



Explanatory Note to Decision 2019/002/R

Update of AMC and GM to Part-MED and Part-ARA (Annexes IV and VI to Commission Regulation (EU) No 1178/2011)

RELATED NPA/CRD 2013-15 — OPINION No 09/2016 — RMT.0287 (MED.001)⁽¹⁾ & RMT.0700⁽²⁾

EXECUTIVE SUMMARY

This Decision addresses efficiency/proportionality as well as 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, the European Aviation Safety Agency (EASA) decided to merge the outcome of the respective consultations and publish one ED Decision on the update of Part-MED and applicable parts of Part ARA to prevent any inconsistencies that may emerge during the rulemaking process.

The specific objectives of RMT.0287 are to solve the consistency issues, close the loopholes in the rules, as identified through the implementation experience, as well as 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 amendments introduced are expected to improve the level of safety by providing further clarification and guidance regarding:

- medical examination for applicants for and holders of class 1 certificates by including drug and alcohol screening and comprehensive mental health assessment as well as improved follow-up in case of medical history of psychiatric conditions;
- medical examination for applicants for and holders of class 2/light aircraft pilot licence (LAPL) medical certificates as well as cabin crew medical reports including operating pilot restriction limitation (ORL) for class 2 pilots and clarification for insulin-treated diabetes for cabin crew;
- decrease of medical fitness and use of different types of medication;
- obligations of the aero-medical centres (AeMCs) and aero-medical examiners (AMEs);
- the training, oversight and competency assessment of the AMEs in order to increase the quality of the aero-medical examinations;
- implementation of the medical provisions in line with the new developments in the field of medicine such as anticoagulation protocols and colour vision tests; and
- the European aeromedical data repository (EAMR).

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

Action area:	Review of rules		
Affected rules:	acceptable means of compliance (AMC)/guidance material (GM) to Part-MED and Part-ARA		
Affected stakeholders:	Aircrew, AMEs, AeMCs, competent authorities		
Driver:	Efficiency/proportionality; Safety	Rulemaking group:	(1) Yes; (2) No
Impact assessment:	None	Rulemaking Procedure:	(1) Standard; (2) Special (Article 15 'Direct publication')

• EASA rulemaking process milestones



(1) 22.10.2012
(2) 20.4.2016

(1) 26.7.2013
(2) N/A

15.8.2016

19.12.2018

28.1.2019



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1. About this Decision

EASA developed ED Decision 2019/002/R in line with Regulation (EU) 2018/1139¹ (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure².

This rulemaking activity is included in the European Plan for Aviation Safety (EPAS)³ under RMT.0287 (MED.001). Given that amendments to medical-related provisions are also proposed through RMT.0700, EASA decided to merge the outcome of the consultations carried out in the context of the activities of the two RMTs and publish one Opinion as well as one ED Decision on the update of Part-MED to prevent any inconsistencies that may emerge during the rulemaking process. The scope and timescales of the tasks were defined in the related Terms of Reference⁴.

The draft text of this Decision has been developed by EASA based on the input of Rulemaking Group (RMG) RMT.0287 (MED.001). All interested parties were consulted⁵ through NPA 2013-15⁶ between 26 July 2013 and 28 October 2013. In total, 392 comments were received from all interested parties, including industry (12 %), national aviation authorities (37 %), social partners(38 %) and private individuals (6 %).

It should be noted that, since the NPA was published, a change to the AMC for LAPL holders has been introduced through ED Decision 2013/016/R⁷. This is reflected in the resulting text presented in the associated Comment-Response Document (CRD) 2013-15⁸.

The responses to the comments received, as well as the resulting text, have been developed by EASA with input from the review group which was established for RMT.0287 and RMT.0288. The review group comprised the same members as the initial RMG⁹, 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.

EASA 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.

¹ 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 (OJ L 212, 22.8.2018, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri=CELEX:32018R1139>).

² EASA is bound to follow a structured rulemaking process as required by Article 115(1) of Regulation (EU) 2018/1139. Such a process has been adopted by the EASA Management Board (MB) and is referred to as the 'Rulemaking Procedure'. See MB Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by EASA for the issuing of opinions, certification specifications and guidance material (<http://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-18-2015-rulemaking-procedure>).

