Commission Implementing Regulation (EU) No 628/2013 of 28 June 2013 on working methods of the European Aviation Safety Agency for conducting standardisation inspections and for monitoring the application of the rules of Regulation (EC) No 216/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 736/2006 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 628/2013

of 28 June 2013

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(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 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[(1)], and in particular Article 24(5) thereof,

Whereas:

(1) Article 24(1) and Article 54 of Regulation (EC) No 216/2008 require the European Aviation Safety Agency (hereinafter 'the Agency'), to assist the Commission in monitoring the application of its provisions, as well as its implementing rules, by Member States' competent authorities, by conducting standardisation inspections.

(2) Article 54(4) of Regulation (EC) No 216/2008 stipulates that where an inspection of a Member State competent authority entails an inspection of an undertaking or an association of undertakings, the Agency should follow the provisions of Article 55.

(3) Commission Regulation (EC) No 736/2006[(2)] lays down the working methods of the Agency for conducting standardisation inspections (hereinafter 'the current working methods').

(4) Six years have passed since the adoption of the current working methods. Considerable changes to the common rules have been adopted; a number of international agreements have also been adopted; the Agency and the Member States have also accumulated valuable experience that needs to be accounted for.

(5) When Regulation (EC) No 736/2006 was adopted, the common rules in the field of civil aviation were limited to initial and continuing airworthiness. Commission Regulation (EC) No 1702/2003[(3)] laid down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances,

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as well as for the certification of design and production organisations; Commission Regulation (EC) No 2042/2003[4] laid down implementing rules for the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks.

(6) Since that time, Regulation (EC) No 216/2008 has replaced Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency[5] and the common rules have been extended twice: first to include air crew, air operations and ramp inspections; secondly to include air traffic management and air navigations services (ATM/ANS) as well as airport safety, as a consequence of which the Commission has adopted several implementing rules corresponding to those new fields of competence such as Commission Regulation (EU) No 805/2011 of 10 August 2011 laying down detailed rules for air traffic controllers' licences and certain certificates[6], Commission Implementing Regulation (EU) No 1034/2011[7] laying down administrative procedures for the safety oversight of air traffic management and air navigation services, Commission Implementing Regulation (EU) No 1035/2011 of 17 October 2011 laying down common requirements for the provision of air navigation services[8], 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 laying down common requirements for the provision of air navigation services[9], Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation[10], amended by Commission Regulation (EC) No 859/2008[11], Directive 2004/36/EC of the European Parliament and of the Council of 21 April 2004 on the safety of third-country aircraft using Community airports[12], amended by Commission Directive 2008/49/EC of 16 April 2008 amending Annex II to Directive 2004/36/EC of the European Parliament and of the Council regarding the criteria for the conduct of ramp inspections on aircraft using Community airports[13] Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations[14], and Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew[15].

(7) Regulation (EC) No 216/2008 has also introduced a number of new provisions that need to be reflected in the Agency's working methods for carrying out standardisation inspections. In particular, Article 11 establishes the conditions for the mutual recognition of certificates issued by competent authorities of Member States, as well as conditions for suspending this recognition, where standardisation inspections constitute an important instrument for such decision-making. Article 15 establishes an information network that provides useful information to be taken into account for standardisation inspections, whilst certain results of such standardisation inspections may need to be made available without delay to this information network. Article 27(3) establishes that the Agency has to support the Member States in discharging their obligations towards ICAO.

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(8) Notwithstanding further changes of the common rules as established by Regulation (EC) No 216/2008 and its implementing rules, the Agency should support the Commission in monitoring the implementation of other aviation safety requirements stemming, for instance, from the Single European Sky legislation or the legislation on accident investigation or occurrence reporting.

(9) Since 2006, the European external aviation policy has also experienced significant developments, both regarding International Civil Aviation Organisation (ICAO), States in the neighbourhood of the European Union and certain key partners at global level.

(10) A Memorandum of Cooperation with the International Civil Aviation Organisation (ICAO) was signed in 2010[16] which creates the framework for a structured cooperation between parties, in particular regarding the exchange of information related to safety, with a view to avoid duplication of tasks where possible, as a consequence of which the Agency's standardisation inspection programme and the ICAO Universal Safety Oversight Audit Programme (USOAP) should become more inter-related. The inspection working methods should also take into account ICAO Doc 9735 — the USOAP continuous Monitoring Manual.

(11) With regard to the States part of the EU neighbourhood and enlargement policy, including notably States Party to the European Common Aviation Area agreement, standardisation inspections should be organised in accordance with the same working methods and in accordance with the same standards as for the Member States, subject to appropriate Agreements or Working Arrangements.

