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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	7 March 2019
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	ANNEX to the Proposal for a COUNCIL DECISION on the position to be taken by the European Union within the Bilateral Oversight Board under the Agreement between the United States of America and the European Community on cooperation in the regulation of civil aviation safety, concerning adding Annex 4 to the Agreement

Delegations will find attached document COM(2019) 122 final - ANNEX 2.

Encl.: COM(2019) 122 final - ANNEX 2



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ANNEX 2

ANNEX

to the

**Proposal for a
COUNCIL DECISION**

**on the position to be taken by the European Union within the Bilateral Oversight Board
under the Agreement between the United States of America and the European
Community on cooperation in the regulation of civil aviation safety, concerning adding
Annex 4 to the Agreement**

FLIGHT SIMULATION TRAINING DEVICES

1. PURPOSE & SCOPE

- 1.1. The Parties have assessed each other's standards, rules, practices, and procedures relating to the recurrent evaluation and continuing qualification of Full Flight Simulators (FFS) for airplanes and concluded that they are sufficiently compatible to permit acceptance of each other's approvals and findings. This Annex covers the reciprocal acceptance of findings of compliance and documentation, and the provision of technical assistance regarding recurrent evaluation and qualification of FFS. Nothing in this Annex shall be construed to limit the authority of a Party to act in accordance with Article 15 of the Agreement.
- 1.2. The scope of this Annex covers recurrent evaluation and continuing qualification of level C, CG, D and DG FFS for airplanes that hold a qualification issued by the Federal Aviation Administration (FAA) and by the European Aviation Safety Agency (EASA) or an Aviation Authority, as applicable. This scope may be extended through an amendment to this Annex pursuant to a decision of the Bilateral Oversight Board (BOB) taken in accordance with Article 19.B of the Agreement.
- 1.3. The extension of the scope of this Annex shall take place following the necessary confidence building process conducted by the Technical Agents.
- 1.4. The scope of this Annex does not cover Flight Simulation Training Devices (FSTD) that are located outside the scope of applicability specified in Article 12 of the Agreement.

2. DEFINITIONS

- 2.1. For the purposes of this Annex, the following definitions apply, in addition to those definitions found in the Agreement:

Initials: ____ (EC)/____ (FAA)

- (a) “FFS Qualification Level” means the level of compliance based on the technical capability of the FFS as determined by an evaluation of the FFS against the established technical evaluation criteria as defined in the applicable requirements. FFS are categorised as level A, B, C, D. Additionally, some EU qualified devices hold qualification level AG, BG, CG, DG under Grandfather Rights.
- (b) “Finding” means a verification whether the FSTD is in compliance or non-compliance with the applicable requirements and which shall be recorded as results/discrepancies in the evaluation report compiled by the FAA, EASA, or an Aviation Authority, as applicable.
- (c) “Flight Simulation Training Device” (FSTD) means:
- (i) For the European Union, a training device which is, in the case of airplanes, a full flight simulator (FFS), a flight training device (FTD), a flight and navigation procedures trainer (FNPT), or a basic instrument training device (BITD).
 - (ii) For the United States, a training device which is, in the case of airplanes, a full flight simulator (FFS) or a flight training device (FTD).
- (d) “Full Flight Simulator” (FFS) means a full-size replica of a specific type or make, model and series of aircraft flight deck/cockpit, including the assemblage of all equipment and computer programmes necessary to represent the aircraft in ground and flight operations, a visual system providing an out-of-the-flight deck/cockpit view, and a force cueing motion system.
- (e) “FSTD Evaluation” means the measure of the FSTD against the established technical criteria for the respective level leading to a FSTD qualification.
- (f) “FSTD Operator” identifies the organization directly responsible to EASA or an Aviation Authority, as applicable, for requesting and maintaining the qualification of a particular FSTD and which has to comply with Part-ORA requirements of

Regulation (EU) No 1178/2011.

