



Brussels, **XXX**
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ANNEX TO EASA OPINION 07/2016

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

of **XXX**

**amending Commission Regulation (EU) No 748/2012 as regards
embodiment of risk-based compliance verification into Part-21**

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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC ⁽¹⁾, and in particular Article 5(5) thereof,

Whereas:

- (1) The European Aviation Safety Agency shall, pursuant to Articles 20(1)(e), (f), (g) and (h) of Regulation (EC) No 216/2008, conduct, itself or through national aviation authorities or qualified entities, investigations associated with products, parts and appliances certification, and issue the appropriate certificates.
- (2) These certificates for design of products, parts and appliances, including changes and repairs thereto, are issued in accordance with Commission Regulation (EU) No 748/2012⁽²⁾ after an investigation that the design of a product, part, appliance or change/repair thereto complies with the established certification basis, including the applicable airworthiness certification specifications and environmental protection requirements.
- (3) While the applicants for these certificates are responsible for demonstrating full compliance with all aspects of the established certification basis, Commission Regulation (EU) No 748/2012 indicates only implicitly that the investigations by the European Aviation Safety Agency to verify compliance are not assumed to be exhaustive and that the European Aviation Safety Agency selects among all compliance demonstration items those relevant for verification.
- (4) There are, however, no selection criteria specified in Commission Regulation (EU) No 748/2012 to guide the European Aviation Safety Agency in its determinations of which compliance demonstrations should be subject to its verification and how deep such a verification should be.
- (5) The risk-based approach to compliance verification reflects the principles of International Civil Aviation Organization (ICAO) Annex 19 on 'Safety Management', in particular the provisions for a state safety programme (SSP) requiring the ICAO States to establish a safety-data-driven oversight system targeted on areas of greater safety concern or need, and based on analysis of hazards and assessment and

⁽¹⁾ OJ L 79, 13.3.2008, p. 1.

⁽²⁾ Commission Regulation (EU) No 748/2014 of 3 August 2012 laying 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 (OJ L 224, 21.8.2012, p. 1).

mitigation of safety risks related to a particular type of activity or process (including the product certification process).

- (6) The structure of Annex I (Part-21) to Commission Regulation (EU) No 748/2012 should be aligned with the structure of the implementing rules in the other domains under Regulation (EC) No 216/2008. This should be achieved by separating the requirements applicable to the applicant for, and holders of, any certificate issued or to be issued in accordance with Part-21 from the requirements applicable to the competent authorities, including the European Aviation Safety Agency.
- (7) Inconsistencies between Regulation (EC) No 216/2008 and Commission Regulation (EU) No 748/2012 as regards the content of the type-certification basis and the notification thereof to the applicants need to be corrected.
- (8) Commission Regulation (EU) No 748/2012 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are based on the Opinion issued by the European Aviation Safety Agency in accordance with Article 19(1) of Regulation (EC) No 216/2008.
- (10) 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

Annex I (Part-21) to Commission Regulation (EU) No 748/2012 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels,

For the Commission
Member of the Commission