



Easy Access Rules for Standardisation Inspections (Regulation (EU) No 628/2013)

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¹ The published date represents the date when the consolidated version of the document was generated.

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NOTE FROM THE EDITOR

The content of this document includes the cover regulation (recitals and articles) of the implementing rule (IR).

The cover regulation (i.e. recitals and articles) is colour-coded and can be identified according to the illustration below. The Commission regulation through which the article was introduced is indicated below each recital and article *in italics*.

<u><i>Cover regulation article</i></u>
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Commission regulation

This document will be updated regularly to incorporate further amendments.

The format of this document has been adjusted to make it user-friendly and for reference purposes. Any comments should be sent to erules@easa.europa.eu.

INCORPORATED AMENDMENTS

IMPLEMENTING RULES (IRs) (COMMISSION REGULATIONS)

Incorporated Commission Regulation	Affected Part	Regulation amendment	Applicability date ¹
Regulation (EU) No 628/2013	N/a	Initial issue	1/01/2014

Note: To access the official source documents, please use the links provided above.

¹ This date is the earliest applicability date for this regulation. Some provisions of the regulation may be applicable at a later date. Besides, there may be some opt-out filed by the Member States.

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COVER REGULATION

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

Regulation (EU) No 628/2013

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, 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

¹ OJ L 79, 19.3.2008, p. 1.

² OJ L 129, 17.5.2006, p. 10.

³ OJ L 243, 27.9.2003, p. 6.

⁴ OJ L 315, 28.11.2003, p. 1.

⁵ OJ L 240, 7.9.2002, p. 1.

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 ⁽¹⁾, Commission Implementing Regulation (EU) No 1034/2011 ⁽²⁾ 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 ⁽³⁾, 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 ⁽⁴⁾, 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 ⁽⁵⁾, amended by Commission Regulation (EC) No 859/2008 ⁽⁶⁾, 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 ⁽⁷⁾, 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 ⁽⁸⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations ⁽⁹⁾, and Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew ⁽¹⁰⁾.

- (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.
- (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.

¹ OJ L 206, 11.8.2011, p. 21.

² OJ L 271, 18.10.2011, p. 15.

³ OJ L 271, 18.10.2011, p. 23.

⁴ OJ L 201, 3.8.2010, p. 1.

⁵ OJ L 373, 31.12.1991, p. 4.

⁶ OJ L 254, 20.9.2008, p. 1.

⁷ OJ L 143, 30.4.2004, p. 76.

⁸ OJ L 109, 19.4.2008, p. 17.

⁹ OJ L 296, 25.10.2012, p. 1.

¹⁰ OJ L 311, 25.11.2011, p. 1.

- (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 ⁽¹⁾ 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.
- (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:

¹ Council Decision 2011/531/EU, OJ L 232, 9.9.2011, p. 8.

Article 1 — Subject matter and scope

Regulation (EU) No 628/2013

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

Regulation (EU) No 628/2013

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;
- (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

Regulation (EU) No 628/2013

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

Regulation (EU) No 628/2013

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 of the industry under their oversight, ensuring as a priority a high and uniform level of safety for commercial air transport.
2. Inspections may include inspections of undertakings or associations of undertakings under the oversight of the competent authority inspected.
3. Inspections may include, when so agreed by the parties concerned, inspections of military facilities open to public use or of services provided by military personnel to the public, for the purpose of verifying that the requirements of Article 1(3) of Regulation (EC) No 216/2008 are complied with.
4. Inspections shall be carried out by a team composed of personnel authorised by the Agency, which shall be qualified and trained in their respective domain(s). Authorised personnel shall apply the principles of independence, integrity, ethical conduct, due diligence, fair presentation and confidentiality.
5. Where the Agency finds that one or more certificates do not comply with Regulation (EC) No 216/2008 and its Implementing Rules, that finding of non-conformity shall be reported to the competent authority concerned. Where the finding of non-conformity is not corrected in a timely manner the Agency shall make recommendations pursuant to Article 11(2) of Regulation (EC) No 216/2008 in order to allow a decision on the mutual recognition of the said certificate(s).
6. The Agency shall classify and follow-up the findings of non-conformity identified during inspections referred to in paragraphs 1, 2 and 3 depending on their impact on safety and safety

related findings shall be prioritised. The Agency shall also inform without delay the competent authorities of Member States when the correction of an immediate safety concern has not been satisfactorily addressed.

