



Terms of reference

for a rulemaking task

Aircrew medical fitness

Implementation of the recommendations made by the EASA-led *Germanwings Task Force* on the accident of the Germanwings Flight 9525

RMT.0700 — ISSUE 1 — 20.4.2016

Applicability		Process map	
Affected regulations and decisions:	Regulation (EU) No 1178/2011; Regulation (EU) No 965/2012; ED Decision 2011/015/R; ED Decision 2014/015/R; ED Decision 2014/017/R; ED Decision 2011/025/R	Procedure:	Direct publication ¹
Affected stakeholders:	Commercial air transport (CAT) operators; national aviation authorities (NAAs); aircrew; aero-medical examiners (AMEs); aero-medical centres	Concept paper:	Yes
Driver:	Safety	Rulemaking group:	No
Reference:	FRAN-2016-011 (BEA); FRAN-2016-014 (BEA); FRAN-2016-016 (BEA); FRAN-2016-021 (BEA)	RIA type:	Light
		Publication date of the NPA:	N/A
		Technical consultation during drafting:	Yes
		Focused consultation:	Yes (conference)
		Advisory bodies' consultation:	Yes
		Publication date of the opinion:	2016/Q4
		Publication date of the decision:	2016/Q4

¹ In accordance with Article 15 of the EASA Management Board Decision No 18-2015 of 15 December 2015.



1. Issue and reasoning for regulatory change

The tragic accident of the Germanwings Flight 9525 reminded the international aviation community that the medical and psychological conditions of flight crews, if not detected, can lead to a catastrophic outcome. Shortly after the accident, the European Commissioner for Transport, Ms Violeta BULC, requested the dedicated Germanwings Task Force, which was led by the European Aviation Safety Agency (hereinafter referred to as the 'Agency'), to examine the preliminary findings of the safety investigation led by the French Bureau d'Enquêtes et d'Analyses and make recommendations in order to prevent such a disaster from happening again and to ensure that the overall system is improved in a proactive manner.

6 recommendations (see Annex II to these Terms of Reference (ToR)) were made by the Germanwings Task Force in July 2015. Following the consultation of the detailed concept papers with the Agency's advisory bodies from 20 January to 19 February 2016, the Agency believes that 4 of these recommendations, namely recommendations 2, 3, 4 and 6, require regulatory changes in the air operations and aircrew domains.

The issues for which regulatory changes are proposed by RMT.0700 are the following:

- pilots' psychological/psychiatric evaluation during Class 1 medical examination (recommendation 2);
- pilots' psychological evaluation as part of the training or before entering service (recommendation 2);
- risk mitigation of aircrew misuse of psychoactive substances (recommendation 3);
- oversight and network of AMEs (recommendation 4 and partially recommendation 2);
- implementation of aircrew support and reporting systems (recommendation 6).

2. Objectives

The objectives of the European Union in the field of civil aviation are defined in Article 2 of Regulation (EC) No 216/2008². This rulemaking task (RMT) will contribute to the achievement of these objectives by addressing the issues outlined above.

The specific objectives of this RMT are, therefore:

- (a) to achieve the level of aviation safety laid down in Regulation (EC) No 216/2008 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 reasonable measures are taken so that flight crew members are psychologically suitable for CAT operations, and thus being able to exercise safely the privileges of their licences;

² 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).



- (3) 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;
- (4) 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) to contribute to the continuous improvement of the aircrew and air operations rules to ensure that a high level of safety is constantly maintained and can be better achieved;
- (c) to develop mitigation measures for aviation safety risks arising from adverse social consequences or conditions such as loss of pilot licences;
- (d) to ensure protection of personal data.

3. Activities

During the development of the draft rules, the following activities shall be considered to address the issues mentioned in Section 1 and the objectives stated in Section 2:

Issue analysis	Objective	Activities
1. Pilots' psychological/ psychiatric evaluation during Class 1 medical examination (recommendation 2) 2. Pilots' psychological evaluation as part of the training or before entering service (recommendation 2)	(a)(1) To achieve the level of aviation safety laid down in Regulation (EC) No 216/2008 by ensuring pilot psychiatric and psychological aero-medical fitness so that their medical condition is less likely to interfere with the safe exercise of the privileges of their licences. (a)(2) To achieve the level of aviation safety laid down in Regulation (EC) No 216/2008 by ensuring that reasonable measures are taken so that flight crew members are psychologically suitable for CAT operations. (b) To contribute to the continuous improvement of the aircrew and air operations rules to ensure that a high level of safety is constantly maintained and can be better achieved.	Review the latest literature and evidence on the subject, including consultation with stakeholders and medical experts; review the structure of existing AMC/GM and assess if new requirements are needed to address the safety issue.
3. Risk mitigation of aircrew misuse of psychoactive substances (recommendation 3)	(a)(3) to achieve the level of aviation safety laid down in Regulation (EC) No 216/2008 by 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. (b) To contribute to the continuous improvement of the aircrew and air operations rules to ensure that a high level of safety is constantly maintained and can be better achieved.	Review existing literature and evidence on the subject, including consultation with stakeholders and medical experts; review the structure of existing AMC/GM and assess if new requirements are needed to address the safety issue. Review and assess peer support and reporting systems and their ability to adequately mitigate the risk of misuse of psychoactive substances.