³ https://www.easa.europa.eu/document-library/general-publications?publication_type%5B%5D=2467

⁴ <https://www.easa.europa.eu/document-library/terms-of-reference/tor-med001-b-rmt0287-rmt0288> and <https://www.easa.europa.eu/document-library/terms-of-reference-and-group-compositions/tor-rmt0700>

⁵ In accordance with Article 52 of Regulation (EC) No 216/2008 and Articles 5(3) and 6 of the Rulemaking Procedure.

⁶ <https://www.easa.europa.eu/document-library/notices-of-proposed-amendments/npa-2013-15>

⁷ <http://easa.europa.eu/document-library/agency-decisions/ed-decision-2013016r>

⁸ <http://www.easa.europa.eu/document-library/comment-response-documents/crd-2013-15>

⁹ <http://easa.europa.eu/system/files/dfu/GC%20to%20ToR%20RMT.0287%20%2B%20%20RMT.0288%20%28MED.001%29%20Issue%202.pdf>



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

- (a) publication on the EASA 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 EASA 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 RMG was set up for this rulemaking task, EASA organised a technical meeting on 9 and 10 May 2016 with a number of representatives of the affected stakeholders. This allowed EASA 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 2016 the EASA Advisory Bodies were consulted on the draft Implementing Rules (IRs) and related AMC and GM proposed through RMT.0700. In parallel to this consultation, EASA 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 comment on the proposed regulatory proposal. The event was organised so as 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 merged with the text resulting from RMT.0287 was published by EASA on 15 August 2016 as Opinion No 09/2016 which was addressed to the European Commission. The related EU Regulation, Commission Implementing Regulation (EU) 2019/27, was adopted on 19 December 2018¹⁰.

The final text of this Decision with the AMC & GM has been developed by EASA based on the input of RG RMT.0287 (MED.001) and the focused consultation detailed above.

The major milestones of this rulemaking activity are presented on the title page.

¹⁰ Commission Implementing Regulation (EU) 2019/27 of 19 December 2018 amending Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council (OJ L 8, 10.1.2019, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1547130029105&uri=CELEX:32019R0027>).



2. In summary — why and what

2.1. Why we need to change the AMC & GM

During the transition from JAR FCL 3 to Part-MED requirements, the principle was to transpose the requirements from JAR-FCL 3 (Medical) into European law. Subsequently, RMT.0287 was developed to update and amend Part MED, to correct editorial errors, where required, and address the issues identified during the implementation and through the standardisation inspections, e.g. 'AME Obligations' and 'AME training'.

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 EASA Advisory Bodies, EASA believes that 4 of these recommendations, namely recommendations 2, 3, 4, and 5, require regulatory changes in the IRs and AMC and GM regarding aircrew medical certification.

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

- pilots' psychological/psychiatric evaluation during class 1 medical examination (recommendation 2);
- risk mitigation of aircrew misuse of psychoactive substances (recommendation 3);
- training, oversight and network of AMEs (recommendation 4 and partially recommendation 2); and
- EAMR (recommendation 5).

In order to put in place the needed changes mentioned above, not only the requirements needed to be updated, but also the associated AMC & GM needed to be aligned. Furthermore, the medical details prescribed in the AMC & GM to Part MED were updated in accordance with the latest medical developments.

2.2. What we want to achieve — objectives

The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation. This proposal will contribute to the achievement of the overall objectives by addressing the issues outlined above.

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

- (a) achieve the level of aviation safety laid down in the Basic Regulation and its implementing rules 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 implementation of the aircrew requirements by either introducing new or amending the existing AMC & GM in order to ensure that a high level of safety is constantly maintained and can be better achieved by:
 - (1) correcting editorial mistakes and ensuring consistency of wording;
 - (2) updating the medical provisions in the light of the new developments in the field of medicine (e.g. direct oral anticoagulants); and
 - (3) addressing consistency issues and loopholes identified through the implementation experience (e.g. enhancing the AMC regarding the obligations of AeMC, AME, GMP and OHMP and developing guidance material on the same topic to support the implementation).

2.3. How we want to achieve it — overview of the amended AMC & GM to Part-MED

2.3.1 Editorial corrections and changes for clarification and consistency

- (a) Editorial changes are made to improve the text of AMC & GM to Part-MED, to ensure consistency of wording and, where necessary, to clarify the meaning of the implementing rules as well as that of the AMC & GM. In some cases, paragraphs are rearranged to better align the AMC with the IRs. These amendments are purely editorial and do not imply a technical change to the AMC or GM.
- (b) The structure, wording and expressions used in Part-MED and in Commission Regulation (EU) 2015/340¹¹ and corresponding AMC and GM are harmonised, where appropriate.