- (g) “FSTD Sponsor” identifies the organization directly responsible to FAA for requesting and maintaining the qualification of a particular FSTD and which has to comply with Title 14 of the United States Code of Federal Regulations, part 60 (hereinafter referred to as part 60) requirements.
- (h) “Grandfather Rights” means:
 - (i) For the United States, the right of an FSTD operator/sponsor to retain the qualified level granted under a previous advisory circular.
 - (ii) For the European Union, the right of an FSTD operator/sponsor to retain the qualified level granted under a previous regulation. It also means the right for an FSTD user to retain the training, testing and checking credits that were gained under that previous regulation.
- (i) “Master Qualification Test Guide” (MQTG) is the authority-approved Qualification Test Guide (QTG) that incorporates the results of tests witnessed by the FAA, EASA, or Aviation Authority, as applicable. The MQTG serves as a reference for future evaluations.
- (j) “Qualification Test Guide” (QTG) means a document used to demonstrate that performance and handling qualities are within prescribed limits with those of the aircraft and that all applicable requirements have been met.
- (k) “Special Conditions” means those requirements that have been found, based on a comparison of the respective regulatory systems related to evaluation and qualification of FFS, not to be common to both systems and which are significant enough to be addressed in this Annex.

3. JOINT COORDINATION BODY

3.1. Composition

Initials: ____ (EC)/____ (FAA)

- 3.1.1. The joint coordination body called the FSTD Oversight Board (FOB), accountable to the Bilateral Oversight Board, is hereby established under the joint leadership of the EASA Flight Standards Director and the FAA Executive Director of Flight Standards. The FOB shall include FSTD experts from each Technical Agent.
- 3.1.2. The joint leadership may invite additional participants to the FOB to facilitate the fulfilment of the objectives of this Annex.
- 3.2. Mandate
- 3.2.1. The FOB shall meet at least once a year to ensure the effective functioning and implementation of this Annex. The FOB functions include:
- (a) Developing, approving, and revising the Technical Implementation Procedures - Simulator (TIP-S) for FFS evaluation and qualification, including cooperation, assistance, exchange of information, and continued confidence activities to be used for the processes covered by this Annex;
 - (b) Sharing information on relevant safety issues and developing action plans to address them;
 - (c) Ensuring the consistent application of this Annex;
 - (d) Exchanging information on planned and ongoing rulemaking activities that could affect the basis and the scope of the Annex;
 - (e) Sharing information on significant changes to the Parties' FSTD qualification systems that could affect the basis and the scope of the Annex;
 - (f) Resolving technical issues falling within the responsibilities of the Technical Agents and Aviation Authorities that cannot be solved at lower level; and

Initials: ____ (EC)/____ (FAA)

- (g) Proposing to the BOB amendments to this Annex.

3.2.2. The FOB shall report unresolved issues to the BOB and ensure the implementation of decisions adopted by the BOB regarding this Annex.

4. IMPLEMENTATION

4.1. The Technical Agents shall, for monitoring purposes, establish and maintain a Master List of FFSs whose qualification falls within the scope of this Annex. The procedures to establish and maintain this Master List shall be detailed in the TIP-S.

4.2. FAA Continuing Qualification

4.2.1. The Parties agree that an FFS that:

- (a) Holds a current qualification in accordance with the applicable EU qualification basis, and
- (b) Complies with the conditions set forth in this Annex, including the FAA Special Conditions set forth in Appendix 1, notwithstanding part 60 Simulator Quality Management System requirements applicable to the FFS certificate holder,

shall be considered to meet the technical requirements for an FAA continuing qualification upon receipt, review and acceptance of the evaluation and special conditions reports issued by EASA or by an Aviation Authority, as applicable.

4.2.2. The competent Aviation Authorities shall carry out the actions defined in Appendix 2 of this Annex when acting on behalf of the FAA for the recurrent evaluation of each FFS covered under this Annex.

4.3. EASA Continuing Qualification

Initials: ____ (EC)/____ (FAA)

4.3.1. The Parties agree that an FFS that:

- (a) Holds a current qualification by the FAA in accordance with the applicable U.S. qualification basis, and
- (b) Complies with the conditions set forth in this Annex, including the EU Special Conditions set forth in Appendix 1, notwithstanding Part-ORA requirements applicable to the FSTD certificate holder,

shall be considered to meet the technical requirements for an EASA continuing qualification upon receipt, review and acceptance of the evaluation and special conditions reports issued by the FAA.

4.4. Mutual Acceptance of Evaluation Reports

4.4.1. Subject to the terms of this Annex, the Parties agree that the Technical Agents and the Aviation Authorities, as appropriate, shall provide to the Technical Agent of the other Party, FFS recurrent evaluation and special conditions reports. These reports shall include findings of compliance with the respective EU and U.S. requirements as the basis for issuance or continued validity of their respective FFS qualifications, as applicable.