(12) With regard to the States having signed Bilateral Air Safety Agreements providing for the mutual acceptance of certain certification findings and approvals, standardisation inspections should support the monitoring of the implementation of the agreement and report the results to the appropriate bilateral oversight board in view of possible adjustments. The inspections of those Member States whose certification findings and approvals are accepted in the framework of the bilaterals should include additional verifications to ensure competent authorities discharge correctly their responsibilities stemming from the bilateral agreements.

(13) In order to monitor the application of Regulation (EC) No 216/2008 and its implementing rules, as well as other aviation safety rules stemming from existing Regulations and agreements efficiently, it is necessary to review the current working methods, notably to ensure they become more system oriented, follow a more continuous monitoring approach more focused on safety performance, provide for more efficient use of resources in order not to generate an undue burden on the competent authorities and include a feedback loop to the Agency's rulemaking activities. Inspection teams should be set up with adequately trained and qualified personnel and the Agency shall endeavour to balance the participation of authorised personnel from different Member States.

(14) The working methods should reflect the definitions and principles of auditing as defined in ISO 19011.

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(15) Beyond the inspection-level, the working methods should elaborate on the monitoring at system-level and at finding-level.

(16) The working methods should provide more flexibility to the Agency in taking action where this corresponds to its technical competence whilst maintaining legal certainty on the working methods.

(17) Regulation (EC) No 736/2006 should therefore be repealed accordingly.

(18) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 65 of Regulation (EC) No 216/2008,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1 This Regulation lays down the working methods for:

a monitoring the application by competent authorities of the Member States of Regulation (EC) No 216/2008 and its implementing rules in the fields covered by Article 1(1) of that Regulation;

b conducting standardisation inspections of the competent authorities of Member States;

c verifying that the competent authorities of Member States are issuing and overseeing certificates in accordance with Regulation (EC) No 216/2008 and its implementing rules;

d contributing to the assessment of the impact of the implementation by the competent authorities of Member States of Regulation (EC) No 216/2008 and its implementing rules.

2 The working methods established in this Regulation shall also apply, as far as practicable, when the Agency is charged with the task to monitor the application of aviation safety requirements established by other EU legislation, agreements concluded by the Union or working arrangements concluded by the Agency.

Article 2

Definitions

For the purposes of this Regulation the following definitions apply:

(1) ‘inspection’ means the standardisation inspection referred to in Article 24(1) and Article 54 of Regulation (EC) No 216/2008, including the inspection of undertakings or associations of undertakings referred to in Article 54(4) and Article 55 of that Regulation, carried out by the Agency;

(2) ‘competent authority’ means the entity designated by the Member State as competent for the implementation of Regulation (EC) No 216/2008 and its implementing rules;

(3) ‘authorised personnel’ means the persons authorised by the Agency to carry out inspections, including seconded personnel;

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(4) 'seconded personnel' means the officials made available by the competent authorities of Member States, the International Civil Aviation Organisation (ICAO), other international aviation organisations or the competent authorities of Third Countries having agreements with the Union or working arrangements with the Agency, who are nominated by these authorities to assist the Agency in carrying out inspections;

(5) 'evidence' means records, statements of fact, or other information which are relevant and verifiable;

(6) 'finding' means the result of the comparison between the available evidence and the applicable requirements;

(7) 'correction' means an action to eliminate a finding of non-conformity with the applicable requirements;

(8) 'corrective action' means an action to eliminate the cause of a finding of non-conformity with the applicable requirements in order to prevent recurrence;

(9) 'immediate safety concern' means a situation where there is evidence that a product, service, system, constituent, equipment or facility is either in such a condition, or is being operated, supplied or maintained in such a manner that harm to persons is likely to occur unless the situation is corrected immediately.

Article 3

Principles applicable to monitoring

1 The Agency shall monitor the application by competent authorities of the requirements referred in Article 1 as well as their uniform implementation according to the methodology laid down in this Regulation and shall report thereon.

2 The monitoring shall be continuous and risk-based, on the basis of the information available to the Agency. It shall entail assessing the competent authorities' ability to discharge their safety oversight responsibilities, conducting inspections as necessary, as well as the follow-up of findings stemming from inspections, in order to ensure that appropriate corrections and corrective actions are timely implemented.

3 The monitoring shall follow a system approach. It shall address all domains and critical elements of the safety oversight system as defined by ICAO. Particular attention shall be given to interfaces between domains.

4 The monitoring shall be conducted in a transparent, efficient, effective, harmonised and consistent manner.

5 The Agency shall analyse the outcome of its monitoring activities in order to identify the need for regulatory improvements.

Article 4

Principles applicable to inspections and findings

1 Inspections of competent authorities shall take into account the results of previous inspections and address in particular changes to the regulatory requirements, to the safety oversight capability of the competent authority and be proportionate to the level and complexity