European Aviation Safety Agency

Comment-Response Document 2017-22

RELATED NPA: 2017-22 — RELATED OPINION: NO 05/2023 — RMT.0190

21.2.2024

Table of contents

1. Summary of the outcome of the consultation 2
2. Individual comments (and responses) 3

Disclaimer

No quality control has been performed on this document.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

1. Summary of the outcome of the consultation

This document comprises individual responses to all comments received for NPA 2020-14.

For an overview of essential comments received and subsequent changes to the draft regulatory material, please refer to the Opinion, Chapter 2.4.2.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

2. Individual comments (and responses)

[This section is extracted from CRT by RPS and is pasted in the template. Optionally, if deemed appropriate by the Agency, individual responses may be provided.]

In responding to comments, a standard terminology has been applied to attest EASA's position. This terminology is as follows:

(a) **Accepted** — EASA agrees with the comment and any proposed amendment is wholly transferred to the revised text.

(b) **Partially accepted** — EASA either agrees partially with the comment, or agrees with it but the proposed amendment is only partially transferred to the revised text.

(c) **Noted** — EASA acknowledges the comment but no change to the existing text is considered necessary.

(d) **Not accepted** — The comment or proposed amendment is not shared by EASA.

(General Comments)	-

comment | 97 | comment by: _Sam Sexton_

There seems to be a problem with a ATCO,s that are also Private Pilots PPL.

They have to hold 2 medical certificates.

A Class 3 for there ATCO,s employment and a Class 2 for the PPL..

This has meant an AME has to issue 2 certificates for basicially doing the 1 medical. And charging two fees.

Can EASA clarify that a Class 2 medical would also cover the Class 3 medical requirements for his ATCO role.

Or would this need to be covered by an AMC.

response

Not Accepted

The aero-medical requirements for pilots and ACTOs are different due to the different working environment. Currently the 2 sets of requirements are totally different and require e separate medical certificates although some of the medical investigations might be similar.

Regarding the statement that Class 2 covers also Class 3, that is incorrect. Although the classes of aero-medical certification are numbered that doesn't necessarily means that they have a direct connection.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment	*198* comment by: *Luftfahrt-Bundesamt*
	General comment with reference to ARA.MED.125, AMC1 ARA.MED.125, ARA.MED.126, ARA.MED.155, ARA.MED.315, AMC1 ARA.MED.315, ARA.MED.325 and AMC1 ARA.MED.325 **We herewith submit our general comment on the a.m. paragraphs as to the use of the term 'licensing authority', but, in addition, specify it in more detail in the relevant paragraphs.** **Due to the federal system in Germany, we have a lot of licensing authorities. However, there is only one aero-medical section, which is responsible for pilots either having their license issued by the LBA or by the Federal States and which is the aero-medical section of the LBA taking the medical decisions. Therefore, we prefer to use our wording 'the aero-medical section of the licensing authority'.**
response	Accepted

General comments	p. 1

comment	*214* comment by: *European Transport Workers Federation - ETF*
	1) ETF is advising EASA against the uniformisation of medical requirements between flight crew and air traffic control officers. We acknowledge that certain administrative issues require some alignments for AME/AeMCs and competent authorities but clear distinction in applicable medical requirements shall be kept.
response	Noted EASA would like to reassure the stakeholders that the actual medical requirements will not be merged. The current NPA has within its scope only the Authorities requirements and Organizations requirements.

comment	*215* comment by: *European Transport Workers Federation - ETF*
	1) It is unclear whether the AMCs and GMs associated with the parts of the flight crew regulation applicable also to ATCO medical regulation are applicable to ATCOs as well or not.
response	Noted To try to further clarify the requirements of Parts ARA and ORA of Aircrew regulation that are applicable to the Competent Authorities and Aero-Medical Centres and do not impose any medical technical requirements for ATCOs.

comment	*300* comment by: *Finnish Transport Safety Agency*
	Finnish Transport Safety Agency supports the proposed NPA 2017-22 with no comments.
response	Noted

comment	*366* comment by: *ATCEUC*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	ATCEUC doesn't agree on the necessity to against the uniform medical requirements between ATCOs and flight crew ATCEUC is aware that there is too much burden on AMEs and AeMCs, nevertheless ATCEUC position is to maintain well distinct the medical requirements among the two profession
response	Noted EASA would like to reassure the stakeholders that the actual medical requirements will not be merged. The current NPA has within its scope only the Authorities requirements and Organizations requirements.

comment	*368* comment by: *René Meier, Europe Air Sports* Europe Air Sports thanks the Agency for the preparation of NPA 2017-22 updating Part-MED and related AMC as well as GM. The texts proposed were checked by medical experts, foremost by Ms Marja Osinga. On her behalf I am submitting the following comments, respecting the structure of the NPA.
response	Noted

comment	*395* comment by: *European Cockpit Association* ECA welcomes the amendments to Part MED related ARA/ORA regulations. As a whole - the proposed changes are acceptable. We have some specific comments which can be found under the respective sections of the NPA.
response	Noted

1. About this NPA p. 3

comment	*253* comment by: *French DGAC* We note that the proposal includes modifications concerning the wording ‘competent authority’ and ‘licensing authority’ (eg ARA.MED.325) Could you please inform us of the reasoning behind these changes? It seems to France that the phrase ‘competent authority’ includes the licencing authority, which itself includes the authority’s medical assessor. Furthermore, we note that the changes proposed presume that the same authority is in charge of pilots and ATCO medical certification, which is not the case in France. For this reason, part of the amendments aiming at rationalizing tasks create in reality an administrative burden in France, as is stated below.
response	Not accepted In cases where the applicants pursue the medical certification in other State than their state of licence issue, the naming convention allows to make the differentiation between the competent authority of the AME/AeMC and the licensing authority of the applicant

2. In summary – whay and what p. 4-8

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment	_301_ comment by: _Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)_ **Section:** In summary – why and what 2.4 **Page**: 7 **Comment**: Section 2.4 very superficially summarises benefits and drawbacks of the proposals. However, this short text is far from the RIA required for a change of a Commission Regulation. **Proposal**: The NPA 2017-22 needs to be amended with a thorough RIA.
response	Noted Impact assessment is addressed in section 4.

3. Proposed amendments – Part-ARA – ARA.MED.120	p. 9

comment	_3_ comment by: _CAA.CZ_ I have no comments
response	Noted

comment	_5_ comment by: _CAA.CZ_ I have no comments
response	Noted

comment	_76_ comment by: _Bruno Herencic_ **<u>Description of problem</u>** There are some very experienced general aviation / aeroclub pilots with sub-standard vision in one eye who cannot obtain class 1 medical certificate. Many of these pilots are highly competent and capable and they cannot cannot progress to become examiners on light aircraft or fly skydiving or banner towing flights. Allowing these pilots to obtain a limited class 1 certificate would be a benefit without introducing additional risks. Suggest to amend this NPA to also include this change that would create an immediate positive impact.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Objective:
- Allow pilots with sub-standard vision in one eye to obtain a limited class 1 medical.

Proposed changes:
Change MED.B.070 (c) by adding following text:

(4) applicants for an initial Class 1 medical certificate with substandard vision in one eye, who hold a Class 2 medical certificate and have more than 500 hours of flying experience shall be referred to the licensing authority and may be assessed as fit with the limitation OCL.

Change MED.B.001 (d) by adding the following text:
(4) Operational Commercial Air Transport Operations Limitation (OCL)
(i) The holder of a medical certificate with an OCL limitation may not operate an aircraft in Commercial Air Transport Operations.

