European Union Aviation Safety Agency

Notice of Proposed Amendment 2025-105 (A)

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

Medical regulation — combination of Part-MED (Annex IV) to Commission Regulation (EU) No 1178/2011 and Part ATCO.MED (Annex IX) to Commission Regulation (EU) 2015/340

RMT.0707 – SUBTASK 2

WHAT THIS NPA IS ABOUT

This Notice of Proposed Amendment (NPA) proposes merging the separate aero-medical certification requirements for aircrew and air traffic controllers (ATCOs) into a single, simplified and harmonised regulatory framework. This unified approach aims to eliminate duplication, resolve inconsistencies, and significantly simplify the structure and implementation of the requirements. By streamlining the existing processes, the proposal is expected to reduce the administrative burden on the competent authorities, aero-medical centres and aero-medical examiners, to promote clarity, and to enhance the efficiency of oversight and certification activities. It is also expected to promote fair and proportionate treatment across all certificate holders, to ensure better use of regulatory and oversight resources, and to enable easier updates aligned with advances in medical science. Additionally, the rulemaking task proposes some small updates to harmonise the medical requirements and ensure a level playing field, as well as reduce safety risks recently identified.

Ultimately, the task fosters simplification, clarity, efficiency, and improved safety oversight in the aviation medical certification system.

REGULATION(S) INTENDED TO BE AMENDED/ISSUED	**ED DECISION(S) INTENDED TO BE AMENDED**
— Regulation (EU) No 1178/2011 (Aircrew) — Regulation (EU) 2015/340 (ATCO)	ED Decisions that issue the AMC & GM to support the application of those Regulations: — ED Decision 2012/006/R — AMC & GM to Part-ARA — ED Decision 2012/007/R — AMC & GM to Part-ORA — ED Decision 2019/002/R — AMC & GM to Part-MED — ED Decision 2015/010/R — AMC & GM to Commission Regulation (EU) 2015/340

AFFECTED STAKEHOLDERS
NCAs, aircrew, ATCOs, AeMCs, AMEs

WORKING METHODS

Development	**Impact assessment(s)**	**Consultation**
By EASA	Light	Focused - affected parties

RELATED DOCUMENTS / INFORMATION

— PIA Medical Regulation issue 1/2017
— ToR RMT.0707, issued on 4.4.2024

PLANNING MILESTONES: Refer to the latest edition of the EPAS *Volume II*.

Contents

1. About this NPA

1.1. How this regulatory material was developed

The European Union Aviation Safety Agency (EASA) identified an issue (as described in Chapter 2), and after having assessed the impacts of the possible intervention actions using a preliminary impact assessment process, which was consulted with the EASA advisory bodies in 2017, it has identified rulemaking as the necessary intervention action.

Rulemaking task (RMT).0707 was firstly introduced in the European Plan for Aviation Safety (EPAS) 2018-2022 and then deprioritised in EPAS 2019-2023. The topic was brought back on the rulemaking agenda with EPAS 2021-2025 where it was merged with the standing task RMT.0424 on *Regular update of medical certification requirements for aircrew and air traffic controllers, and the related oversight*. In 2023, EASA consulted the Medical Experts' Group (MEG), the advisory body including the medical representatives of all competent authorities and of the industry and concluded that merging this task with RMT.0424 is not appropriate as RMT.0424 is focused on the update of the medical-related parts of Regulation (EU) 1178/2011[1] (the Aircrew Regulation). Consequently, the MEG recommended that RMT.0707 becomes once again a stand-alone task and is included in the 2025 edition of Volume II of the EPAS[2].

EASA developed the regulatory material in question in line with Regulation (EU) 2018/1139[3] (the Basic Regulation) and the Rulemaking Procedure[4], as well as in accordance with the objectives and working methods described in the Terms of Reference (ToR) for this RMT[5].

When developing the regulatory material, EASA received the input from the MEG members as regards additional harmonisation to be included in the proposal, further to the merging itself during the rulemaking update presented by EASA as part of the regular MEG meetings.

1.2. How to comment on this NPA

The draft regulatory material is hereby submitted for consultation with the affected parties as represented in the MEG, the Aircrew TeB, ATM/ANS TeB, and relevant stakeholders of the SAB.

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1 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://data.europa.eu/eli/reg/2011/1178/oj).

2 European Plan for Aviation Safety (EPAS) 2025 - 14th edition | EASA

3 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) (http://data.europa.eu/eli/reg/2018/1139/oj).