7. This Regulation is without prejudice to Articles 15 and 58 of Regulation (EC) No 216/2008, to Commission Decision 2001/844/EC, ECSC, Euratom ⁽¹⁾, to Regulation (EC) No 2111/2005 of the European Parliament and of the Council ⁽²⁾ and Commission Regulation (EC) No 473/2006 ⁽³⁾.

Article 5 — Exchange of information

Regulation (EU) No 628/2013

1. Competent authorities of Member States shall provide the Agency with all necessary information relevant to their safety oversight, addressing all the critical elements of their safety oversight system, including the undertakings or associations of undertakings under their oversight. The information shall be provided in a form and a manner specified by the Agency, taking into account the information that has been made available to ICAO.
2. The Agency may also request ad-hoc information from the competent authorities of Member States. When submitting such a request for information the Agency shall state its legal basis and purpose, specify what information is required and set the time-limit within which the information is to be provided.
3. The Agency shall provide competent authorities of Member States with relevant information to support the uniform implementation of the applicable requirements.

Article 6 — National Standardisation Coordinator

Regulation (EU) No 628/2013

1. Member States shall designate a national standardisation coordinator, acting as their primary point of contact for all standardisation activities and in particular to coordinate the exchange of information provided for in [Article 5](#)(1). The national standardisation coordinator shall be responsible for:
 - (a) maintaining and updating the information provided to the Agency on an on-going basis, including information requested in accordance with Articles 3, 4 and 5, corrections and corrective action plans and evidence of implementation of the agreed corrective actions;
 - (b) assisting the Agency at all stages of an inspection and ensuring that the inspection team is accompanied throughout the on-site inspections.
2. Competent authorities shall ensure that there are clear lines of communication between the national standardisation coordinator designated and their internal organisation, in order for him/her to properly discharge his/her responsibilities.

Article 7 — Continuous monitoring

Regulation (EU) No 628/2013

1. The continuous monitoring referred to in [Article 3](#) shall comprise the following:

¹ OJ L 317, 3.12.2001, p. 1.

² OJ L 344, 27.12.2005, p. 15.

³ OJ L 84, 23.3.2006, p. 8.

- (a) the collection and analysis of data and information provided by the competent authorities of Member States, the International Civil Aviation Organisation (ICAO), the Commission or other relevant sources;
 - (b) the assessment of the competent authority's ability to discharge its safety oversight responsibilities;
 - (c) depending on the assessment referred to in point (b), the prioritisation, planning and determination of the scope of inspections;
 - (d) the conduct of such inspections, including the related reporting;
 - (e) the follow-up and closure of findings of non-conformity stemming from the inspections.
2. For the assessment referred to in point (b) of paragraph 1, the Agency shall establish, develop and maintain a single model taking into account at least the following elements:
 - (a) the size and complexity of the aviation industry;
 - (b) serious incidents, accidents, fatal accidents and related fatalities;
 - (c) the results of ramp inspections;
 - (d) the results of previous inspections;
 - (e) the ability of the competent authorities to implement effectively corrections and corrective actions;
 - (f) the result of audits carried out under international conventions or State safety assessment programmes;
 - (g) the existence of measures pursuant to Article 11(2) of Regulation (EC) No 216/2008 or to Article 258 of the Treaty.
3. The outcome of the model as established in paragraph 2 and the input data and results of the assessment shall be made available to the national standardisation coordinator of the Member State concerned.
4. The Agency shall adapt the inspection programme in the light of its continuous monitoring, reflecting both improvements and deteriorations in safety performance. The Agency shall take appropriate action when there is evidence that the safety performance deteriorates.