Risk mitigation:
- Risk in commercial air transport operations is eliminated by introducing the OCL limitation

There is really no additional risk because these pilots already fly, they demonstrate during their skill tests and prof. checks that they are competent and capable of performing their duties.

response

Not accepted
The scope of this NPA is to ament the medical relevant subparts of Part-ARA and Part-ORA. An amendment to Part- MED is not within the scope of this NPA. However we will consider your proposal during a future rulemaking task dedicated to Part-MED

comment

77 comment by: *Sven Larsson*

It came to our attention that there are pilots with sub-standard vision in one eye that cannot obtain CPL or become examiners although they are more than competent. Allowing these pilots to obtain a Class 1 medical with a specific limitation would not increase risks.

We propose the following to be included with this NPA:
Amend MED.B.070 to allow applicants for an initial Class 1 medical certificate with substandard vision in one eye to be assessed as fit with a specific limitation.

Amend MED.B.001 by specifying such a limitation, e.g. "Not Authorized to operate in CAT operation on complex aircraft".

response

Not accepted
The scope of this NPA is to ament the medical relevant subparts of Part-ARA and Part-ORA. An amendment to Part- MED is not within the scope of this NPA. However we will consider your proposal during a future rulemaking task dedicated to Part-MED

comment

83 comment by: *Aivars PRIEKULIS*

(a) <experience in clinical medicine>

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	- Do we really need clinical doctors (which speciality?) dealing mostly with admin issues. Not sure if experienced clinical doctor would be happy to start AMS duties. *- Proposed text* <experience in medicine>
response	Not accepted The main task of the medical assessors is to review the medical files and to make the aero-medical assessment in the referred cases. In accordance with MED.B.001 (a)(1) *"If the applicant does not fully comply with the requirements for the relevant class of medical certificate but is considered to be not likely to jeopardise flight safety, the AeMC or AME shall:* *(i) in the case of applicants for a Class 1 medical certificate, refer the decision on fitness of the applicant to the licensing authority"* The referred cases are the class 1 borderline cases which have the highest safety impact and need a more in depth assessment and more clinical experience to assess. A doctor with pathologist with 20-30 years of experience in medicine, but without evaluating at least one patient will most likely not be able to make the proper aero-medical assessment.

comment	*84* comment by: *Aivars PRIEKULIS* (c) specific training in aero-medical certification *- It looks to be possible only for those who have working experience at AMS, as there are no specific training courses/possibilities available.* *- Proposed text:* (c) specific training in medical certification
response	Not accepted The others types of medical certification are not relevant for the activity of medical assessor. However such training should be organized by the competent authority and could be part of the initial training after employment.

comment	*94* comment by: *Dr.Beiderwellen, Vice President of GAAME* Sowohl die Qualifikation eines Medical assessors bei Ernennung als auch der Nachweis über die geforderte Fortbildung muss supranational (EASA?) überprüft werden. Die Ernennung ist zeitlich zu befristen. (S. GM 1.ARA.MED.120) Auf Grund der erheblichen Verantwortung des medical assessors, nicht zuletzt im Bezug auf die second review procedure (AMC1.ARA.MED.325) ist eine entsprechend hohe Qualifikation des medical assessor sicher zu stellen. Darüber hinaus bedarf diese Qualifikation einer ständigen Aktualisierung und Überprüfung. Erfüllt der medical assessor diese Qualifikation nicht oder nicht mehr, ist die Ernennung umgehend zu widerrufen. (4) Die Ernennung eines Medical assessor erfolgt für längsten 3 Jahre (5) Zur Verlängerung dieser Periode ist die nach (c) 1-3 geforderte Fortbildung und wissenschaftliche Tätigkeit des medical assessor der EASA nachzuweisen.
response	Noted EASA agrees that the qualifications and maintenance of competence of the medical assessors are very important. For this reason, and giving proper consideration to the principle of balanced requirements, EASA has included in AMC1 ARA.MED.120 means of

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

compliance for initial qualification and recurrent training of the medical assessors. Further detailed procedures shall be developed by each individual competent authority for their member state. EASA is assessing the national procedures as part of its standardisation activities.

comment | *95* | comment by: *Martina Prpic*

We have noticed that there are many pilots with substandard vision in one eye, who hold Class 2 medical certificate and are unable to become examiners on light/general aviation aircrafts.

Allowing these pilots to obtain limited Class 1 medical would not increase risk since they already fly the same aircrafts and demonstrate they are able to do so during their skill test and proficiency checks.

We propose the following to be included with this NPA:

Amend MED.B.070 to allow applicants for an initial Class 1 medical certificate with substandard vision in one eye, who hold Class 2 medical certificate and have more than 500 hours of flying experience to be assessed as fit with a limitation.

Amend MED.B.001 by adding the limitation "The holder may not operate an aircraft in Commercial Air Transport Operations"

response | Not accepted
The scope of this NPA is to ament the medical relevant subparts of Part-ARA and Part-ORA. An amendment to Part- MED is not within the scope of this NPA. However we will consider your proposal during a future rulemaking task dedicated to Part-MED

comment | *96* | comment by: *Dr.Beiderwellen, Vice President of GAAME*

NPA 2017-22
Comments oft he German association of aeromedical examiners (GAAME)
Number
comment proposal
ARA.MED.120
AMC1.ARA.MED.120
AMC1.ARA.MED.325
Sowohl die Qualifikation eines
Medical assessors bei Ernennung
als auch der Nachweis über die
geforderte Fortbildung muss
supranational (EASA?) überprüft
werden.
Die Ernennung ist zeitlich zu
befristen. (S. GM
1.ARA.MED.120)

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Auf Grund der erheblichen
Verantwortung des medical
assessors, nicht zuletzt im Bezug
auf die second review procedure
(AMC1.ARA.MED.325) ist eine
entsprechend hohe Qualifikation
des medical assessor sicher zu
stellen.
Darüber hinaus bedarf diese
Qualifikation einer ständigen
Aktualisierung und Überprüfung.
Erfüllt der medical assessor
diese Qualifikation nicht oder
nicht mehr, ist die Ernennung
umgehend zu widerrufen.
(4) Die Ernennung eines Medical
assessor erfolgt für längsten 3 Jahre
(5) Zur Verlängerung dieser Periode ist
die nach (c) 1-3 geforderte Fortbildung
und wissenschaftliche Tätigkeit des
medical assessor der EASA
nachzuweisen.
GM1.ARA.MED 120
Expert pool:
Nicht nur AME aus Industrie
oder Militär sollten berufen
werden Können. Erehebliches
Fachwissen findet sich in den
AeMC und bei den nationalen
AME-Verbänden
- qualified AMEs from the industriy and
AeMC or AME-associations
ARA.MED.126
Bei Aufhebung eines medicals
muss der ausstellende
AME/AeMC über diesen Vorgang
und die Gründe informiert
werden.
Dies dient der
Qualitätssicherung und stellt
sicher, dass zukünftig in gleich
gelagerten Fällen eine korrekte
Tauglichkeitsentscheidung
getroffen werden kann.
(d) in case of limitation,suspension or
revocation of a medical certificate, the
medical assessor shall inform the
issuing AME/AeMC about the reason
for limitation , suspension or
revocation.
ARA.MED.128

