include requirements on the safety of air navigation services. While providers are responsible for the safe provision of air navigation services, Member States should ensure effective supervision through competent authorities.

(3) This Regulation should 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 Regulations (EC) No 216/2008 and (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 deliver efficient and coherent supervision.

(6) Air navigation services, as well as air traffic flow management (ATFM) and airspace management (ASM), 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 should 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 5 or 6 of Regulation (EC) No 552/2004 to conduct specific investigations with regard to that technical system.

(8) Annual safety oversight reporting by competent authorities should contribute to the transparency and accountability of safety oversight. Such reports should be addressed to the Commission, the Agency and the Member State nominating or establishing the

⁽¹⁾ OJ L 96, 31.3.2004, p. 10.

⁽²⁾ OJ L 96, 31.3.2004, p. 20.

⁽³⁾ OJ L 79, 19.3.2008, p. 1.

⁽⁴⁾ OJ L 96, 31.3.2004, p. 1.

⁽⁵⁾ OJ L 291, 9.11.2007, p. 16.

⁽⁶⁾ OJ L 96, 31.3.2004, p. 26.

competent authority. Furthermore, annual safety oversight reports should be used in the context of regional cooperation, standardisation inspections under Regulation (EC) No 216/2008 and international safety oversight monitoring. The content of the reports should include relevant information with regard to the monitoring of safety performance, compliance with applicable safety regulatory requirements by supervised organisations, the programme of safety regulatory audits, the review of the safety arguments, changes to functional systems implemented by supervised organisations in accordance with procedures accepted by the competent authority and safety directives issued by such 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 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, competent 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 such changes towards a total system approach, taking into account the integration of these provisions into the future 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 State Safety Programme (SSP) of the International Civil Aviation Organisation (ICAO) within the Union as part of this total system approach.
- (11) The safe execution of some of the network functions set up according to Regulation (EC) No 551/2004 requires that the entity involved should be subject to certain safety requirements. These requirements, which aim to ensure that such entity or organisation operates in a safe manner, are laid down in Commission Regulation (EU) No 677/2011 of 7 July 2011 laying down detailed rules for the implementation of air traffic management (ATM) network functions and amending Regulation (EU) No 691/2010⁽¹⁾. These are organisation safety requirements which are very similar to those general requirements laid down in Commission Implementing Regulation (EU) No 1035/2011⁽²⁾, but adapted to the safety responsibilities of the network functions. In order to support a total system approach for safety regulation in the field of civil aviation, the execution of these requirements needs to be overseen in the same manner as air navigation service providers are overseen.

- (12) In its recommendations of July 2007, the High Level Group for the Future European Aviation Regulatory Framework highlighted the need to separate regulatory oversight from the provision of services or functions. In line with this principle, Article 6 of Regulation (EC) No 551/2004 provides that the entity nominated to perform the network functions needs to be subject to appropriate oversight arrangements. Since the Agency already carries out the independent safety oversight function of the pan-European ATM/ANS providers in accordance with Article 22a of Regulation (EC) No 216/2008, it would be fully in line with the European aviation safety policy to entrust it with supporting the Commission in performing the same tasks concerning the European network functions.
- (13) Regulation (EC) No 1315/2007 should therefore be repealed.
- (14) Commission Regulation (EU) No 691/2010 of 29 July 2010 laying down a performance scheme for air navigation services and network functions and amending Regulation (EC) No 2096/2005⁽³⁾ should be amended in order to be adapted to this Regulation.
- (15) 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), airspace management (ASM) for general air traffic and other network functions.
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, ASM and other network functions.

Article 2

Definitions

For the purposes of this Regulation, the definitions in Article 2 of Regulation (EC) No 549/2004 and Article 3 of Regulation (EC) No 216/2008 apply. However, the definition of 'certificate' in Article 2(15) of Regulation (EC) No 549/2004 does not apply.

The following definitions also apply:

- (1) 'corrective action' means an action to eliminate the cause of a detected non-conformity;

⁽¹⁾ OJ L 185, 15.7.2011, p. 1.

⁽²⁾ See page 23 of this Official Journal.

⁽³⁾ OJ L 201, 3.8.2010, p. 1.

- (2) 'functional system' means a combination of systems, procedures and human resources organised to perform a function within the context of ATM;
- (3) 'Network Manager' means the impartial and competent body entrusted pursuant to Article 6(2) or (6) of Regulation (EC) No 551/2004 to perform the duties described in that Article and this Regulation;
- (4) 'network functions' means the specific functions described in Article 6 of Regulation (EC) No 551/2004;
- (5) 'organisation' means either an air navigation service provider or an entity providing ATFM or ASM or other network functions;
- (6) 'process' means a set of interrelated or interacting activities which transforms inputs into outputs;
- (7) '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;
- (8) '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;
- (9) 'safety objective' means a qualitative or quantitative statement that defines the maximum frequency or probability at which a hazard can be expected to occur;
- (10) '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;
- (11) 'safety regulatory requirements' means the requirements established by the Union or national regulations for the provision of air navigation services or ATFM and ASM functions or other network functions as well as 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;
- (12) '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;
- (13) 'verification' means confirmation through the provision of objective evidence that specified requirements have been fulfilled;
- (14) 'pan-European ATM/ANS' means an activity which is designed and established for users within most or all Member States and which may also extend beyond the airspace of the territory to which the Treaty applies.