4.5. Follow-up on Evaluation Report Findings

4.5.1. The FSTD operator/sponsor shall resolve findings with the Technical Agent or the Aviation Authority that conducted the evaluation unless otherwise instructed by the relevant Technical Agent for the cases defined in the TIP-S. In such cases, when an on-site visit is necessary to assess the closure of the finding, this on-site visit shall be conducted, as resources permit, by the Technical Agent or, where applicable, an Aviation Authority that conducted the evaluation.

4.6. When circumstances arise outside the scope of recurrent evaluations, each Party's Technical

Initials: ____ (EC)/____ (FAA)

Agent, or where applicable an Aviation Authority, shall provide, as necessary, upon request and after mutual agreement, technical assistance in FFS evaluations to the other Party's Technical Agent, or where applicable to an Aviation Authority. The Technical Agents or an Aviation Authority may decline to provide such technical assistance due to lack of resource availability. Such areas of assistance may include, but are not limited to:

- (a) Conducting and reporting on investigations upon request;
- (b) Obtaining and providing data where requested; and
- (c) Conducting a special evaluation of an FFS in the event of a relocation or a modification to the device.

4.7. In accordance with Article 15.B of the Agreement, the Technical Agents may conduct independent evaluations of devices in the event of specific safety concerns.

4.8. Revisions by either Party to its organizational structure, laws, regulations, procedures, policy, or standards, including those of the Technical Agents and Aviation Authorities, may affect the basis on which this Annex is executed. The Parties, through the Technical Agents and Aviation Authorities, as appropriate, shall advise one another of plans for such changes at the earliest possible opportunity, and discuss the extent to which such planned changes affect the basis of this Annex. If consultations pursuant to Article 15.C of the Agreement result in an agreement to amend this Annex, the Parties shall seek to ensure that such an amendment enters into force at the same time as, or as soon as possible thereafter, the entry into force or implementation of the change that prompted such amendment.

5. COMMUNICATION AND COOPERATION

5.1. The Technical Agents shall exchange and maintain a list of contact points for the various technical aspects of this Annex.

5.2. All communications, including technical documentation, between the Technical Agents, and

Initials: ____ (EC)/____ (FAA)

where applicable the Aviation Authorities, shall be in the English language.

- 5.3. The format for all dates used in communications shall be DD MMM YYYY, e.g., “05 MAY 2014”.
- 5.4. The Technical Agents and the Aviation Authorities shall inform each other of exemptions and derogations granted to FFSs falling within the scope of this Annex.
- 5.5. Evaluation Instructions
The Technical Agents and the Aviation Authorities shall submit for review any special instructions or requests to be completed during an evaluation at least 30 calendar days prior to the evaluation.

6. QUALIFICATION REQUIREMENTS FOR THE ACCEPTANCE OF FINDINGS OF COMPLIANCE

6.1. Basic Requirements

- 6.1.1. Each Technical Agent and Aviation Authority, as applicable, shall demonstrate to the other Technical Agent the effectiveness of its respective system for the regulatory oversight of FSTD. In order to carry out evaluations of FFSs on each other’s behalf, the Technical Agents and the Aviation Authorities, as applicable, shall demonstrate effective and adequate:
 - (a) Legal and regulatory structure;
 - (b) Organizational structure;
 - (c) Resources, including sufficient qualified staff;
 - (d) Training programme for their technical staff;

Initials: ____ (EC)/____ (FAA)

- (e) Internal policies, processes and procedures including a quality system;
- (f) Documentation and records;
- (g) Oversight programme; and
- (h) Authority on regulated entities and devices.

6.2. Initial Confidence

6.2.1. Each Technical Agent has demonstrated to the other Technical Agent the effectiveness of its respective system for the regulatory oversight of activities covered under this Annex through initial confidence building activities. The Technical Agents have also demonstrated to each other the effectiveness of their quality audits and standardization activities, including audits of Aviation Authorities, as referred to in paragraph 6.3.1.

6.2.2. The EU Technical Agent shall, before an Aviation Authority starts carrying out evaluations of FFS on behalf of the U.S. Technical Agent, conduct an assessment of that Aviation Authority in accordance with the provisions of the TIP-S.

6.3. Continued Confidence

6.3.1. The Technical Agents and the Aviation Authorities shall continue to demonstrate effective oversight, as detailed in paragraph 6.1.1 in accordance with the relevant provisions of the TIP-S developed and approved by the FOB.