4 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 01-2022 of 2 May 2022 on the procedure to be applied by EASA for the issuing of opinions, certification specifications and other detailed specifications, acceptable means of compliance and guidance material ('Rulemaking Procedure'), and repealing Management Board Decision No 18-2015 (EASA MB Decision No 01-2022 on the Rulemaking Procedure, repealing MB Decision 18-2015 (by written procedure) | EASA (europa.eu)).

5 ToR RMT.0707 - Medical regulation — combination of Part-MED (Annex IV) of Commission Regulation (EU) No 1178/2011 and Part ATCO.MED (Annex IV) of Commission Regulation (EU) 2015/340 | EASA

NPA 2025-105 is divided into five parts (A) – (E). The present NPA 2025-105 (A) includes the background information pertaining to the regulatory proposal. NPAs 2025-105 (B), (C), (D) and (E) include the proposed new provisions as well as the proposed amendments to the Aircrew Regulation and to Regulation (EU) 2015/340[6] (the ATCO Regulation).

Please submit your comments via email to **medical@easa.europa.eu**.

The deadline for the submission of comments is **2 February 2026**.

1.3. The next steps

Following the consultation of the draft regulatory material, EASA will review all the comments received and will duly consider them in the subsequent phases of this rulemaking activity.

Considering the above, EASA may issue an opinion proposing a new implementing regulation detailing the requirements for aero-medical certification of aircrew and air traffic controllers (ATCOs) as well as amendments to the Aircrew and ATCO Regulations. The opinion will be submitted to the European Commission which shall consider its content and decide whether to adopt the new implementing regulation and issue amendments to those Regulations.

Following the adoption of the new implementing regulation and the amendment of the above-mentioned Regulations, EASA will issue decisions issuing the acceptable means of compliance (AMC) and guidance material (GM) to support the implementation of the above-mentioned new implementing regulation and updating the relevant AMC and GM associated with the amended Regulations mentioned above.

When issuing the opinion and decisions, EASA will also provide feedback to the commentators and information to the public on who engaged in the process and/or provided comments during the consultation of the draft regulatory material, which comments were received, how such engagement and/or consultation was used in rulemaking, and how the comments were considered.

[6] Commission Implementing Regulation (EU) No 923/2012 of 26 September 2012 laying down the common rules of the air and operational provisions regarding services and procedures in air navigation and amending Implementing Regulation (EU) No 1035/2011 and Regulations (EC) No 1265/2007, (EC) No 1794/2006, (EC) No 730/2006, (EC) No 1033/2006 and (EU) No 255/2010 (OJ L 281, 13.10.2012, p. 1) (http://data.europa.eu/eli/reg_impl/2012/923/oj).

2. In summary — why and what

2.1. Why we need to act

Maintaining two separate but very similar medical certification regulations for aircrew and ATCOs has led to duplicated processes, wasted resources, and confusion among medical examiners — ultimately straining oversight capacity and potentially impacting aviation safety as explained in more detail in the following section.

2.1.1. Description of the issue

Currently, medical requirements for aero-medical certification of aircrew members and ATCOs are very similar apart from a few domain-specific requirements. However, they are governed by two different regulations, namely the Aircrew Regulation and the ATCO Regulation. Although these regulations were developed with consistent principles, their parallel structure has resulted in a number of issues and has created significant and unnecessary complexity for stakeholders, competent authorities, and the Agency.

Firstly, the dual regulatory framework leads to duplication of administrative procedures and resources. Aero-medical examiners (AMEs) and aero-medical centres (AeMCs) are required to hold and maintain separate certificates under each regulation, despite operating under almost identical requirements in terms of facilities, training, and medical standards. This results in increased administrative burden, duplicate oversight processes, and additional certification costs without contributing to any measurable increase in safety. In recent years a number of AMEs and AeMCs have surrendered their certificates — triggered mostly by the increasing administrative burden.

Secondly, the evolution of the medical requirements across the two regulations has not remained synchronised. In many cases updates made to one Regulation are not automatically reflected in the other. For instance, amendments introduced by Regulation (EU) 2019/27[7] significantly updated the medical requirements for aircrew under Part-MED. However, no corresponding updates were made to Part-ATCO.MED, resulting in divergences in content and implementation.

Thirdly, the continued existence of two separate but similar regulations generates a perception of unequal treatment among licence holders. Representatives of ATCOs have raised concerns about the differences in medical requirements, which are seen as unjustified and discriminatory, particularly given that the safety-critical nature of their roles is similar to that of aircrew[8].