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Ein befristeter Zeitrahmen für
die endgültige Entscheidung im
Falle einer Konsultation ist
zwingend vorzugeben.
A final decision has to be taken by the
competent authority within 3 months
after having received the case.
ARA.MED.125
Ein befristeter Zeitrahmen für
die endgültige Entscheidung im
Falle einer Verweisung ist
zwingend vorzugeben.
A final decision has to be taken by the
competent authority within 3 months
after having received the case.
ARA.MED.130
Eine Vereinheitlichung der
Medicals in allen EASA
Mitgliedsstaaten ist
anzustreben.
Da die Mehrzahl der
Mitgliedsstaaten „EMPIC“
eingeführt hat, ist das Medical
dort EASA weit zu installieren.
Ein Medical-Vordruck für alle EASAMitgliedsstaaten.
Es ist sicherzustellen, dass allen
AME/AeMC
- die Vordrucke rechtzeitig und
kostenlos
zur Verfügung gestellt werden.
- Die Vordrucke rechtzeitig in „Empic „
installiert werden
ARA.MED.135
AMC1.ARA.MED.135(a)
Eine Vereinheitlichung der
Formblätter in allen EASA
Mitgliedsstaaten ist
anzustreben.
Da die Mehrzahl der
Mitgliedsstaaten „EMPIC“
eingeführt hat, ist das Medical
dort EASA weit zu installieren.
Ein Formularvordruck für alle EASAMitgliedsstaaten.
Es ist sicherzustellen, dass allen
AME/AeMC
- die Vordrucke rechtzeitig und
kostenlos zur Verfügung gestellt
werden.
- Die Vordrucke rechtzeitig in „Empic „
installiert werden
ARA.MED.135

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

AMC1.ARA.MED.135
(b) (c)
s. oben
s.oben
ARA.MED.240
ARA.MED.245
Für GMP, welche
Tauglichkeitsuntersuchungen
durchführen, ist ein
Überprüfungssystem zu
etablieren, dass sich an den
Überprüfungen und
Fortbildungsverpflichtungen der
AME orientiert.
Die Zulassung eines GMP ist
ebenfalls auf 3 Jahre zu
befristen.
Alle GMP, die
Tauglichkeitsuntersuchungen
durchführen, haben gegenüber der
competent authority nachzuweisen,
dass
- sie über geeignete Räumlichkeiten
und Geräte verfügen
- sie an regelmäßigen Fortbildungsveranstaltungen/
refresher Seminaren
teilgenommen haben.
- sie eine minimale Anzahl von
Tauglichkeitsuntersuchungen
innerhalb
des Zulassungszeitraumes durchgeführt
haben.
ARA.MED.250
s. oben GMP ist zu ergänzen wie in
ARA.MED.255 bereits geschehen
ARA.MED.330
Da die competent authorithy
nicht über vollständige
Informationen zu medizinischen
Neuerungen oder geänderte
Leitlinien verfügt, muss eine
Möglichkeit geschaffen werden,
ein certification protocol durch
AME oder AeMC zu initiieren
(a) (i) : AME and AeMC may inform
the comptent authority about
new medical procedures,
technology or
medication and initiate the
development of a certification
protocol.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Partially accepted New point was added to AMC1 ARA.MED.126 to require the time limits to be defined in the referral procedure.

comment	*98* comment by: *AESA* (b) specific knowledge and experience in aeromedical practice. How to quantify i?. We understand a novel candidate is excluded. Guidance material should be available. (c) specific training in aeromedical certification. Guidance material should be available.
response	Not accepted Guidance material is provided explaining that not fully qualified candidate may be employed and trained on the job before being appointed as medical assessors.

comment	*132* comment by: *AMABEL* In **ARA.MED.120** about Medical Assessors, AMABEL recommends to leave the chapter as it was, namely to request from the Medical Assessor that he or she has to be qualified in Medicine and have: 1. a. postgraduate work experience in clinical medicine of at least 5 years ; 2. b. specific knowledge and experience in aviation medicine; and 3. c. specific training in aero- medical certification included a large experience in Class 1 certification or equivalent as it is mentioned in the **AMC1 ARA.MED.120**
response	Not accepted As you mentioned the prescriptive criteria are part of the corresponding AMC because they are in fact an acceptable way to comply with the high level implementing rules. This is intended to present the level of qualification and experience needed to ensure the safety and in the same time allows the competent authority flexibility to find alternative solutions that would ensure an equivalent level of safety (e.g. experience in assessing fitness of military pilots).

comment	*192* comment by: *German Military Aviation Authority* My perception is, that it became official policy of EASA decided by the Management Board, to introduce performance based rulemaking. Following that idea, prescribed numbers and time periods should be critically reconsidered, to abandon such an approach on a general basis would be the logical consequence of performance based rulemaking There are examples in the field of medicine like ARA.MED.120 (a) where that idea seemes to be executed already, but others (e.g. AMC 1 ORA.AeMC.135) where prescribed numbers and timelines are still used, contradicting the above mentioned idea.
response	Not accepted Although it is true that the prescriptive part of ARA.MED.120 was removed, those provisions can be found in slightly different form in the corresponding AMC because they are in fact an acceptable way to comply with the high level implementing rules. This is intended to

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

present the level of qualification and experience needed to ensure the safety and in the same time allows the competent authority flexibility to find alternative solutions that would ensure an equivalent level of safety (e.g. experience in assessing fitness of military pilots).
It is similar in the case of ORA.AeMC.135 and corresponding AMC.

comment *197* comment by: *German NSA (BAF)*

“aero-medical” tasks: Not all tasks of medical assessors are specifically medical. E.g. certification of an AME or AeMC is an administrative task of issuing a certificate to a person or organisation.

Proposal:
Delete 'aero-medical'

response Not accepted
The meaning of the requirement is that for the aero-medical tasks the competent authority shall appoint a medical assessor. The other purely administrative tasks can be undertaken by the medical assessor or by other support staff, subject to the decision of the competent authority, as explained in the corresponding AMC/GM.
Regarding your example of authorization of an AME or AeMC, if you reduce it to issuing the certificate then it is true it is a purely administrative tasks which can be performed by non-medical staff. However, this is based on the assessment of the qualification and experience and an audit of the medical facilities and practice which has several medical components like assessing the patients flows, the investigation equipment, providing guidance to the AME or AeMC and answering their questions (e.g. why do we need to use a 12 lead ECG and not a 6 lead)

comment *199* comment by: *Luftfahrt-Bundesamt*

ARA.MED.120 Medical assessors
Due to the amendments proposed under (a), the required specialist qualification of a medical assessor is considerably reduced. A job starter with only a few months of professional experience would comply with the requirement under (a). Furthermore, the term “clinical medicine” is not defined in Germany. There is no equivalent in German for the English term “clinical medicine”, namely the study of disease by direct examination of the living patient. In Germany, clinical medicine includes dentistry, environmental medicine, radiology etc. For such doctors it should be doubted, if they have sufficient professional skills for operating as a medical assessor. A simple transfer of the English term into German makes no sense and is not possible.
Therefore, a medical specialist qualification must be requested whereby the discipline requires a direct contact with the patient including diagnosis and therapy of health problems. The specialist qualification of the medical assessors should not either fall behind the specialist qualification as a medical specialist required for AMEs, since the medical assessors are to supervise the work of the AME/AeMC (audits, referrals, consultations). Without a corresponding specialist qualification, trustworthiness and assertiveness of official decisions would be lost. For a sufficient specialist qualification, however, a certification or activity of the medical assessors as AME is dispensable or even counterproductive (conflict of interests).