- (a) In particular, Technical Agents and, as applicable, Aviation Authorities shall:
 - i) Have the right to participate as observer: for EASA, to FAA quality audits and standardization meetings; for the FAA, to EASA standardization activities.

Initials: ____ (EC)/____ (FAA)

- ii) Ensure that FSTD operators/sponsors provide access to both Technical Agents for audits, evaluations and inspections, as applicable;
 - iii) Make available the reports from audits, standardization and mutual inspections applicable to this Annex;
 - iv) Share relevant safety information and known limitations that may affect an Aviation Authority or Technical Agent's capability to fully meet applicable international safety standards or any safety requirements established under the Agreement;
 - v) Make the appropriate personnel available to participate in audits and inspections applicable to this Annex;
 - vi) Make available FSTD operators'/sponsors' records, including evaluation reports and Special Conditions reports;
 - vii) Provide interpretive assistance at the Aviation Authorities' office during the review of FFS records and documentation that are recorded in its national language, where necessary; and
 - viii) Assist each other in the closure of any findings from mutual inspections.
- (b) The EU Technical Agent shall conduct supplemental standardization audits to ensure the Aviation Authority's compliance with the terms of the Annex and, in particular, the FAA Special Conditions that are applicable to EU-based FFS, as specified in the TIP-S.
- (c) The Technical Agents shall notify each other at the earliest opportunity in the event that a Technical Agent or an Aviation Authority is not able to meet a requirement in paragraph 6.3.1. If either Technical Agent believes that technical competency is no

Initials: ____ (EC)/____ (FAA)

longer adequate, the Technical Agents shall consult and propose an action plan, including any necessary corrective activities, in order to address deficiencies.

- (d) In the event that a Technical Agent or an Aviation Authority does not correct deficiencies within the timeframe specified in the action plan, either Technical Agent may refer the matter to the FOB.
- (e) When a Party intends to suspend acceptance of findings or qualifications made by a Technical Agent or Aviation Authority within the scope of this Annex, the Party shall promptly notify the other Party in accordance with Article 18.A of the Agreement.

7. INVESTIGATION AND ENFORCEMENT ACTION

- 7.1. The Parties retain the right to take enforcement actions against the operators/sponsors of FSTDs that have FAA or EASA approvals
- 7.2. In accordance with the provisions of Article 8 of the Agreement, each Party, through its Technical Agent and, where applicable, the Aviation Authorities, shall notify the other promptly of any investigation and subsequent closure actions for non-compliance within the scope of this Annex, when the non-compliance could result in a penalty, revocation, suspension or downgrade of the FFS qualification.
- 7.3. In the event of a revocation or suspension of an FFS qualification, the Technical Agent and, where applicable, an Aviation Authority shall notify the other Technical Agent of the revocation or suspension.
- 7.4. The above notifications shall be sent to the other Party's appropriate contact point.

8. TRANSFER PROVISIONS

- 8.1 Recurrent evaluations for FFS whose qualifications were issued by the FAA under the

Initials: ____ (EC)/____ (FAA)

provisions defined in the U.S. - UK Simulator Implementation Procedures (SIP) shall continue to be conducted until the transition of evaluation activities as defined in 8.2 has been completed. (The U.S. – UK SIP, which was agreed on December 20, 1995, was revised on October 6, 2005. It was concluded pursuant to the Agreement between the Government of the United States of America and the Government of the United Kingdom of Great Britain and Northern Ireland for Promotion of Aviation Safety, signed at London on December 12, 1995.)

8.2 The Parties agree that the transfer of the FFS evaluations under this Annex shall be accomplished in accordance with the following transfer provisions:

- (a) An Aviation Authority and the Technical Agents shall complete training of sufficient personnel regarding procedures relating to the Agreement, this Annex, and the EU and U.S. Special Conditions, as applicable, prior to the transfer.
- (b) Once a sufficient number of staff has completed the training, the Technical Agents shall transfer evaluation activities of qualified FFS to the Technical Agents or the Aviation Authorities, as applicable.
- (c) The transfers shall take place within 18 months of the date of the entry into force of this Annex.
- (d) The Technical Agents and the Aviation Authorities shall agree on a procedural plan and time schedule for:
 - i) Synchronising recurrent evaluations, and
 - ii) Conducting all evaluations in accordance with this Annex.

9. FEES

9.1 Fees shall be applied in accordance with Article 14 of the Agreement and in accordance

Initials: ____ (EC)/____ (FAA)

with applicable regulatory requirements.

