



European Union Aviation Safety Agency

Notice of Proposed Amendment 2025-105 (B)

in accordance with Article 6 of Management Board Decision 01-2022

Proposed Medical Regulation and associated AMC & GM

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Proposed Medical Regulation and associated AMC & GM

Cover Regulation

COMMISSION IMPLEMENTING REGULATION (EU) 202x/xxxx

of dd month 2026

laying down technical requirements and administrative procedures related to the fitness assessment of civil aviation personnel pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91, and in particular Articles 23, 27, 50, 53 and 62 (14) and (15) thereof,

Whereas:

- (1) Regulation (EU) 2018/1139 aims at establishing and maintaining a high uniform level of civil aviation safety in the Union.
- (2) Pilots involved in the operation of aircraft, as well as persons and organisations involved in the assessment of fitness of those pilots, have to comply with the relevant essential requirements set out in Annex IV to Regulation (EU) 2018/1139. In accordance with that Regulation, pilots as well as aero-medical examiners and aero-medical centres responsible for assessment of fitness should be certified once they have been found to comply with the relevant essential requirements. However, Regulation (EU) 2018/1139 envisages the possibility for general medical practitioners to act as aero-medical examiners under certain conditions and if permitted under national law.
- (3) Cabin crew involved in the operation of certain aircraft have to comply with the relevant essential requirements set out in Annex IV to Regulation (EU) 2018/1139. In accordance with that Regulation, cabin crew should be periodically assessed for medical fitness to safely exercise their assigned safety duties. Compliance must be demonstrated by an appropriate assessment based on aero-medical best practice.
- (4) Similarly, air traffic controllers (ATCOs), as well as persons and organisations involved in the assessment of fitness of those ATCOs, have to comply with the relevant essential requirements set out in Annex VIII to Regulation (EU) 2018/1139. ATCOs should be issued with a medical

certificate, and aero-medical examiners and aero-medical centres responsible for assessing the medical fitness of ATCOs should be certified once they have been found to comply with the relevant essential requirements.

- (5) Regulation (EU) 2018/1139 requires the Commission to adopt the necessary implementing rules for establishing the conditions for certifying pilots, air traffic controllers and cabin crew members as well as persons and organisations responsible for the assessment of their medical fitness.
- (6) In order to ensure a high uniform level of civil aviation safety in the Union, implementing measures should reflect the state of the art, including best practices, and scientific and technical progress in the field of aero-medical fitness. Accordingly, technical requirements and administrative procedures agreed by the International Civil Aviation Organization (ICAO) should be considered in the development of implementing measures.
- (7) The Agency prepared draft implementing rules and submitted them as an opinion to the Commission in accordance with Article 75(2), points (b) and (c), and with Article 76(1) of Regulation (EU) No 2018/1139.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 127(1) of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

Article 1 - Subject matter

1. This Regulation lays down detailed rules for:
 - (a) the aero-medical certification of pilots and ATCOs, the conditions for issuing, maintaining, amending, limiting, suspending or revoking medical certificates as well as the privileges and responsibilities of the holders of medical certificates;
 - (b) the aero-medical fitness assessment of cabin crew members, as well as the qualifications of persons that are responsible for that assessment;
 - (c) the certification and oversight of aero-medical examiners including the training requirements needed in accordance with the privileges applied for, as well as the conditions under which general medical practitioners may act as aero-medical examiners;
 - (d) the conditions for issuing, maintaining, amending, limiting, suspending or revoking certificates of aero-medical centres involved in the qualification and aero-medical assessment of civil aviation aircrew;
 - (e) the requirements for the administration and management system to be fulfilled by the Member States, the European Union Aviation Safety Agency ('EASA') and organisations in relation to the rules referred to in points (a) to (d).
2. Annex I (Part-MED) to this Regulation shall apply to pilot licences issued or to be issued in accordance with Commission Regulation (EU) 1178/2011, Commission Regulation (EU) 2018/395 and Commission Implementing Regulation (EU) 2018/1976, as well as to air traffic controller licences issued or to be issued in accordance with Regulation (EU) 2015/340.

3. Subparts GEN of Annex VI (Part-ARA) and Annex VII (Part-ORA) to Regulation (EU) 1178/2011 are applicable and complement the requirements of this Regulation.