Article 8 — Inspection programme

Regulation (EU) No 628/2013

1. The Agency shall establish, in coordination with the Commission, a multi-annual programme, indicating the inspections referred to in [Article 10\(1\)\(a\)](#), as well as an annual programme indicating the inspections referred to in [Article 10\(1\)\(a\)](#) and (b).
2. The inspection programmes shall specify the Member State(s) concerned, the type of inspection, the domains to be inspected and the foreseen timeframe for the on-site phase, taking into account the model referred to in [Article 7](#).
3. The inspection programmes may be adjusted by the Agency to take into account emerging risks stemming from the continuous monitoring referred to in [Article 7](#).
4. The annual programme shall be communicated to the Commission, to the members of the Management Board of the Agency as part of the Agency's work programme pursuant to Article 33(2)(c) of Regulation (EC) No 216/2008, and to the national standardisation coordinator of the Member State concerned.

Article 9 — Inspection domains

Regulation (EU) No 628/2013

1. The Agency shall carry out inspections addressing each domain defined in Chapter II of Regulation (EC) No 216/2008. These domains shall include:
 - (a) airworthiness, as defined in Article 5 and environmental protection, as defined in Article 6 of the said Regulation
 - (b) Air crew, as defined in Articles 7 and 8 of the said Regulation;
 - (c) Air operations, as defined in Articles 8 and 9 of the said Regulation;
 - (d) Ramp inspections, as defined in Article 10 of the said Regulation;
 - (e) Aerodromes, as defined in Article 8a of the said Regulation;
 - (f) ATM/ANS and air traffic controllers, as defined in Articles 8b and 8c of the said Regulation;

Further domains may be defined depending on the evolutions of Regulation (EC) No 216/2008 or upon the request of the Commission.
2. The Agency shall ensure that its resources are appropriately allocated to monitoring and inspecting the different domains depending on the results of the continuous monitoring referred to in [Article 7](#).

Article 10 — Types of inspections

Regulation (EU) No 628/2013

1. The Agency shall conduct:
 - (a) comprehensive inspections, for the purpose of inspecting one or more domains; these inspections shall be performed at intervals determined based on the results of the continuous monitoring;
 - (b) focused inspections, for the purpose of inspecting specific areas within one or more domains, and/or for the purpose of assessing the implementation status of agreed corrections and corrective actions;
 - (c) ad hoc inspections, for the purpose of investigating specific concerns arising from the Agency's continuous monitoring or upon request from the Commission.
2. Notwithstanding the inspections referred to in paragraph 1, the Agency may raise off-site findings when it has collected sufficient evidence of non-conformity.

Article 11 — Training, qualification and authorisation criteria for inspection teams

Regulation (EU) No 628/2013

1. The Agency shall establish qualification criteria for the personnel who participate in inspection teams.
2. The qualification criteria shall include:
 - (a) knowledge of the institutional and regulatory framework, in particular of this Regulation as well as on the relevant international agreements;
 - (b) knowledge and experience of auditing techniques;

- (c) technical competence and practical experience in the relevant domain(s) referred to in [Article 9](#).
3. Team leaders shall be personnel employed by the Agency. Their qualification criteria shall include in addition to those referred to in paragraph 2, team management and communication capabilities in an international environment and in sensitive situations.
 4. Team members shall be personnel employed by the Agency or seconded personnel.
 5. Both team leaders and team members shall be trained on the applicable requirements and the Agency's procedures. The Agency shall ensure the continued competence of team leaders and team members in order to participate in inspections as authorised personnel. The Agency shall establish appropriate continuous training programmes for that purpose.
 6. Personnel who meet the qualification criteria and have received appropriate training may be authorised by the Agency to participate in inspection teams.

Article 12 — Setting up teams for inspections

Regulation (EU) No 628/2013

1. Inspections shall be carried out by teams set up by the Agency composed by authorised personnel pursuant to [Article 11](#).
2. The Agency shall determine the team composition in order to establish the minimum team size necessary to cover the required technical competencies and workload, taking into account the type of inspection, the scope, the number of domains considered and the expected programme. Each team shall have a team leader and one team member as a minimum. In all cases, the Agency shall ensure the size of the teams remains commensurate to the scope.
3. The Agency shall ensure that, in setting up the teams, there shall be no conflict of interests either with the competent authorities inspected or with the undertakings or associations of undertakings inspected.
4. The Agency shall request in due time before an inspection information from seconding authorities or organisations as to the availability of team members for participating in the on-site phase.
5. Expenses arising from the participation of national standardisation coordinators as provided for in [Article 14](#)(2), [Article 19](#)(2) and of seconded personnel to inspections carried out by the Agency shall be borne by the Agency, in compliance with Union rules and without prejudice to the annual budgetary procedure of the Union.