Furthermore, the dual regulatory system imposes a significant workload on competent authorities and the Agency. Oversight, certification, and standardisation activities must be carried out for two sets of requirements, often by the same personnel, leading to inefficiencies and suboptimal allocation of resources. This may affect the ability of authorities to prioritise safety-relevant tasks effectively. In

[7] 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) (http://data.europa.eu/eli/reg_impl/2019/27/oj).

[8] Feedback received from ATCO representatives in 2016.

some cases, the Agency standardisation teams are stretched to the point of working overtime, simply to cover both frameworks, diverting attention from other vital safety oversight tasks.

In short, the current dual-regulation system leads to inefficiency, duplication, confusion, and even perceived unfairness — without offering any tangible safety benefits.

2.1.2. Who is affected by the issue

The merging of these requirements, related to the aero-medical certification of ATCOs and aircrew, is expected to impact the Member States and national competent authorities, aircrew, ATCOs, AeMCs and AMEs.

2.1.3. How the issue could develop

Over time, this lack of regulatory harmonisation complicates the work of AMEs and AeMCs who must operate under two different, and increasingly inconsistent, regulatory frameworks as well as that of the competent authorities that have to duplicate certification and oversight processes. In the context of limited resources having duplicated processes may leave gaps in other safety-relevant areas. Furthermore, the complicated and duplicated AME/AeMC certification and oversight may lead to AMEs and AeMCs leaving the system and discourage new AMEs and AeMCs from entering the system.

Additionally, maintaining two separate sets of very similar requirements is expected to also hinder the timely and consistent incorporation of developments in medical science and the resolution of operational gaps identified during implementation and standardisation activities.

2.1.4. Conclusion on the need for rulemaking

EASA concluded, as explained further in Chapter 3 below, that an intervention was necessary and that non-regulatory actions cannot effectively address the issue. Therefore, the merging of the medical requirements and related authority and organisational requirements into a separate implementing regulation and the corresponding AMC and GM material is needed.

2.2. What we want to achieve — objectives

The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation. The regulatory material presented here is expected to contribute to achieving these overall objectives by addressing the issue described in Section 2.1.

More specifically, with the regulatory material presented here, EASA intends to harmonise, clarify and simplify the regulatory framework related to the aero-medical certification of aircrew and ATCOs. Furthermore, the proposed regulatory material aims to reduce duplication of certification and oversight processes and allow for a more efficient use of resources. Finally, the proposed regulatory material aims to resolve inconsistencies and foster easier regulatory maintenance of these requirements and associated AMC and GM.

In addition, together with the merging of the requirements, there will be slight updates to harmonise the ATCO and aircrew requirements as well as some updates to address a small number of safety issues that have been identified during accident investigations or reported by European stakeholders. Moreover, in several meetings of the Medical Experts' Group, Member States expressed concerns regarding the possibility for applicants with suspended or revoked medical certificates, or those under

investigation pursuant to point ARA.GEN.355(b) of Annex VI (Part-ARA) to Commission Regulation (EU) No 1178/2011, to change their competent authority. Member States underlined that permitting such applicants—who do not hold a valid medical certificate—to apply for a change of competent authority is likely to increase the administrative burden on competent authorities and may encourage 'medical certificate shopping', thereby potentially giving rise to hazardous situations.

2.3. How we want to achieve it — overview of the proposed amendments

In order to achieve the objectives mentioned in Section 2.2, EASA proposes to merge the requirements related to the aero-medical certification of aircrew members and ATCOs, including the administrative requirements related to training, certification and oversight of AMEs and AeMCs.

EASA assessed by means of the PIA mentioned above that an intervention was required. To this end, it has proposed the adoption of a new stand-alone regulation consolidating the provisions governing the aero-medical certification of aircrew and ATCOs. Concurrently, it is proposed to amend the Aircrew Regulation and the ATCO Regulation for the purpose of repealing the aforementioned provisions therein. Furthermore, the development of a new Executive Director's Decision is deemed appropriate to consolidate the applicable AMC and GM. These measures are considered essential to adequately address the issues identified in Section 2.1, as the objectives set out in Section 2.2 cannot be effectively attained through non-regulatory means.

Among the updates mentioned in Section 2.2 above, the most important are:

— Extension of the medical certificate validity period until the end of the month of the expiry date, similar to the ratings.

— Update of the requirement to hold a valid medical certificate before commencing flight instruction rather than when flying solo to mitigate risks identified as a result of a recent accident investigation.

