European Aviation Safety Agency

Notice of Proposed Amendment 2017-22

Updating Part-MED and related AMC and GM

RMT.0287(b) (MED.001)

EXECUTIVE SUMMARY

The objective of this Notice of Proposed Amendment (NPA) is to improve the level of safety, clarify already existing rule text in order to make the regulatory framework more precise and effective, fill the gaps identified through the implementation experience and remove unnecessary burden for competent authorities (CAs), aeromedical examiners (AMEs) and aeromedical centres (AeMCs).

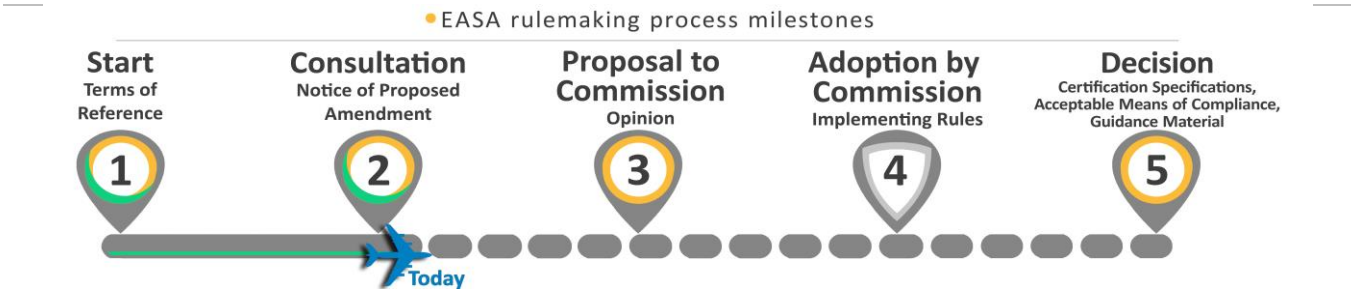
In summary, the proposed amendments are expected to improve the level of safety and clarity by:

— introducing new requirements to strengthen the procedure of limitation, suspension and revocation of medical certificates in order to reflect the amendments in Annex IV (Part-MED) of Regulation (EU) No 1178/2011 ('Aircrew Regulation');
— introducing new requirements to reduce the burden for flight crew licence holders as well as for CAs in case of an application for the change of state of licence issue;
— introducing new requirements for cooperative oversight in cases where the activity of an AME or AeMC involves more than one Member State (MS);
— adding 'class 3' to the existing requirements and related training for AeMCs to ensure harmonisation between the Aircrew Regulation and Part ATCO.MED (Annex IV to Regulation (EU) 2015/340);
— adding the obligation for AeMCs to report the statistical information regarding the aeromedical assessments, including reports of the drugs and alcohol screening and risk factors identified;
— adding the possibility for AeMCs to have contracted activities;
— improving the requirement for CAs to establish a secondary review procedure in order to increase the quality of the aeromedical examinations;
— mandating the acknowledgement of AeMC's management system assessment performed by other national authorities or organisations involved in the assessment of medical facilities.

Moreover, the proposed amendments aim to ensure harmonisation between the requirements of Part-MED, Annex VI (Part-ARA) and Annex VII (Part-ORA) to the Aircrew Regulation. Finally, the proposed amendments are expected to enhance clarity and consistency of rules in line with better regulation principles, promote a competitive environment and maintain the current level of safety through harmonisation of the Aircrew Regulation requirements.

This proposed amendment addresses efficiency/proportionality as well safety issues related to Part-ARA and Part-ORA.

Action area:	Regular updates		
Affected rules:	Regulation (EU) No 1178/2011, Part-ARA and related AMC/GM; Part-ORA and related AMC/GM		
Affected stakeholders:	Pilots, AMEs, AeMCs, CAs		
Driver:	Efficiency/proportionality	**Rulemaking group:**	Yes
Impact assessment:	None	**Rulemaking Procedure:**	Standard



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1. About this NPA

1.1. How this NPA was developed

The European Aviation Safety Agency (EASA) developed this NPA in line with Regulation (EC) No 216/2008[1] (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure[2]. This rulemaking activity is included in the EASA 5-year Rulemaking Programme[3] under rulemaking task (RMT).0287 (MED.001). The text of this NPA has been developed by EASA based on the input of the Rulemaking Group (RMG) RMT.0287 (MED.001). It is hereby submitted to all interested parties[4] for consultation.

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

1.2. How to comment on this NPA

Please submit your comments using the automated **Comment-Response Tool (CRT)** available at **http://hub.easa.europa.eu/crt/**[5].

The deadline for submission of comments is **21 March 2018.**

1.3. The next steps

Following the closing of the public commenting period, EASA will review all comments.

Based on the comments received, EASA will develop an opinion containing the proposed amendments to the Aircrew Regulation. The opinion will be submitted to the European Commission, which will use it as a technical basis in order to prepare an EU regulation.

Following the adoption of the regulation, EASA will issue a decision containing the related acceptable means of compliance (AMC)/guidance material (GM).

The comments received and the EASA responses thereto will be reflected in a comment-response document (CRD). The CRD will be annexed to the opinion.

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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=1467719701894&uri=CELEX:32008R0216).

2 EASA is bound to follow a structured rulemaking process as required by Article 52(1) of Regulation (EC) No 216/2008. 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 http://easa.europa.eu/rulemaking/annual-programme-and-planning.php

4 In accordance with Article 52 of Regulation (EC) No 216/2008 and Articles 6(3) and 7) of the Rulemaking Procedure.

5 In case of technical problems, please contact the CRT webmaster (crt@easa.europa.eu).

2. In summary — why and what

2.1. Why we need to change the rules — issue/rationale

Following the implementation of the Aircrew Regulation, certain errors (e.g. using 'competent authority' instead of 'licensing authority') and gaps (e.g. requirements in Part-MED related to procedures to be followed by the AMEs or AeMCs were not reflected in the requirements for the CAs to create such procedures or processes) in Part-ARA, Subpart MED and Part-ORA, Subpart AeMC were reported by the MSs or were identified through the standardisation inspections.

Additionally, the issue of the transfer of medical files between MSs was enabled by FCL.015(d) but not regulated in any way with regard to the content and format of the transferred file; thus, the medical assessors of the CAs required specific requirements to be added in Part-ARA.

In 2015 the amendment to the Aircrew Regulation introduced the new requirements in point ARA.MED.330 — 'Special Medical Circumstances' in order to allow new medical developments (e.g. treatments or investigations) to be used within a research protocol. These requirements raised some concerns within the aeromedical environment and also among members of the RMG. For this reason, the RMT proposed, with the majority of votes, to completely remove ARA.MED.330. However, EASA considers that these requirements should be kept in an improved version that would allow the implementation of new medical developments based on existing evidence within a certification protocol rather than performing the research during commercial flights which may impact not only flight crew but also passengers and third parties on the ground, thus improving the level of safety while maintaining the possibility of introducing new developments in the medical field.

In 2015 Regulation (EU) 2015/340 was published and included Part ATCO.MED, which stipulates that certain paragraphs in Subpart MED of Part-ARA and in Subpart AeMC of Part-ORA are also applicable for medical certification of air traffic controllers (ATCOs). For this reason, the RMG in coordination with EASA's legal department decided to introduce 'class 3' in the applicable paragraphs to further clarify the meaning and ease the implementation of such requirements.

Part-MED describes in detail in which cases a medical certificate can be limited, suspended, or revoked; however, these provisions are not reflected in the authority requirements. For this reason, new requirements have been added to mandate the licensing authority to limit, suspend or revoke a medical certificate that was fraudulently obtained or that would jeopardise flight safety in the case where the holder of such certificate exercises its privileges. These requirements are also meant to ensure a level playing field.

In order to improve the traceability of decisions regarding 'class 2' applicants taken in consultation with the licensing authority, new requirements have been added to establish a consultation procedure that would include documentation of the outcome of the consultation. The procedure is expected to have a deterrent effect on fraud, thereby increasing the level of safety related to class 2 applicants.

New requirements are proposed in order to ensure proper cooperative oversight of AMEs and AeMCs in the cases where their activity involves more than one MS. The CA that certificated the AME/AeMC should ensure the exchange of information with the CA of the Member State where the AME/AeMC has its secondary place of business. Furthermore, the CA of the Member State where the AME/AeMC has its secondary place of business shall include these AMEs/AeMCs in its continuing oversight programme.

Additional requirements are proposed to mandate that the CA shall retrieve the revoked certificate and inform the CAs of the other Member States to prevent fraud by non-compliant AMEs which had their AME certificate revoked.

In order to ensure that passengers are not affected by the pilots being involved in a research protocol for which the conclusion regarding the safe use has not yet been reached, the RMG decided, with vast majority, to propose to remove the requirement ARA.MED.330 — 'Special Medical Circumstances'. However, after giving proper consideration to the RMG justification, EASA decided to propose an amendment to the requirements that would transpose the research protocol to a certification protocol in order to increase the level of safety while still allowing new medical developments to be implemented before they would be undertaken within an RMT. For such new medical developments evidence should be available prior to the development of the certification protocol demonstrating that the flight safety will not be negatively impacted.

In accordance with ORA.GEN.200(a)(3) the AeMCs shall establish a management system that includes the identifications of safety hazards. However, unlike for other organisations, for the AeMC, due to the medical profile of the activity, there are two types of risks that can be identified: the first one is related to the organisation and the second one related to the increasing incidence of certain medical conditions, including the use and misuse of alcohol and other psychoactive substances. The latter category of safety risks should be reported to the CA in an aggregated manner in order for the authority to assess the trends and propose mitigating measures where applicable. In order to mandate the AeMCs to report the above mentioned data to their CA, new requirements have been added to Subpart AeMC of Part-ORA.

Exemptions[6] **in accordance with Article 14 'Flexibility provisions'** of Regulation (EC) No 216/2008 (if applicable) pertinent to the scope of this RMT are:

EASA cases 2016/093, 2016/094 and 2014–74(2)&(3) regarding AME and AeMC certificate format submitted by Austria, as well as EASA case 2013/1 submitted by Switzerland and 2012/28 submitted by UK regarding the medical certificate for flight crew.

Alternative means of compliance (AltMoC) having an impact on the development of the content of this RMT are: cases 2012-00004, 2012-00005, 2012-00006 and 2014-00018 submitted by UK regarding AMC to ARA.MED.135 — 'Aero-medical Forms' as well as cases 2014-00007 submitted by Croatia and 2016-00026 submitted by Austria regarding AMC to ORA.AeMC.210 AeMC — 'Personnel requirements'.

The proposed updates will facilitate the compliance with Safety Recommendation 2017-S35 issued by the Finnish Safety Investigation Authority by mandating the CAs to have a competency-based revalidation of the AME certificates and add to the existing procedures for referral of a specific procedure for consultation. In addition to the safety recommendation specified above, the recommendations 2, 3 and 4 of the EASA-led Germanwings Task Force regarding the AME training and

[6] Exemptions having an impact on the development of this RMT content and referring to:
— Article 14.1: Measures taken as an immediate reaction to a safety problem
— Article 14.4: Exemptions from substantive requirements laid down in the Basic Regulation and its implementing rules in the event of unforeseen urgent operational circumstances or operational needs of a limited duration;
— Article 14.6: Derogation from the rule(s) implementing the Basic Regulation where an equivalent level of protection to that attained by the application of the said rules can be achieved by other means;
— Article 22.2(b): Individual flight time specifications schemes deviating from the applicable certification specifications which ensure compliance with essential requirements and, as appropriate, the related implementing rules.

oversight as well as drugs and alcohol screening during medical examinations, that have been implemented in Part-MED, are reinforced within the current RMT by enabling the CAs to evaluate AME competencies and by enabling the AeMCs to report to their CAs the safety statistical data, including the data regarding drugs and alcohol screening.

Neither of the proposed amendments is expected to interfere with MSs' obligations to ICAO. Furthermore, there is no impact expected for other States other than EASA States and the ones using the EU requirements based on working arrangements.

2.2. What we want to achieve — objectives

The overall objectives of the EASA system 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 above.

The specific objectives of this proposal are to ensure efficient and effective legislation in line with the Better Regulation principle, as well as to improve the level of flight safety by:

— correcting editorial mistakes and ensuring consistency of wording;

— improving the clarity of the requirements that are also applicable to ATCOs in accordance with Regulation (EU) 2015/340 by adding 'class 3' where necessary;

— updating the provisions in the light of the specificity of the medical field (e.g. amending ARA.MED.330 to be compliant with European requirements for medical research); and

— addressing consistency issues and gaps identified through the implementation experience (e.g. mandating and providing guidance to the CA to create procedures for transfer of medical files, consultation in case of borderline class 2 applicants and retrieval of revoked AME/AeMC certificates, mandating the AeMCs to report identified safety risks to the CA).