2.3.2 Subpart A — General requirements

- (a) The new GM1 MED.A.020 'Decrease in medical fitness' is inserted to provide guidance for aircrew on the use of medication and alternative medicine.
- (b) AMC1 MED.A.025 'Obligations of the AeMC, AME, GMP and OHMP' is amended to ensure that AeMCs, AMEs, general medical practitioners (GMPs) and occupational health medical practitioners (OHMPs):
 - (1) give advice to aircrew regarding treatments and preventive measures regarding identified medical conditions or risk factors; and
 - (2) inform the aircrew regarding the implications of incomplete, inaccurate or false statements on their medical history.
- (c) The new GM1 MED.A.025 'Obligations of the AeMC, AME, GMP and OHMP' is added to provide guidance on conducting the medical examinations and assessments of flight crew.

¹¹ 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>).

2.3.3 Subpart B — Requirements for pilot medical certificates, Section 1 — General

AMC1 MED.B.001 'Limitations to medical certificates' is divided into two in order to facilitate understanding:

- (a) The new AMC1 MED.B.001 describes the process to be followed in order to apply and remove limitations.
- (b) AMC2 MED.B.001 defines the limitations and details the actions to be taken for each limitation.

2.3.4 Subpart B, Section 2 — Medical requirements for class 1 and class 2 medical certificates

2.3.4.1 Cardiovascular system

- (a) Class 1 and class 2
 - (1) AMC1 MED.B.010(d)(1) and AMC2 MED.B.010(d)(1) include improved criteria for fitness assessment of class 1 pilots with infra-renal aortic aneurysm.
 - (2) The new AMC1 MED.B.010(i)(1) enables a fit assessment to be considered in cases of a single episode of vasovagal syncope which can be explained and is compatible with flight safety.
 - (3) AMC1 MED.B.010(k)(1) specifies that applicants with angina pectoris should be assessed as unfit.
 - (4) AMC1 MED.B.010(f)(3), (g), and (l)(5)(i)(B) are amended to include as accepted anticoagulation therapy Direct Oral Anticoagulants.
 - (5) The new AMC1 MED.B.010(l)(3) is introduced to clarify the type of anticoagulation therapy in case of rhythm and conduction disturbances.
 - (6) The new AMC1 MED.B.010(l)(7)(ii) includes new criteria for fitness with operational multi-pilot limitation (OML) and for removal of the OML for applicants with complete right bundle branch block.
 - (7) AMC1 MED.B.010(l) and AMC2 MED.B.010(l) are amended to provide clarification regarding the fitness assessment of applicants with Brugada pattern on their ECG.
 - (8) The new GM1 MED.B.010 is added to provide guidance to the medical assessors, AeMCs and AMEs performing assessments of applicants with mitral valve disease.
 - (9) The new GM2 MED.B.010 is added to provide guidance to the medical assessors, AeMCs and AMEs performing assessments of applicants with ventricular pre-excitation.
- (b) Class 2
 - (1) The new AMC2 MED.B.010(e)(3)&(4) are added to provide further details on the assessment of applicants for class 2 medical certificate with aortic or mitral valve disease.
 - (2) AMC2 MED.B.010(d), (f), (g), (k)(4) and (l) are amended to refer to the newly introduced ORL.
 - (3) AMC2 MED.B.010(l) is amended to include additional criteria for the assessment of applicants for class 2 medical certificate with rhythm and conduction disturbances.

- (3) The new AMC2 MED.B.010 (m) is introduced to cover the issue of heart and heart/lung transplantation.
- (4) The new GM3 MED.B.010 is added to provide guidance to applicants for or holders of class 2 medical certificates as well as the examining AeMC or AME in regard to the 'near patient' anticoagulation self-assessment.

2.3.4.2 Respiratory system

Class 2

AMC2 MED.B.015 is amended to provide more details regarding the spirometric examination of applicants for class 2 medical certificate.

2.3.4.3 Digestive system

The new AMC1 MED.B.020(g) and AMC2 MED.B.020(g) are added to provide additional details for the fit assessment of applicants for class 1 and, respectively, class 2 medical certificates with liver disease.

2.3.4.4 Haematology

Class 1

- (a) The new AMC1 MED.B.030(e)(2) is added to provide further details regarding the fitness assessment of applicants with thrombocytopenia.
- (b) AMC1 MED.B.030(g) is amended to include anticoagulation therapy and criteria for assessment of fitness in case of thromboembolic disorders.