Article 2 - Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (1) 'Part-FCL licence' means a flight crew licence which complies with the requirements of Annex I (Par-FCL) to Regulation (EU) 1178/2011;
- (2) 'Part-SFCL licence' means a flight crew licence which complies with the requirements of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976;
- (3) 'Part-BFCL licence' means a flight crew licence which complies with the requirements of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395;
- (4) 'applicant' means a person applying for, or being the holder of, a medical certificate or cabin crew medical report who undergoes an aero-medical assessment of fitness to exercise the privileges of the licence or to carry out cabin crew safety duties;
- (5) 'cabin crew member' means an appropriately qualified crew member, other than a flight crew or technical crew member, who is assigned by an operator to perform duties related to the safety of passengers and flight during operations;
- (6) 'aircrew' means flight crew and cabin crew;
- (7) 'aero-medical assessment' means the conclusion on the medical fitness of an applicant based on the evaluation of the applicant's medical history and aero-medical examinations as required in this Annex (Part-MED) and further examinations and medical tests as clinically indicated;
- (8) 'aero-medical examination' means an inspection, palpation, percussion, auscultation or any other means of investigation especially for determining the medical fitness to exercise the privileges of the licence or to carry out cabin crew safety duties;
- (9) 'medical history' means a narrative or record of past diseases, injuries, treatments or other medical facts, including unfit assessment(s) or limitation on a medical certificate, that are or may be relevant to an applicant's current state of health and aero-medical fitness;
- (10) 'credit' means the recognition of prior experience, qualifications or examinations;
- (11) 'significant' means a degree of a medical condition, the effect of which would prevent the safe exercise of the privileges of the licence or of the cabin crew safety duties;
- (12) 'limitation' means a condition placed on the medical certificate or cabin crew medical report that shall be complied with whilst exercising the privileges of the licence or cabin crew attestation;
- (13) 'licensing authority' means the competent authority of the Member State that issued the licence, or to which a person applies for the issue of a licence, or, when a person has not yet applied for the issue of a licence, the competent authority of the Member State where the applicant intends to apply for the issue of a licence'

(14) ‘acceptable means of compliance (AMC)’ means non-binding standards adopted by the Agency to illustrate means to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts;

(15) ‘alternative means of compliance (AltMoC)’ means those means that propose an alternative to an existing AMC or those that propose new means to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts for which no associated AMC have been adopted by the Agency or for which an alternative way to achieve compliance is preferred subject to ensuring at least the same level of safety as the AMC adopted by the Agency;

(16) ‘helicopter emergency medical services (HEMS) operation’ means a ‘HEMS flight’ as defined in point 61 of Annex I to Regulation (EU) No 965/2012;

(17) ‘principal place of business’ of an organisation means the head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised.

GM1 Article 2 Definitions

The following is a list of abbreviations that are used throughout the AMC and GM to the Medical Regulation:

(A)	aeroplane
(H)	helicopter
A/C	aircraft
AeMC	aero-medical centre
ALARP	as low as reasonably practicable
AMC	acceptable means of compliance
AME	aero-medical examiner
ARA	authority requirements for aircrew
ATCO	air traffic controller
ATPL	airline transport pilot licence
bpm	beats per minute
CC	cabin crew
cm	centimetre
CPL	commercial pilot licence
CRM	crew resource management
dB	decibel
ECG	electrocardiogram
ENT	ear, nose and throat

EU	European Union
FTE	full-time equivalent
ft	foot; feet
FVC	forced vital capacity
GM	guidance material
HF	human factors
Hg	mercury
Hz	Herz
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IRs	implementing rules
kg	kilogram
LAPL	light aircraft pilot licence
m	metre
mm	millimetre
ORA	organisation requirements for aircrew
PPL	private pilot licence
TRM	team resource management

Article 3 - Aero-medical certification of pilots

Without prejudice to Commission Delegated Regulation (EU) 2020/723, pilots of aircraft involved in the operation of aircraft referred to in points (b)(i) and (ii) of Article 2(1) of Regulation (EU) 2018/1139 shall comply with the technical requirements and administrative procedures laid down in Annex I (Part-MED) to this Regulation.

Article 4 - Aero-medical certification of air traffic controllers

Air traffic controllers involved in the provision of ATM/ANS referred to in point (g) of Article 2(1) of Regulation (EU) 2018/1139 shall comply with the technical requirements and administrative procedures laid down in Annex I (Part-MED) to this Regulation.

Article 5 - Aero-medical assessment of cabin crew members

Cabin crew members involved in the operation of aircraft referred to in points (b)(i) and (ii) of Article 2(1) of Regulation (EU) 2018/1139 shall comply with the technical requirements and administrative procedures laid down in Annex I (Part-MED) to this Regulation.