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

The proposed amendments will contribute to the achievement of the objectives described in point 2.2 above by implementing the following changes:

— introducing new requirements to strengthen the procedure of limitation, suspension, and revocation of medical certificates in order to reflect the requirements in Part-MED;

— introducing new requirements for the CA to create procedures for transfer of medical files in order to ensure equal treatment and reduce the burden for flight crew licence holders as well as for the national aviation authorities (NAAs) in case of an application for the change of state of licence issue;

— introducing new requirements for cooperative oversight in cases when the activity of AME or AeMC involves more than one MS;

— adding 'class 3' to the existing requirements and related training for AeMCs to ensure harmonisation between the Aircrew Regulation and Part ATCO.MED;

— improving the requirement for CAs to establish a secondary review procedure in order to increase the quality of the aeromedical assessments;

— introducing new requirements for the CA to develop a consultation procedure for borderline aeromedical assessments of class 2 applicants;

— amending ARA.MED.330 in order to maintain the flexibility for the MSs to implement new medical developments that could potentially increase flight safety or allow aircrew members and ATCOs with pathological medical conditions to safely exercise the privileges of their licence while respecting the ethical and scientific requirements for medical research;

— adding the obligation for AeMCs to report the statistical information regarding the aeromedical assessments, including reports of the drugs and alcohol screening and risk factors identified;

— adding the possibility for AeMCs to have contracted activities;

— mandating the acknowledgement of AeMC's management system assessment performed by other national medical authorities.

2.4. What are the expected benefits and drawbacks of the proposals

The expected benefits and drawbacks of the proposal are summarised below.

The proposed amendments are expected to address the errors and gaps identified through the implementation experience and to improve the clarity of the provisions, thus making it more effective, as well as to enhance flight safety.

The drawbacks of the proposal are that the CAs will have an increased workload regarding the development and implementation of the newly required procedures. However, that is a one-off increase that is expected to be compensated by reducing the workload behind certain tasks following the implementation of a standardised procedure, as well as by an increase in flight safety.

2.5. Sensitivity analysis

The most sensitive topic is the update of ARA.MED.330 and the applicable AMC/GM. The current requirements raised a lot of comments from various stakeholders.

On the one hand, a few MSs, along with pilot representatives, argued in favour of the option of having an implementation protocol for new medical developments that would allow applicants with certain medical conditions, previously incompatible with the privileges of their licence, to perform their duties before an RMT is developed to incorporate such development into the requirements.

On the other hand, a higher number of MSs and stakeholders expressed concerns regarding the current wording of ARA.MED.330 in regard to the flight safety as well as to the compliance with the 'European Textbook on Ethics in Research' issued by the European Commission and 'A Practical Guide for Health Researchers' issued by the World Health Organization.

In the end, all of the RMG members agreed that a research protocol, as it is worded now, does not comply with the requirements regarding medical research and does not fulfil the safety objectives defined in the Basic Regulation; thus, the RMG decided, with vast majority, to propose to remove ARA.MED.330 — Special Medical Circumstances from the requirements. However, after giving proper consideration to the RMG justification, EASA decided to propose an amendment to the requirements that would transpose the research protocol to a certification protocol in order to increase the level of safety while still allowing new medical developments to be implemented before they would be undertaken within an RMT. For such new medical developments evidence should be available prior to the development of the certification protocol demonstrating that the flight safety will not be negatively impacted.

2.6. Monitoring and evaluation

EASA will monitor the implementation of the adopted rules by means of EASA standardisation visits, CA oversight, surveys, and any other suitable means to verify the relevance, utility and benefits in using the newly updated requirements.

For the moment it is not considered necessary to plan an ex post evaluation. However, it might be still planned as part of the EASA Medical Expert Group (MEG) meetings or as a standalone event, if deemed necessary, in the course of the implementation process of the updated requirements.

2.7. Proposed actions to support implementation

EASA will support the implementation through focused communication for advisory body meetings (Aircrew TeB and Aircrew TEC) as well as detailed explanations during EASA's MEG Meetings.

3. Proposed amendments and rationale in detail

The text of the amendment is arranged to show deleted text, new or amended text as shown below:

— deleted text is ~~struck through~~;
— new or amended text is highlighted in grey;
— an ellipsis '[…]' indicates that the rest of the text is unchanged.

3.1. Draft regulation (Draft EASA opinion)

3.1.1. Part-ARA

Subpart MED SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION is amended as follows:

SUBPART MED - SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

SECTION I — GENERAL

ARA.MED.120 Medical assessors

The competent authority shall appoint one or more medical assessor(s) to undertake the aero-medical tasks described in this ~~Section~~ Regulation. The medical assessor shall be licensed and qualified in medicine and have:

(a) postgraduate work experience in clinical medicine ~~of at least 5 years~~;

(b) specific knowledge and experience in ~~aviation medicine~~ aero-medical practice; and

(c) specific training in aero-medical certification.

ARA.MED.125 Referral to the licensing authority

When an AeMC, or aero-medical examiner (AME) has referred the decision on the fitness of an applicant to the medical assessor of the licensing authority:

(a) the medical assessor or medical staff designated by the ~~competent authority~~ medical assessor shall evaluate the relevant medical documentation and request further medical documentation, examinations and tests where necessary; ~~and~~

(b) the medical assessor shall determine the applicant's fitness for the issuance of a medical certificate with one or more limitation(s) as necessary;

(c) in case of a fit assessment, the medical assessor shall issue the medical certificate; and

(d) the medical assessor shall inform the AeMC or AME of the decision.

ARA.MED.126 Limitation, suspension or revocation of medical certificates

(a) The licensing authority shall establish a procedure to enable its medical assessor(s) to limit, suspend, or revoke a medical certificate

(b) The medical assessor of the licensing authority shall limit, suspend or revoke a medical certificate if there is evidence that:

(1) a medical certificate is falsified or obtained by a false declaration;

(2) a medical certificate is used in violation of the provisions of paragraph MED.A.020;

(3) the holder of a medical certificate is no longer compliant with Part-MED;

(c) The medical assessor of the licensing authority may also suspend or revoke a medical certificate upon the written request of the holder of a medical certificate.

(d) The licensing authority shall establish a procedure for reinstating a medical certificate.

ARA.MED.128 Consultation Procedure

The competent authority shall establish a consultation procedure for the AeMCs and AMEs in accordance with Part-MED.

ARA.MED.130 Medical certificate format

The medical certificate shall conform to the following specifications:

(a) Content

(1) State where the pilot licence has been issued or applied for (I)

~~(2) Class of medical certificate (II),~~

(~~3~~2) Medical ~~C~~certificate number commencing with the UN country code of the State where the pilot licence has been issued or applied for and followed by a code of numbers and/or letters in Arabic numerals and ~~l~~Latin script (III)

(~~4~~3) Name of holder (IV)

(~~5~~4) Nationality of holder (VI)

(~~6~~5) Date of birth of holder: (dd/mm/yyy) (XIV)

(~~7~~6) Signature of holder (VII)

(~~8~~7) Limitation(s) (XIII)

(~~9~~8) Expiry date of the medical certificate (IX) for:

(i) Class 1~~single pilot commercial operations carrying passengers~~,

(ii) Class 1 single-pilot commercial operations carrying passengers ~~other commercial operations~~,

(iii) Class 2,

(iv) Class 2 with instrument rating

(~~iv~~ v) LAPL.

(~~10~~9) Date of medical examination

(~~11~~10) Date of last and next electrocardiogram

(~~12~~11) Date of last and next audiogram

(12) Date of last and next ophthalmological examination

(13) Date of issue and signature of the AME or medical assessor that issued the certificate. GMP may be added to this field if they have the competence to issue medical certificates under the national law of the Member State where the licence is issued,

(14) Seal or stamp (XI).

(b) Material: Except for the case of LAPL medical certificate issued by a GMP the paper or other material used shall prevent or readily show any alterations or erasures. Any entries or deletions to the form shall be clearly authorised by the licensing authority.

(c) Language: medical ~~C~~certificates shall be written in the national language(s) and in English and such other languages as the ~~licensing~~ competent authority deems appropriate.

(d) All dates on the medical certificate shall be written in a dd/mm/yyyy format.

ARA.MED.135 Aero-medical forms

The competent authority shall ~~use~~ provide the AMEs with ~~forms~~ the format for:

(a) the application form for a medical certificate;

(b) the examination report form for class 1 and class 2 applicants; and

(c) the examination report form for light aircraft pilot licence (LAPL) applicants.

ARA.MED.145 GMP notification to the competent authority

The competent authority, when applicable, shall establish a notification process for general medical practitioners (GMPs) to ensure that the GMP is aware of the ~~medical~~ applicable requirements laid down in ~~MED.B.095~~this Regulation.

ARA.MED.150 Record-keeping

(a) In addition to the records required in ARA.GEN.220, the competent authority shall include in its system of record-keeping, details of aero-medical examinations, and assessments submitted by AMEs, AeMCs or GMPs.

(b) All aero-medical records of licence holders shall be kept for a minimum period of 10 years after the expiry of their last medical certificate.

(c) For the purpose of aero-medical assessments and standardisation, aero-medical records shall be made available after written consent of the applicant/licence holder to:

(1) an AeMC, AME or GMP for the purpose of completion of an aero-medical assessment;

(2) a medical review board that may be established by the competent authority for secondary review of borderline cases;

(3) relevant medical specialists for the purpose of completion of an aero-medical assessment;

(4) the medical assessor of the competent authority of another Member State for the purpose of cooperative oversight;

(5) the applicant/licence holder concerned upon their written request; and

(6) ~~after disidentification of the applicant/licence holder,~~ ~~to~~ the Agency for standardisation purposes, in a manner that ensures medical confidentiality is respected at all times.

(d) The competent authority may make aero-medical records available for other purposes than those mentioned in (c) in accordance with Directive 95/46/EC as implemented under national law.

(e) The competent authority shall maintain a list~~s~~ of:

~~(1) of all AMEs that hold a valid certificate issued by that authority; and~~

~~(2) where applicable, of all GMPs acting as AMEs on their territory.~~

~~These lists shall be disclosed to other Member States and the Agency upon request~~.

(1) AeMCs and AMEs it has certified;

(2) AMEs certified by other competent authorities exercising their privileges in its territory and to which it has provided a briefing in accordance with MED.D.001(f)(3);

(3) GMPs exercising their privileges in accordance with MED.A.040, where applicable.

The list shall state the privileges and shall be published and kept updated by the competent authority.

(f) The competent authority shall ensure that the flight crew medical certificate data is uploaded and kept up to date in the European Aero-medical Repository.

ARA.MED.151 Medical confidentiality

All persons involved in aero-medical examinations, assessments, and certification shall ensure that medical confidentiality is respected at all times.

ARA.MED.155 Transfer of medical files

(a) Upon receiving a medical file transfer request from medical certificate or medical report holders to a new licensing authority, the existing licensing authority shall:

(1) transfer a summary of the relevant medical history of the applicant verified and signed by the medical assessor of the existing licensing authority.

(2) attach a copy of the most recent aero-medical report containing the detailed results of the aero-medical examinations and assessments as required for the class of medical certificate, and a copy of the application form, the examination form, and the medical certificate;

(3) where available, attach copies of the most recent ECG, audiometry; and

(4) where available, attach a copy of the initial medical examination or a copy of the documents supporting the last medical file transfer between licensing authorities;

(b) The new licensing authority shall confirm to the existing licensing authority that all documents have been received and that the medical certificate and, where relevant, the licence have been transferred to the new licensing authority.

SECTION II — AERO-MEDICAL EXAMINERS (AMEs)

ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate

Without prejudice to the provisions laid down in ARA.GEN.315:

(a) The competent authority shall ensure that before the issue revalidation, renewal, or extension of privileges of an AME certificate, applicants demonstrate their aero-medical competency in accordance with Part-MED.

(~~a~~b) ~~The certification procedure for an AME shall follow the provisions laid down in ARA.GEN.315.~~The competent authority shall have a procedure in place to ensure that, before issuing the AME certificate, ~~the competent authority~~ it ~~shall have~~ has the evidence that the AME practice is ~~fully~~ equipped and the appropriate procedures are in place to perform aero-medical examinations within the scope of the AME certificate applied for. In the case of multiple AME practice locations, all of them shall be specified on the AME certificate.

(~~b~~c) When satisfied that the AME is in compliance with the applicable requirements, the competent authority shall issue, revalidate, renew or change the AME certificate for a period not exceeding 3 years, using the form established in Appendix VII to this Part.

ARA.MED.240 General medical practitioners (GMPs) exercising the privileges in accordance with MED.A.040 ~~**acting as AMEs**~~

The competent authority of a Member State shall notify the Agency and competent authorities of other Member States if aero-medical examinations for the LAPL can be carried out on its territory by GMPs.

