



Update of Part-MED (Annex IV to Commission Regulation (EU) No 1178/2011)

RELATED NPA/CRD: 2013-15 — RMT.0287 & RMT.0700 — 11.8.2016

EXECUTIVE SUMMARY

This Opinion addresses efficiency/proportionality as well safety issues related to Annex IV (Part-MED) to Commission Regulation (EU) No 1178/2011. As both rulemaking tasks (RMTs), RMT.0287 and RMT.0700, amend the provisions prescribed in Part-MED, EASA decided to merge the outcome of the respective consultations and publish one Opinion on the update of Part-MED to prevent any inconsistencies that may emerge during the rulemaking process.

The specific objectives of RMT.0287 are to solve the consistency issues, fill the gaps identified through the implementation experience, and keep the requirements up to date with the new developments in the field of medicine in order to ensure that they are fit for purpose and can be implemented in practice.

The objective of RMT.0700 is to address the recommendations issued by the EASA-led Germanwings Task Force on the accident of the Germanwings Flight 9525 and the related safety recommendations issued by the Bureau d'Enquêtes et d'Analyses pour la Sécurité de l'Aviation Civile (BEA).

In summary, the proposed changes are expected to improve the level of safety by introducing new requirements:

- to strengthen class 1 medical examination for applicants for and holders of certificates by including drugs and alcohol screening and comprehensive mental health assessment as well as improved follow-up in case of medical history of psychiatric conditions;
- for aero-medical centres (AeMCs) and aero-medical examiners (AMEs) to report to the competent authority all incomplete medical assessments, thus preventing fraud attempts;
- to increase the quality of the aero-medical examinations by improving the training, oversight and competency assessment of the AMEs; and
- for the holders of medical certificates to return them to the licensing authority in case of suspension and revocation of their medical certificates.

Moreover, the proposed changes aim to ensure harmonisation between the requirements of Part-MED and Part ATCO.MED (Annex IV to Commission Regulation (EU) 2015/340). Finally, the changes proposed by this Opinion are expected to enhance clarity and consistency of rules in line with better regulation principles.

Applicability		Process map	
Affected regulations and decisions:	Part-MED (Annex IV to Commission Regulation (EU) No 1178/2011)	RMT.0287	RMT.0700
Affected stakeholders:	Pilots, AMEs, AeMCs, competent authorities	Concept paper: No	Yes
Driver/origin:	Efficiency/proportionality; Safety	Rulemaking group: Yes	No
Reference:	Final accident investigation report of the BEA) Safety recommendations FRAN 2016 011 and FRAN-2016-016	RIA type: Light	Light
		Technical consultation during drafting: No	Technical meeting
		Publication date of the NPA: 26.7.2013	N/A
		Duration of NPA consultation: 3 months	N/A
		Review group: Yes	N/A
		Focused consultation: No	Conference
		Publication date of the Decision: 2016/Q4	2016/Q4



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1. Procedural information

The rule development procedure

The European Aviation Safety Agency (hereinafter referred to as the 'Agency') developed this Opinion in line with Regulation (EC) No 216/2008¹ (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure².

RMT.0287 is included in the Agency's [5-year Rulemaking Programme](#). Originally, two numbers were attributed to the task; one for the opinion (RMT.0287) and one for the ED decision (RMT.0288). Both deliverables are now included in RMT.0287. The scope and timescales for the task are defined in the related Terms of Reference (ToR) which were published on 9 November 2011 on the Agency's website, as last amended by [Issue 2](#) which was published on 22 October 2012. Issue 2 widened the scope to include a review of the medical aspects contained in Annexes VI (Part-ARA) and VII (Part-ORA) to Commission Regulation (EU) No 1178/2011³ (hereinafter referred to as the 'Aircrew Regulation'). The results of the Part-ARA and Part-ORA review will be published separately in a future NPA.

The main objective of the task is to review and update Part-MED as well as the acceptable means of compliance (AMC) and guidance material (GM) to Part-MED ([ED Decision 2011/015/R](#)⁴). Some changes to Part-MED were introduced through the present RMT, e.g. 'Direct Oral Anticoagulants' and 'ORL limitation'. Other more specific medical issues will be handled under RMT.0424, in the context of which individual organ systems will be reviewed in smaller packages to propose improvements and to take account of medical advancements.

The public consultation of the NPA related to RMT.0287 and RMT.0288 ([NPA 2013-15](#)) was launched on 26 July 2013. Said consultation expired on 28 October 2013.

It should be noted that, since the NPA was published, a change to the AMC for light aircraft pilot licence (LAPL) holders has been introduced through [ED Decision 2013/016/R](#). This is reflected in the resulting text to the CRD.

The responses to the comments received, as well as the resulting text, have been developed by the Agency with input from the review group which was established for RMT.0287 and RMT.0288. The

¹ 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 (OJ L 79, 19.3.2008, p. 1) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1468311922641&uri=CELEX:32008R0216>).

² The Agency is bound to follow a structured rulemaking process as required by Article 52(1) of the Basic Regulation. Such process has been adopted by the Agency's Management Board and is referred to as the 'Rulemaking Procedure'. See Management Board Decision 01-2012 of 13 March 2012 concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications and guidance material — for RMT.0287. See Article 15 'Special rulemaking procedure: direct publication' of Management Board Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications, acceptable means of compliance and guidance material ('Rulemaking Procedure') — for RMT.0700.

³ Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p.1) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1468312238909&uri=CELEX:32011R1178>).