Article 3

Competent authorities for oversight

For the purpose of this Regulation and without prejudice to the mutual recognition of air navigation service providers certificates in accordance with Article 7(8) of Regulation (EC) No 550/2004 and Article 11 of Regulation (EC) No 216/2008, competent authorities for oversight shall be:

- (a) for organisations having their principal place of operation and, if any, their registered office located in a Member State while providing air navigation services in the territory of that Member State, the national supervisory authority nominated or established by that Member State;
- (b) for organisations for which under the agreements concluded among Member States in accordance with Article 2 of Regulation (EC) No 550/2004, the responsibilities for safety oversight have been allocated differently from point (a), the competent authorities nominated or established under those agreements. These agreements shall comply with the requirements of Article 2(3) to (6) of Regulation (EC) No 550/2004;
- (c) for organisations providing ATM/air navigation services in the airspace of the territory to which the Treaty applies and having their principal place of operation and, if any, their registered office located outside the territory subject to the provisions of the Treaty, the European Aviation Safety Agency ('the Agency');
- (d) for organisations providing pan-European ATM/ANS as well as for all other network functions in the airspace of the territory to which the Treaty applies, the Agency.

Article 4

Safety oversight function

1. Competent authorities shall exercise safety oversight as part of their supervision of requirements applicable to air navigation services as well as to ATFM, ASM and other network functions, 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 or in cases of cross-border provision, 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) Member States have visibility of the safety oversight mechanisms and their results;
- (c) relevant information exchange is ensured between the overseeing authorities and the certifying authority.

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

3. When concluding an agreement on the supervision of organisations active in functional airspace blocks or in cross-border activities in which the Agency is the competent authority for at least one of the organisations in accordance with Article 3(b), the Member States concerned shall coordinate with the Agency so as to ensure that points (a), (b) and (c) of paragraph 2 are met.

Article 5

Monitoring of safety performance

1. 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. 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. 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, ASM and the Network Manager;

- (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 organisations 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 competent authorities 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 Implementing Regulation (EU) No 1035/2011, 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, services and network functions 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 2 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, functions, 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.

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

Article 8

Corrective actions

1. Competent authorities shall communicate the audit findings to audited organisations 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. Audited organisations shall determine the corrective actions deemed necessary to correct non-conformities and the time frame for their implementation.

3. Competent authorities shall assess the corrective actions as well as their implementation as determined by audited organisations and accept them if the assessment concludes that they are sufficient to address the non-conformities.

4. Audited organisations shall initiate the corrective actions accepted by competent authorities. These corrective actions and the subsequent follow-up process shall be completed within the time period accepted by competent authorities.

Article 9

Safety oversight of changes to functional systems

1. Organisations shall only use procedures accepted by the relevant competent authority when deciding whether to introduce a safety-related change to their functional systems. In case of air traffic service providers and communication, navigation or surveillance service providers, the relevant competent authority shall accept these procedures in the framework of Implementing Regulation (EU) No 1035/2011.

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

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

Article 10

Review procedure of the proposed changes

1. Competent authorities 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 Implementing Regulation (EU) No 1035/2011 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 competent authorities determine the need for a review in situations other than those referred to in points (a) and (b), they shall notify the organisation that they will undertake a safety review of the notified changes.

2. Reviews shall be conducted in a manner commensurate with the level of risk posed by the new functional systems or by the proposed changes to existing functional systems.

Reviews 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 changes under consideration 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 changes, 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 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 changes under consideration in the review shall be subject to acceptance by competent authorities.

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. Such 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 2 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, ASM and other network functions 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. Competent authorities shall issue a safety directive when they have determined the existence of an unsafe condition in a functional system requiring immediate action.

2. Safety directives 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. Competent authorities 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. Competent authorities 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. Competent authorities shall report annually on safety oversight actions pursuant to this Regulation. The annual safety oversight report shall also include information on the following:

- (a) organisational structure and procedures of the competent authority;
- (b) airspace falling under the responsibility of Member States which established or nominated the competent authority, if applicable, and organisations falling under the supervision of that competent authority;
- (c) qualified entities commissioned to conduct safety regulatory audits;
- (d) existing levels of resources of the competent 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 submitting their annual reports to the Commission as required by Article 12 of Regulation (EC) No 549/2004.

The annual safety oversight reports 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, ASM and other network functions.

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 initiated before the entry into force of this Regulation on the basis of Regulation (EC) No 1315/2007 shall be managed in accordance with 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 12 months after the date of entry into force of this Regulation, except in the case of the safety oversight of the Network Manager where the transfer, if any, to the Commission, assisted by the Agency, shall be made on the date of entry into force of this Regulation.

Article 18

Repeal

Regulation (EC) No 1315/2007 is repealed.

*Article 19***Amendment to Regulation (EU) No 691/2010**

In Annex IV to Regulation (EU) No 691/2010, point 1.1(e) is replaced by the following:

‘(e) NSA safety reports as referred to in Articles 7, 8 and 14 of Commission Implementing Regulation (EU) No 1034/2011 (*) as well as NSA reports on resolution of safety deficiencies identified that are subject to corrective action plans;

(*) OJ L 271, 18.10.2011, p. 15.’

*Article 20***Entry into force**

This Regulation shall enter into force on the 20th 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, 17 October 2011.

For the Commission

The President

José Manuel BARROSO