ARA.MED.245 Continuing oversight of AMEs and GMPs

When developing the continuing oversight programme referred to in ARA.GEN.305, the competent authority shall take into account:

(1) the number of AMEs and GMPs exercising their privileges within the territory where the competent authority exercises oversight;

(2) the number of AMEs certified by competent authorities of other Member States exercising their privileges within the territory where the competent authority exercises oversight;

(3) a risk based assessment of the AMEs' and GMPs' activity.

ARA.MED.246 Cooperative oversight of AMEs and AeMCs

(a) Where the activity of an AME or AeMC involves more than one Member State, the competent authority that certified the AME/AeMC shall have a procedure in place to ensure the exchange of information in accordance with ARA.GEN.200(c) and ARA.GEN.300(d) and (e) with the competent authority of the Member State where the AME/AeMC has its secondary place of business. The procedure shall be agreed upon by the competent authorities involved.

(b) In the case mentioned in (a), the competent authority of the Member State where the AME/AeMC has its secondary place of business shall share all information relevant to the oversight of the AME/AeMC with the competent authority certificating the AME/AeMC.

ARA.MED.250 Limitation, suspension or revocation of an AME certificate

(a) The competent authority shall limit, suspend, or revoke an AME certificate in, but not limited to, the following circumstances ~~cases where~~:

(1) the AME ~~no longer complies~~ does not comply with applicable requirements;

(2) failure to meet the criteria for certification or continuing certification;

(3) deficiency of aero-medical record-keeping or submission of incorrect data or information;

(4) falsification of medical records, certificates or documentation;

(5) concealment of facts appertaining to an application for, or holder of, a medical certificate or false or fraudulent statements or representations to the competent authority;

(6) failure to correct findings from audit of the AME practice; and

(7) at the request of the certified AME.

(b) The certificate of an AME ~~shall be automatically~~ is revoked in either of the following circumstances:

(1) revocation of medical licence to practice; or

(2) removal from the Medical Register.

(c) The competent authority shall have a process in place for retrieval of the revoked AME certificates, shall update the AME list, and inform the competent authorities of the other member states accordingly.

ARA.MED.255 Enforcement measures

If, during oversight or by any other means, evidence is found showing a non-compliance of an AeMC, an AME or a GMP, the ~~licensing~~ competent authority shall have a process to review the medical certificates issued by that AeMC, AME or GMP and may render them invalid, where required, to ensure flight safety.

SECTION III — MEDICAL CERTIFICATION

ARA.MED.315 Review of examination reports

The licensing authority shall have a process in place for the medical assessor to:

(a) review examination and assessment reports received from the AeMCs, AMEs and GMPs and inform them of any inconsistencies, mistakes or errors made in the assessment process; and

(b) assist AMEs and AeMCs on their request regarding their decision on aero-medical fitness ~~in contentious cases~~.

ARA.MED.325 Secondary review procedure

The ~~competent~~ licensing authority shall establish a procedure for the review of borderline and contentious cases and cases where an applicant requests a review ~~with independent medical advisor s , experienced in the practice of aviation medicine, to consider and advise on an applicant's fitness for medical certification~~ in accordance with the applicable medical requirements.

ARA.MED.330 Special medical circumstances

(a) When new medical technology, medication, or procedures are identified that may justify a fit assessment of applicants otherwise not in compliance with the requirements, a certification protocol ~~research~~ may be developed using ~~carried out to gather~~ evidence from existing research supporting ~~on~~ the safe exercise of the privileges of the licence in order to inform future rulemaking tasks.

(b) ~~In order to undertake research, a~~ ~~competent~~ A licensing authority, in cooperation with at least ~~one~~ two other ~~competent~~ licensing authority~~y~~ies, may develop and evaluate a medical ~~assessment~~ certification protocol based on which they ~~these competent authorities~~ may issue a defined number of pilot medical certificates with appropriate limitations.

(c) AeMCs and AMEs may only issue medical certificates on the basis of ~~a research~~ the certification protocol if ~~instructed~~ approved to do so by their competent authority.

(d) The protocol shall be agreed between the ~~competent~~ licensing authorities concerned and the Agency and shall include as a minimum:

(1) a risk assessment;

(2) a literature review and evaluation ~~to provide~~ of the existing evidence that issuing a medical certificate based on the ~~research~~ certification protocol would not jeopardise the safe exercise of the privileges of the licence;

(3) detailed selection criteria based on the existing evidence for ~~pilots~~ applicants to be admitted to the certification protocol;

(4) the limitations that will be endorsed on the medical certificate;

(5) the monitoring procedures to be implemented by the ~~competent~~ licensing authorities concerned;

(6) the determination of end points for terminating the protocol;

(e) The protocol shall be compliant with relevant ethical principles.

(f) The exercise of licence privileges shall be restricted ~~by~~ to licence holders ~~with a medical certificate issued~~ belonging to a licensing authority involved ~~on the basis of~~ in the certification protocol ~~shall be restricted~~ and to flights in aircraft registered in the Member States involved in the ~~research~~ certification protocol. This restriction shall be indicated on the medical certificate.

(g) The participating competent authorities shall:

(1) provide the Agency with:

(i) the ~~research~~ certification protocol before implementation;

(ii) the details and qualifications of the nominated focal point of each participating competent authority;

(iii) documented reports of regular evaluations of its effectiveness;

(2) provide the AeMCs and AMEs within their jurisdiction with details of the protocol before implementation for their information.

APPENDIX V TO ANNEX VI PART-ARA - CERTIFICATE FOR AERO-MEDICAL CENTRES (AeMCs)

European Union *

Competent Authority

AERO-MEDICAL CENTRE CERTIFICATE

REFERENCE:

Pursuant to Commission Regulation (EU) No 1178/2011and Regulation (EU) 2015/340 and subject to the conditions specified below, the [competent authority] hereby certifies

[NAME OF THE ORGANISATION]

[ADDRESS OF THE ORGANISATION]

as a Part-ORA certified ~~A~~aero-medical centre with the privileges and the scope of activities as listed in the attached terms of approval.

CONDITIONS:

1. This certificate is limited to that specified in the scope of approval section of the approved organisation manual;
2. This certificate requires compliance with the procedures specified in the organisation documentation as required by Part-ORA.
3. This certificate shall remain valid subject to compliance with the requirements of Part-ORA unless it has been surrendered, superseded, suspended or revoked.

Date of issue…….Signed:……

* ~~"~~"European Union"~~"~~ to be deleted for non-EU Member States

EASA Form 146 Issue 1

AERO-MEDICAL CENTRE CERTIFICATE

Attachment to AeMC certificate number:

PRIVILEGES AND SCOPE

[Name of the organisation] has obtained the privilege(s) to undertake aero-medical examinations and assessments for the issuance of medical certificates and medical reports as stated in the table below and to issue these medical certificates and medical reports for:

	Initial/revalidation/renewal	Date of issue
Class 1		
Class 2/ LAPL/ Cabin Crew		
Class 3		

Date: dd/mm/yyyy Signature: [Competent Authority]

APPENDIX VII TO ANNEX VI PART-ARA

CERTIFICATE FOR AERO-MEDICAL EXAMINERS (AMEs)

European Union *

Competent Authority

AERO-MEDICAL EXAMINER CERTIFICATE

CERTIFICATE NUMBER/REFERENCE:

Pursuant to Commission Regulation (EU) No 1178/2011 and Regulation (EU) 2015/340 and subject to the conditions specified below, the [competent authority] hereby certifies

[NAME OF THE AERO-MEDICAL EXAMINER]

[PRACTICE ADDRESS(ES) OF THE AERO-MEDICAL EXAMINER]

as aero-medical examiner

CONDITIONS:

1. This certificate is limited to the privileges specified in the attachment to this AME certificate;
2. This certificate requires compliance with the implementing rules and procedures specified in Part-MED / Part ATCO.MED.
3. This certificate shall remain valid for a period ~~of~~ not exceeding three years ~~until [xx/yy/zzzz**]~~ subject to compliance with the requirements of Part-MED/ Part ATCO.MED unless it has been surrendered, superseded, suspended or revoked.

Date of issue: ~~xx~~dd/~~yy~~mm/~~zzzz~~yyyy Signature: [Competent Authority]

* ~~"~~European Union~~"~~ to be deleted for non-EU Member States

****** Expiry date: day/month/year

EASA Form 148 Issue 1

AERO-MEDICAL EXAMINER CERTIFICATE

Attachment to AME certificate number:

PRIVILEGES AND SCOPE

[Name and academic title of the aero-medical examiner] has obtained the privilege(s) to undertake aero-medical examinations and assessments for the issuance of medical certificates and medical reports as stated in the table below and to issue these medical certificates and medical reports for:

~~LAPL~~	~~[yes/date]~~
~~Class 2~~	~~[yes/date]~~
~~Class 1 revalidation/renewal~~	~~[yes/date] / [no]~~

Class 1 revalidation/renewal	[valid until] / [Not Applicable]
Class 2/ LAPL/ Cabin crew initial/revalidation/renewal	[valid until]
Class 3 revalidation/renewal	[valid until] / [Not Applicable]

Date of issue: ~~xx~~dd/~~yy~~mm/~~zzzz~~yyyy Signature: [Competent Authority]

3.1.2. Part-ORA

Subpart AeMC SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CENTRES (AeMCs) is amended as follows:

SUBPART AeMC — AERO-MEDICAL CENTRES

SECTION I — GENERAL

ORA.AeMC.105 Scope

This Subpart establishes the additional requirements to be met by an organisation to qualify for the issue or continuation of an approval as an aero-medical centre (AeMC) to provide aero-medical expertise and practical training for AMEs and to issue medical certificates, including initial class 1 or class 3 medical certificates, as applicable, in accordance with the privileges defined in the terms of approval attached to the AeMC's certificate.

ORA.AeMC.115 Application

Applicants for an AeMC certificate shall:

(a) comply with MED.D.005; and

(b) in addition to the documentation for the approval of an organisation required in ORA.GEN.115, provide details of ~~clinical attachments to or liaison~~ contracted activities with designated hospitals or medical institutes for the purpose of specialist medical examinations.

ORA.AeMC.120 AeMC Certificate

An organisation holding an AeMC certificate shall not, at any time, hold more than one AeMC certificate issued in accordance with Regulation (EC) No 216/2008 and its implementing rules.

ORA.AeMC.135 Continued validity

The AeMC certificate shall be issued for an unlimited duration. It shall remain valid subject to the holder and the aero-medical examiners of the organisation:

(a) complying with MED.D.030;and

(b) ensuring their continued experience by performing an adequate number of class 1 or class 3 medical examinations, as appropriate, every year.

ORA.AeMC.160 Reporting

The AeMC shall provide the competent authority with statistical reports regarding the aero-medical assessments of applicants, including reports of the drugs and alcohol screening and risk factors identified.

SECTION II — MANAGEMENT

ORA.AeMC.200 Management system

The AeMC shall establish and maintain a management system that includes the items addressed in ORA.GEN.200 and, in addition, processes:

(a) for medical certification in compliance with Part-MED;

(b) for cooperation between the AMEs and other medical experts of the AeMC; and

(~~b~~c) to ensure medical confidentiality at all times.

ORA.AeMC.205 Contracted activities

Notwithstanding ORA.GEN.205:

(a) Minimum required aero-medical examinations shall be performed within the organisation of the AeMC, in accordance with the scope and privileges defined in the terms of approval attached to the AeMC's certificate.

(b) Additional medical examinations and investigations may be performed by contracted individual experts or organisations. The organisation shall ensure that when contracting any part of its activity, the contracted service or product conforms to the applicable requirements.

ORA.AeMC.210 Personnel requirements

(a) The AeMC shall:

(1) have an aero-medical examiner (AME) nominated as head of the AeMC, with privileges to issue class 1 or class 3 medical certificates, as applicable, in accordance with the scope defined in the terms of approval attached to the AeMC's certificate and sufficient experience in aviation medicine to exercise his/her duties; ~~and~~

(2) have on staff ~~an adequate number of~~ ~~fully~~ at least one additional qualified AME~~s~~ with a class 1 or class 3 medical certificate, as applicable, in accordance with the scope defined in the terms of approval attached to the AeMC's certificate privileges and other technical staff; ~~and~~ ~~experts.~~

(3) have available medical experts.

(b) The head of the AeMC shall be responsible for coordinating: ~~the assessment of examination results and signing reports, certificates, and initial class 1 medical certificates.~~

(1) the assessment of examination results

(2) signing reports, certificates, and initial class 1 and class 3 medical certificates.