⁴ ED Decision 2011/015/R of 15 December 2011 on Acceptable Means of Compliance and Guidance Material to Commission Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008.



review group comprised the same members as the initial Rulemaking group⁵, augmented by two extra members from competent authorities. The review group met twice between November 2013 and January 2014 to finalise the CRD. During these meetings, the review group discussed the comments received on the NPA and changes to the amendments proposed in the NPA.

The Agency published the associated [CRD](#) on 25 September 2014 for a further public consultation which expired on 25 November 2014. There were 42 reactions to the CRD from various stakeholders. After carefully analysing these reactions, some more changes were made to the text of the CRD.

The draft text of this Opinion has been developed by the Agency based on the input of the Review Group RMT.0287.

In regard to RMT.0700, the scope and timescales were defined in the related Terms of Reference (ToR) which were published on 20 April 2016 on the Agency's website⁶. The ToR for RMT.0700 are the outcome of a set of preliminary consultation activities carried out by the Agency in the period from November 2015 until February 2016. These activities include the:

- (a) publication on the Agency's website of preliminary concept papers on how to address the recommendations of the Germanwings Task Force. The objective of this publication was to provide for a more focused discussion during the workshop (see point (b));
- (b) Aircrew Medical Fitness workshop on 7 and 8 December 2015; and
- (c) 4-week Advisory Bodies' consultation of the final concept papers addressing the feedback received by the aviation community during the workshop.

123 valuable comments were received by the Advisory Bodies on the concept papers, providing thus the Agency with a better understanding of what the regulatory proposal should include. Additional comments on how to address the safety issues raised by the Germanwings Task Force recommendations were received in March 2016 as a result of the consultation of the ToR for RMT.0700.

As no rulemaking group was set up for this rulemaking task, the Agency organised a technical meeting on 9 and 10 May 2016 with a number of representatives of the affected stakeholders. This allowed the Agency to have a technical discussion during the drafting of the regulatory text and thus have immediate technical feedback on most of the proposals which were then sent for consultation.

From 1 to 30 June the Agency's Advisory Bodies were consulted on the draft Implementing Rules (IRs) and related AMC and GM included in RMT.0700. In parallel to this consultation, the Agency held on 15–16 June 2016, in Cologne, the Aircrew EASA Action plan Conference in order to update the aviation community on the proposed draft rules. The draft IRs and related AMC and GM were distributed to the Conference participants two weeks before the event. All interested stakeholders had the opportunity to express their opinion and commented on the proposed regulatory proposal. The event was organised to ensure enough time for questions and comments.

Following the consultation with the Advisory Bodies and the feedback received during the conference, the regulatory proposal was revised and the resulting text is annexed to the present Opinion.

⁵ <http://easa.europa.eu/system/files/dfu/GC%20to%20ToR%20RMT.0287%20%2B%20%20RMT.0288%20%28MED.001%29%20Issue%202.pdf>
⁶ <http://www.easa.europa.eu/system/files/dfu/ToR%20RMT.0700%20Issue%201.pdf>



The structure of this Opinion and related documents

Chapter 1 of this Opinion contains the procedural information related to this task. Chapter 2 'Explanatory note' explains the core technical content. The draft rule text proposed by the Agency is published on the Agency's website⁷.

The next steps in the procedure

This Opinion contains proposed changes to Annex IV to the Aircrew Regulation. It is addressed to the European Commission to be used as a technical basis in order to prepare a legislative proposal.

For information, the Agency published the draft text for the related Agency decision containing AMC/GM to Part-MED of the Aircrew Regulation. The final decision issuing the AMC/GM to the amended Part-MED will be published by the Agency once the related IR is adopted by the Commission.

⁷ <http://easa.europa.eu/document-library/opinions>



2. Explanatory Note

Issues to be addressed

Part-MED contains rules for medical fitness of pilots and cabin crew, provisions for certification of AMEs, as well as the requirements for general medical practitioners (GMPs) and occupational health medical practitioners (OHMPs). The associated AMC and GM are provided in ED Decision 2011/015/R.

During the drafting phase for the Part-MED requirements, the principle was to transpose the requirements from JAR-FCL 3 (Medical) into European law and to update and amend them through the present follow-up rulemaking task together with corrections of editorial errors, where required, and covering of the identified gaps, e.g. 'AME Obligations'. Other more specific medical issues will be handled under RMT.0424, in the context of which individual organ systems will be reviewed in smaller packages to propose improvements and to take account of medical advancements.

Following the accident of the Germanwings Flight 9525, the EASA-led Germanwings Task Force issued 6 recommendations. Following the consultation of the detailed concept papers with the Agency's Advisory Bodies, the Agency believes that 3 of these recommendations, namely recommendations 2, 3 and 4, require regulatory changes in the requirements regarding aircrew medical certification.

The following issues to be addressed were added, via RMT.0700, to the existing changes resulting from the RMT.0287:

- pilots' psychological/psychiatric evaluation during Class 1 medical examination (recommendation 2);
- risk mitigation of aircrew misuse of psychoactive substances (recommendation 3); and
- training, oversight and network of AMEs (recommendation 4 and partially recommendation 2);

Objectives

The overall objectives of the Agency are defined in Article 2 of the Basic Regulation. This proposal will contribute to the achievement of the overall objectives by addressing the issues outlined in Chapter 2.

