

**Draft ANNEX IV to draft COMMISSION IMPLEMENTING REGULATION (EU) .../...
amending Regulation (EU) No 965/2012, Regulation (EU) No 1178/2011, Implementing
Regulation (EU) No 923/2012 and Implementing Regulation (EU) 2017/373 as regards the
establishment of requirements for the operation of manned aircraft with a vertical take-off and
landing capability**

ANNEX IV

Annex V (Part-SPA) to Regulation (EU) No 965/2012 is amended as follows:

(1) point SPA.GEN.100 is replaced by the following:

‘SPA.GEN.100 Competent authority

(a) The competent authority for the issuing of a specific approval shall be:

- (1) for a commercial operator of aeroplanes or helicopters, the authority of the Member State where the operator has its principal place of business;
- (2) for a non-commercial operator of aeroplanes or helicopters, the authority of the Member State where the operator has its principal place of business, is established or is resides;
- (3) for an operator of VTOL-capable aircraft (VCA) in IAM operations, the authority of the Member State where the operator has its principal place of business or resides.

(b) Notwithstanding point (a)(2), for a non-commercial operator that uses an aeroplane or a helicopter registered in a third country, the applicable requirements under this Annex for the approval of the following operations shall not apply if that approval is issued by a third-country State of Registry:

- (1) performance-based navigation (PBN);
- (2) minimum navigation performance specifications (MNPS);
- (3) reduced vertical separation minima (RVSM) airspace;
- (4) low-visibility operations (LVOs).’;

(2) point SPA.MNPS.100 is replaced by the following:

‘SPA.MNPS.100 MNPS operations

Aeroplanes and helicopters shall only be operated in designated minimum navigation performance specifications (MNPS) airspace in accordance with regional supplementary procedures, where MNPS are established, if the operator has been granted an approval by the competent authority to conduct such operations.’;

- (3) point SPA.RVSM.100 is replaced by the following:

‘SPA.RVSM.100 RVSM operations

Aeroplanes and helicopters shall only be operated in designated airspace where a reduced vertical separation minimum of 300 m (1 000 ft) applies between flight level (FL) 290 and FL 410, inclusive, if the operator has been granted an approval by the competent authority to conduct such operations.’;

- (4) point SPA.LVO.100 is replaced by the following:

‘SPA.LVO.100 Low-visibility operations and operations with operational credits

An operator of aeroplanes or helicopters shall conduct the following operations only if they are approved by the competent authority:

- (a) take-off operations with visibility conditions of less than 400 m RVR;
- (b) instrument approach operations in low-visibility conditions; and
- (c) operations with operational credits, except for EFVS 200 operations, which shall not be subject to a specific approval.’;

- (5) point SPA.DG.100 is replaced by the following:

‘SPA.DG.100 Transport of dangerous goods

Except as provided for in Annex IV (Part-CAT), Annex VI (Part-NCC), Annex VII (Part-NCO), Annex VIII (Part-SPO) and Annex IX (Part-IAM) to this Regulation, the operator shall only transport dangerous goods by air if it has been approved by the competent authority.’;

- (6) in point SPA.EFB.100, point (a) is replaced by the following:

‘(a) A commercial air transport operator of aeroplanes or helicopters or an IAM operator shall only use a type B EFB application if the operator has been granted an approval by the competent authority for such use.’;

- (7) The following [Subpart O] is added:

‘SUBPART O — EMERGENCY MEDICAL SERVICE OPERATIONS WITH MANNED VTOL-CAPABLE AIRCRAFT (VEMS)

SPA.VEMS.100 Emergency medical service operations with manned VTOL-capable aircraft (VEMS)

- (a) An operator shall only conduct emergency medical service operations with manned VTOL-capable aircraft (VEMS) if the operator has been granted an approval by the competent authority for such operations.
- (b) To obtain such approval by the competent authority, the operator shall:
 - (1) hold an AOC in accordance with Annex III (Part-ORO);
 - (2) conduct operations in accordance with the relevant requirements of Annex IX (Part-IAM); and

- (3) demonstrate to the competent authority compliance with the requirements contained in this Subpart.
- (c) The operator shall use adequate vertiports for its VEMS operating base and hospital sites unless approved by the competent authority to use a public interest site (PIS) at a hospital site.
- (d) The operator may use adequate operating sites for the purpose of VEMS missions or VEMS training flights taking into account:
 - (1) the aircraft performance requirements applicable for take-off and landing;
 - (2) operating site characteristics, including dimensions, obstacles, and surface condition;
 - (3) the safe separation of VTOL-capable aircraft (VCA) from people on the ground; and
 - (4) privacy, data protection, liability, insurance, security, and environmental protection requirements.

SPA.VEMS.110 Equipment requirements for VEMS operations

- (a) The installation on a VTOL-capable aircraft (VCA) of all dedicated medical equipment and any subsequent modifications to that installation and, where appropriate, its operation, shall be approved in accordance with Regulation (EU) No 748/2012.
- (b) For VFR flights by day over routes or areas navigated by reference to visual landmarks, the VCA shall be equipped with tools providing own-ship position and obstacles on a moving map display. The map and obstacle database(s) shall be kept up to date.
- (c) Reserved.
- (d) For VFR flights by day, the VCA shall be equipped with a means of measuring and displaying to the pilot the attitude and the stabilised heading or with other equivalent tools to mitigate pilot disorientation in case of reduced visual cues.
- (e) Reserved.
- (f) Any VCA used in VEMS missions shall be equipped with tools having an ADS-B Out capability.
- (g) Instruments and equipment required under point (f) shall be certified in accordance with the applicable airworthiness requirements.
- (h) The operator shall ensure that all relevant information is documented in the minimum equipment list (MEL).