3.2. Draft acceptable means of compliance and guidance material (Draft EASA decision)

3.2.1. AMC/GM to Part ARA

Subpart MED SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION is amended as follows:

SUBPART MED - SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CERTIFICATION

SECTION I — GENERAL

AMC1 ARA.MED.120 Medical assessors

EXPERIENCE AND KNOWLEDGE

Medical assessors should:

(a) have ~~considerable experience of aero-medical practice~~ held class 1 privileges for at least 5 years and have undertaken a minimum of 200 class 1 medical examinations, or equivalent;

(b) have specific training on the regulatory processes and aero-medical certification of referred cases; and

(~~b~~c) maintain their medical professional competence in aviation medicine. The following should count towards maintaining medical professional competence:

(1) undertaking regular refresher training;

(2) participating in international aviation medicine conferences;

(3) undertaking research activities, including publication of results of the research.

AMC2 ARA.MED.120 Medical assessors

TASKS

Specific tasks of the ~~M~~medical assessors ~~should~~are, but not limited to:

(a) ~~provide~~ to approve and oversee lectures in basic, advanced and refresher training courses for aero-medical examiners (AMEs) and aero-medical centres (AeMCs)~~.~~; Medical assessors may also deliver lectures during those training courses provided that a procedure is in place to avoid conflict of interest;

(b) to carry-out supervision and audits of AeMCs, AMEs and AME training facilities; ~~and~~

(c) to perform the aero-medical assessment of applicants for, or holders of, medical certificates ~~after~~ in case of referral ~~to the licensing authority~~ secondary review or when medical certificates have been issued by non-compliant AMEs ;~~.~~

(d) to certify and oversee AeMCs and AMEs, including reviewing of medical files submitted by them to the competent authority;

(e) to manage medical files including transfers of medical files in case of a change of state of licence issue; and

(f) to provide technical support to AMEs and AeMCs in borderline and difficult cases.

AMC3 ARA.MED.120 Medical assessors

The medical assessor may delegate certain tasks to other staff or contract agents. The medical assessor should ensure that such person has relevant training and experience for the delegated task and that the entire process is properly documented.

GM1 ARA.MED.120 Medical assessors

DELEGATION OF MEDICAL ASSESSOR'S TASKS

Properly qualified medical assessors are essential for maintaining flight safety and an efficient and functional aero-medical system. Medical assessors, like any inspector of the competent authority, should, by their qualifications and competencies, command the professional respect of the personnel and organisations they inspect, authorise, or oversee. These guidelines aim to establish possible solutions to optimise the use of qualified medical assessors as well as temporary solutions until properly qualified medical assessors are readily available. These guidelines should be interpreted and implemented only to the extent that they provide for sound and effective oversight in accordance with principles of the safety risk management.

For all of the medical assessor's tasks, the support staff may provide administrative support in regard to the paperwork and preparation work. Furthermore, some tasks may be partially delegated to other staff members of the competent authority. The medical assessor should select to whom the tasks are delegated based on their qualifications in order to ensure that the entire performance is in line with the applicable provision both in the field of aviation and in the medical field and is properly documented. The compliance monitoring system of the competent authority should ensure that delegation of certain tasks has no negative impact on issues related to flight safety and data protection.

In order to maintain their medical proficiency the medical assessors may act as an AME subject to the proper procedure in place to avoid conflict of interest.

The following steps may be considered when required:

(a) Employment of a not fully qualified medical assessor.

When recruiting a fully qualified medical assessor is not possible the competent authority may employ a medical doctor to be trained and nominated as a medical assessor once the training is finalised. The performance of these doctors should be supervised by a qualified medical assessor from the pool of experts.

(b) Assign role to qualified inspectors as a team member (e.g. assessing the SMS system of an AeMC).

In this context, the non-medical inspectors performing duties within the inspection/oversight team are expected to document their work and to report to the medical assessor as the accountable person for the process.

(c) Use an appropriately qualified medical assessors and AMEs from pool of experts.

The use of AMEs or MAs from a pool of experts should be limited to the sharing of experts to cover unplanned activity or temporary/transitional shortage of expertise rather than a consistent long term use.

The following types of expert pools may be considered:

— qualified AMEs from the industry
— medical assessors from the NAAs of other States or EASA
— medical assessors/AMEs from military aviation.

The following risks should be assessed and mitigated in case of using a pool of experts:

— assessment and oversight of expert's performance as well as enforcement in case of non-compliance.
— authorisation of the expert to: access medical practices, investigate, conduct interviews, and collect evidence.
— financial, contracting and administrative aspects; recurrent training on administrative procedures.
— ability of the nominated expert to write reports and findings.
— avoidance of conflict of interest;
— sustainability (i.e. to avoid to permanently rely on the pool of experts);
— commercial sensitivity of AMEs/AeMCs, cultural issues.
— data protection issues
— language barriers
— recognition between states, including the right to practice medicine in a different State and medical indemnity/liability insurance.

Bilateral sharing of experts is convenient when:

— the requesting authority is aware of the resources available in the resource provider;
— the agreement between the NAAs exists or is easy to establish;
— the planning for the availability of the resources can easily be managed;

Whether the sharing of medical assessors is concluded directly between two NAAs or through a sharing platform, sustainability can only be ensured if all stakeholders are willing to consider global optimisation as a priority. The challenge is that the management system of each NAA may systematically reduce its resources so that all qualified medical assessors are fully occupied all the times. Such planning strategy does not provide any extra margin for contingencies and may easily drift towards understaffing. It is always difficult to swiftly adjust the number of permanently employed experts to the short term oversight needs. Therefore, while attempting to 'optimise' its own resources, each NAA may rely more and more on the experts from other NAAs and further reduce its staff. While this may work for a limited period of time, in the long run the sharing of experts may simply become impossible as all NAAs will be requesting qualified medical assessors while no NAA would be able to provide any. A similar reasoning applies when experts from the industry are shared.

The concept of sharing implies availability of resources. Availability means extra capacity. Therefore all stakeholders involved in the sharing are expected to coordinate their staffing strategies globally. This ensures global optimisation by reallocating resources so that no expert is underused and that

the costs are shared based on the level of support obtained. Additionally, it is expected that activity planning is coordinated among all involved stakeholders.

AMC1 ARA.MED.125 Referral to the licensing authority

REFERRAL TO THE LICENSING AUTHORITY

(a) The licensing authority should supply the AeMC or AME with all necessary information that led to the decision on aero-medical fitness.

(b) The licensing authority should ensure that ~~unusual or~~ borderline cases or those not regulated in Part-MED are evaluated on a common basis.

AMC 1 ARA.MED.128 Consultation Procedure

This procedure should include at least the minutes of the consultation.

AMC1 ARA.MED.130 Medical certificate format

STANDARD ~~EASA~~ MEDICAL CERTIFICATE FORMAT

The format of the medical certificate should be as shown below.

Competent authority name and logo (English and any language(s) determined by the competent authority) EUROPEAN UNION (English only) ~~Class 1/2/LAPL~~MEDICAL CERTIFICATE pertaining to a Part-FCL licence (English and any language(s) determined by the competent authority) Issued in accordance with Part-MED This medical certificate complies with ICAO standards, except for the LAPL medical certificate (English and any language(s) determined by the competent authority)		Requirements ~~"~~"European Union"~~"~~ to be deleted for non-EU Member States Size of each page shall be one eighth A4

I	National language(s)/*Authority that issued or is to issue the pilot licence:*
III	National language(s)÷/*Certificate number*
IV	National language(s)÷/ *Last and first name of holder:*
XIV	National language(s)÷/*Date of birth: (dd/mm/yyyy):*
VI	National language(s)/*Nationality(ies):*
VII	National language(s)/ *Signature of holder:*
2	

XIII National language(s)/*Limitations:*
Code~~:~~.
~~Description~~ Operational remark:

X National language(s)/**Date of issue:*
(dd/mm/yyyy)

Name and ~~S~~signature of the issuing AME/medical assessor /~~(~~GMP~~)~~:

XI National language(s)/*Stamp:*

3

	IX Nat. lang(s)/ Expiry date of this certificate	Class 1 ~~single pilot commercial operations carrying passengers~~ (dd/mm/yyyy or 'N/A')			
		Class 1 single pilot commercial operations carrying passengers (dd/mm/yyyy or 'N/A')			
		Class 2 (dd/mm/yyyy or 'N/A')			
		Class 2 with IR (dd/mm/yyyy or 'N/A')			
		LAPL (dd/mm/yyyy)			
	Nat. lang(s)./*Examination date*: (dd/mm/yyyy)				
	Type of examination	Last	Next		
			Class 1	Class 2	LAPL
	ECG				
	Audiogram				
	Ophthalmological examination				

MED.A.020 Decrease in medical fitness

(a) Licence holders shall not exercise the privileges of their licence and related ratings or certificates, and student pilots shall not fly solo, at any time when they:

(1) are aware of any decrease in their medical fitness that might render them unable to safely exercise those privileges;

(2) take or use any prescribed or non-prescribed medication that is likely to interfere with the safe exercise of the privileges of the applicable licence; ~~or~~

(3) receive any medical, surgical or other treatment that is likely to interfere with the safe exercise of the privileges of the applicable licence. ~~flight safety.~~

(b) In addition, licence holders shall, without undue delay and before exercising the privileges of their licence, seek aero-medical advice from the AeMC, AME or GMP, as applicable, when they:

(1) have undergone a surgical operation or invasive procedure;

(2) have commenced the regular use of any medication;

(3) have suffered any significant personal injury involving incapacity to function as a member of the flight crew;

(4) have been suffering from any significant illness involving incapacity to function as a member of the flight crew;

(5) are pregnant;

(6) have been admitted to hospital or medical clinic; ~~or~~

(7) first require correcting lenses.

4

* Date of issue is the date the certificate is issued and signed

AMC1 ARA.MED.135(a) Aero-medical forms

APPLICATION FORM FOR A MEDICAL CERTIFICATE

The form referred to in ARA.MED.135(a) should reflect the information indicated in the following form and corresponding instructions for completion.

LOGO

CIVIL AVIATION ADMINISTRATION/MEMBER STATE

APPLICATION FORM FOR A MEDICAL CERTIFICATE

MEDICAL IN CONFIDENCE

Complete this page fully and in block capitals - Refer to instructions for completion.

(1) State of licence issue:	(2) Medical certificate applied for: class 1 ☐ class 2 ☐ LAPL ☐ Class 3 ☐		
(3) Surname:	(4) Previous surname(s):		(12) Application: Initial ☐ Revalidation/Renewal ☐
(5) Forename(s):	(6) Date of birth(dd/mm/yyyy):	(7) Sex: Male ☐ Female ☐	(13) Reference number:
(8) Place and country of birth:	(9) Nationality:		(14) Type of licence applied for:
(10) Permanent address: Country: Telephone No.: Mobile No.: E-mail:	(11) Postal address (if different): Country: Telephone No.:		(15) Occupation (principal): (16) Employer: (17) Last medical examination: Date: Place:
(18) Licence(s) held (type): Licence number: State of issue:	(19) Any limitations on licence(s)/medical certificate held No ☐ Yes ☐ Details:		
(20) Have you ever had a medical certificate denied, suspended or revoked by any licensing authority? No ☐ Yes ☐ Date: Country: Details:	(21) Flight time total:	(22) Flight time since last medical:	
	(23) Aircraft class/type(s) presently flown:		
(24) Any aviation accident or ~~reported incident~~ medical event whilst exercising the privileges of the licence since the last medical examination? No ☐ Yes ☐ Date: Place: Details:	(25) ~~Type of flying intended~~ Current/intended pilot activity: Commercial ☐ Non-commercial ☐ Other …….. Single pilot ☐ Multi pilot ☐		
	(26) ~~Present flying activity~~ Current/intended ATC activity: ADI ☐ APS ☐ ACS ☐		
(27) Do you drink alcohol or use drugs? ☐ No ☐ Yes, state average weekly amount.	(28) Do you currently use any medication? No ☐ Yes ☐ State medication, dose, date started and why:		
(29) Do you smoke tobacco? ☐ No, never ☐ No, date stopped: ☐ Yes, state type and amount:			

General and medical history: Do you have, or have you ever had, any of the following? (Please tick a response for each question**). If yes, give details in remarks section (30).**

	Yes	No		Yes	No		Yes	No	**Family history of:**	Yes	No
101 Eye trouble/eye operation			112 Nose, throat or speech disorder			123 Malaria or other tropical disease			170 Heart or vascular disease		
102 Spectacles and/or contact lenses ever worn			113 Head injury or concussion			124 A positive HIV test			171 High blood pressure		
			114 Frequent or severe headaches			125 Sexually transmitted disease			172 High cholesterol level		
103 Spectacle/contact lens prescriptions change since last medical exam.			115 Dizziness or fainting spells			126 Sleep disorder/apnoea syndrome			173 Epilepsy		
			116 Unconsciousness for any reason			127 Musculoskeletal illness/impairment			174 Mental illness or suicide		
104 Hay fever, other allergy			117 Neurological disorders; stroke, epilepsy, seizure, paralysis, etc.			128 Any other illness or injury			175 Diabetes		
105 Asthma, lung disease						129 Admission to hospital			176 Tuberculosis		
106 Heart or vascular trouble			118 Psychological/psychiatric trouble of any sort			130 Visit to medical practitioner since last medical examination			177 Allergy/asthma/eczema		
107 High or low blood pressure									178 Inherited disorders		
108 Kidney stone or blood in urine			119 ~~Alcohol/drug/substance abuse~~ misuse of psychoactive substances			131 Refusal of life insurance			179 Glaucoma		
109 Diabetes, hormone disorder			120 Attempted suicide or self-harm			132 Refusal of ~~flying~~ aviation licence					
110 Stomach, liver or intestinal trouble			121 Motion sickness requiring medication			133 Medical rejection from or for military service			**Females only:** 150 Gynaecological, menstrual problems		
111 Deafness, ear disorder			122 Anaemia/sickle cell trait/other blood disorders			134 Award of pension or compensation for injury or illness			151 Are you pregnant?		