Article 6 - Aero-medical centres

Aero-medical centres involved in the medical assessment of pilots, cabin crew members and air traffic controllers referred to in Articles 3 to 5 of this Regulation shall comply with the technical requirements and administrative procedures laid down in Annex I (Part-MED) and Annex III (Part-ORA.AeMC) to this Regulation as well as in Subpart GEN of Annex VII (Part-ORA) to Regulation (EU) No 1178/2011 in relation to the privileges of their organisation.

Article 7 - Aero-medical examiners

Aero-medical examiners involved in the medical assessment of medical assessment of pilots, cabin crew members and air traffic controllers referred to in Articles 3 to 5 of this Regulation shall comply with the technical requirements and administrative procedures laid down in Annex I (Part-MED) to this Regulation in relation to the privileges they hold or apply for.

Article 8 - Credit for aero-medical certification obtained during military service

1. In order for holders of military flight crew licences or military air traffic controller licences to obtain a corresponding medical certificate in accordance with Annex I (Part-MED) to this Regulation, they shall hold a medical certificate that is valid or has expired for no longer than 12 months before the date of their application and apply to the Member State where they served.
2. The examinations performed as part of their military medical certification for pilot or air traffic controller shall be given credit for the purposes of the relevant requirements of Annex I (Part-MED) to this Regulation in accordance with the elements of a credit report established by the Member State as detailed in Annex I (Part-MED) to this Regulation.

Article 9 - Oversight capabilities

1. Member States shall designate one or more entities as the competent authority within that Member State with the necessary powers and allocated responsibilities for the certification and oversight of persons and organisations subject to Regulation (EU) 2018/1139 and its delegated and implementing acts.

2. If a Member State designates more than one entity as competent authority:
 - (a) the areas of competence of each competent authority shall be clearly defined in terms of responsibilities and geographic limitation;
 - (b) coordination shall be established between those entities to ensure effective oversight of all organisations and persons subject to Regulation (EU) 2018/1139 and its delegated and implementing acts within their respective remits.
3. Member States shall ensure that the competent authority(ies) has (have) the necessary capability to ensure the oversight of all persons and organisations covered by their oversight programme, including sufficient resources to fulfil the requirements of this Regulation.
4. Member States shall ensure that competent authority personnel do not perform oversight activities when there is evidence that this could result directly or indirectly in a conflict of interest, in particular when relating to family or financial interest.
5. Personnel authorised by the competent authority to carry out certification and/or oversight tasks shall be empowered to perform at least the following tasks:
 - (a) examine the records, data, procedures and any other material relevant to the execution of the certification and/or oversight task;
 - (b) take copies of or extracts from such records, data, procedures and other material;
 - (c) ask for an oral explanation on site;
 - (d) enter relevant premises, operating sites or means of transport;
 - (e) perform audits, investigations, assessments and inspections, including ramp inspections and unannounced inspections; and
 - (f) take or initiate enforcement measures as appropriate.
6. The tasks under paragraph 5 shall be carried out in compliance with the legal provisions of the relevant Member State.

Article 10 - Transitional measures for medical assessment protocols applied in accordance with point ARA.MED.330 of Annex VI (Part-ARA) to Regulation (EU) 1178/2011 and medical certificates issued on the basis thereof

1. Competent authorities involved in medical assessment protocols, or wishing to join an existing medical assessment protocol, in accordance with point ARA.MED.330 of Annex VI (Part-ARA) to Regulation (EU) No 1178/2011, applicable before 13 February 2025 may continue to apply, or join, the relevant protocol until the end of its validity, where the validity has been determined before 13 August 2024.
2. Holders of medical certificates issued in accordance with the medical assessment protocols referred to in paragraph 1 may exercise the privileges of their pilot licences on the basis of their medical certificates, as long as the relevant medical assessment protocol continues to apply in accordance with paragraph 1.

Article 11 - Transitional measures

Member States shall:

- (a) replace all aero-medical certificates, AME certificates and cabin crew medical reports issued in accordance with Regulation (EU) No 1178/2011 and Regulation (EU) 2015/340 at the first revalidation following the entry into force of this Regulation;
- (b) replace all aero-medical centre certificates within 12 months from the entry into force of this Regulation.

Article 12 - Entry into force and applicability

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
It shall apply from [date of entry into force plus six months].
2. This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission

The President

Ursula VON DER LEYEN