The specific objective of this proposal is to ensure an efficient and effective legislation on Part-MED, To this end, it aims to:

- (a) achieve the level of aviation safety laid down in the Basic Regulation by:
 - (1) ensuring pilot physical, psychological and psychiatric aero-medical fitness so that their medical condition is less likely to interfere with the safe exercise of the privileges of their licences;
 - (2) ensuring that medical conditions of aircrew members misusing psychoactive substances are less likely to interfere with the safe exercise of the privileges of their licences; and
 - (3) enhancing aero-medical examination so that the risks of undetected pilot medical and psychological conditions are reduced through improved training, practice, oversight and fostering networks of AMEs;
- (b) contribute to the continuous improvement of the aircrew requirements in order to ensure that a high level of safety is constantly maintained and can be better achieved;



- (c) correcting editorial mistakes and ensuring consistency of wording;
- (d) updating the medical provisions in the light of the new developments in the field of medicine; and
- (e) addressing consistency issues and gaps identified through the implementation experience (e.g. notification of the licensing authority in case of applicants for or holders of medical certificates that started medical examinations but did not complete them).

Outcome of the consultation

Having duly taken into account:

- the comments received during the consultation phases of the RMT.0287 (NPA and CRD);
 - the comments received during the RMT.0700 ToR consultation;
 - the technical meeting held on 9 and 10 May for RMT.0700;
 - the comments received during the consultation of the advisory bodies for RMT.0700; and
 - the comments received during the Aircrew EASA Action plan Conference on 15–16 of June,
- the main proposals put forward are the ones in the following sections.

2.1.1 Editorial corrections and changes for clarification and consistency

- (a) Editorial changes are made to improve the text of Part-MED, to ensure consistency of wording and, where necessary, to clarify the meaning of an IR or AMC or GM. In some cases, paragraphs are rearranged to better align the IRs and AMC. These amendments are purely editorial and do not imply a technical change to the IR, AMC or GM.
- (b) The structure, wording and expressions used in Part-MED and in Commission Regulation (EU) 2015/340⁸ are harmonised, where appropriate.

2.1.2 Subpart A — General requirements

- (a) MED.A.010 'Definitions': The introduction of a definition for 'applicant' proposed in the NPA is deleted, as it did not provide for a better understanding of the applicable provisions, which also refer to applicants for a Part-FCL licence and applicants for a cabin crew attestation. Definitions for 'psychoactive substances', 'misuse of substances' and 'medical history' are introduced in order to ensure better understanding of the terms and harmonisation with Part ATCO.MED.
- (b) MED.A.025 'Obligations of the AeMC, AME, GMP and OHMP':
 - (1) Point (a)(3) is added mandating the notification of licensing authority, or, in case of cabin crew, the competent authority when the applicant provides incomplete, inaccurate or false statements on their medical history;

⁸ Commission Regulation (EU) 2015/340 of 20 February 2015 laying down technical requirements and administrative procedures relating to air traffic controllers' licences and certificates pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 923/2012 and repealing Commission Regulation (EU) No 805/2011 (OJ L 63, 6.3.2015, p. 1) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1468315553275&uri=CELEX:32015R0340>).



- (2) Point (a)(4) is added mandating the notification of licensing authority if an applicant withdraws the application for a medical certificate at any stage of the process;
- (3) The NPA contained a proposal to delete point (b)(3) on the applicant's right to a review if assessed as unfit, for reasons explained in the NPA. In response to comments received, this point is retained; however, with more generic wording and including reference to the procedures of the competent authority.
- (c) MED.A.030 'Medical certificates': Changes are made because the medical certificate is only needed for the issue of the licence (in alignment with ICAO Annex 1 point 2.1.1.3) and for exercising the privileges of the applicable licence (in alignment with ICAO Annex 1 point 1.2.4.4).
- (d) MED.A.040 'Issue, revalidation and renewal of medical certificates': Point (f)(2) is amended to allow the licensing authority to ask for a medical certificate to be returned.
- (e) MED.A.046 'Suspension or revocation of medical certificates': The text is amended to be less burdensome than what was proposed in the NPA, as the licensing authority can choose, as appropriate, to ask the pilot to return a suspended medical certificate or not.

2.1.3 Subpart B — Requirements for pilot medical certificates — Section 1 — General

MED.B.001 'Limitations to medical certificates'

- (a) The text in points (a)(1) and (b)(1) is amended to clarify the intent, which is to provide the possibility for a fit assessment with appropriate limitations only where the applicant is not likely to jeopardise the safe exercise of the privileges of the applicable licence. The aim is to allow competent authorities to consider medical advancements and to establish whether a fit assessment may be possible for certain medical conditions for which the existing provisions inevitably lead to an unfit assessment. Under new medical assessment protocols via research, it will be possible to collect specific data in a controlled aviation environment, and to develop specific risk assessments for certain medical conditions.
- (b) A new point (d)(2)(iii) is added, whereby requirements on who is to impose and remove operational safety pilot limitation (OSL) for LAPL medical certificates are introduced.
- (c) In response to comments received, a new point (d)(4) is added, whereby a new limitation, operational pilot restriction limitation (ORL), is introduced to ensure that holders of a class 2 or LAPL medical certificate either operate an aircraft with a safety pilot or without passengers.

2.1.4 Subpart B, Section 2 — Medical requirements for Class 1 and Class 2 medical certificates

2.1.4.1 General

- (a) The aim of RMT.0287 was not to substantially change the specific medical requirements, but to apply editorial improvements, to address gaps identified, to ensure consistency of the wording, and to update the rules where feasible. More detailed amendments and technical improvements will be considered under RMT.0424 'Regular update of Part-MED', in the context of which organ systems will be addressed in individual packages, e.g. 'update cardiovascular system' or 'update respiratory system', etc.
- (b) Many provisions on the specific organ systems started with a general point which stated, for example, 'Applicants shall not suffer from any disorder of the [...] system which is likely to



interfere with the safe exercise of the applicable licence(s)'. This point is deleted, where appropriate, because it was considered to be a repetition of MED.B.005(a). In some cases, it is retained as it provides the necessary legal basis for the AMC.