(30) **Remarks:** ~~If previously reported and no change since, so state.~~

(31) **Declaration:** I hereby declare that I have carefully considered the statements made above and to the best of my belief they are complete and correct and that I have not withheld any relevant information or made any misleading statements. I understand that, if I have made any false or misleading statements in connection with this application, or fail to release the supporting medical information, the licensing authority may refuse to grant me a medical certificate or may withdraw any medical certificate granted, without prejudice to any other action applicable under national law.

~~CONSENT TO RELEASE OF MEDICAL INFORMATION:~~ I hereby ~~authorise the release of~~ declare that I have been informed and I understand that all information provided to my AME contained in this report, ~~and any or all~~ its attachments ~~to the AME and, where necessary~~ and all information which is provided to my licensing authority and that relates to me, may be released to the medical assessor of the my licensing authority, other health professionals and medical administration staff as part of the aero-medical assessment process and to the medical assessor of the competent authority of my AME, recognising that these documents or electronically stored data are to be used for completion of a aero-medical assessment and ~~for~~ for oversight purpose ~~will become and remain the property of the licensing authority~~, providing that I or my physician may have access to them according to national law. Medical confidentiality will be respected at all times.

NOTIFICATION OF DISCLOSURE OF PERSONAL DATA: I hereby declare that I have been informed and I understand that the data contained in my medical certificate according to ARA.MED.130 may be electronically stored and made available to my AME in order to provide historical data required in MED.A.035(b)(2)(ii)/(iii) and to the medical assessors of the competent authorities of the Member States in order to facilitate the enforcement of ARA.MED.150 (c)(4).

Date	Signature of applicant	Signature of AME/(GMP)/(medical assessor)
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INSTRUCTIONS FOR COMPLETION OF THE APPLICATION FORM FOR A MEDICAL CERTIFICATE

This application form and all attached report forms will be transmitted to the licensing authority. Medical confidentiality shall be respected at all times.

The applicant should personally complete, in full, all questions (sections) on the application form. Writing should be legible and in block capitals, using a ball-point pen. Completion of this form by typing/printing is also acceptable. If more space is required to answer any questions, a plain sheet of paper should be used, bearing the applicant's name and signature, and the date of signing. The following numbered instructions apply to the numbered headings on the application form for a medical certificate.

Failure to complete the application form in full, or to write legibly, may result in non-acceptance of the application form. The making of false or misleading statements or the withholding of relevant information in respect of this application may result in criminal prosecution, denial of this application and/or withdrawal of any medical certificate(s) granted.

1. LICENSING AUTHORITY: State name of country this application is to be forwarded to.	**17. LAST APPLICATION FOR A MEDICAL CERTIFICATE:** State date (day, month, year) and place (town, country). Initial applicants state 'NONE'.
2. MEDICAL CERTIFICATE APPLIED FOR: Tick appropriate box representing the type of medical certificate applied for e.g. class 1, class 2, class 3 or LAPL. ~~Class 1: Professional Pilot~~ ~~Class 2: Private Pilot~~ ~~LAPL~~	**18. LICENCE(S) HELD (TYPE):** State type of licence(s) held. Enter licence number and State of issue. If no licences are held, state 'NONE'.
3. SURNAME: State surname/family name.	**19. ANY LIMITATIONS ON THE LICENCE(S)/MEDICAL CERTIFICATE:** Tick appropriate box and give details of any limitations on your licence(s)/medical certificate, e.g. vision, colour vision, safety pilot, etc.
4. PREVIOUS SURNAME(S): If your surname or family name has changed for any reason, state previous name(s).	**20. MEDICAL CERTIFICATE DENIAL, SUSPENSION OR REVOCATION:** Tick 'YES' box if you have ever had a medical certificate denied, suspended or revoked~~, even if only temporary~~. If 'YES', state date (dd/mm/yyyy) and country where it occurred.
5. FORENAME(S): State first and middle names (maximum three).	**21. FLIGHT TIME TOTAL:** State total number of hours flown.
6. DATE OF BIRTH: Specify in order dd/mm/yyyy.	**22. FLIGHT TIME SINCE LAST MEDICAL:** State number of hours flown since your last medical examination.
7. SEX: Tick appropriate box.	**23. AIRCRAFT CLASS/TYPE(S) PRESENTLY FLOWN:** State name of principal aircraft flown, e.g. Boeing 737, Cessna 150, etc.
8. PLACE AND COUNTRY OF BIRTH: State town and country of birth.	**24. ANY AVIATION ACCIDENT OR ~~REPORTED INCIDENT~~ MEDICAL EVENT WHILST EXERCISING THE PRIVILEGES OF THE LICENCE SINCE THE LAST MEDICAL EXAMINATION:** If 'YES' box ticked, state date (dd/mm/yyyy) and country of ~~accident/incident~~ occurrence and provide details.
9. NATIONALITY: State name of country of citizenship.	**25. ~~TYPE OF FLYING INTENDED~~ CURRENT/INTENDED PILOT ACTIVITY:** ~~State whether airline, charter, single-pilot, commercial air transport, carrying passengers, agriculture, pleasure, etc.~~ Please-tick the appropriate box regarding the intended activity during the following certification period: • Commercial, non-commercial or other (for other please specify the type of operation) • Single-pilot or multi-pilot
10. PERMANENT ADDRESS: State permanent postal address and country. Enter telephone area code as well as telephone number.	**26. ~~PRESENT FLYING ACTIVITY~~ CURRENT/INTENDED ATC ACTIVITY:** ~~Tick appropriate box to indicate whether you fly as the SOLE pilot or not.~~ Please-tick the appropriate box regarding the intended activity during the following certification period e.g. ADI, APS, ACS
11. POSTAL ADDRESS (IF DIFFERENT): If different from permanent address, state full current postal address including telephone number and area code. If the same, enter 'SAME'.	**27. DO YOU DRINK ALCOHOL OR USE DRUGS?** Tick applicable box. If yes, state weekly alcohol consumption e.g. 2 litres of beer.
12. APPLICATION: Tick appropriate box.	**28. DO YOU CURRENTLY USE ANY MEDICATION?:** If 'YES', give full details - name, how much you take and when, etc. Include any non-prescription medication.
13. REFERENCE NUMBER: State reference number allocated to you by the licensing authority Initial applicants enter 'NONE'.	**29. DO YOU SMOKE TOBACCO?** Tick applicable box. Current smokers state type (cigarettes, cigars, pipe) and amount (e.g. 2 cigars daily; pipe – 1 oz. weekly)
14. TYPE OF LICENCE APPLIED FOR: State type of licence applied for from the following list: ~~Aeroplane~~ Airline Transport Pilot Licence* Multi-Pilot Licence* Commercial Pilot Licence/Instrument Rating* Commercial Pilot Licence* Private Pilot Licence/Instrument Rating* Private Pilot Licence* Sailplane Pilot Licence Balloon Pilot Licence Light Aircraft Pilot Licence* ~~And whether Fixed Wing / Rotary Wing / Both~~ Air Traffic Controller	**GENERAL AND MEDICAL HISTORY** All items under this heading from number 101 to 179 inclusive should have the answer 'YES' or 'NO' ticked. You should tick 'YES' if you have ever had the condition in your life and describe the condition and approximate date in the (30) remarks section. All questions asked are medically important even though this may not be readily apparent. Items numbered 170 to 179 relate to immediate family history, whereas items numbered 150 to 151 should be answered by female applicants only. ~~If information has been reported on a previous application form for a medical certificate and there has been no change in your condition, you may state 'Previously reported; no change since'. However, you should~~

Other – Please specify *Please specify whether Fixed Wing / Rotary Wing / Both	~~still tick 'YES' to the condition.~~ Do not report occasional common illnesses such as colds.
15. OCCUPATION (PRINCIPAL): Indicate your principal employment.	
16. EMPLOYER: If principal occupation is pilot, then state employer's name or if self-employed, state 'self'.	**31. DECLARATION AND ~~CONSENT TO OBTAINING AND RELEASING INFORMATION~~ NOTIFICATION OF DISCLOSURE OF PERSONAL DATA:** Do not sign or date these declarations until indicated to do so by the AME/GMP who will act as witness and sign accordingly.

AMC1 ARA.MED.135(b);(c) Aero-medical forms

MEDICAL EXAMINATION REPORT FORMS

The forms referred to in ARA.MED.135(b) and (c) should reflect the information indicated in the following forms and corresponding instructions for completion.

MEDICAL IN CONFIDENCE

MEDICAL EXAMINATION REPORT FORM FOR CLASS 1, ~~& CLASS~~ 2 & 3 APPLICANTS

(201) Examination category	(202) Height (cm)	(203) Weight (kg)	(204) Colour eye	(205) Colour hair	(206) Blood pressure-seated (mmHg)		(207) Pulse - resting	
Initial ☐							Rate (bpm)	Rhythm: regular ☐
Revalidation ☐ Renewal ☐								irregular ☐
Special referral ☐					Systolic	Diastolic		

Clinical exam: Check each item	Normal	Abnormal		Normal	Abnormal
(208) Head, face, neck, scalp			(218) Abdomen, hernia, liver, spleen		
(209) Mouth, throat, teeth			(219) Anus, rectum		
(210) Nose, sinuses			(220) Genito-urinary system		
(211) Ears, drums, eardrum motility			(221) Endocrine system		
(212) Eyes - orbit & adnexa; visual fields			(222) Upper & lower limbs, joints		
(213) Eyes - pupils and optic fundi			(223) Spine, other musculoskeletal		
(214) Eyes - ocular motility; nystagmus			(224) Neurologic - reflexes, etc.		
(215) Lungs, chest, breasts			(225) Psychiatric		
(216) Heart			(226) Skin, identifying marks and lymphatics		
(217) Vascular system			(227) General systemic		

(228) **Notes:** Describe every abnormal finding. Enter applicable item number before each comment.

Visual acuity

(229) *Distant vision at 5m/6m*

	Uncorrected		Spectacles	Contact lenses
Right eye		Corr. to		
Left eye		Corr. to		
Both eyes		Corr. to		

(230) *Intermediate vision*	Uncorrected		Corrected	
N14 at 100 cm	Yes	No	Yes	No
Right eye				
Left eye				
Both eyes				

(231) *Near vision*	Uncorrected		Corrected	
N5 at 30-50 cm	Yes	No	Yes	No
Right eye				
Left eye				
Both eyes				

(232) **Spectacles** (233) **Contact lenses**

Yes ☐ No ☐	Yes ☐ No ☐
Type:	Type:

Refraction	Sph	Cyl	Axis	Add
Right eye				
Left eye				

(313) **Colour perception** Normal ☐ Abnormal ☐

Pseudo-isochromatic plates	Type: Ishihara (24 plates)
No of plates:	No of errors:

(234) **Hearing**

(when 239/241 not performed)	Right ear	Left ear
Conversational voice test (2m) with back turned to examiner	Yes ☐ No ☐	Yes ☐ No ☐

Audiometry				
Hz	500	1000	2000	3000
Right				
Left				

(236) **Pulmonary function**

FEV_1/FVC _____ %

Normal ☐ Abnormal ☐

(237) **Haemoglobin**

_____ _____ (***unit)***

Normal ☐ Abnormal ☐

(235) **Urinalysis** Normal ☐ Abnormal ☐

Glucose	Protein	Blood	Other

Accompanying reports

	Not performed	Normal	Abnormal/Comment
(238) ECG			
(239) Audiogram			
(240) Ophthalmology			
(241) ORL (ENT)			
(242) Blood lipids			
(243) Pulmonary function			
(244) Other (what?)			

(247) **AME recommendation:**

Name of applicant: Date of birth: Reference number:

---------- ---------- ----------

☐ Fit for class: ----------

☐ Medical certificate issued by undersigned (copy attached) for class: ----------

☐ Unfit for class: ----------

☐ Deferred for further evaluation. If yes, why and to whom?

(248) **Comments, limitations**

(249) **AME declaration:**

I hereby certify that I/my AME group have personally examined the applicant named on this medical examination report and that this report with any attachment embodies my findings completely and correctly.