response Noted
The term ‘clinical medicine’ to be defined in the definition section

comment	*227* comment by: *The Norwegian Civil Aviation Authority* "Postgraduate work experience in clinical medicine of at least 5 years" is a more relevant requirement than class 1 privileges for at least 5 years, considering that the most demanding tasks of a medical assessor is the assessment of complex medical issues (e.g. cardiological, neurological and psychiatric issues). In ARA.MED.120 (b) the term "aviation medicine" should be kept in addition to "aero-medical practice" as these may have slightly different meanings. Knowledge in aerospace medicine is most important in assessment of referred medical cases, while knowledge about aero-medical practice is relevant in the oversight of AMEs.
response	Partially accepted It is true that the most demanding tasks of the medical assessor are to assess the complex medical cases in case of referral, consultation or secondary review. However, having an experience of 5 years of class 1 privileges is more important because of the following reasons: • class 1 privileges presumably mean that the AME has completed the specialist training • the cases might be of a different body system (e.g. a psychiatrist might have cardiology or other cases) and in this case the 5 years of experience in examining and assessing the entire body will be much more relevant that having 5 years in their own speciality • the aviation medicine knowledge and experience as well as the integration of a pathology in the aviation environment is more important than knowledge and experience in a particular speciality. Furthermore, for the purpose of a diagnosis and prognosis the medical assessor can ask for additional specialist examinations. We acknowledge that although it is a small difference in meanings of the 2 terms, it is still a difference and we will consider both terms for the IR.

comment	*369* comment by: *René Meier, Europe Air Sports* 3.1.1. Part-ARA – Section 1 General page 9/52 In our view the wording is inconsistent: In the document the words "Competent Authority" and "Licensing Authority" are used, this is not consistent and correct. Rationale: Using two different terms for one functions leads to confusion. Proposal: Please check the NPA for the correct and consistent wording, by applying the term "Competent Authority" only.
response	Noted In cases where the applicants pursue the medical certification in other State than their state of licence issue, the naming convention allows to make the differentiation between the competent authority of the AME/AeMC and the licensing authority of the applicant

comment	*370* comment by: *René Meier, Europe Air Sports* ARA.MED.120 Medical assessors page 9/52 Inconsistency in wording: One or more medical assessor(s). Please apply an identical wording throughout the document. In many chapters the used wording is: medical assessor. Rationale: Applying the plural form in one sentence, the singular form in another leads to confusion. Proposal: Please check the NPA for a consistent wording an use "medical assessor(s)" only.
response	Noted

comment	*433* comment by: *German NSA (BAF)* Tasks of the medical assessors are only mentioned in this Part. A reference to “this Regulation” is not compatible with class 3 because Part-MED of “this Regulation” is not applicable to ATCOs. Also it is not possible to make the whole Reg (EU) No 1178/2011 binding for AeMCs with privileges according to Reg (EU) 2015/340 only. Proposal: Replace 'Regulation' by 'Part-ARA' or 'ANNEX VI' of this Regulation' or revert to the original text.
response	Not Accepted By way of derogation specific requirements of Reg 1178/2011 are also applicable to ATCO as detailed in ATCO.AR.F.001 and ATCO.OR.E.001

ARA.MED.125 p. 9

comment	*4* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*6* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*99* comment by: *AESA*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	make sure that AeMc or AME enclosed reports & detailed medical information of applicant.
response	Noted – the obligation of the AMEs/AeMCs for referral are defined in Part MED.

comment	*100* comment by: *AESA* (c) in case of a fit assessment, the medical assessor shall handle the medical certificate and issue if appropiate.
response	Noted

comment	*129* comment by: *AESA* (a) Leave as its was described previously: the medical assessor or medical staff designated by the competent authority shall evaluate the relevant medical documentation and request further medical documentation and request further medical documentation, examinations and test where necessary.
response	Not Accepted – the wording was developed to be in line with the provisions of MED.A.015

comment	*130* comment by: *AESA* ARA.MED.126. (a)Procedures must be established by the Licensing Authority. Of course the actual report of the medical assessor must be taken into account. Not all the reasons for limitation, suspension or revokation are purely medical issues. (b) It is the Licensing Authority the one able to limit, suspend or revoke, according to the report provided by the medical assessor and following the appropiate procedure. NOTE I have enclosed ARA.MED. 126 in segment corresponding to ARA.MED. 125, once the system did not allow an slot for ARA.MED. 126.
response	Not Accepted – the detailed procedure has to be established by the licensing authority, and is expected to define possible situations.

comment	*141* comment by: *UK CAA* **Paragraph No:** ARA.MED.125 (c) and (d) **Comment:** Not always appropriate for the medical assessor to issue a medical certificate. Combine (c) and (d) **Justification:** The pilot may have been made temporarily unfit and therefore already hold a certificate with residual validity or the certificate may have expired and a renewal examination be required. **Proposed Text:** (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 and issue a medical certificate if appropriate
response	Accepted

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment	*142* comment by: *UK CAA* **Paragraph No:** ARA.MED.126 (b) **Comment:** False evidence should also be included as a reason for limitation, suspension or revocation of a medical certificate **Justification:** The UK CAA has experience of applicants attempting to obtain a medical certificate by providing false evidence/medical reports **Proposed Text:** (1) a medical certificate is falsified or obtained by a false declaration or false evidence;
response	Accepted

comment	*143* comment by: *UK CAA* **Paragraph No:** ARA.MED.126 **Comment:** Further text is required to indicate that a medical certificate shall be returned to the licensing authority following revocation. **Justification:** Prevent misuse of medical certificates **Proposed Text:** (e) Following revocation the medical certificate shall be returned to the licensing authority.
response	Accepted

comment	*202* comment by: *Luftfahrt-Bundesamt* **<u>ARA.MED.125</u>** The LBA appoints medical assessors but the Federal States also deal with pilot licensing. Therefore we would prefer the following wording: "ARA.MED.125 Referral to the *aero-medical section* of the licensing authority" "When an AeMC, or aero-medical examiner (AME) has referred the decision on the fitness of an applicant to the *aero-medical section* of the licensing authority:" **<u>ARA.MED.126</u>** **ARA.MED.126 Limitation, suspension or revocation of medical certificates** The Federal States are responsible for pilot licensing but do not appoint medical assessors. All medical examination reports concerning pilots with a license issued by the LBA or a Federal State are to be submitted to the medical assessors appointed by the LBA. Therefore the wording "licensing authority" does not fit. We suggest the following:

	“(a) The *aero-medical section of the licensing authority* shall establish a procedure to enable its medical assessor(s) to limit, suspend, or revoke a medical certificate. (d) The *aero-medical section of the licensing authority* shall establish a procedure for reinstating a medical certificate.
response	Not Accepted – the definition of licensing authority in MED.A.010 clearly defines the licensing authority as “the competent authority of the Member State that issued the licence”. This excludes the regional licensing authorities of the Federal States.

comment	*225* comment by: *German NSA (BAF)* Due to the federal system in Germany, there are licensing authorities which are responsible for the licenses of pilots/ ATCOs and there are competent authorities which are responsible for the certification of AeMCs and AMEs and for medical certificates. Proposal: Replace 'licensing authority' by 'competent authority' in the heading and in the text of ARA.MED.125.
response	Not Accepted – the definition of licensing authority in MED.A.010 clearly defines the licensing authority as “the competent authority of the Member State that issued the licence”. This excludes the regional licensing authorities of the Federal States.

comment	*242* comment by: *German NSA (BAF)* The competent authority is responsible for the licenses and certificates it issues. The direct referral to the medical assessor in all cases may bypass the staff who have to react if a medical certificate is not revalidated on time. Proposal: Delete 'medical assessor' in ARA.MED. 125 'when an AeMC [...] authority' and do not change the original text of ARA.MED.125 (a)
response	Not Accepted – the wording was developed to be in line with the provisions of MED.A.015 in order to ensure medical confidentiality is preserved at all times

comment	*243* comment by: *German NSA (BAF)* 'ARA.MED.125 (c) in case of a fit assessment, the medical assessor shall issue the medical certificate; and' The Basic Regulation does not give the medical assessor the right to issue a medical certificate as this special position is not foreseen in Reg No 216/2008. Reg (EU) No 216/2008, Article 7 (2): “…... This medical certificate may be issued by aero-medical examiners or by aero-medical centres.”