2.1.4.2 Cardiovascular system

(a) Class 1 and Class 2

- (1) A new point (4) is added to MED.B.010(b) to cover the gap of other cardiological pathological conditions that are not specified in MED.B.010(b)(1) and (2).
- (2) Blood pressure: The text for applicants taking medication to control blood pressure is amended to avoid the expression 'temporary suspension', which, according to comments received, creates an unnecessary administrative burden.
- (3) Vasovagal syncope: Concerns were expressed by commentators that deletion of 'recurrent' from vasovagal syncope could lead to an unfit assessment for an 'one-off' (insignificant) event. The Agency agrees that an 'one-off' event should not systematically lead to an unfit assessment. The text is amended to 'vasovagal syncope of uncertain cause', which also reflects 'a single episode of disturbance of consciousness of uncertain cause' in MED.B.065.
- (4) In the current provisions for LAPL, applicants with symptomatic hypertrophic cardiomyopathy should be assessed as unfit. This is added for Class 1 and Class 2, as it was missing from the existing rules. In addition, a new point (b)(4) for other cardiac disorders is added to the IR for Class 1 and Class 2, to support cardiac disorders which are currently addressed in the AMC for Class 1 and Class 2, but which are not included in the current IR.

(b) Class 2

Examination: Multiple comments were received in support of the introduction of an electrocardiogram (ECG) at the initial examination for Class 2 applicants. Many commentators asked for the ECG to also be performed at the first examination after age 40, in line with the existing rules. Point (a)(1)(ii) of MED.B.010 is, therefore, amended to require a standard 12-lead ECG at the initial examination, then at the first examination after age 40 and then at the first examination after age 50, and every 2 years thereafter. This is in line with the ICAO Annex 1 standard requiring an ECG at the first examination after age 40.

2.1.4.3 Respiratory system

Class 1

MED.B.015 did not include any reference to chronic obstructive pulmonary disease. It was mentioned only in AMC1 MED.B.015(b), that applicants with chronic obstructive pulmonary disease with minor impairment of pulmonary function may be considered for a fit assessment. The text in MED.B.015(d) is amended to include chronic obstructive pulmonary disease.

2.1.4.4 Haematology

Class 1 and Class 2



Leukaemia: MED.B.030 is changed from 'chronic leukaemia' to 'leukaemia', as the AMC provide fit and unfit criteria for both acute and chronic leukaemia. In addition, this will ensure licensing authority involvement for acute as well as chronic leukaemia.

2.1.4.5 Obstetrics and gynaecology

Class 1 and Class 2

Pregnancy: Multiple comments were received regarding the burden of formally suspending the validity of the medical certificate after the 26th week of gestation and subsequently requiring a certificate renewal examination after the pregnancy before the pilot can exercise the privileges of her licence. Therefore, the text in MED.B.045 is changed to retain the same standards, such as 'recovery' but without mandating physical suspension of the medical certificate during the pregnancy or examination after the end of the pregnancy.

2.1.4.6 Mental Health

Class 1 and Class 2

- (a) MED.B.055 'Psychiatry' and MED.B.060 'Psychology' are merged under the new MED.B.055 'Mental health'
- (b) The new MED.B.055 'Mental health' introduces a new requirement for a comprehensive mental health assessment as part of initial class 1 medical examination.
- (c) In addition, the new MED.B.055 'Mental Health' includes a new requirement for drugs and alcohol screening as part of initial class 1 medical examination. Corresponding AMC have been developed to provide further details on drugs and alcohol screening. Also, AMC is added to allow the Member States to include additional drugs on the list of drugs to be tested and perform random drug screening tests during renewal/revalidation examination based on the risk assessment.
- (a) Terminology: As the term 'psychoactive' also includes medication such as sedatives and opioids, it was decided to use this throughout Part-MED and corresponding AMC, instead of 'psychotropic'.
- (b) The requirement for referral to, and consultation with, the licensing authority, was duplicated in MED.B.055(b) and MED.B.055(e), the rule is amended so that it now only remains under point (f) on aero-medical assessment.

2.1.4.7 Neurology

Class 1 and Class 2

The MED.B.065 text is changed to require further evaluation and also licensing authority involvement for applicants diagnosed with migraine, inflammatory central or peripheral nerve disease or disorders of the nervous system due to vascular deficiencies including haemorrhagic and ischaemic events, as this was missing from the existing provisions. Criteria for assessing applicants diagnosed with migraine are added to AMC1 MED.B.065.



2.1.4.8 Visual system

Class 1

Refractive error: Additional criteria and examinations are introduced for applicants with hypermetropia exceeding +5.0 dioptres. One of the criteria is to require corrected distant visual acuity in each eye to be 6/6 or better. As this is more restrictive than the 6/9 required for initial applicants according to the IR, it is moved to the IR (MED.B.070(c)). This does not directly conflict with ICAO Annex I which sets a general standard of 6/9 or better. Referral to the licensing authority is also moved from the AMC to MED.B.070(c).

2.1.4.9 Colour vision

Class 1

Colour vision testing: AMC1 MED.B.075 indicates that the applicant should be a normal trichromat to pass the anomaloscopy test; this would be more restrictive than the IR, so it is added to MED.B.075(b)(2).

2.1.4.10 Otorhinolaryngology (ENT)

Class 1 and Class 2

- (a) There was a change proposed in the NPA text for MED.B.080 which was unclear. This is amended to correctly reflect the original intention, i.e. that hearing shall be tested with pure-tone audiometry for Class 1 medical certificates, and for Class 2 medical certificates when an instrument rating or en route instrument rating is to be added to the licence (MED.B.080(a)(1)(i)).
- (b) 'Sequelae of surgery of the internal or middle ear' is added to MED.B.080(b) as it was missing from the existing provisions and further examination is appropriate. Criteria for the assessment are added to AMC1 MED.B.080(j) .