(250) Place and date:	AME name and address:	AME certificate No.:
AME signature:	E-mail: Telephone No.: Telefax No.:	

Shaded areas do not require completion

MEDICAL IN CONFIDENCE

MEDICAL EXAMINATION REPORT FORM FOR LAPL APPLICANTS

(201) Examination category	(202) Height (cm)	(203) Weight (kg)	(204) Colour eyes	(205) Colour hair	(206) Blood pressure-seated (mmHg)		(207) Pulse - resting	
Initial ☐							Rate (bpm)	Rhythm: regular ☐
Revalidation ☐ Renewal ☐								irregular ☐
Special referral ☐					Systolic	Diastolic		

Clinical exam: Check each item

	Normal	Abnormal		Normal	Abnormal
(208) Head, face, neck, scalp			(218) Abdomen, hernia, liver, spleen		
(209) Mouth, throat, teeth			(219) Anus, rectum		
(210) Nose, sinuses			(220) Genito-urinary system		
(211) Ears, drums, eardrum motility			(221) Endocrine system		
(212) Eyes - orbit & adnexa; visual fields			(222) Upper & lower limbs, joints		
(213) Eyes - pupils and optic fundi			(223) Spine, other musculoskeletal		
(214) Eyes - ocular motility; nystagmus			(224) Neurologic - reflexes, etc.		
(215) Lungs, chest, breasts			(225) Psychiatric		
(216) Heart			(226) Skin, identifying marks and lymphatics		
(217) Vascular system			(227) General systemic		

(228) **Notes:** Describe every abnormal finding. Enter applicable item number before each comment.

Visual acuity

(229) *Distant vision at 5m /6m*

	Uncorrected		Spectacles	Contact lenses
Right eye		Corr. to		
Left eye		Corr. to		
Both eyes		Corr. to		

(230) *Intermediate vision* N14 at 100 cm

	Uncorrected		Corrected	
	Yes	No	Yes	No
Right eye				
Left eye				
Both eyes				

(231) *Near vision* N5 at 30-50 cm

	Uncorrected		Corrected	
	Yes	No	Yes	No
Right eye				
Left eye				
Both eyes				

(232) **Spectacles** Yes ☐ No ☐

Type:

(233) **Contact lenses** Yes ☐ No ☐

Type:

Refraction	Sph	Cyl	Axis	Add
Right eye				
Left eye				

(313) **Colour perception** Normal ☐ Abnormal ☐

Pseudo-isochromatic plates No of plates:

Type: Ishihara (24 plates) No of errors:

(234) **Hearing** (when 239/241 not performed)

	Right ear	Left ear
Conversational voice test (2m) with back turned to examiner	Yes ☐ No ☐	Yes ☐ No ☐

Audiometry

Hz	500	1000	2000	3000
Right				
Left				

(236) **Pulmonary function**

FEV_1/FVC _____ %

Normal ☐ Abnormal ☐

(237) **Haemoglobin**

_____ _____ (***unit)***

Normal ☐ Abnormal ☐

(235) **Urinalysis** Normal ☐ Abnormal ☐

Glucose	Protein	Blood	Other

Accompanying reports

	Not performed	Normal	Abnormal/Comment
(238) ECG			
(239) Audiogram			
(240) Ophthalmology			
(241) ORL (ENT)			
(242) Blood lipids			
(243) Pulmonary function			
(244) Other (what?)			

(247) **AME/GMP recommendation:**

Name of applicant: Date of birth: Reference number:

---------- ---------- ----------

☐ Fit for medical certificate for LAPL

☐ Medical certificate issued by undersigned (copy attached) for LAPL

☐ Unfit for class: ----------

☐ Deferred for further evaluation. If yes, why and to whom?

(248) **Comments, limitations**

(249) **AME/GMP declaration:**

I hereby certify that I have personally examined the applicant named on this medical examination report and that this report with any attachment embodies my findings completely and correctly.

(250) Place and date:	AME/GMP name and address:	AME certificate No./GMP identification No.:
AME/GMP signature:	E-mail: Telephone No.: Telefax No.:	

INSTRUCTIONS FOR COMPLETION OF THE MEDICAL EXAMINATION REPORT FORMS

The AME performing the examination should verify the identity of the applicant.

All questions (sections) on the medical examination report form should be completed in full. If an otorhinolaryngology examination report form is attached, then questions 209, 210, 211, and 234 may be omitted. If an ophthalmology examination report form is attached, then questions 212, 213, 214, 229, 230, 231, 232, and 233 may be omitted.

Writing should be legible and in block capitals using a ball-point pen. Completion of this form by typing/printing is also acceptable. If more space is required to answer any question, a plain sheet of paper should be used, bearing the applicant's name, the AME's name and signature, and the date of signing. The following numbered instructions apply to the numbered headings on the medical examination report form.

Failure to complete the medical examination report form in full, as required, or to write legibly, may result in non-acceptance of the application in total and may lead to withdrawal of any medical certificate issued. The making of false or misleading statements or the withholding of relevant information by an AME may result in criminal prosecution, denial of an application or withdrawal of any medical certificate(s) granted.

Shaded areas do not require completion for the medical examination report form for the LAPL.

201 EXAMINATION CATEGORY – Tick appropriate box.

Initial – Initial examination for either LAPL, class 1, ~~or~~ 2 or 3; also initial examination for upgrading from LAPL to class 2, or class 2 to 1 (~~notate~~ insert 'upgrading' in box 248).

Renewal/Revalidation – Subsequent ROUTINE examinations.

Extended Renewal/Revalidation – Subsequent ROUTINE examinations, which include comprehensive ophthalmological and otorhinolaryngology examinations.

202 HEIGHT – Measure height, without shoes, in centimetres to nearest cm.

203 WEIGHT – Measure weight, in indoor clothes, in kilograms to nearest kg.

204 COLOUR EYE – State colour of applicant's eyes from the following list: brown, blue, green, hazel, grey, multi.

205 COLOUR HAIR – State colour of applicant's hair from the following list: brown, black, red, fair, bald.

206 BLOOD PRESSURE – Blood pressure readings should be recorded as Phase 1 for Systolic pressure and Phase 5 for Diastolic pressure. The applicant should be seated and rested. Recordings in mm Hg.

207 PULSE (RESTING) – The pulse rate should be recorded in beats per minute and the rhythm should be recorded as regular or irregular. Further comments if necessary may be written in section 228, 248 or separately.

208 to 227 inclusive constitute the general clinical examination, and each of the boxes should be marked (with a tick) as normal or abnormal.

208 HEAD, FACE, NECK, SCALP – To include appearance, range of neck and facial movements, symmetry, etc.

209 MOUTH, THROAT, TEETH – To include appearance of buccal cavity, palate motility, tonsillar area, pharynx and also gums, teeth and tongue.

210 NOSE, SINUSES – To include appearance and any evidence of nasal obstruction or sinus tenderness on palpation.

211 EARS, DRUMS, EARDRUM MOTILITY – To include otoscopy of external ear, canal, tympanic membrane. Eardrum motility by valsalva manoeuvre or by pneumatic otoscopy.

212 EYES – ORBIT AND ADNEXA; VISUAL FIELDS – To include appearance, position and movement of eyes and their surrounding structures in general, including eyelids and conjunctiva. Visual fields check by campimetry, perimetry or confrontation.

213 EYES – PUPILS AND OPTIC FUNDI – To include appearance, size, reflexes, red reflex and fundoscopy. Special note of corneal scars.

214 EYES – OCULAR MOTILITY, NYSTAGMUS – To include range of movement of eyes in all directions; symmetry of movement of both eyes; ocular muscle balance; convergence; accommodation; signs of nystagmus.

215 LUNGS, CHEST, BREASTS – To include inspection of chest for deformities, operation scars, abnormality of respiratory movement, auscultation of breath sounds. Physical examination of female applicant's breasts should only be performed with informed consent.

216 HEART – To include apical heartbeat, position, auscultation for murmurs, carotid bruits, palpation for thrills.

217 VASCULAR SYSTEM – To include examination for varicose veins, character and feel of pulse, peripheral pulses, evidence of peripheral circulatory disease.

218 ABDOMEN, HERNIA, LIVER, SPLEEN – To include inspection of abdomen; palpation of internal organs; check for inquinal hernias in particular.

219 ANUS, RECTUM – Examination only on clinical indication ~~with~~ following an informed consent.

220 GENITO-URINARY SYSTEM – To include renal palpation; inspection palpation male/female reproductive organs only on clinical indication ~~with~~ following an informed consent.

221 ENDOCRINE SYSTEM – To include inspection, palpation for evidence of hormonal abnormalities/imbalance; thyroid gland.

222 UPPER AND LOWER LIMBS, JOINTS – To include full range of movements of joints and limbs, any deformities, weakness or loss. Evidence of arthritis.

223 SPINE, OTHER MUSCULOSKELETAL – To include range of movements, abnormalities of joints.

224 NEUROLOGIC – REFLEXES ETC. To include reflexes, sensation, power, vestibular system – balance, romberg test, etc.

225 PSYCHIATRIC – To include appearance, appropriate mood/thought, unusual behaviour.

226 SKIN, IDENTIFYING MARKS AND LYMPHATICS – To include inspection of skin; inspection, palpation for lymphadenopathy, etc. Briefly describe scars, tattoos, birthmarks, etc. which could be used for identification purposes.

227 GENERAL SYSTEMIC – All other areas, systems and nutritional status.

228 NOTES – Any notes, comments or abnormalities to be described – extra notes if required on separate sheet of paper, signed and dated.

229 DISTANT VISION AT 5/6 METRES – Each eye to be examined separately and then both together. First without correction, then with spectacles (if used) and lastly with contact lenses, if used. Record visual acuity in appropriate boxes. Visual acuity to be tested at either 5 or 6 metres with the appropriate chart for the distance.

230 INTERMEDIATE VISION AT 100 CM – Each eye to be examined separately and then both together. First without correction, then with spectacles if used and lastly with contact lenses if used. Record visual acuity in appropriate boxes as ability to read N14 at 100 cm (Yes/No).

231 NEAR VISION AT 30-50 CM. – Each eye to be examined separately and then both together. First without correction, then with spectacles if used and lastly with contact lenses, if used. Record visual acuity in appropriate boxes as ability to read N5 at 30-50 cm (Yes/No).

Note: Bifocal contact lenses and contact lenses correcting for near vision only are not acceptable.

232 SPECTACLES – Tick appropriate box signifying if spectacles are or are not worn by applicant. If used, state whether unifocal, bifocal, varifocal or look-over.

233 CONTACT LENSES – Tick appropriate box signifying if contact lenses are or are not worn. If worn, state type from the following list; hard, soft, gas-permeable or disposable.

313 COLOUR PERCEPTION – Tick appropriate box signifying if colour perception is normal or not. If abnormal; state number of plates of the first 15 of the pseudo-isochromatic plates (Ishihara 24 plates) have not been read correctly.

234 HEARING – Tick appropriate box to indicate hearing level ability as tested separately in each ear at 2 m.

235 URINALYSIS – State whether result of urinalysis is normal or not by ticking appropriate box. If no abnormal constituents, state NIL in each appropriate box.

236 PULMONARY FUNCTION – When required or on indication, state actual FEV_1/FVC value obtained in % and state if normal or not with reference to height, age, sex and race.

237 HAEMOGLOBIN – Enter actual haemoglobin test result and state units used. Then state whether normal value or not, by ticking appropriate box.

238 to 244 inclusive: ACCOMPANYING REPORTS – One box opposite each of these sections must be ticked. If the test is not required and has not been performed, then tick the NOT PERFORMED box. If the test has been performed (whether required or on indication) complete the normal or abnormal box as appropriate. In the case of question 244, the number of other accompanying reports must be stated.

247 AME RECOMMENDATION – The applicant's name, date of birth and reference number, should be entered here in block capitals. The applicable class of medical certificate should be indicated by a tick in the appropriate box. If a fit assessment is recommended and a medical certificate has been issued, this should be indicated in the appropriate box. An applicant may be recommended as fit for a lower class of medical certificate (e.g. class 2), but also be deferred or recommended as unfit for a higher class of medical certificate (e.g. class 1). If an unfit recommendation is made, applicable Part-MED paragraph references should be entered. If an applicant is deferred for further evaluation, the reason and the doctor or licensing authority to whom the applicant is referred should be indicated.

248 COMMENTS, LIMITATIONS, ETC. – The AME's findings and assessment of any abnormality in the history or examination, should be entered here. The AME should also state any limitation required.

249 AME DETAILS – The AME should sign the declaration, complete his/her name and address in block capitals, contact details and lastly stamp the relevant section with his/her designated AME stamp incorporating his/her AME number. The GMP identification no. is the number provided by the national medical system.