2.3.4.5 Infectious disease

- (a) AMC1 MED.B.040(b) and AMC2 MED.B.040(a) are amended to provide additional criteria for the assessment of applicants with tuberculosis.
- (b) AMC1 MED.B.040(d) and AMC2 MED.B.040(b) are reworded for clarity and additional criteria for assessment of applicants with HIV positive results are inserted.

2.3.4.6 Mental health

Class 1 and class 2

- (c) MED.B.055 'Psychiatry' and MED.B.060 'Psychology' are merged under the new MED.B.055 'Mental health'. The associated AMC and GM regarding the mental health assessment of applicant for class 1, class 2 and LAPL medical certificates are also merged for consistency with the IRs.
- (d) In addition, the new AMC and GM to MED.B.055 'Mental Health' provide details on the mental health assessment, including the comprehensive assessment during the initial class 1 examination, psychoactive substance screening and criteria for assessment of applicants with a clinical diagnosis or medical history of psychiatric conditions. 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 performed by the competent authority.



2.3.4.7 Neurology

- (a) Criteria for assessing applicants diagnosed with migraine and disorders of the nervous system due to vascular deficiencies are added to AMC1 MED.B.065 and respectively to AMC2 MED.B.065.
- (b) Criteria for assessing applicants diagnosed with spinal or peripheral nerve injury are added to AMC2 MED.B.065.

2.3.4.8 Visual system

Class 1 and class 2

- (a) AMC1 MED.B.070(a) takes into consideration the cumulative effect of more than one pathological condition.
- (b) AMC1 MED.B.070 (d) & (f) provide improved criteria for assessment of applicants with refractive error and impaired visual acuity.
- (c) AMC2 MED.B.070(c) & (d) provide improved criteria for assessment of applicants for class 2 medical certificates with impaired visual acuity and binocular function.
- (d) The new GM1 MED.B.070 is added to provide guidance regarding different reading charts to be used.
- (e) The new GM2 MED.B.070 is added to provide a better understanding of the term 'eye specialist'.

2.3.4.9 Otorhinolaryngology (ENT)

Class 1 and class 2

- (a) Criteria for the assessment of applicants with 'air passage restrictions', 'Eustachian tube(s) dysfunction' and 'sequelae of surgery of the internal or middle ear' are added to AMC1 MED.B.080.
- (b) The new GM1 MED.B.080 and GM2 MED.B.080 are added to provide guidance for AeMCs and AMEs regarding the pure tone audiogram.
- (1) The new AMC2 MED.B.080(a)(4) is added to provide criteria for assessment of applicants for class 2 medical certificates with profound deafness or major disorder of speech.

2.3.4.10 Oncology

AMC1 MED.B.090 and AMC2 MED.B.090 are amended to include criteria for assessment of applicants receiving chemotherapy or radiation treatment.

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

2.3.5.1 Cardiovascular system

- (a) Additional details are added to AMC2 MED.B.095 to further clarify the assessment of anticoagulation therapy for applicants for the LAPL medical certificate.
- (b) Additional criteria for the assessment of applicant with automatic implantable defibrillators are added.



2.3.5.2 Respiratory system

Additional criteria for pulmonary morphological or functional testing are added.

2.3.5.3 Digestive system

- (a) Additional criteria for the assessment of applicants with peptic ulceration are added.
- (b) Additional clarifications for the assessment of applicants following digestive tract and abdominal surgery are added.
- (c) Additional criteria for the assessment of applicants with liver disease are added.

2.3.5.4 Diabetes mellitus

New GM is added to provide additional guidance regarding the conversion of HbA1c units of measure.

2.3.5.5 Genitourinary system

New criteria for assessment of applicants following renal transplantation are added.

2.3.5.6 Infectious disease

New criteria are added for the assessment of applicants with chronic infections other than HIV.

2.3.5.7 Mental health

- (a) Additional clarifications are added regarding the assessment of applicants with mental or behavioural disorder following the use of psychoactive substances.
- (b) Additional clarifications are added regarding the assessment of applicants with schizophrenia, schizotypal and delusional disorders.
- (c) New criteria for the assessment of applicants with functional psychotic disorder are added.
- (d) New criteria for psychological evaluation or review are added.
- (e) New criteria for specialist evaluation are added.
- (f) New GM regarding the assessment of applicants with mood disorders is added.