2.1.5 Subpart B, Section 3 — Specific requirements for LAPL medical certificates

2.1.5.1 LAPL urine test

In response to multiple comments received, the urine test will not be deleted from the IR (MED.B.095(c)). Commentators explained that the test was simple, inexpensive and beneficial for identifying safety-relevant conditions or for early detection of metabolic or kidney conditions.

2.1.6 Subpart D — Requirements for AME, GMP, OHMP

2.1.6.1 Section 1 — Aero-Medical Examiners (AMEs)

- (a) MED.D.010 'Requirements for the issue of an AME certificate': One comment suggested that 'hold a Certificate of Completion, or have other evidence, of specialist medical training' in point (a) should be changed to 'either hold a Certificate of Completion of specialist training, or a statement from the doctor's national regulatory body that the applicant is eligible to work as a specialist in that country'. MED.D.010 is changed to make it clear that the intent was for the applicant to have evidence of completion of specialist medical training.



- (b) MED.D.015 'Requirements for the extension of privileges': Comments received indicated that the rule on practical training at an AeMC (in point (c)) was difficult to comply with. The Agency established, during a meeting with medical experts, including representation from competent authorities, that the duration of practical training ranged between 2 and 10 days across the EASA Member States. Therefore, a duration of 2 to 4 days is introduced in MED.D.015, in order to keep the minimum and maximum to a reasonable duration.
- (c) MED.D.030 'Validity of AME certificates': The wording is changed to include new requirements for AMEs to demonstrate maintenance of aero-medical competency in order to revalidate/renew their AME certificate. New requirements for the renewal of AME certificate are introduced.

The expression 'medical practitioner' which may be referred to in different ways across the EASA Member States is replaced for better understanding. The wording of MED.D.010(a) is replicated instead (i.e. licensed to practise medicine).



3. Regulatory impact assessment (RIA)

Issues to be assessed with the RIA

Background

Part-MED contains rules for medical fitness of pilots and cabin crew, provisions for certification of AMEs, as well as the requirements for GMPs and OHMPs. The associated AMC and GM are provided in Decision 2011/015/R of the Executive Director of the European Aviation Safety Agency.

During the drafting phase for the Part-MED requirements that are presently in place, the underlying principle was to transpose the requirements from JAR-FCL 3 (Medical) into European law in order to facilitate implementation of Part-MED. The follow-up rulemaking task, RMT.0287 and RMT.0288, was already envisaged at that time with the specific objective of reviewing and amending the initial version, correcting editorial errors, covering gaps where required, and also ensuring consistency as promised during the discussions on Part-MED in the EASA Committee during the adoption phase of the Aircrew Regulation. This RMT should also address possible implementation and transitional problems (e.g. specifying the duration of AME practical training).

More detailed amendments and technical improvements will be considered in the context of RMT.0424 'Regular update of Part-MED', where organ systems will be addressed in individual packages, e.g. 'update cardiovascular system' or 'update respiratory system', etc.

During the Medical Expert Group (MEG) meetings held since 2011 — after the publication of the Aircrew Regulation — some of the EASA Member States pointed out that certain requirements (e.g. practical training of AMEs (MED.D.015)) were either ambiguous or open to interpretation and that led to implementation problems and subsequently problems in maintaining the same level of safety in all EASA Member States. Therefore, proposals for amending the regulation were made almost in every MEG meeting.

Following the accident of the Germanwings Flight 9525, the EASA-led Germanwings Task Force examined the preliminary findings of the safety investigation led by the French BEA and issued 6 recommendations in order to reduce the risk of such a disaster happening again, and to ensure that the overall system is improved in a proactive manner.

The Task Force focused on the initial and recurrent medical assessments of pilots including psychological evaluation (Recommendation 2), the AME framework and aero-medical data systems (Recommendation 4); however, they recognised that the misuse of drugs and alcohol (Recommendation 3) is one of the disorders potentially affecting the mental health of pilots for which screening tests are readily available.

The Agency decided to include the mitigating measures for the safety risks identified by the EASA-led Task Force in this Opinion as they consist of further amendments to requirements that were already proposed by RMT.0287. An analysis of the recommendations requiring changes in the requirements regarding aircrew medical certification is provided below.

Recommendation 2 — Psychological/psychiatric assessment of applicants for Class 1 medical certificates

Medical and psychological conditions of flight crews, if not detected, can lead to a tragic outcome.



It is recognised that:

- although the overall number of aviation accidents with a medical cause or contribution is small, they have the propensity to result in rare, catastrophic accidents; and
- not all medical events are predictable.

An initial Class 1 medical assessment includes a review of the medical history, examination and several tests, among which a general mental health assessment. If the medical history or discussion raises concerns about the candidate's psychiatric or psychological status, the candidate is referred to a psychiatrist or a clinical psychologist for review prior to their fit status being decided.

The system puts emphasis on the ability of the AMEs to detect disorders in all fields of medicine, including psychiatric and psychological disorders. Sometimes these disorders are difficult to detect, for example because no early symptoms exist, or when individuals are not open about their symptoms, thoughts or behaviour.

Psychiatric conditions or disorders, which are likely to interfere with the safe exercise of the privileges of the licence, may remain undetected. The probability of such occurrences depends on the competency of physicians performing aero-medical assessments. Currently, aero-medical assessments of pilots include questions and interview techniques that can be used to assess mental fitness. However, it is recognised that the effectiveness of such methods is limited due to the following:

- Clinical signs of psychiatric deficiencies may vary over time.
- Aero-medical training in psychology/psychiatry of AMEs does not provide them with the sufficient knowledge to diagnose (and treat) these medical conditions on a professional level.
- There are barriers affecting a frank discussion on mental health issues between an AME and a pilot.