250 PLACE AND DATE – The place (town or city) and the date of examination should be entered here. The date of examination is the date of the general examination and not the date of finalisation of the form. If the medical examination report is finalised on a different date, the date of finalisation should be entered in section 248 as 'Report finalised on .....'.

GM1 ARA.MED.135(b);(c) Aero-medical forms

OPHTHALMOLOGY AND OTORHINOLARYNGOLOGY EXAMINATION REPORT FORMS

The ophthalmology and otorhinolaryngology examination report forms may be used as indicated in the following forms and corresponding instructions for completion.

OPHTHALMOLOGY EXAMINATION REPORT FORM

Complete this page fully and in block capitals – Refer to instructions for completion.

MEDICAL IN CONFIDENCE

Applicant's details

(1) State applied to:	(2) Medical certificate applied for: class 1 ☐ class 2 ☐ class 3 ☐		
(3) Surname:	(4) Previous surname(s):		(12) Application: Initial ☐ Revalidation/Renewal ☐
(5) Forename(s):	(6) Date of birth:	(7) Sex: Male ☐ Female ☐	(13) Reference number:

(301) ~~**Consent to release of medical information:**~~ I hereby ~~authorise the release of~~ declare that I have been informed and I understand that all information provided to my AME, contained in this report and ~~any or all~~ its attachments ~~to the AME and, where necessary~~, may be released to the medical assessor of the my licensing authority and to the medical assessor of the competent authority of my AME, recognising that these documents or electronically stored data are to be used for completion of a medical assessment and for oversight purpose ~~will become and remain the property of the licensing authority~~, providing that I or my physician may have access to them according to national law. Medical confidentiality will be respected at all times.

---------- Date ---------- Signature of applicant ---------- ~~Signature of AME~~

(302) Examination category:
Initial ☐
Revalidation ☐
Renewal ☐
Special referral ☐

(303) Ophthalmological history:

Clinical examination

Check each item		Normal	Abnormal
(304) Eyes, external & eyelids			
(305) Eyes, Exterior (slit lamp, ophth.)			
(306) Eye position and movements			
(307) Visual fields (confrontation)			
(308) Pupillary reflexes			
(309) Fundi (Ophthalmoscopy)			
(310) Convergence	cm		
(311) Accommodation	D		

(312) *Ocular muscle balance* (in prisme dioptres)

Distant at 5m/6m	Near at 30-50 cm
Ortho	Ortho
Eso	Eso
Exo	Exo
Hyper	Hyper
Cyclo	Cyclo
Tropia Yes No	Phoria Yes No
Fusional reserve testing Not performed	Normal Abnormal

(313) *Colour perception*

Pseudo-Isochromatic plates	Type: Ishihara (24 plates)
No of plates:	No of errors:
Advanced colour perception testing indicated Yes No Method:	
Colour SAFE	Colour UNSAFE

Visual acuity

(314) *Distant vision at 5m/6m*

	Uncorrected		Spectacles	Contact lenses
Right eye		Corrected to		
Left eye		Corrected to		
Both eyes		Corrected to		

(315) *Intermediate vision at 1m*

	Uncorrected		Spectacles	Contact lenses
Right eye		Corrected to		
Left eye		Corrected to		
Both eyes		Corrected to		

(316) *Near vision at 30-50cm*

	Uncorrected		Spectacles	Contact lenses
Right eye		Corrected to		
Left eye		Corrected to		
Both eyes		Corrected to		

(317) *Refraction*

	Sph	Cylinder	Axis	Near (add)
Right eye				
Left eye				

Actual refraction examined Spectacles prescription based

(318) *Spectacles*

Yes ☐ No ☐
Type:

(319) *Contact lenses*

Yes ☐ No ☐
Type:

(320) *Intra-ocular pressure*

Right (mmHg)	Left (mmHg)
Method	Normal ☐ Abnormal ☐

(321) **Ophthalmological remarks ~~and recommendation:~~**

(322) **Examiner's declaration:**

I hereby certify that I~~/my AME group~~ have personally examined or assessed the eye specialist's examination report of the applicant named ~~o~~in this medical examination report and that this report with any attachment embodies ~~my~~ the findings completely and correctly.

(323) Place and date:	~~Ophth examiner's~~ nName and address: (block capitals)	AME or eye specialist stamp with No.:
AME or eye specialist signature:	E-mail: Telephone No.: Telefax No.:	

INSTRUCTIONS FOR COMPLETION OF THE OPHTHALMOLOGY EXAMINATION REPORT FORM

Writing should be legible and in block capitals using a ball-point pen. Completion of this form by typing or printing is also acceptable. If more space is required to answer any question, a plain sheet of paper should be used, bearing the applicant's name, the name and signature of the AME or ophthalmology specialist performing the examination and the date of signing. The following numbered instructions apply to the numbered headings on the ophthalmology examination report form.

Failure to complete the medical examination report form in full, as required, or to write legibly may result in non-acceptance of the application in total and may lead to withdrawal of any medical certificate issued. The making of false or misleading statements or the withholding of relevant information by an examiner may result in criminal prosecution, denial of an application or withdrawal of any medical certificate granted.

The AME or ophthalmology specialist performing the examination should verify the identity of the applicant. The applicant should then be requested to complete the sections 1, 2, 3, 4, 5, 6, 7, 12 and 13 on the form and then sign and date the consent to release of medical information (section 301) with the examiner countersigning as witness.

302 EXAMINATION CATEGORY – Tick appropriate box.

Initial – Initial examination for either class 1 or 2; also initial examination for upgrading from class 2 to 1 (~~notate~~ insert 'upgrading' in section 303).

Renewal/Revalidation – Subsequent comprehensive ophthalmological examinations (due to refractive error).

Special referral – NON-ROUTINE examination for assessment of an ophthalmological symptom or finding.

303 OPHTHALMOLOGICAL HISTORY – Detail here any history of note or reasons for special referral.

304 to 309 inclusive: CLINICAL EXAMINATION – These sections together cover the general clinical examination and each of the sections should be marked (with a tick) as normal or abnormal. Any abnormal findings or comments on findings should be entered in section 321.

310 CONVERGENCE – Enter near point of convergence in cm, as measured using RAF near point rule or equivalent. Tick whether normal or abnormal. Any abnormal findings or comments on findings should be entered in section 321.

311 ACCOMMODATION – Enter measurement recorded in dioptres using RAF near point rule or equivalent. Tick whether normal or abnormal. Any abnormal findings or comments on findings should be entered in section 321.

312 OCULAR MUSCLE BALANCE – Ocular muscle balance is tested at distant 5 or 6 m and near at 30-50 cm and results recorded. Presence of tropia or phoria must be entered accordingly and also whether fusional reserve testing was NOT performed and if performed whether normal or not.

313 COLOUR PERCEPTION – Enter type of pseudo-isochromatic plates (ishihara) as well as number of plates presented with number of errors made by examinee. 15 plates should normally be presented from the 24 plate series, in random order. State whether advanced colour perception testing is indicated and what methods used (which colour lantern or anomaloscopy) and finally whether judged to be colour safe or unsafe. Advanced colour perception testing is usually only required for initial assessment, unless indicated by change in applicant's colour perception.

314–316 VISUAL ACUITY TESTING AT 5 m/6 m, 1 m and 30-50 cm – Record actual visual acuity obtained in appropriate boxes. If correction not worn nor required, put line through corrected vision boxes. Distant visual acuity to be tested at either 5 m or 6 m with the appropriate chart for that distance.

317 REFRACTION – Record results of refraction. Indicate also whether for class 2 applicants, refraction details are based upon spectacle prescription.

318 SPECTACLES – Tick appropriate box signifying if spectacles are or are not worn by applicant. If used, state whether unifocal, bifocal, varifocal or look-over.

319 CONTACT LENSES – Tick appropriate box signifying if contact lenses are or are not worn. If worn, state type from the following list; hard, soft, gas-permeable, disposable.

320 INTRA-OCULAR PRESSURE – Enter intra-ocular pressure recorded for right and left eyes and indicate whether normal or not. Also indicate method used – applanation, air etc.

321 OPHTHALMOLOGICAL REMARKS AND RECOMMENDATION – Enter here all remarks, abnormal findings and assessment results. Also enter any limitations recommended. If there is any doubt about findings or recommendations, the examiner may contact the ~~AMS~~ medical assessor of the licensing authority for advice before finalising the report form.

322 OPHTHALMOLOGY EXAMINER'S DETAILS – The ophthalmology examiner must sign the declaration, complete his/her name and address in block capitals, contact details and lastly stamp the report with his/her designated stamp incorporating his/her AME or specialist number.

323 PLACE AND DATE – Enter the place (town or city) and the date of examination. The date of examination is the date of the clinical examination and not the date of finalisation of form. If the ophthalmology examination report is finalised on a different date, enter date of finalisation on section 321 as 'Report finalised on .....'.

OTORHINOLARYNGOLOGY (ENT) EXAMINATION REPORT FORM

Complete this page fully and in block capitals – Refer to instructions for completion.

MEDICAL IN CONFIDENCE

Applicant's details

(1) State applied to:	(2) Medical certificate applied for: class 1 ☐ class 2 ☐ class 3 ☐		
(3) Surname:	(4) Previous surname(s):		(12) Application: Initial ☐ Revalidation/Renewal ☐
(5) Forename(s):	(6) Date of birth:	(7) Sex: Male ☐ Female ☐	(13) Reference number:

(401) ~~**Consent to release of medical information:**~~ I hereby ~~authorise the release of~~ declare that I have been informed and I understand that all information provided to my AME, contained in this report and ~~any or all~~ its attachments ~~to the AME and, where necessary~~, may be released to the medical assessor of the my licensing authority and to the medical assessor of the competent authority of my AME, recognising that these documents or electronically stored data are to be used for completion of a medical assessment and for oversight purpose ~~will become and remain the property of the licensing authority~~, providing that I or my physician may have access to them according to national law. Medical confidentiality will be respected at all times.

---------- ---------- ----------

Date Signature of applicant ~~Signature of AME~~

(402) Examination category:

Initial ☐
Special referral ☐

(403) Otorhinolaryngological (ENT) history:

Clinical examination

Check each item	Normal	Abnormal
(404) Head, face, neck, scalp		
(405) Buccal cavity, teeth		
(406) Pharynx		
(407) Nasal passages and naso-pharyn~~n~~x (incl. anterior rhinoscopy)		
(408) Vestibular system incl. Romberg test		
(409) Speech		
(410) Sinuses		
(411) Ext acoustic meati, tympanic membranes		
(412) Pneumatic otoscopy		
(413) ~~Impedance t~~Tympanometry including Valsalva me~~a~~noeuvre (initial~~only~~ or if clinically indicated)		

(419) *Pure tone audiometry*

dB HL (hearing level)

Hz	Right ear	Left ear
250		
500		
1000		
2000		
3000		
4000		
6000		
8000		

(420) *Audiogram*

o = Right – – – = Air
x = Left ..... = Bone

dB/HL	Hz 250	500	1000	2000	3000	4000	6000	8000
–10								
0								
10								
20								
30								
40								
50								
60								
70								
80								
90								
100								
110								
120								

Additional testing (if indicated)	Not performed	Normal	Abnormal
(414) Speech ~~audiometry~~ discrimination test with/without hearing aids,as applicable			
(415) Posterior rhinoscopy			
(416) E~~O~~NG; spontaneous and positional nystagm~~u~~s			
(417) ~~Differential c~~Caloric test or vestibular ~~auto~~rotation test			
(418) Mirror or fibre laryngoscopy			

(421) **Otorhinolaryngology remarks~~and recommendation~~:**

(422) **Examiner's declaration:**

I hereby certify that I~~/my AME group~~ have personally examined or assessed the ENT specialist's examination report of the applicant named ~~o~~in this medical examination report and that this report with any attachment embodies ~~my~~ the findings completely and correctly.

(423) Place and date:	~~ORL examiner's~~ nName and address: (block capitals)	AME or ENT specialist stamp with No:
AME or ENT specialist signature:	E-mail: Telephone No.: Telefax No.:	

INSTRUCTIONS FOR COMPLETION OF THE OTORHINOLARYNGOLOGY (ENT) EXAMINATION REPORT FORM

Writing should be legible and in block capitals using a ball-point pen. Completion of this form by typing or printing is also acceptable. If more space is required to answer any question, a plain sheet of paper should be used, bearing the applicant's name, the name and signature of the AME or otorhinolaryngology specialist performing the examination and the date of signing. The following numbered instructions apply to the numbered headings on the otorhinolaryngology examination report form.

Failure to complete the medical examination report form in full, as required, or to write legibly may result in non-acceptance of the application in total and may lead to withdrawal of any medical certificate issued. The making of false or misleading statements or the withholding of relevant information by an examiner may result in criminal prosecution, denial of an application or withdrawal of any medical certificate granted.