Article 13 — Conduct of inspections

Regulation (EU) No 628/2013

1. Inspections referred to in [Article 10](#)(1)(a) and (b) shall include the following phases:
 - (a) a preparatory phase, lasting a minimum of 10 weeks prior to the inspection;
 - (b) an on-site phase;
 - (c) a reporting phase, lasting a maximum of 10 weeks following the end of the on-site phase.
2. Ad hoc inspections referred to in [Article 10](#)(1)(c) shall be announced to the competent authority concerned with a notice of two weeks but need not to comply with the deadlines and the procedures provided for in Articles 14, 15 and 16, except for the need of a final report.

3. Findings of non-conformity identified during inspections referred to in [Article 10](#) shall be reported in accordance with [Article 16](#), followed-up and closed in accordance with [Article 17](#) and classified in accordance with [Article 18](#).

Article 14 — Preparatory phase

Regulation (EU) No 628/2013

1. During the preparatory phase of an inspection, the Agency shall:
 - (a) give notice of the inspection to the competent authority at least 10 weeks before the on-site phase, including the intended type, domain(s) and areas for inspection;
 - (b) collect the necessary information for the preparation of the inspection, taking duly into account the information available from continuous monitoring;
 - (c) define the scope, the extent and the programme of the inspection, including the inspection of undertakings or association of undertakings, taking into account the information from continuous monitoring;
 - (d) determine the size and the composition of the inspection team.
2. Upon notice of the inspection, the competent authority shall cooperate with the Agency in order to prepare the on-site phase swiftly. If deemed necessary, a preliminary meeting may be organised between the inspection team and the national standardisation coordinator.
3. The Agency shall provide the inspection programme and the composition of the team to the competent authority at least 2 weeks before the on-site phase.

Article 15 — On-site phase

Regulation (EU) No 628/2013

1. During the on-site phase of an inspection, the Agency shall:
 - (a) organise an opening meeting with the national standardisation coordinator and the competent authority inspected;
 - (b) follow up findings of non-conformity identified in previous inspections and that remain open, and review the corresponding corrections and corrective actions;
 - (c) notify the competent authority of any immediate safety concern, where such concern is identified during the inspection;
 - (d) at a closing session, present to the competent authority inspected a list of preliminary findings of non-conformity identified or followed up in the course of the inspection.
2. In addition, the Agency may:
 - (a) inspect the main offices and to the extent deemed necessary, any regional offices of the competent authority and of the qualified entities to which the competent authority may have allocated tasks;
 - (b) inspect undertakings or associations of undertakings under the oversight of the competent authority as part of the inspection of this competent authority; in that case, the competent authority may accompany the inspection team;
 - (c) carry out interviews with the staff of the competent authority inspected and qualified entities, if any, and of undertakings or association of undertakings visited, if any;
 - (d) examine legislation, procedures, certificates, records, data and any other relevant material.

Article 16 — Reporting phase

Regulation (EU) No 628/2013

1. During the reporting phase of an inspection, the Agency shall, within 6 weeks after the closing session of the on-site phase, review the preliminary findings, classify them and establish on this basis a draft report addressed to the competent authority inspected.
2. The draft report shall contain at least:
 - (a) an executive summary presenting the conclusions;
 - (b) details on the conduct of the inspection, including the type of the inspection, domains covered, scope and composition of the team;
 - (c) an analysis by critical element focusing on the main findings;
 - (d) a list of findings of non-conformity identified or followed up during the inspection together with their classification;
 - (e) recommendations, including where necessary on the mutual recognition of certificates.
3. Findings of non-conformity shall be notified by means of the draft report referred to in paragraph 2, except if already notified in writing by the Agency by other means.
4. The competent authority may submit written comments to the Agency within two weeks from the notification.
5. The Agency shall, within 10 weeks after the closing session, issue a final report on the basis of the draft report mentioned in paragraph 2, reflecting the comments of the competent authority inspected, if any. The Agency may adapt the description of the finding of non-conformity, its legal basis, its classification or its status as appropriate to take into account the comments as well as the corrections or corrective actions submitted during the reporting phase.
6. The Agency shall establish and maintain a continuous monitoring status for each Member State which shall be provided on request to the Member State concerned and to the Commission.
7. The final report shall be addressed to the competent authority inspected and to the Commission, who may subsequently transmit this report to the Member State concerned and other competent authorities as appropriate.