In addition, no systematic satisfactory psychiatric assessment is required for the renewal of class 1 medical certificates of applicants with an established medical history of psychiatric condition such as: mood disorder, neurotic disorder, personality disorder, mental or behavioural disorder or misuse of psychoactive substances.

Consequently, current aero-medical assessment techniques do not efficiently address the risks related to psychiatric conditions which are likely to interfere with the safe exercise of the privileges of a licence, as initially intended by MED.B.055.

Furthermore, currently aero-medical assessments do not include systematic psychological assessment. Therefore, psychological deficiencies, which are likely to interfere with the safe exercise of the privileges of the licence, may remain undetected, for the reasons explained above.

Consequently, current aero-medical assessment techniques do not efficiently address the risks related to mental or behavioural disorders which are likely to interfere with the safe exercise of the privileges of a licence, as initially intended by MED.B.060.

The available guidance on risk assessment for pilot incapacitation in a multi-crew environment is not adapted to mental impairment and incapacitation. Mental illnesses may lead to deliberate harmful actions, which may be conducted to 'maximise damage'. The second pilot can be physically prevented



from taking over. Acceptable mitigation measures for other medical incapacitations are not adequate for mental impairment.

Recommendation 3 — Psychoactive substances testing for initial Class 1 medical examination

The misuse of psychoactive substances is one of the few disorders that has the potential to affect the mental health of pilots, for which screening by means of biochemical tests is available.

The misuse of psychoactive substances may substantially increase risk-taking behaviours. Therefore it is unlikely that pilots engaged in such problematic psychoactive substance use, will readily refrain from exercising the privileges of their licence and related ratings or certificates, as initially intended by MED.A.020.

Currently, aero-medical assessments of pilots include questions and interview techniques that can be used to assess mental health and consequently substance-induced mood disorder. However, it is recognised that the effectiveness of such methods is limited due to the following:

- Clinical signs of mental or behavioural disorders may be easily compensated by educated persons.
- The physicians performing aero-medical assessments receive insufficient training on mental health evaluation techniques.
- There are barriers affecting a frank discussion on mental health issues between an AME and a pilot.

Recommendation 4 — Training, oversight and network of AMEs

Current requirements on training of AMEs follow a similar template for all trainees without differentiation based on their previous competency. A competency-based training programme is very difficult to implement especially for the initial training but may be much easier to implement for refresher training. Such a competency-based refresher training programme should take into account the outcomes of a risk assessment related to incidence of certain medical conditions of aircrew as well as a risk assessment based on the continuous oversight and competency of AMEs.

Current rules on the auditing of AMEs and visits by medical standardisation teams are compliance-based and focus on written processes and facilities. The main recommendation from the Task Force in this domain was to shift focus from aero-medical audits to the assessment of AMEs' performance including the application of their knowledge in practice.

Moving to a performance-based audit and oversight system would bring great benefits by showing the actual issues faced by AMEs when making judgements on pilot fitness. This assessment of the AME performance should demonstrate how their knowledge is applied in practice. To support this change, authority medical assessors should receive training in performance-based audit techniques.

A general oversight of aero-medical practice and proper aero-medical decisions can be achieved by continuous oversight of aero-medical assessments in the digital systems used by the competent authorities. Any individual deviation can be registered, evaluated and completed with comments. The evaluation should include the number of mistakes made by the AME, the analysis of the severity of the mistakes, conclusions based on the analysis, and individual recommendations for the improvement of the AME's work as applicable.



The oversight programme should promote best aero-medical practices and encourage competent authorities to share them with their AME community. Nationwide review of the AMEs' performance and discussions related to the typology of the most frequent mistakes should be regularly conducted by aero-medical assessors or accredited heads of AeMCs. Performance indicators and targets, aiming to reduce the most frequent and common mistakes, should be discussed and set on the largest possible consensual basis involving AMEs.

Although competency per se does not reliably predict performance in clinical practice, it is necessary to maintain and strengthen the aero-medical competency of the AME. Taking in account recent developments in medical clinical specialist training where periodical examinations are, or will become, mandatory, as well as already implemented systems within the aviation medicine environment, the high majority of the consulted stakeholders considered that it is recommendable to mandate such examinations as assessment tools for aero-medical competency of AMEs. The examination can also be used in cases of application for renewal after previous loss of AME certificate due to lack of aero-medical competency.

The effectiveness of promoting better performance of AMEs can be further increased by establishing small AME peer support groups (PSGs), which will have contacts both via the communication network (email, telephone), and also hold 3 to 4 group meetings a year. These AME groups enhance the professional education and competency as well as the trust relationship amongst colleagues by encouraging the sharing of experience and socialising. Such socially shared knowledge has an interactive nature. The view of the Task Force to create AME networks fits perfectly the reasoning that was behind the implementation of GMP PSGs in many countries (e.g. Ireland, the UK, the Netherlands, Norway). Many AMEs do their aero-medical work part-time or work in professionally isolated conditions and, therefore, perform a limited number of aero-medical examinations per year with consequently limited opportunities to gain experience with borderline and contentious cases. The aim of the small group network is professional support and educational enhancement. The PSG should be chaired by a leader who is experienced in peer review as well as communication and interview techniques.

Experience with GMP PSGs shows that group members feel that the meetings are a safe place to discuss their personal and professional difficulties. They build up a social/professional network with low thresholds to consult each other about difficult cases, also between meetings.