— Addition of a requirement for drug and alcohol testing at all flight crew initial medical examinations to mitigate risks identified as a result of a recent accident investigation and to deter the initial applicants from using alcohol or other psychoactive substances when performing activities related to flight safety.

— Update of the psychiatric and psychological requirements for ATCOs in line with the more preventive and proactive approach of the mental health requirements for aircrew that were updated in 2019 as part of RMT.0287 *Regular update of Part-MED, of Part-ARA Subpart ARA.AeMC and ARA.MED, and of Part-ORA Subpart ORA.AeMC, as well as of the related AMC and GM*.

— Update of the AMC and GM pertaining to colour vision for aircrew to remove the use of lantern tests as a secondary testing option in line with the recommendations of the EASA-commissioned literature review study regarding the colour vision requirements for aircrew.

— Update of the AME training requirements to incorporate both ATCO and aircrew working environment and specific risks in the advanced training.

— Update of the requirements related to the application for the change of competent authority to clarify that applicants whose medical certificates have been suspended or revoked, as well as those who are subject to an ongoing investigation pursuant to point ARA.GEN.355(b) of

Annex VI (Part-ARA) to Commission Regulation (EU) No 1178/2011, may not request such a change until the suspension has been lifted, a valid medical certificate has been reissued, or the investigation has been concluded without resulting in the suspension or revocation of the medical certificate, as appropriate. Considering that the current rulemaking task also proposes amendments to point FCL.015, a corresponding clarification has been introduced in point FCL.015 to ensure consistency. This amendment specifies that applicants seeking a change of competent authority whose licences are suspended or revoked, or who are under investigation pursuant to point ARA.GEN.355(b) of Annex VI (Part-ARA) to Commission Regulation (EU) No 1178/2011, are likewise not eligible to apply until those conditions have been resolved.

EASA has not identified a need for a transition period before the regulatory material could be fully applied, due to the fact that the new regulation represents the merging of the existing requirements related to aero-medical certification of aircrew members and ATCOs and slight changes to address inconsistencies which do not require additional time for implementation. Nevertheless, to support the adjustment of the procedures, the new provisions will become applicable six months after the date of entry into force.

The legal basis for amending Regulation (EU) No 965/2012 is Articles 23, 27, 50, 53 and 62 (14) and (15) of the Basic Regulation.

2.4. Stakeholders' views

The feedback received from the stakeholders during the PIA consultation as well as during the EPAS consultation was in its vast majority supportive to the idea of merging the two sets of similar requirements and harmonising these requirements as much as possible to ensure a level playing field as well as efficiency and proportionality. Some of the stakeholders highlighted the need to maintain the medical requirements proportionate to the tasks to be performed by each category of aviation personnel.

3. Expected benefits and drawbacks of the proposed regulatory material

EASA assessed the impacts of the proposed regulatory material to ensure that the regulatory material delivers its full benefits with minimum drawbacks. Considering that the task is intended to simplify and clarify the legal framework, to reduce the administrative burden caused by the duplication of administrative processes and address certain inconsistences, and that there will not be any new requirements introduced, the change is expected to create a very limited, one-off, workload increase among the national competent authorities to adjust the legal references in their documentation as well as, to occasionally adjust some of their relevant procedures and templates. In this context, the Agency decided not to develop a further impact assessment for this NPA. Nevertheless, a more detailed impact assessment on specific simplification elements will be added to the Opinion.

The proposed regulatory material has been developed in view of the better regulation principles and, particularly, the rule simplification principles.

Specifically, the proposed regulatory material is expected to:

— alleviate existing administrative burden by reducing the duplication of administrative and regulatory processes;

— limit the regulatory burden created by implementation of the merged requirements to the minimum due to the fact that the vast majority of the requirements are already in force except for the areas where small changes have been made in the interest of harmonisation and simplification;

— ensure a level playing field by having the same level of updates for aircrew members and ATCOs in EASA MSs. This will ensure equal opportunities for the affected stakeholders;

— allow savings for the AMEs and AeMCs as they will pay only one certification fee instead of two. Additionally, there would be a decrease in the AMEs' and AeMCs' workload by having one certification process instead of two separate ones (circa 10 % decrease per year). The action would improve the efficiency of daily work of AMEs as they would not be required to switch between the rules depending on the category of aviation personnel examined;

— decrease the overall workload of the competent authorities which will perform only one certification and oversight programme for AMEs that work with both requirements instead of duplicating the entire process (circa 20 % decrease per year). It should be noted that this benefit may differ for each competent authority, depending on their organisational structure and procedures;

— optimise the EASA standardisation teams' work time and process as they will only need to verify compliance with one set of requirements instead of two. This would result in efficiency gains as regards the time needed for a standardisation inspection as within only five days they would be able to verify compliance with the new combined requirements. Currently, five days are needed for verification of compliance with the aircrew requirements and another five days for verification of compliance with the ATCO requirements;

— increase of safety level by reducing the risk of mistakes and misinterpretation of the requirements by the AMEs that work with both Part-MED and Part ATCO.MED;

— ensure consistent interpretation and implementation of the requirements by the competent authorities;

— simplify the medical limitations structure by merging all the visual limitations requiring corrective lenses into one single limitation.