Article 17 — Findings follow-up and closure

Regulation (EU) No 628/2013

1. For all findings of non-conformity classified under [Article 18](#)(1)(b) and (c), the competent authority shall propose a correction and a corrective action no later than four weeks after receipt of the notification from the Agency.
2. For all findings of non-conformity classified under [Article 18](#)(1)(a), the competent authority shall propose a corrective action no later than 10 weeks after receipt of the notification from the Agency;
3. The competent authority shall report to the Agency in due time on the completion of corrective actions and provide evidence thereof.
4. The Agency shall:
 - (a) evaluate the corrections and the corrective actions submitted by the competent authority or request further clarification in a timely manner;

- (b) agree with or reject the corrections and/or corrective actions submitted within 16 weeks after the notification;
 - (c) monitor the satisfactory implementation of corrective actions;
 - (d) identify any need for supplementary actions in accordance with [Article 22](#);
 - (e) report on a regular basis to the competent authority and to the Commission the status of findings of non-conformity and the related corrections/corrective actions by means of status reports;
 - (f) close the findings of non-conformity once satisfied with the completion of the corrective actions and the evidence provided, record the closure of the findings of non-conformity and inform the competent authority accordingly.
5. For the purposes of point (c), the Agency may request evidence or clarifications to the competent authority. The Agency may also decide to verify the implementation on site by means of an inspection.
6. When findings of non-conformity are subject to an infringement action pursuant to [Article 11\(2\)](#) of Regulation (EC) No 216/2008 or to the Treaties, the Agency shall ensure appropriate follow-up in consultation with the Commission and shall not close any such finding without prior coordination with the Commission.

Article 18 — Classification of findings

Regulation (EU) No 628/2013

1. All findings of non-conformity identified by the Agency in the framework of the inspections referred to in [Article 10](#) shall be classified and reported by the Agency, whether they pertain to administrative requirements or to technical requirements, in one of the following classes:
- (a) Class C: non-conformity with the applicable requirements, raising mainly standardisation concerns;
 - (b) Class D: non-conformity with the applicable requirements, raising standardisation concerns and safety concerns if not timely corrected;
 - (c) Class G: immediate safety concern.
2. The reporting, follow-up and closure shall be prioritised depending on their classification.

Article 19 — Immediate safety concern

Regulation (EU) No 628/2013

1. When an immediate safety concern has been notified by the Agency:
- (a) the Agency shall request the competent authority to take adequate corrective actions, including immediate corrections;
 - (b) the competent authority shall apply effective corrections to remove the finding and shall provide the Agency with evidence thereof.
2. The Agency may request within two weeks from the notification of the immediate safety concern the competent authority to attend a meeting to assess the implementation of the immediate corrections.
3. When the corrections do not satisfy the Agency, the Agency shall make recommendations to the Commission, including where necessary a request with regard to the mutual recognition of

the certificate(s) issued by the competent authority. The Agency shall also inform the competent authorities of the Member States immediately.

Article 20 — Records

Regulation (EU) No 628/2013

1. The Agency shall establish a system of record-keeping providing for adequate storage, accessibility and reliable traceability of changes for:
 - (a) training, qualification and authorisation of team leaders and team members;
 - (b) inspection programmes;
 - (c) reports;
 - (d) findings and related evidence;
 - (e) agreed corrections and corrective actions;
 - (f) closure of findings of non-conformity and related evidence;
 - (g) recommendations regarding the mutual recognition of certificates;
 - (h) assessments referred to in [Article 7\(1\)\(b\)](#).
2. All records shall be kept for a minimum period of 15 years, subject to applicable data protection law.