2.3.5.8 Neurology

- (a) New criteria for the assessment of applicants with migraine are added.
- (b) New criteria for the assessment of applicants with disorders of the nervous system due to vascular deficiencies are added.

2.3.5.9 Otorhinolaryngology (ENT)

- (a) New criteria for the assessment of applicants requiring hearing aids are added.
- (b) New criteria for the assessment of applicant with profound deafness or major disorder of speech are added.

2.3.5.10 Oncology

New criteria for the assessment of applicants with an established history or clinical diagnosis of intracerebral malignant tumour is added.



2.3.6 Subpart D — Aero-medical examiners, general medical practitioners, occupational health medical practitioners

2.3.6.1 Section 1 — Aero-medical examiners (AMEs)

- (a) The new AMC1 MED.D.020 is added to provide compliance criteria regarding the duration, learning objectives and topics of the basic training course in aviation medicine.
- (b) The new GM1 MED.D.020 is added to further detail the curriculum of the basic training course in aviation medicine.
- (c) The new AMC2 MED.D.020 is added to provide compliance criteria regarding the duration, learning objectives and topics of the advance training course in aviation medicine.
- (d) The new GM2 MED.D.020 is added to further detail the curriculum of the advanced training course in aviation medicine.
- (e) The new GM3 MED.D.020 is added to further detail the training principles and the expected outcomes of the training courses in aviation medicine.
- (f) The new AMC1 MED.D.030 is added to provide compliance criteria regarding the refresher training in aviation medicine.
- (g) GM1 MED.D.030 is reworded to provide further details on the curriculum of the refresher training in aviation medicine, as well as the scientific events and aviation activity that can be credited as refresher training.
- (h) The new GM2 MED.D.030 is added to promote the establishment of AME peer support groups to provide both professional support and educational enhancement to the AMEs.

2.4. How we want to achieve it — overview of the amended AMC & GM to Part-ARA

2.4.1 European aero-medical repository (EAMR)

- (a) AMC1 ARA.MED.135(a), on the application form for a medical certificate, is amended to incorporate the 'notification of disclosure of personal data' for usage in the EAMR.
- (b) The new AMC1 ARA.MED.160(a), AMC1 ARA.MED.160(b), AMC2 ARA.MED.160(b), AMC3 ARA.MED.160(b), AMC1 ARA.MED.160(b)(1), AMC1 ARA.MED.160(b)(2) and AMC1 ARA.MED.160(b)(3) are added to provide the NAAs with guidance regarding the use of the EAMR.

2.4.2 Procedure for the issue, revalidation, renewal or change of an AME certificate

The new AMC2 ARA.MED.200 is added to ensure that revalidation, renewal and extension of privileges of the AME certificate are competency based.



3. Impact assessment (IA)

This Decision contributes to updating the aero-medical requirements performed via RMT.0287 by updating the corresponding AMC & GM to Part-MED and Part-ARA (subpart ARA.MED) corresponding to the draft implementing rule update published with the Opinion 09/2016. As the updates to the AMC & GM were already included in the impact assessment (IA) developed regarding the update of the medical provisions which was published with Opinion 09/2016, EASA considers there is no need to further develop a specific IA for this Decision



4. References

4.1. Related 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) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1485167951357&uri=CELEX:32011R1178>)

4.2. Affected decisions

- ED Decision 2011/015/R of 15 December 2011 on Acceptable Means of Compliance and Guidance Material to 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 ‘Acceptable Means of Compliance and Guidance Material to Part-MED (Annex IV)’ (<http://www.easa.europa.eu/document-library/agency-decisions/ed-decision-2011015r>)
- ED Decision 2013/016/R of 8 August 2013 amending Decision 2011/015/R of the Executive Director of the Agency of 15 December 2011 on Acceptable Means of Compliance and Guidance Material to Part-MED1 ‘Amendment of the AMC for pilot medical certification (LAPL2)’ (<https://www.easa.europa.eu/document-library/agency-decisions/ed-decision-2013016r>)
- [ED Decision 2012/006/R](#) of 19 April 2012 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 of the European Parliament and of the Council ‘Acceptable Means of Compliance and Guidance Material to Part-ARA’ (<http://www.easa.europa.eu/document-library/agency-decisions/ed-decision-2012006r>)

4.3. Other reference documents

- 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 (https://ec.europa.eu/transport/modes/air/news/2015-10-20-easa-action-plan_en)
- 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_elyextendtnews/BEA2015-0125.en-LR_08.pdf)