SPA.VEMS.115 Communication

In addition to the requirements for instruments and equipment applicable to VCA in manned configuration, VCA that conduct VEMS flights shall have communication equipment capable of conducting two-way communication with the organisation for which the VEMS operation is conducted and, where possible, to communicate with ground emergency service personnel at the scene of the operation.

SPA.VEMS.120 Visibility and distance from cloud minima

The minima for the dispatch and en-route phase of the VEMS flight shall be those established in accordance with point SERA.5001. If during the en-route phase the weather conditions fall below the applicable minima:

- (a) VCA certified for flights only under VFR by day shall land as soon as practicable or return to the VEMS base.
- (b) Reserved.

SPA.VEMS.125 Performance requirements for VEMS operations

VCA that conduct VEMS operations shall be operated in accordance with the applicable performance requirements established in point UAM.POL.VCA.100.

SPA.VEMS.130 Crew requirements

- (a) *Selection.* The operator shall establish criteria for the selection of flight crew members for VEMS operations, taking their prior experience into account.
- (b) *Operational training.* Crew members shall successfully complete operational training in accordance with the VEMS procedures contained in the operations manual.

(c) Reserved.

(d) *Crew composition*

- (1) *Day flight.* The minimum crew composition at dispatch for a VEMS flight under VFR day shall be two pilots or one pilot and one VEMS technical crew member.

After landing at the VEMS operating site, subsequent flights may be conducted by one pilot:

- (i) if there is a need for additional medical supplies, refuel/battery recharge or reposition while the VEMS technical crew member provides medical assistance on the ground; or
- (ii) if the VEMS technical crew member provides medical assistance to the medical patient in flight or during transport in another vehicle.

(2) *Reserved.*

- (3) The operator shall ensure that the continuity of the crew concept is maintained throughout the VEMS mission.

(e) *Flight and technical crew training and checking*

- (1) Training and checking shall be conducted by suitably qualified personnel in accordance with a syllabus included in the operations manual and approved by the competent authority.

(2) Crew members

- (i) All relevant elements of the crew training programme shall improve crew knowledge of the VEMS working environment and equipment, improve crew

coordination, and include measures to minimise the risks associated with an en-route transit to low-visibility conditions, the selection of VEMS operating sites, and approach and departure profiles.

- (ii) The measures referred to in point (i) shall be assessed during both of the following:
 - (A) VMC day proficiency checks;
 - (B) line checks.
- (iii) The VEMS components of the proficiency checks and line checks referred to in point (ii) shall have a validity period of 6 and 12 calendar months respectively.

SPA.VEMS.135 Briefing of medical passengers and of other personnel

- (a) *Medical passengers.* Prior to any VEMS flight, or series of VEMS flights, medical passengers shall be briefed to ensure they are familiar with the VEMS working environment and equipment, can operate on-board emergency equipment, and can take part in normal and emergency entry and exit procedures.
- (b) *Ground emergency service personnel.* Where ground emergency service personnel are employed, the operator shall take all necessary measures to ensure that such personnel are familiar with the VEMS working environment and equipment, and the risks associated with ground operations at an airborne EMS operating site.
- (c) *Medical patients.* Notwithstanding point UAM.OP.MVCA.170 of Annex IX (Part-IAM), a briefing shall be held only if the medical condition of the medical patient renders it practicable.

SPA.VEMS.140 Information, procedures and documentation

- (a) The operator shall assess, mitigate and minimise the risks associated with the VEMS environment as part of its risk analysis and management process. The operator shall describe its mitigating measures, including operating procedures, in the operations manual.
- (b) The operator shall ensure that the pilot-in-command (PIC) assesses specific risks associated with a particular VEMS flight.
- (c) Relevant extracts from the operations manual shall be made available to the organisation for which the VEMS operation is being provided.

SPA.VEMS.145 Facilities at the VEMS operating base

- (a) If crew members are required to be on standby with a reaction time of less than 45 minutes, dedicated suitable accommodation shall be provided close to each VEMS operating base.
- (b) At each VEMS operating base, the flight crew shall be granted access to facilities for obtaining current and forecast weather information and shall be provided with adequate communications with the appropriate air traffic service (ATS) units. Adequate facilities shall be available for the planning of all related tasks.

SPA.VEMS.150 Fuelling / defuelling / battery charging / battery swapping while passengers are embarking, on board, or disembarking

Refuelling / defuelling / battery charging or battery swapping procedures with either rotors powered on or off shall only be performed in accordance with point UAM.OP.MVCA.200 or point UAM.OP.MVCA.205 as applicable.

SPA.VEMS.155 Aircraft tracking system

The operator shall establish and maintain a monitored aircraft tracking system for VEMS operations for the entire duration of the VEMS flight.’.