Article 21 — Access to information contained in inspection reports

Regulation (EU) No 628/2013

1. Where information contained in an inspection report concerns an undertaking or association of undertakings under the safety oversight of a third country and falls within the scope of application of a Union agreement concluded pursuant to Article 12 of Regulation (EC) No 216/2008, that information shall be made available to the third country as a party to such an agreement in accordance with its relevant provisions.
2. Where information contained in an inspection report falls within the scope of application of the Memorandum of Cooperation between the Union and ICAO, that information shall be made available to ICAO in accordance with the provisions of this Memorandum of Cooperation and the corresponding safety annex.
3. Where information contained in an inspection report relates to ongoing safety investigations conducted in accordance with Regulation (EU) No 996/2010 of the European Parliament and of the Council ⁽¹⁾, that information shall be made available without delay to the authority in charge of the safety investigation.
4. For the purpose of Regulation (EC) No 1049/2001 of the European Parliament and of the Council ⁽²⁾, the decision-making process related to an inspection report shall not be deemed to be concluded before the related findings of non-conformity are closed.

Article 22 — Supplementary actions

Regulation (EU) No 628/2013

1. The Agency shall identify any failure to follow up a finding of non-conformity such as:

¹ OJ L 295, 12.11.2010, p. 35.

² OJ L 145, 31.5.2001, p. 43.

- (a) corrective action not submitted within the period referred to in [Article 17](#)(1);
 - (b) corrective action not agreed by the Agency within the period referred to in [Article 17](#)(4)(b);
 - (c) corrective action not duly implemented.
2. In the cases referred to in paragraph 1, the Agency shall request the competent authority to provide clarifications on the failure and to submit supplementary actions, setting a time-limit for the response.
3. The Agency shall assess the consequence of the failure together with the response provided by the competent authority within the set time-limit. Based on the outcome of such assessment, the Agency may:
 - (a) agree with the supplementary actions submitted; or
 - (b) issue a supplementary report to the competent authority concerned and to the Commission. That report shall include the Agency's assessment and recommendations to the Commission, including when deemed necessary recommendations on the mutual recognition of certificate(s) issued by the competent authority.
4. Without prejudice to Regulation (EC) No 2111/2005, following receipt of the supplementary report referred to in paragraph 3(b), the Commission may take any of the following steps:
 - (a) address comments to the Member State concerned or request further explanation to clarify all or part of the findings of non-conformity;
 - (b) require the Agency to carry out an ad-hoc inspection to check the satisfactory implementation of corrections and corrective actions;
 - (c) initiate the procedure referred to in Article 11(2) of Regulation (EC) No 216/2008 to decide whether certificates issued by the competent authority comply with the applicable requirements;
 - (d) initiate a procedure under Article 258 of the Treaty.

Article 23 — Annual report

Regulation (EU) No 628/2013

The Agency shall submit to the Commission, no later than 31 March of each year, an annual report on the continuous monitoring activities and the inspections carried out in the previous year. The report shall include an analysis of the results of the activities and inspections, reflecting the competent authorities' ability to discharge their safety oversight responsibilities, as well as recommendations for possible improvements. The recommendations shall in particular identify those technical rules that would need to be established or amended pursuant to Article 17(2)(b) of Regulation (EC) No 216/2008 as well as those Agency measures that would need to be established or amended pursuant to Article 18(c) of Regulation (EC) No 216/2008.

Article 24 — Working procedures

Regulation (EU) No 628/2013

The Agency shall revise its working procedures in order to implement the tasks conferred upon it under Articles 3 to 23 within six months following the entry into force of this Regulation at the latest.

Article 25 — Transitional arrangements

Regulation (EU) No 628/2013

1. Findings of non-conformity identified by the Agency pursuant to Regulation (EC) No 736/2006 and for which evidence of closure has not been submitted to the Agency at the time of entry into force of this Regulation shall be deemed to have been made in accordance with this Regulation and shall be treated accordingly.
2. Corrective action plans agreed by the Agency pursuant to Regulation (EC) No 736/2006 shall be deemed to have been agreed in accordance with this Regulation.
3. Team members and team leaders authorised by the Agency pursuant to Regulation (EC) No 736/2006 shall be deemed authorised personnel according to this Regulation.

Article 26 — Repeal

Regulation (EU) No 628/2013

Regulation (EC) No 736/2006 is repealed.

Article 27 — Entry into force and application

Regulation (EU) No 628/2013

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

It shall apply from 1 January 2014.

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

Done at Brussels, 28 June 2013.

For the Commission

The President

José Manuel BARROSO