The AME or otorhinolaryngology specialist performing the examination should verify the identity of the applicant. The applicant should then be requested to complete the sections 1, 2, 3, 4, 5, 6, 7, 12 and 13 on the form and then sign and date the consent to release of medical information (section 401) with the examiner countersigning as witness.

402 EXAMINATION CATEGORY – Tick appropriate box.

Initial – Initial examination for class 1; also initial examination for upgrading from class 2 to 1 (~~notate~~ insert 'upgrading' in section 403)

Special Referral – NON-ROUTINE examination for assessment of an ORL (ENT) symptom or finding

403 OTORHINOLARYNGOLOGICAL (ENT) HISTORY – Detail here any history of note or reasons for special referral.

404-413 inclusive: CLINICAL EXAMINATION – These sections together cover the general clinical examination and each of the sections should be marked (with a tick) as normal or abnormal. Any abnormal findings or comments on findings should be entered in section 421.

414-418 inclusive: ADDITIONAL TESTING – These tests are only required to be performed if indicated by history or clinical findings and are not routinely required. For each test one of the boxes must be completed – if the test is not performed then tick that box – if the test has been performed then tick the appropriate box for a normal or abnormal result. All remarks and abnormal findings should be entered in section 421.

419 PURE TONE AUDIOMETRY – Complete figures for dB HL (hearing level) in each ear at all listed frequencies.

420 AUDIOGRAM – Complete audiogram from figures as listed in section 419.

421 OTORHINOLARYNGOLOGY (ENT) REMARKS AND RECOMMENDATION – Enter here all remarks, abnormal findings and assessment results. Also enter any limitations recommended. If there is any doubt about findings or recommendations the examiner may contact the ~~AMS~~ medical assessor of the licensing authority for advice before finalising the report form.

422 OTORHINOLARYNGOLOGY (ENT) EXAMINER'S DETAILS – The otorhinolaryngology (ENT) examiner must sign the declaration, complete his/her name and address in block capitals, contact details and lastly stamp the report with his/her designated stamp incorporating his/her AME or specialist number.

423 PLACE AND DATE – Enter the place (town or city) and the date of examination. The date of examination is the date of the clinical examination and not the date of finalisation of form. If the ORL (ENT) examination report is finalised on a different date, enter date of finalisation in section 421 as 'Report finalised on .....'.

AMC1 ARA.MED.151 Medical Confidentiality

To ensure medical confidentiality, all medical reports and records should be securely held with accessibility restricted to personnel authorised by the medical assessor.

GM1 ARA.MED.155 Transfer of Medical Files

INFORMATION FORM FOR THE TRANSFER OF A PILOT LICENCE MEDICAL DETAILS, IN CONFIDENCE				
ITEM	Ref. to ICAO Annex 1	Description		
1	I	State of licence issue		
2	II	Title of licence		
3	III	Serial number of any licence held (or national medical reference number)		
4	IV	Full name of holder		
5	V	Address of holder		
6	XIV	Date of birth		
7	VI	Nationality of holder		
8	VIII	Issuing authority		
9	-	Initial medical certificate:	Date of issue	
			Date of examination	
			Type (JAR, Part-Med or National)	
			Class	
10	-	Dates of last three Revalidation/renewal examinations (if any)		
11	XIII	Limitations (if any)		
12	-	Comments on any relevant aspect of the applicant's medical history or examination (if appropriate please enclose reports) Enclose latest general examination, ophthalmic and ENT reports as minimum		

If there is insufficient space on this form for any information please use additional page.

Certification		
I, Dr ……., as medical assessor of the (NAA name)……., certify that the details given above and on any additional pages included are true and correct.		
Date	Signature	Licensing authority and stamp

SECTION II — AERO-MEDICAL EXAMINERS (AMEs)

AMC1 ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate

INSPECTION OF THE AME PRACTICE

Before issuing the AME certificate, the competent authority should conduct an inspection of the AME practice to verify compliance with ARA.MED.200(a).

For applicants for an AME Certificate to exercise the privileges of class 2 medical certification only, a virtual inspection of the AME premises may be acceptable. In case of concerns regarding compliance with this regulation, an on-site inspection should be conducted.

AMC2 ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate

The procedure should include:

(a) for the initial issue or extension of privileges, evidence of successful completion of an approved aviation medicine training course in accordance with the privileges of the AME certificate applied for;

(b) for revalidation and renewal, evidence of refresher training and maintenance of aero-medical competency

AMC1 ARA.MED.246 Cooperative oversight of AMEs and AeMCs

The cooperative oversight procedure may include oversight tasks to be undertaken by the competent authority of the Member State where the AME/AeMC has its secondary place of business.

The results of the oversight should be shared among the Member States involved.

SECTION III — MEDICAL CERTIFICATION

AMC1 ARA.MED.315(a) Review of examination reports

GENERAL

(a) The process to review examination and assessment reports received from AeMCs, AMEs and GMPs should aim to check all reports ~~received~~.

(b) The licensing authority may develop an assessment process to ~~should~~ take account of the proportion of inconsistencies or errors found~~in the assessment process and~~, adapt the sample size accordingly and consider corrective action~~to review all reports if necessary~~.

(c) The licensing authority should implement a medical review process of all examination and assessment reports received from AeMCs, AMEs and GMPs certified by the competent authority of another Member State.

AMC1 ARA.MED.325 Secondary review procedure

(a) The procedure should specify:
  (1) the establishment of a review board and its composition;
  (2) how the accredited medical conclusions of the review board will be implemented.

(b) The composition of the review board should be decided by the licensing authority preceded by the advice of the medical assessor and may consist of, but no limited to:
  (1) clinical medical experts according to the case;
  (2) other technical experts according to the case;
  (3) aviation medicine experts;
  (4) AME with privileges according to the class on medical certificate in question.

AMC1 ARA.MED.330 Special medical circumstances

GENERAL

The protocol should:

(a) ~~assess the incapacitation risk~~ include rationale and background information as well as the goals and objectives of the intended certification activity;

(b) include description of the following aspects:
  (i) quality assurance;
  (ii) expected outcomes;
  (iii) project management;

(c~~b~~) assess the risk of incapacitation and subtle impairment of performance;

(d~~c~~) undertake a risk-benefit analysis;

(e~~d~~) include a review of the regulations in use in other major aviation states and ICAO;

(~~e~~) ~~determine which class of medical certificate is included in the scope;~~

(f) estimate the number of ~~pilots~~ applicants likely to be included;

(g) list all anticipated risks to the protocol and provide a risk management strategy including appropriate limitations for ~~every~~ anticipated risks. Where the risk of subtle impairment of performance is identified, the protocol should include requirements for minimum simulator testing or minimum line-flying under supervision or both.

(h) nominate medical research institutions or scientists ~~experts~~, if necessary, to provide advice on research methods.

AMC1 ARA.MED.330(b)(c) Special medical circumstances

GENERAL

Initial medical certificates issued on the basis of the certification ~~a research~~ protocol should only be issued by the ~~competent~~ participating licensing authority. Thereafter, the ~~competent~~ participating licensing authority should decide whether or not ~~the~~ an AeMC or AME may ~~issue~~ renew/revalidate the medical certificate.

GM1 ARA.MED.330 Special medical circumstances

GENERAL

~~(a) When the terms 'medical assessment protocol', 'research protocol' and 'protocol' (as mentioned in ARA.MED.330 and its associated AMC) are used, they all refer to a 'medical assessment protocol'.~~

(~~b~~a) The protocol ~~is to enable~~ should allow experience to be gained on special medical circumstances in a controlled manner. This is to facilitate a better understanding of the treatment or condition, so that an evidence-based decision concerning its implementation may be considered.

(~~c~~b) The protocol and its implementation should comply with the principles described in the following publication by the World Medical Association (WMA): 'WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects', as last amended.

3.2.2. AMC/GM to Part ORA

Subpart AeMC SPECIFIC REQUIREMENTS RELATING TO AERO-MEDICAL CENTRES (AeMCs) is amended as follows:

Subpart AeMC – Aero-medical Centres

SECTION I — GENERAL

GM1 ORA.AeMC.105 Scope

The AeMC should support the regional AME peer groups in order to enhance the professional expertise

AMC1 ORA.AeMC.115 Application

GENERAL

(a) The documentation for the approval of an AeMC should include the names and qualifications of all medical staff, a list of medical and technical facilities for initial class 1 and class 3 aero-medical examinations and of supporting specialist consultants.

~~(b) The AeMC should provide details of clinical attachments to hospitals, medical institutions and/or specialists.~~

(b) Medical staff should cover the minimum required medical examinations to be performed within the organisation of the AeMC

(c) Contracted activities with designated hospitals or medical institutes for the purpose of additional specialist medical examinations include clinical attachments or liaison with hospitals, medical institutions and/or specialists.

AMC1 ORA.AeMC.135 Continued validity

EXPERIENCE

(a) At least a total of 200 class 1 or class 3 aero-medical examinations and assessments should be performed at the AeMC every year.

(b) In Member States where the number of aero-medical examinations and assessments mentioned in (a) cannot be reached due a low number of professional pilots and ATCOs, a proportionate number of class 1 or class 3 aero-medical examinations and assessments should be performed.

(c) In these cases, the continuing experience of the head of the AeMC and aero-medical examiners on staff should also be ensured by them performing aero-medical examinations and assessments for:

(1) class 2 medical certificates as established in Part-MED; and/or

(2) third country class 1 or class 3 medical certificates, as applicable.

(d) Aero-medical research including publication in peer reviewed journals may also be accepted as contributing to the continued experience of the head of, and aero-medical examiners at, an AeMC.

SECTION II — MANAGEMENT

AMC1 ORA.AeMC.200 Management system

(1) Assessment of the AeMC's management system by a national medical authority may be included in the overall aero-medical management system;

(2) In order to maintain personnel trained and competent to perform their tasks as specified in ORA.GEN.200(a)(4) the management system should ensure that each AME performs a proportionate number of aero-medical assessments in accordance with their AME certificate. The proportion of aero-medical assessments carried out by each AME at an AeMC should take into consideration their activity in the AeMC and be specified in the management system.

GM2 ORA.AeMC.200 Management system

The management system should encompass regular exchange of professional expertise including case analysis.

AMC1 ORA.AeMC.205 Contracted activities

(1) The minimum required medical examinations should at least encompass the following specialities: ophthalmology including colour vision, otorhinolaryngology, cardiology and mental health

AMC1 ORA.AeMC.210 Personnel requirements

GENERAL

(a) The aero-medical examiner (AME) should have held AME ~~class 1~~ privileges , as applicable in accordance with the scope defined in the terms of approval attached to the AeMC's certificate for at least 5 years and have performed at least 200 aero-medical examinations for a class 1 or class 3 medical certificate before being nominated as head of an AeMC.

~~(b) The AeMC may provide practical AME training for persons fully qualified and licensed in medicine.~~

AMC1 ORA.AeMC.215 Facility requirements

MEDICAL-TECHNICAL FACILITIES

The medical-technical facilities of an AeMC should consist of the equipment of a general medical practice and, in addition, of equipment for:

(a) Cardiology

Facilities to perform:

(1) 12-lead resting ECG;

(2) ~~stress~~ exercise ECG;

(3) 24-hour blood pressure monitoring; and

(4) 24-hour heart rhythm monitoring.

(b) Ophthalmology

Facilities for the examination of:

(1) near, intermediate and distant vision;

(2) external eye, anatomy, media and fundoscopy;

(3) ocular motility;

(4) binocular vision;

(5) colour vision (anomaloscopy or equivalent);

(6) visual fields;

(7) refraction; and

(8) heterophoria.

(c) Hearing

(1) pure-tone audiometer

(d) Otorhinolaryngology (ENT)

Facilities for the clinical examination of mouth and throat and:

(1) otoscopy;

(2) rhinoscopy;

(3) tympanometry or equivalent; and

(4) clinical assessment of vestibular system.

(e) Examination of pulmonary function

(1) spirometry

(f) The following facilities should be available at the AeMC or arranged with a service provider:

(1) clinical laboratory facilities; and

(2) ultrasound of the abdomen.

4. Impact assessment (IA)

This NPA contributes to updating the medical relevant subpart of Part-ARA and Part-ORA to reflect the latest updates to Part-MED and addresses the inconsistencies identified throughout the implementation process. Overall, this would provide a moderate safety benefit while providing a socially acceptable opportunity for the affected stakeholders. Furthermore, it would have no environmental and economic impacts. There is no need to develop a regulatory impact assessment (RIA).

5. Proposed actions to support implementation

Focused communication for advisory body meetings – Aircrew TeB, FS TEC and MEG.

6. References

6.1. 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) 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)

6.2. Affected AMC and GM

— Decision No 2012/006/Directorate R of the Executive Director of the Agency of 19th April 2012 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-ARA'

— Decision No 2012/007/Directorate R of the Executive Director of the Agency of 19th April 2012 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-ORA'

6.3. Other 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)

7. Appendix

N/A