	The medical assessor may take the decision on fitness of an applicant after a review of the documentation received. However, a medical certificate can only be issued after the examinations required for the class of medical certificate were performed and this is done by the AME who referred the case (ATCO/MED.A.040 (a)). The applicant should sign the medical certificate when it is issued. The person who issues the medical certificate should explain the limitations that may be placed on the medical certificate to the applicant and the AME is the best person to do that. It may not be very practical to invite the applicant to see the medical assessor for the purpose of signing a medical certificate and getting explanations regarding the limitations. Proposal: 'ARA.MED.125 (c) in case of fit assessment, the medical assessor ~~shall~~ may issue the medical certificate or delegate the task to the AME who referred the applicant.'
response	Accepted

comment	*244* comment by: *German NSA (BAF)* **ARA.MED.126** This paragraph is not referenced in Reg (EU) 2015/340, ATCO.AR.F.001 and will therefore not apply to AMEs with the privilege to issue class 3 medical certificates.
response	Noted – will be considered with RMT.0424 on the merger of Part MED and Part ATCO.MED

comment	*245* comment by: *German NSA (BAF)* **ARA.MED.126** ARA.MED.126 (a) 'The licensing authority shall etablish [...]' 'Licensing authority' is not correct. The competent authority limits, revokes or, suspends the individual medical certificate. All procedures covered in the QM of an authority are established by the competent authority (also see ARA.GEN.200 (a)(1)). Proposal: Replace the term 'licensing authority" by 'competent authority' in ARA.MED.126 (a), ARA.MED.126 (b), ARA.MED.126 (c) and ARA.MED.126 (d).
response	Not Accepted – the definition of licensing authority in MED.A.010 clearly defines the licensing authority as “the competent authority of the Member State that issued the licence”.

comment	*246* comment by: *German NSA (BAF)* **ARA.MED.126** In cases where an AeMC or AME is aware of one of the non-compliances in (b) (1)-(3) he must be in a position to limit, suspend or revoke a medical certificate that he has issued. Important time may be lost if he has to inform the licensing authority for the medical assessor to take action. An AME may also enter a limitation (e.g. spectacles) on the medical certificate, thus limiting it, if an applicant contacts him due to his obligation under MED.A.020.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Proposal:
Insert the AeMC and AME in the text as follows:
'ARA.MED.126 (a)
The ~~licensing~~ competent authority shall establish a procedure to enable its medical assessor(s) and the AeMCs and AMEs it has certified to limit, suspend, or revoke a medical certificate. An AeMC or AME can only limit, suspend or revoke a medical certificate that it/he did itself/himself issue.'

and

'ARA.MED.126 (b)
The medical assessor of the ~~licensing~~ competent authority or an AME or AeMC shall limit, suspend, or revoke a medical certificate if there is evidence that:'

response

Not Accepted – the definition of licensing authority in MED.A.010 clearly defines the licensing authority as “the competent authority of the Member State that issued the licence”.

comment

_247_ comment by: _German NSA (BAF)_

ARA.MED:126
ARA.MED.126 (c) 'The medical assessor [...] of a medical certificate.'

This is the case if the request is directed to the competent authority. However, it could also be directed to an AME or AeMC and there is no reason why they should not suspend or revoke the medical certificate and inform the competent authority accordingly. This information should also be directed to the licensing authority due to the consequence on the licence itself.

Proposal:
'The medical assessor of the the ~~licensing~~ competent authority, or an AME or AeMC, may ~~also~~ suspend or revoke a medical certificate upon the written request of the hlder of a medical certificate.'

response

Not Accepted – the definition of licensing authority in MED.A.010 clearly defines the licensing authority as “the competent authority of the Member State that issued the licence”. Furthermore the AeMC/AME do not have privileges to suspend or revoke a medical certificate issued on behalf of any licensing authority.

comment

_254_ comment by: _French DGAC_

ARA.MED.125 : France DGAC supports the proposed wording, which will clarify the responsibilities of the medical assessor, and thanks EASA for it.

ARA.MED.126
(Added in the previous comment segment, as the commentable segment of ARA.MED.126 is not accessible in CRT)

France DGAC believes that ARA.MED.126 (d) is an unnecessary administrative burden. Reinstating a medical certificate should be no different than issuing a certificate.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

	Besides, this provision raises the question of its scope. Does EASA intend it to be applicable to air traffic controllers (ATCO) ? If so, it would be necessary : - To amend ATCO.AR.F.001 (regulation 2015/340) and add the reference to ARA.MED.126 to the list of Aircrew provisions that are applicable as far as regulation 2015/340 is concerned ; - In ARA.MED.126 (b)(2), add : “or ATCO.MED.A.020” - In ARA.MED.126 (b) (3), add : “or Part ATCO.MED”. If it isn’t meant to be applicable to ATCO, will EASA please inform us. The same question goes for all provisions below not listed in ATCO.AR.F.001.
response	Noted – will be considered with RMT.0424 on the merger of Part MED and Part ATCO.MED

comment	*302* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** ARA.MED.125(a) **Comment**: The proposed text limits the designation of other medical staff to the medical assessor only, which affects the organisation and procedures of the competent authority. This is a matter of internal procedures of the competent authority, which should not be regulated by EU. **Proposal**: Keep the present text of ARA.MED.125(a): **‘the medical assessor or medical staff designated by the competent authority shall ...’**
response	Not Accepted – the wording was developed to be in line with the provisions of MED.A.015 in order to ensure medical confidentiality is preserved at all times. This should not interfere with the organisational structure of the CA.

comment	*303* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** ARA.MED.125(a) **Comment**: The proposed text limits the designation of other medical staff to the medical assessor only, which affects the organisation and procedures of the competent authority. This is a matter of internal procedures of the competent authority, which should not be regulated by EU.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

	Proposal: Keep the present text of ARA.MED.125(a): **'the medical assessor or medical staff designated by the competent authority shall ...'**
response	Not Accepted – the wording was developed to be in line with the provisions of MED.A.015 in order to ensure medical confidentiality is preserved at all times. This should not interfere with the organisational structure of the CA.

comment	_371_ comment by: _René Meier, Europe Air Sports_ ARA.MED.125(b) page 9/52 Inconsistency in wording, possibly even misleading: "...with one or more limitations as necessary": Why not create two sentences or at least clearly distinguish different situations? Rationale: (b)(1) could describe the situation without any limitation. (b)(2) could do so when limitations are required. Alternative proposal: Replace "as" by "where" or "if" in order to establish clarity.
response	Accepted

comment	_410_ comment by: _marina vanbrabant_ ARA.MED.126 proposed text : (e) following revocation, the medical certificate shall be returned to the licensing authority
response	Accepted