Initials: ____ (EC)/____ (FAA)

SPECIAL CONDITIONS

1. EU SPECIAL CONDITIONS APPLICABLE TO U.S.-BASED FULL FLIGHT SIMULATORS (FFS) IN THE AIRPLANE AIRCRAFT CATEGORY
 - 1.1. The special conditions referred to in Section 4.3.1, as detailed in the TIP-S, are the following:
 - (a) The FSTD sponsor shall provide to the FAA the following:
 - i. Recurrent evaluation dossier;
 - ii. Annual fly-out records;
 - iii. Simulator safety features check records (ORA.FSTD.115 (b) Installations of Regulation (EU) 1178/2011); and
 - iv. Changes to the published EASA FSTD datasheet.
 - (b) The instructor operating station manual shall include operating instructions with EU standards.
 - (c) Instructor operating station settings and indications shall conform to the International System of Units (SI).
 - (d) At least one declared qualification European airport/airfield model featuring proper modelling and navigation/communication facilities shall be evaluated.
 - (e) Category I, II, or III (as applicable) instrument approaches and low visibility take-off operations shall be demonstrated at a European airport and with corresponding

Initials: ____ (EC)/____ (FAA)

settings selectable from the instructor operating station.

- (f) The FFS shall reflect the European configuration of the simulated airplane.
- (g) A continuous, uninterrupted flight phase shall be conducted during the evaluation.
- (h) All engine fits listed in the EASA FFS qualification certificate shall be evaluated during each evaluation.
- (i) When several EASA FFS qualification certificates are issued for several avionics configuration of a single FFS, each configuration – with each engine fit if applicable – shall be evaluated during each evaluation.
- (j) FFS-specific objective, functional and subjective tests as per applicable European requirements that are not covered by the applicable FAA FFS standard level of qualification shall be performed.

2. FAA SPECIAL CONDITIONS APPLICABLE TO EU BASED APPROVED FULL FLIGHT SIMULATORS (FFS) IN THE AIRPLANE AIRCRAFT CATEGORY

2.1. The special conditions referred to in Section 4.2.1, as detailed in the TIP-S, are the following:

- (a) The FSTD operator shall:
 - i) Provide to the Aviation Authority or EASA, as applicable, evidence that FAA FSTD directives have been incorporated into the MQTG, and
 - ii) Identify any changes to the published FAA FFS configuration list.
- (b) The instructor operating station manual shall include operating instructions with U.S. standards.

Initials: ____ (EC)/____ (FAA)

- (c) Instructor operating station settings and indications shall conform to the U.S. units of measurement.
- (d) At least one declared qualification U.S. airport/airfield model featuring proper modelling and navigation/communication facilities shall be evaluated.
- (e) Category I, II, or III (as applicable) instrument approaches shall be demonstrated at a U.S. airport and with corresponding settings selectable from the instructor operating station.
- (f) The FFS shall reflect the U.S. configuration of the simulated airplane.
- (g) All configurations listed in the FAA FFS qualification certificate shall be evaluated during each evaluation.
- (h) A circling approach to a U.S. airport at the maximum demonstrated landing weight shall be conducted.
- (i) FFS-specific objective, functional, and subjective tests as per applicable U.S. requirements that are not covered by the applicable European FFS standard level of qualification shall be performed.

Initials: ____ (EC)/____ (FAA)

Appendix 2

AVIATION AUTHORITY ACTIONS

The competent Aviation Authority acting on behalf of the FAA shall carry out the following actions for the recurrent evaluations of each FFS covered under this Annex, as detailed in the TIP-S:

1. Schedule the recurrent evaluation and provide the scheduled date for the evaluation to the FAA.
2. Perform evaluation preparation. The evaluating Aviation Authority inspector(s) shall:
 - (a) Identify the special conditions;
 - (b) Obtain the appropriate forms and checklists; and
 - (c) Identify any modifications that have occurred between recurrent evaluations.
3. Perform the evaluation, taking the special conditions and the relevant TIP-S provisions into account.
4. Perform post evaluation activities to include:
 - (a) Transmitting the following information/documents to the FAA within five working days following completion of the evaluation:
 - i. Evaluation report;
 - ii. FFS configuration list; and
 - iii. Special Conditions report.
 - (b) Performing the on-site visit referred to in paragraph 4.5.1. of this Annex.

Initials: ____ (EC)/____ (FAA)