4. Oversight and network of AMEs (recommendation 4 and partially recommendation 2)	<p>(a)(4) To achieve the level of aviation safety laid down in Regulation (EC) No 216/2008 by enhancing aero-medical examination so that the risks of undetected pilot medical conditions are reduced through improved training, practice, oversight and fostering networks of AMEs.</p> <p>(b) To contribute to the continuous improvement of the aircrew and air operations rules to ensure that a high level of safety is constantly maintained and can be better achieved.</p>	Review current systems in place; review the structure of existing AMC/GM.
5. Implementation of aircrew support and reporting systems (recommendation 6)	<p>(a)(1), (2) & (3) To achieve the level of aviation safety laid down in Regulation (EC) No 216/2008 by mitigating the risks related to psychological/psychiatric medical conditions including disorders associated to the misuse of psychoactive substances by aircrews.</p> <p>(b) To contribute to the continuous improvement of the aircrew and air operations rules to ensure that a high level of safety is constantly maintained and can be better achieved.</p> <p>(c) To develop mitigation measures for aviation safety risks arising from adverse social consequences or conditions such as loss of pilot licences.</p> <p>(d) To ensure protection of personal data.</p>	<p>Review existing literature and evidence on the subject, as well as current systems in place, including consultation with stakeholders.</p> <p>Review existing requirements and assess if new requirements are needed to address the safety issue.</p>



More specifically, the following activities are planned as part of this RMT:

- For the pilots' psychological evaluation by operators (recommendation 2), to assess the need to issue new AMC/GM in order to ensure that flight crews undergo a psychological evaluation before starting, or as part of, the training, or before entering airline service. The AMC/GM would provide further details on the content and quality of the evaluation, who is allowed to conduct such an evaluation, and how operators can implement this evaluation.
- For the pilots' psychological/psychiatric evaluation during Class 1 medical examination, to assess the need to issue new AMC/GM in order to ensure that flight crews undergo a psychiatric/psychological evaluation as part of the Class 1 medical examination. The AMC/GM would provide further details on how the psychiatric/psychological evaluation should be performed and by whom.
- For the prevention of problematic use of psychoactive substances (recommendation 3), to assess the need to issue new AMC/GM on how to mitigate the risks related to the misuse of psychoactive substances with reference to existing guidance material, e.g. ICAO Doc 9654 'Manual on Prevention of Problematic Use of Substances in the Aviation Workplace', First Edition — 1995, as well as with reference to experience gained with peer support and reporting systems and their ability to adequately mitigate, in a proportionate manner, the related safety risk.

As regards the specific issue of random testing, this RMT will look into the implementation of the recommendations made by the EASA Germanwings Task Force by conducting an impact assessment to decide whether random testing should be made mandatory or whether other means are needed, such as AMC/GM or safety promotion material.

- For the drug and alcohol testing during initial Class 1 medical examination (recommendation 3), to assess the need to issue new AMC/GM on how to perform the drug and alcohol testing on aircrew and by whom it should be performed. The AMC/GM will refer to existing guidance material, e.g. ICAO Doc 9654 'Manual on Prevention of Problematic Use of Substances in the Aviation Workplace', First Edition — 1995.
- For the oversight of AMEs (recommendation 4), to assess the need to issue new AMC/GM on how to develop the oversight programme as well as how to revalidate/renew an AME certificate.
- For the aircrew support and reporting systems (recommendation 6), to assess if a new implementing rule (IR) to Regulation (EU) No 965/2012³ (the Air OPS regulation) is necessary in order to ensure that all flight and cabin crew members have access to a support programme. Such a support programme must enable self-declaration in case of a decrease in medical fitness and, if appropriate, allow the crew member to receive temporary relief from flight and cabin crew duties and be referred to professional advice. In order to effectively and efficiently foster self-declaration, the supporting system should ensure that risks related to fear of loss of licence are properly mitigated. Apart from the proposed new IR, it will be considered to provide operators and NAAs with AMC and GM on how to start implementing the recommendations in a proactive

³ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).



manner, including best practices. The AMC and GM will state the enablers of an effective support programme, such as:

- protection of personal data;
- essential trust between management and crew being the foundation of a successful support programme;
- an effective safety culture; and
- support in case of loss of licence.