Stakeholders affected

The stakeholders affected are:

- flight crew as regards the maintenance of their fitness (e.g. migraine will require further evaluation);
- AMEs, AeMCs, GMPs and OHMPs because of their assessments and training programme in order to maintain their compliance with the changes in Part-MED and AMC/GM to Part-MED; and
- competent authorities because of the certification and oversight procedures in order to maintain compliance with the changes in Part-MED and AMC/GM to Part-MED.

How could the situation evolve?

The safety risks identified by the EASA-led Germanwings Task Force were also independently identified by other investigation bodies. The gaps in the system may allow pilots with psychiatric conditions,



including drugs or alcohol dependency, to exercise the privileges of their licence, thus endangering public safety. As shown above, the persons that have an established medical history or clinical diagnosis of a psychiatric condition may have, as symptoms of their condition, certain mental or behavioural impairment that would make it difficult for them to understand and admit that they pose a safety risk for them and for their passengers and colleagues. Non-reporting by the AME of possible fraud attempts along with insufficient training and oversight of AMEs may allow unfit flight crew to perform flying duty, endangering thus flight safety.

This may lead, in case the issues are not solved, to more and more pilots with disqualifying medical conditions being able to take advantage of the identified gaps in the system and thus endanger flight safety.

In addition, without updating Part-MED, some of the requirements would still be misinterpreted and not up to date with recent medical guidelines and recommendations. The level of uncertainty on the implementation of Part-MED requirements by competent authorities would remain; this could cause misinterpretation of key requirements with potential negative effects on safety. Furthermore, without this update, the system would allow people to circumvent some of the requirements (e.g. applicants could start medical examination with more than one AMEs, allowing thus fraud attempts from the pilots that were unfit by starting multiple examinations and finishing where they would see the most favourable potential assessment).

Options

The below options take into consideration the consistency issues and gaps identified through the implementation experience (RMT.0287) and the safety improvements proposed by the EASA-led Germanwings Task Force (RMT.0700).

List of options

- Option 0: Maintain the current version of Part-MED (baseline scenario).
- Option 1: Make only editorial changes without taking into account the identified gaps.
 - Amend the provisions that address the identified gaps (e.g. mental health assessment of the class 1 applicant training and oversight of AMEs; AME obligations), but without taking into account editorial changes.
- Option 2: applicant training and oversight of AMEs; AME obligations, but without taking into account editorial changes.
- Option 3: Update Part-MED as presented in the Annex to this Opinion, which encompasses both Option 1 and Option 2.

Impact analysis

Safety impacts

Option 0: No supplementary benefits will be gained.

Option 1 would bring slight improvements for countries where part of the requirements are misinterpreted due to editorial mistakes.



Option 2 would bring improvements to safety by filling the gaps related to AME oversight, training and obligations and medical certificate holders' obligations. New requirements on drugs and alcohol screening and comprehensive mental health assessment as part of the initial class 1 examination will further increase the level of safety.

Option 3 would have a high positive safety impact by solving both consistency and editorial problems as well as harmonising the obligations of AMEs and licence holders.

Environmental impacts

Not applicable.

Economic impacts

Option 0: The current version of Part-MED is already implemented and in force; therefore, no economic impacts.

Option 1 would have non-significant economic impacts as the changes do not require any change in the way the medical examination and assessment are performed.

Option 2 could slightly increase the workload for AMEs, AeMCs (e.g. comprehensive mental health assessment and new investigations, as well as enhanced follow-up for flight crew with a history of psychiatric condition) and competent authorities (e.g. complexity of AME certification, oversight and competency evaluation, as well as approval of new training programs for AMEs). The requirements on drugs and alcohol screening and comprehensive mental health assessment as part of the initial class 1 examination may increase the costs of the medical examination.

Additionally, the new requirements and AMC/GM for AME training will have a negative economic impact on the AMEs due to the an increase of the costs for both advanced and recurrent training.

However, the new limitation 'ORL' will allow Class 2 and LAPL holders to operate an aircraft with a safety pilot on board or without passengers; this would encourage more applicants for the above-mentioned categories to attend a training programme and therefore would create more business opportunities for training organisations. Due to the low foreseen number of beneficiaries of the 'ORL' limitation, the positive economic impact of this change will only partially compensate for the negative economic impact presented above.

Option 3 would have the combination of the impacts described for Options 1 and 2.

Impacts on General Aviation

Option 0: No supplementary benefits will be gained.

Option 1 would have no impact on General Aviation as the changes do not require any change in the way the medical examination and assessment are performed.

Option 2 would bring benefits for General Aviation by introducing a new limitation 'ORL' that will allow Class 2 and LAPL holders to choose to fly with a safety pilot on board or fly without passengers. This would encourage Class 2 and LAPL holders to keep flying, even if they no longer comply with all class 2 medical requirements, but they are considered to be not likely to jeopardise flight safety.

Option 3 would have a similar impact as that of Option 2.



Better regulation and harmonisation impacts

Regulatory harmonisation across EASA Member States is ensured by Options 1, 2, and 3. However, Option 3 respects the principles of ‘better regulation’ with proportionate requirements, together with more efficient and effective legislation. Hence, it has a higher positive impact: it would indeed cover gaps, correct editorial mistakes and ensure consistency of wording that would be very helpful in the implementation process.

Conclusion

As summarised in **Table 1**, Option 3 offers the most positive impacts across the different criteria. It will allow the implementation of requirements for medical certification of aircrew.