ARA.MED.128	p. 10

comment	_177_ comment by: _EAAP_ **Comment to ARA.MED.128:** Please mention the specific Part-MED article in ARA.MED.128 as to leave no uncertainty or lack of clarity as to what kind of consultation is meant in this requirement.
response	Not Accepted – consultation is required for specific conditions for class 2 and LAPL applicants and the applicable situations are clearly specified in Part-MED.

comment	_210_ comment by: _AESA/DSANA_

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	Comment What kind of consultation is it referring to? The extent of the consultation should be defined. Justification This consultation procedure is not defined or mentioned through Regulation (EU) No 1178/2011, nor defined in this NPA.
response	Not Accepted – consultation is required for specific conditions for class 2 and LAPL applicants and the applicable situations are clearly specified in Part-MED.

comment	*226* comment by: *German NSA (BAF)* This paragraph is not referenced in Regulation 2015/340, ATCO.AR.F.001 and will therefore not apply to AMEs with the privilege to issue class 3 medical certificates.
response	Noted – this is not applicable for class 3 applicants as consultation is only foreseen for class 2 and LAPL.

comment	*398* comment by: *European Cockpit Association* **ARA.MED.128 Consultation Procedure** The competent authority shall establish a consultation procedure for the AeMCs and AMEs in accordance with Part-MED. ECA Comment: ECA welcomes the change above. It will increase harmonization between pilots when consultation is needed.
response	Noted

ARA.MED.130	p. 10-11

comment	*7* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*8* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*9* comment by: *CAA.CZ* I have no comments
response	Noted

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

comment	*85*	comment by: *Aivars PRIEKULIS*
	(a) (8) (iv) Class 2 with instrument rating *Preferable* - IR checked - YES or NO. *Rationale - This is just a rating, this is not another medical certificate Class.*	
response	Accepted	

comment	*86*	comment by: *Aivars PRIEKULIS*
	a) (10) Date of last and next electrocardiogram *Date of next ECG - AME should know it anyway. Do not see rationale.* - *Proposed text:* Date of last electrocardiogram	
response	Not Accepted – it provides guidance for AMEs and for applicants to what examinations have to be performed	

comment	*87*	comment by: *Aivars PRIEKULIS*
	a) (11) Date of last and next audiogram *Date of next audiogram - AME should know it anyway. Do not see rationale.* - *Proposed text:* Date of last audiogram	
response	Not Accepted – it provides guidance for AMEs and for applicants to what examinations have to be performed	

comment	*134*	comment by: *AMABEL*
	In **ARA.MED.130** about the Medical Certificate format, why should the class of the medical certificate be removed? AMABEL recommends to keep it on the Medical Certificate.	
response	Not Accepted – the class of certificate is reflected in the table with the validity dates	

comment	*144*	comment by: *UK CAA*
	Paragraph No: ARA.MED.130 (a)(2) **Comment:** Text “Class of medical certificate” should not be deleted **Justification:** The removal of the text “Class of medical certificate” will require significant editorial changes throughout Part MED, Part ARA and any other Part making reference to Class 1, Class 2 or LAPL medical certificates e.g. “**MED.A.050 Referral** (a) If an applicant for a Class 1 or Class 2 medical certificate….”. This may also be non-compliant with ICAO SARPS. **Proposed Text:** No change	
response	Not Accepted – the class of certificate is reflected in the table with the validity dates	

comment	*145*	comment by: *UK CAA*

	Paragraph No: ARA.MED.130 (a)(8)(i) and (ii) **Comment:** This change is unnecessary **Justification:** There is no need to change these around or to delete “other commercial operations” as the meaning will be lost i.e. the meaning of “Class 1” (on its own) will be unclear and not differentiated from “single pilot commercial operations carrying passengers” Making such administrative/IT changes will be a significant administrative and cost burden to NAAs **Proposed Text:** No change
response	Not Accepted -

comment	*146* comment by: *UK CAA* **Paragraph No:** ARA.MED.130 (a)(8)(iv) **Comment:** This addition is unnecessary **Justification:** There is no need to add an additional Class 2 category as it will create a conflict between the periodicity of the medical certificate and the periodicity of the investigation (audiogram). It should be the duty of the AME to check the applicant’s requirement for an audiogram at the time of the medical examination and ensure that the appropriate investigations occur with the correct periodicity, aligned with that of the medical certificate. Making such administrative/IT changes will be a significant administrative and cost burden to NAAs **Proposed Text:** No change
response	Accepted

comment	*147* comment by: *UK CAA* **Paragraph No:** ARA.MED.130 (a)(10), (11) and (12) **Comment:** These additions are unnecessary and cause confusion as to the validity dates of the certificate. These next due dates have previously been removed from the certificate as they caused considerable confusion for flight operations inspectors on the ramp and resulted in flights being grounded unnecessarily. **Justification:** There is no need to add additional “next due” dates they will create conflicts between the periodicity of the medical certificate and the periodicity of the investigation (ECG, audiogram and ophthalmological investigation). Reference to the “ophthalmological examination” is confusing as it is not clear whether this refers to the routine examination as part of the periodic medical or where the extended ophthalmological examination for applicants with (for example) high refractive error is required.

	In addition, making such administrative/IT changes will be a significant administrative and cost burden to NAAs **Proposed Text:** No change
response	Not Accepted – it allows the AMEs to easily identify what investigations are required and acts as a tracking aid

comment	*211* comment by: *AESA/DSANA* Comment What kind of criteria has been used for the classification in point (a).(8)? Is it related in any way with cases in MED.A.045.(a)? Or is it just intended to highlight single-pilot commercial operations carrying passangers from the rest in Class 1, and instrument rating in Class 2? In this case, we consider that previous classification was clearer: class 1 was divided in two types (single-pilot commercial operations carrying passangers and the rest). Now it seems to be an overlap, because class 1 in (i) includes all kind of class 1, even single-pilot commercial operations carrying passangers (ii). That is, (i) covers (ii). And it happens the same with class 2: (iii) covers (iv). The following classification is suggested: (i) Class 1 single-pilot commercial operations carrying passangers. (ii) Other Class 1 operations. (iii) Class 2 with instrument rating. (iv) Other Class 2. (v) LAPL. Justification New classification is not clear, it has some overlaps. Class 1 also includes Class 1 single-pilot commercial operations carrying passangers. And similarly, Class 2 also includes Class with instrument rating.
response	Noted

comment	*212* comment by: *AESA/DSANA* Comment Roman numeral (IVa) should be included in point (5) instead of (XIV) to be coherent with Appendix I Flight crew licence of Regulation (EU) No 1178/2011. This should be also modified in AMC1 ARA.MED.130 Medical certificate format.
response	Accepted

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

comment	*213* comment by: *AESA/DSANA* <u>Comment</u> Roman numeral (X) should be included in point (13) to be coherent with AMC1.ARA.MED.130.
response	Accepted

comment	*228* comment by: *The Norwegian Civil Aviation Authority* ARA.MED.130 (a)(8)(iv) Agreed, there should be information regarding IR-rights on the medical licence. ARA.MED.130 (a)(12) The date of the next opthalmological examination should only appear on the medical licence if the examination is required by Part-MED and/or AMC.
response	Partially accepted

comment	*248* comment by: *German NSA (BAF)* This paragraph is not referenced in Reg (EU) 2015/340, ATCO.AR.F.001 and will therefore not apply to class 3 medical certificates. s. ICAO Annex 1, 1.2.4 Medical fitness where the "<u>appropriate Medical Assessment</u>, <u>Class 1, Class 2 or Class 3" is required.</u>
response	Noted

comment	*259* comment by: *French DGAC* Regarding this proposal and other forms and certificate format in the current NPA, France would like to remind EASA that any change to a document template causes burden and cost (software parameters adjustment, printer cost for new forms, wasting the obsolete forms already bought from the printer, and in some cases translation into the national language). We believe that only necessary changes should be implemented. At the very least, such changes should be accompanied by a provision stating that : *"certificates issued before the new regulation entry into force remain valid until the date of their next revalidation".* Regarding the scope of this provision and its application to ATCOs: Since a similar provision exists in regulation 2015/340 (ATCO.AR.F.005), our understanding is that this provision is not meant to be applicable to ATCO certificates. Please inform us if it is otherwise. For your information, the current wording in regulation 2015/340 (ATCO.AR.F.005) is satisfactory in that no changes are required to the section "date of last electrocardiogram" and "date of last audiogram".