How this proposal contributes to rule simplification

Specifically, the proposed regulatory material is expected to contribute to regulatory simplification by:

— alleviating existing administrative burden and reducing the duplication of administrative and regulatory processes in relation to the training, certification and oversight of AMEs and AeMCs as currently required by the applicable provisions of Regulation (EU) No 1178/2011 and associated AMC & GM and those of Regulation (EU) 2015/340 and associated AMC & GM;

— decreasing the overall workload of the competent authorities which will perform only one certification and oversight programme for AMEs that work with both requirements instead of duplicating the entire process (circa 20 % decrease per year);

— reducing certification-related costs and workload for the AMEs and AeMCs by having one certification process instead of two separate ones (circa 10 % decrease per year);

— improving the efficiency of AMEs' work as they would not be required to switch between different Regulations depending on the category of aviation personnel examined;

— reducing the workload of the Agency in both the standardisation and oversight domains, as well as the maintenance of the regulatory framework;

— simplifying the implementation of certain medical requirements such as the medical limitations structure by merging some limitations and clarifying others.

Stakeholders are invited to provide their feedback on these elements, specifically on how they perceive the reduction of administrative burden that the proposals of this NPA will produce. This feedback will be used in the development of the impact assessment mentioned above.

Conclusion

The improvement level in terms of having equal opportunities for the affected stakeholders is expected to be significant. Additionally, the merging and updates proposed are expected to also have a slight positive impact on safety.

4. Proposed regulatory material

Please refer to:

— NPA 2025-105 (B) *Proposed Medical Regulation and associated AMC & GM*

— NPA 2025-105 (C) *Proposed annexes to the Medical Regulation and associated AMC & GM*

— NPA 2025-105 (D) *Proposed amendments to Regulation (EU) No 1178/2011 and associated AMC & GM*

— NPA 2025-105 (E) *Proposed amendments to Regulation (EU) 2015/340 and associated AMC & GM*

5. Monitoring and evaluation

EASA plans to monitor during its standardisation activities whether the objectives described in Section 2.2 will be achieved with the proposed regulatory material. As the changes to the actual requirements are limited, EASA does not see a need to put additional monitoring tasks in place.

In addition, EASA plans to evaluate the resulting requirements as part of the regular-update task RMT.0424 to ensure that they are fit for purpose and up to date with the developments of medical science.

6. Actions to support implementation

In order to support affected stakeholders in the implementation of the new regulatory material, EASA plans to organise a webinar to present the updated provisions.

7. References

Not applicable

Appendix 1 — Quality of the NPA

To continuously improve the quality of its documents, EASA welcomes your feedback on the quality of this document with regard to the following aspects:

Please provide your feedback on the quality of this document as part of the other comments you have on this NPA. We invite you to also provide a brief justification, especially when you disagree or strongly disagree, so that we consider this for improvement. Your comments will be considered for internal quality assurance and management purposes only and will not be published (e.g. as part of the CRD).

1. The regulatory proposal is of technically good/high quality

Please choose one of the options

Fully agree / Agree / Neutral / Disagree / Strongly disagree

2. The text is clear, readable and understandable

Please choose one of the options

Fully agree / Agree / Neutral / Disagree / Strongly disagree

3. The regulatory proposal is well substantiated

Please choose one of the options

Fully agree / Agree / Neutral / Disagree / Strongly disagree

4. The regulatory proposal is fit for purpose (achieving the objectives set)

Please choose one of the options

Fully agree / Agree / Neutral / Disagree / Strongly disagree

5. The regulatory proposal is proportionate to the size of the issue

Please choose one of the options

Fully agree / Agree / Neutral / Disagree / Strongly disagree

6. The regulatory proposal applies the 'better regulation' principles[1]

Please choose one of the options

Fully agree / Agree / Neutral / Disagree / Strongly disagree

7. Any other comments on the quality of this document (please specify)

[1] For information and guidance, see:

- https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en
- https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en