Table 1 — Summary of impacts per criterion and option

<i>Impact criterion</i>	<i>Option 0</i>	<i>Option 1</i>	<i>Option 2</i>	<i>Option 3</i>
Safety	0	+	++	++
Environment	Not applicable	Not applicable	Not applicable	Not applicable
Economic	0	0	0/-	0/-
General Aviation	0	0	+	+
Better regulation and harmonisation	0	+	+	++
Overall	0	0/+	+	+ / ++

Option 0 would maintain the current version of the text with all the inconsistencies and standardisation problems that it created. Therefore, the overall effect would be that the current errors and gaps will remain unaddressed.

Option 1 would only solve the consistency issues without addressing the identified gaps and the lack of harmonisation. Therefore, this would not be the preferred option as the gaps will not be addressed and the medical certification system will not be improved.

Option 2 would address some of the problems identified during the implementation phase and the safety risks identified by the EASA-led Germanwings Task Force but without correcting editorial mistakes or unclear or ambiguous requirements. Therefore, this would not be the preferred option as it does maintain the inconsistency in the wording, allowing thus different interpretations of the rules.

Option 3 would address the identified gaps that would have led to safety risk, the consistency issues and harmonisation with the ATCO medical certification requirements and the recommendations of the EASA-led Germanwings Task Force. Therefore, this option would be the preferred option as it addresses editorial errors as well as the gaps and the lack of harmonisation.

Actions to support implementation

The Opinion will be presented during the MEG meeting to take place on 11 of October 2016 and during the Member States Advisory Body (MAB — formerly known as RAG) meeting on 25–26 October 2016 to support the Member States with the implementation of the updated Part-MED.

Monitoring and evaluation

In support of the evaluation, after implementation, the Agency will assess the efficiency and effectiveness of the updated Part-MED provisions through the feedback received from stakeholders



during the MEG meetings and Standardisation meetings as well as through standardisation visits to the Member States.

The Agency will monitor the implementation of these provisions via the standardisation visits to the Member States.



4. Overview of the proposed Part-MED

As explained above, the Agency proposes to amend Annex IV (Part-MED) to the Aircrew Regulation. As demonstrated in the RIA, this change is expected to have a positive impact on both safety and social level as well as on regulatory harmonisation.

Therefore, this Opinion contains the amended Part-MED establishing the requirements for the issue of the medical certificate required for exercising the privileges of a pilot licence; certification and oversight of AMEs; and qualification of GMPs and OHMPs.

In addition, a document, courtesy of the Agency, containing the latest draft AMC and GM to the proposed draft Part-MED is provided.

Done at Cologne, on 11 August 2016.

Patrick KY
Executive Director



5. References

Affected regulations

Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p.1).

Related decisions

[ED Decision 2011/015/R](#) on Acceptable Means of Compliance and Guidance Material to Commission Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 — ‘Acceptable Means of Compliance and Guidance Material to Part-MED (Annex IV)’.

Reference documents

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 (OJ L 79, 19.3.2008, p. 1).

Commission Regulation (EU) 2015/340 of 20 February 2015 laying down technical requirements and administrative procedures relating to air traffic controllers' licences and certificates pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 923/2012 and repealing Commission Regulation (EU) No 805/2011 (OJ L 63, 6.3.2015, p. 1).

- Final Report of the Task Force on Measures Following the Accident of Germanwings Flight 9525 (<http://ec.europa.eu/transport/modes/air/news/doc/2015-07-17-germanwings-report/germanwings-task-force-final-report.pdf>)
- Action plan for the implementation of the Germanwings Task Force recommendations (http://easa.europa.eu/download/various/GW_actionplan_final.pdf)
- Final accident investigation report of the Bureau d'Enquêtes et d'Analyses pour la sécurité de l'aviation civile (BEA) (https://www.bea.aero/uploads/tx_elyextndtnews/BEA2015-0125.en-LR_08.pdf)



6. EASA Germanwings Task Force recommendations⁹

1. The Task Force recommends that the **2-persons-in-the-cockpit recommendation** is maintained. Its benefits should be evaluated after one year. Operators should introduce appropriate supplemental measures including training for crew to ensure any associated risks are mitigated.
2. The Task Force recommends that all airline pilots should undergo **psychological evaluation** as part of training or before entering service. The airline shall verify that a satisfactory evaluation has been carried out. The psychological part of the initial and recurrent aeromedical assessment and the related training for aero-medical examiners should be strengthened. EASA will prepare guidance material for this purpose.
3. The Task Force recommends to mandate **drugs and alcohol testing** as part of a random programme of testing by the operator and at least in the following cases: initial Class 1 medical assessment or when employed by an airline, post-incident/accident, with due cause, and as part of follow-up after a positive test result.
4. The Task Force recommends the establishment of robust oversight programme over the **performance of aero-medical examiners** including the practical application of their knowledge. In addition, national authorities should strengthen the psychological and communication aspects of aero-medical examiners training and practice. Networks of aero-medical examiners should be created to foster peer support.
5. The Task Force recommends that national regulations ensure that an **appropriate balance is found between patient confidentiality and the protection of public safety**.

The Task Force recommends the creation of a **European aeromedical data repository** as a first step to facilitate the sharing of aeromedical information and tackle the issue of pilot non-declaration. EASA will lead the project to deliver the necessary software tool.
6. The Task Force recommends the implementation of **pilot support and reporting systems**, linked to the employer Safety Management System within the framework of a non-punitive work environment and without compromising Just Culture principles. Requirements should be adapted to different organisation sizes and maturity levels, and provide provisions that take into account the range of work arrangements and contract types.

⁹ 'Action plan for the implementation of the Germanwings Task Force recommendations', Version 1 — 7 October 2015 (http://easa.europa.eu/download/various/GW_actionplan_final.pdf).