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Noted

comment	*304* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*
	Section: ARA.MED.130(b)
	Comment: Although the only change of ARA.MED.130 (b) is the insertion of 'medical certificate' the exclusion of document standards when issued by a GMP must be questioned. While a LAPL medical certificate may be used for flying on a PPL as long as only LAPL privileges are exercised, there should not be any reduced document standards only because the issuance was done by a GMP. During a ramp check in another state the inspector will have difficulties to identify if the document is true or false. 'Except for the case of LAPL medical certificate issued by a GMP' should thus be deleted.
	Proposal: Amend ARA.MED.130(b), deleting 'Except for the case of LAPL medical certificate issued by a GMP'.
response	Accepted

comment	*399* comment by: *European Cockpit Association*
	ARA.MED.130 Medical certificate format The medical certificate shall conform to the following specifications: (a) Content (9) Date of medical examination (10) Date of last and next electrocardiogram (11) Date of last and next audiogram (12) Date of last and next ophthalmological examination **ECA comment:** Also the dates of next examinations needed help pilots knowing what tests are needed in each medical examination. Keep these in the forms.
response	Accepted

ARA.MED.135	p. 11

comment	*102* comment by: *AESA*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	(b) and (c) to provide 2 separated forms for classes 1 & 2 and a different one for class LAPL in our understanding add no necessary paperwork to the process, forms could be the same, and for each one it will be applicable whatever is established in the regulation, if a particular item is not applicable just leave blank. We propose a single examination report that fit in all classes 1,2 & LAPL.
response	Not Accepted – LAPL medicals can be performed by GMPs that are not so familiar with the requirements, consequently having one single form could potentially lead to errors.

comment	_305_ comment by: _Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)_ **Section:** ARA.MED.135(a) **Comment**: The format of the application form for a medical report for CC should also be decided and provided by the competent authority. **Proposal**: Amend ARA.MED.135(a): **(a) 'the application form for a medical certificate and a medical report;**
response	Noted – in several Member States the CC medical report is issued by OHMPs and the medical files are not centralised by the competent authorities. This would be an additional burden for the competent authorities. The suggestion may be further discussed at the next update of subpart C of Part MED

comment	_306_ comment by: _Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)_ **Section:** ARA.MED.135 **Comment**: The format of the examination report form for a medical report for CC should also be decided and provided by the competent authority. A new subparagraph (d) is needed. **Proposal**: Amend ARA.MED.135: **(d) 'the examination report form for a medical report.**

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Noted – in several Member States the CC medical report is issued by OHMPs and the medical files are not centralised by the competent authorities. This would be an additional burden for the competent authorities. The suggestion may be further discussed at the next update of subpart C of Part MED

ARA.MED.145 p. 11

comment	*372* comment by: *René Meier, Europe Air Sports* ARA.MED.145 GMP notification to the competent authority page 11/52 Unclear text: ".… applicable requirements laid down in this regulation." It is not clear to us what is meant by "this" regulation. Question: Did the author(s) think of Part-MED? Of Part- ARA? Thank you for clarification. Proposal: Please delete "laid down in this regulation".
response	Not Accepted – This Regulation means the applicable requirements of Regulation (EU) 1178/2011 including all subsequent updates.

ARA.MED.150 p. 11-12

comment	*10* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*11* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*88* comment by: *Aivars PRIEKULIS* (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. *- Impossible to ensure if CA has no pilot data <search by name > or <search by DOB> access to EAMR database.*

An agency of the European Union

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

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

response

Not Accepted – ARA.MED requirements are applicable to the competent authorities. A similar requirement is already captured in MED.A.025(f).
Furthermore, CA shall have a procedure /system for cross-checking the medical examinations performed by AMEs/AeMCs and their data in EAMR to ensure that AMEs and AeMCs have fulfilled their obligation to introduced the data in the repository in accordance with the requirements of MED.A.025(f)

comment *175* comment by: *EAAP*

EAAP comment to ARA.MED.150 (c) (3):
Specialists from the **aviation psychology profession** should be explicitly named here as well.

Explanatory note:
According draft AMC1 MED B.055 Mental Health (a)(4) and (b)(2), "Where there are signs or is established evidence that an applicant may have a psychiatric or psychological disorder, the applicant should be referred for specialist opinion and advice".

According draft AMC1 MED.B.055, "Specialist opinion and advice" may come from suitably qualified clinical psychologists with expertise and experience in aviation psychology on request of the AME, AeMC or medical assessor for the purpose of completion of an aero-medical assessment. The clinical psychologists that are to be involved should have access to the aero-medical records as any other medical specialist. Like the medical specialists, they are committed to confidentiality rules and codes of ethics, as are the medical specialists. As clinical psychologists are not medical specialists they should be expressly named under (c)(3).

response

Not Accepted – the term relevant medical specialists also includes psychiatrists and psychologists.

comment *216* comment by: *AESA/DSANA*

<u>Comment</u>
The reference MED.D.001(f)(3) does not exist in Regulation 1178/2011; this seems to be a mistake and it should be modified as MED.D.001(d)(3).

response

Not Accepted – The NPA already included the updates to part MED adopted with Regulation (EU) 2019/27. The reference is correct.

comment *217* comment by: *European Transport Workers Federation - ETF*

Page 12 : ARA.MED.150 (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.	This requirements shall not be extended to ATCOs as their mobility is not the same as this of the flight crew.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	According to EU Reg 2015/340, this paragraph is also applicable to ATCOs !

response | Not Accepted – This is not applicable to ATCOs – point (f) specifically refers to flight crew (pilots) not to other categories of personnel.

comment | *249* comment by: *German NSA (BAF)*

ATCO.MED.150 (c) (6)
Medical data are sensible data and a good reason is needed to release them. There is no sufficient reason for EASA inspectors to see medical files with all personal details.
It might be difficult to reach an ATCO or pilot during a standardisation visit and to get written consent to release his file which would be necessary to respect medical confidentiality according to the data protection rules.

Proposal:
Revert to original text in ATCO.MED.150 (c) (6)

response | Not Accepted – All EASA Medical standardisation team members are medical doctors and are bound by medical confidentiality. Complete deidentification will not allow traceability in case non-compliances are identified in the medical files.

comment | *250* comment by: *German NSA (BAF)*

ARA.MED.150 (d)

Directive 95/46/EC is repealed with effect from 25 May 2018 by Reg (EU) 2016/679 (General Data Protection Regulation).

response | Accepted

comment | *251* comment by: *German NSA (BAF)*

ARA.MED.150 (e) (1)

There is no reason to keep AeMCs or AMEs on a list after their certificate has expired. These AeMCs or AMEs will not appear on an active list and any certificate issued by an AME without a valid certificate will be detected immediately.
Nevertheless, files of AMEs who no longer hold a valid certificate will always be retrievable as they are filed as any other documentation according to the record-keeping procedure in the authority.