4. Deliverables

The following rulemaking deliverables are envisaged:

- as regards pilots' psychological evaluation by operators: a decision with draft AMC/GM to Regulation (EU) No 965/2012;
- as regards the prevention of misuse of psychoactive substances: an opinion and a decision with draft new IRs and AMC/GM to Regulation (EU) No 965/2012;
- as regards pilots' psychological/psychiatric evaluation during initial Class 1 medical examination: an opinion and a decision with new draft IRs and AMC/GM to Annex IV (Part-MED) to Regulation (EU) No 1178/2011;
- as regards drug and alcohol testing during initial Class 1 medical examination: an opinion and a decision with new draft IRs and AMC/GM to Annex IV (Part-MED) to Regulation (EU) No 1178/2011;
- as regards the oversight of AMEs: a decision with draft AMC/GM to Annex VI (Part-ARA) to Regulation (EU) No 1178/2011;
- as regards aircrew support and reporting systems: an opinion and a decision with a draft new IR and AMC/GM to Regulation (EU) No 965/2012.

5. Interface issues

The deliverables regarding drug and alcohol testing and pilots' psychological/psychiatric evaluation during Class 1 medical examination will enhance the existing AMC/GM to Annex IV (Part-MED) to Regulation (EU) No 1178/2011. Both Part-MED and the corresponding AMC/GM are currently being updated by RMT.0287 and RMT.0288, which are at their final stages pending the publication of the related opinion. The deliverables expected by RMT.0700 and the ones to be produced by RMT.0287 & RMT.0288 will complement each other towards creating a safer aviation environment. The gaps regarding the training of AMEs were already identified and are addressed by RMT.0287 & RMT.0288, which include also updated AMC/GM regarding initial and recurrent training of AMEs.

6. Rulemaking process and consultation phases

ToR RMT.0700 is part of a series of consultation phases that EASA has planned for the implementation of the EASA Germanwings Task Force recommendations. The first consultation phase was the Aircrew Medical Fitness workshop, which was organised by EASA on 7 and 8 December 2015 in Cologne. The outcome of the workshop was reflected in the concept papers, which were consulted with RAG, TAGs,



SSCC and sub-SSCC for 4 weeks before drafting ToR RMT.0700. Furthermore, before the workshop, preliminary versions of the concept papers were published on the EASA website for a more focused discussion during the event.

If deemed necessary to seek additional technical expertise, during the drafting of the regulatory text a technical meeting will be organised in May 2016 with the most affected stakeholders.

The draft rules will be consulted for 1 month with the advisory bodies (refer to Article 15 'Special rulemaking procedure: direct publication' of [MB Decision No 18-2015](#)). Additionally, a conference will be organised to discuss the proposed draft rules with the affected stakeholders. The conference will be advertised on the EASA website and registration will be open.

If the consultation with the advisory bodies and the conference result in major changes to the proposed draft rules, an additional 3-week consultation of the proposed draft rule with the advisory bodies will take place before its publication.



7. Annex I: Reference documents

7.1. 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)
- Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1)

7.2. Affected decisions

- Decision N° 2011/015/R of the Executive Director of the European Aviation Safety Agency 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)’
- Decision 2014/015/R of the Executive Director of the European Aviation Safety Agency of 24 April 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-CAT of Regulation (EU) No 965/2012 and repealing Decision 2012/018/R of the Executive Director of the Agency of 24 October 2012 — ‘AMC and GM to Part-CAT — Issue 2’
- Decision 2014/017/R of the Executive Director of the European Aviation Safety Agency of 24 April 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-ORO of Regulation (EU) No 965/2012 and repealing Decision 2012/017/R of the Executive Director of the Agency of 24 October 2012 — ‘AMC and GM to Part-ORO — Issue 2’
- Decision 2014/025/R of the Executive Director of the European Aviation Safety Agency of 28 July 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-ARO of Regulation (EU) No 965/2012 and repealing Decision 2014/014/R of the Executive Director of the Agency of 24 April 2014 — ‘AMC and GM to Part-ARO — Issue 3’

7.3. 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 (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_elyextendtnews/BEA2015-0125.en-LR_08.pdf)
- IATA ‘Guidance Material and Best Practices for Pilot Aptitude Testing’, Effective March 2012, 2nd Edition (<https://www.iata.org/publications/Documents/pilot-aptitude-testing-guide.pdf>)
- ICAO Doc 9654 AN/945 ‘Manual on Prevention of Problematic Use of Substances in the Aviation Workplace’, First Edition — 1995



- ICAO Doc 8984 AN/895 'Manual of Civil Aviation Medicine', Third Edition — 2012; Part I 'LICENSING PRACTICES', Chapter 2 'MEDICAL REQUIREMENTS'

8. Annex II: EASA Germanwings Task Force recommendations⁴

- '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.'

⁴ '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).