Proposal:
Revert to the original text.

response

Not Accepted – For the purpose of traceability the AeMCs and AMEs should still be kept on the list until all the certificates issued by the respective AME/AeMC have expired. However, it should be mentioned that the AME certificate is no longer valid.

comment

260 comment by: *French DGAC*

France DGAC would like to raise the issue of the technical difficulties met by using in the European Aero-medical Repository.
Given the current unreliability of the system, rendering its use mandatory might be premature.
At best, EASA auditors should be instructed to show clemency regarding its use until it is proven to function reliably.

response

Noted

comment

307 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: ARA.MED.150(f)
Comment: The draft Regulation updating Part-MED, as adopted by the Council, also includes a new paragraph ARA.MED.160, detailing the access to EAMR and the procedures to be followed by the competent authority. ARA.MED.160 is missing in this NPA. This inadvertently prevents comments on ARA.MED.160 which needs to be updated. ARA.MED.150(f) is insufficient for a correct implementation of EAMR.
Proposal: The NPA 2017-22 needs to be amended with the adopted ARA.MED.160 and corresponding AMC including detailed requirements regarding provisions for the use of EAMR.

response

Noted

comment

373 comment by: *René Meier, Europe Air Sports*

ARA.MED.150(b, c, c(5)
page 11/52

Inconsistency in the wording: No consistent use of "applicants" and/or "licence holders"

Rationale:
Appying two terms may add to confusion.

	Proposal: Use "applicants/medical licence holder". This prevents any confusion with Part-FCL licences.
response	Accepted

comment	*374* comment by: *Croatian Civil Aviation Agency* **ARA.MED.150 (e)** For the purpose of sharing information with industry, it might be useful to add a list of OHMPs which have notified the competent authority of activity to perform cabin crew aero-medical assessment.
response	Accepted

comment	*381* comment by: *René Meier, Europe Air Sports* ARA.MED.150(b) page 11/52 Missing word? Proposal: Please add "date" after the word "expiry". Rationale: This makes the understanding easier.
response	Accepted

ARA.MED.151 p. 12

comment	*176* comment by: *EAAP* **Comment to ARA.MED.151 Medical confidentiality** We think reference should be made in ARA.MED.151 to **how exactly 'medical confidentiality' is defined and where the relevant article defining medical confidentiality is to be found in the regulations** following the considerations and decision by the commission (see below). The EASA timeline presented at https://www.easa.europa.eu/easa-and-you/aircrew-and-medical/follow-up-germanwings-flight-9525-accident#0, milestone September 2016 says, quote: "In line with its Action Plan, EASA submits a Working Paper to the European Commission on the issue of balancing patient confidentiality and public safety.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Medical confidentiality is a fundamental principle in the provision of health care services. The chain of events that led to the Germanwings accident, brought the accident investigation board to observe that there might be cases in which personal information should be disclosed in the interest of safety even without the patients' consent, if the benefits of the disclosure outweigh both the public and the patient's interest in keeping the information confidential.

This paper, for consideration by the Commission, outlines how medical confidentiality is regulated in different Member States. It addresses the European data protection legal framework, highlights examples of the national council of doctors in France and the UK, and proposes actions aiming at striking a balance between medical confidentiality and public safety at European level, as laid down in Recommendation no. 5a) of the EASA-led Task Force."

response | Noted

comment | *400* comment by: *European Cockpit Association*

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.

ECA comment:
ECA thinks that this is fundamental part of aeromedical examination and assessment and this should be kept in the regulation.

response | Noted

ARA.MED.155 p. 12

comment | *12* comment by: *CAA.CZ*

I have no comments

response | Noted – ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment | *13* comment by: *CAA.CZ*

I have no comments

response | Noted – ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment | *89* comment by: *Aivars PRIEKULIS*

(b) The new licensing authority shall confirm to the existing licensing authority that...
A new procedure, just makes more admin work flow & bureaucracy
Proposal to delete this para.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment	*103* comment by: *AESA* It will be desirable an EASA format available for all authorities. Benefit of a standarized form to be used by all MS.
response	Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment	*148* comment by: *UK CAA* **Paragraph No:** ARA.MED.155 (a) **Comment:** Medical report holders should not be included in this rule. **Justification:** Cabin crew medical reports and related medical files are not required to be held by the competent authority. If transfer of medical information is required the crew member can request a copy of their medical record in accordance with data protection legislation. To make the authority responsible for the transfer of records would be an unjustified additional administrative burden. **Proposed Text:** (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:
response	Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment	*204* comment by: *Luftfahrt-Bundesamt* **ARA.MED.155 Transfer of medical files** A transfer of medical files concerns not only the medical files but also licensing information. According to FCL.015 d) a pilot may request a change of competent authority and a transfer of his licensing and medical records. In our understanding the pilot submits <u>one</u> application to the "new" licensing authority including the change of competent authority and the transfer of his licensing and medical records. Due to the fact that the Federal States are not responsible for the medical files and to align to FCL.015 we recommend a slightly different wording: *(a)* Upon receiving a *transfer* request to a new licensing authority*, the aero-medical section of the* existing licensing authority *shall:* *(1)* transfer a summary of the relevant medical history of the applicant verified and signed by the medical assessor. ... (4) where available, attach a copy of the initial medical examination or a copy of the documents supporting the last medical file transfer The new licensing authority is not able to assess the completeness of files.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	In case of a transfer to Germany, the medical certificate would be transferred to the LBA (medical assessor) and the license to either the LBA (licensing unit) or a Federal State (licensing unit). We suggest the following: (b) The *aero-medical section* of the new licensing authority shall *inform the existing medical assessor about the medical documents received. The change of responsibility takes place after confirmation of the transfer of the medical file and the license to the existing licensing authority by the new licensing authority.*
response	Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment	*229* comment by: *The Norwegian Civil Aviation Authority* ARA.MED.155 The "transfer of medical-process" should be formalized like proposed.
response	Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment	*252* comment by: *German NSA (BAF)* This paragraph is not referenced in Reg (EU) 2015/340, ATCO.AR.F.001, and will therefore not apply to transfer requests of ATCOs.
response	Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment	*261* comment by: *French DGAC* France DGAC supports ARA.MED.155 (a). However, point (b) represents an unnecessary administrative burden and should be removed. Each licensing authority should be trusted to get in touch with its counterpart if needs be, and no systematic acknowledgement of receipt is needed. Concerning ATCO, please let us know whether this provision is meant to be applicable to them.
response	Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment	*355* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* Attachment #1 **Section:** ARA.MED.155(a) **Page**: 12 **Comment**: The text does not clearly state to which licensing authority the applicant shall send the medical file transfer request: to the existing or the receiving licensing authority. For clarity

An agency of the European Union
TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

this needs to be written in an unequivocal way, either in ARA.MED.155(a) or in an AMC to ARA.MED.155(a).
An ARA.GEN.320 and a detailed AMC1 ARA.GEN.320 'Procedure to change the State Of Licence Issue' were drafted by RMT.0412 and RMT.0413 in 2014, but has not yet been published or included in an NPA. *These draft texts are attached.*
As a transfer of State Of Licence Issue can occur even before a licence is issued, a paragraph is needed to cover this situation. A corresponding text is needed for transfer of medical files.

Proposal:
Amend the text in ARA.MED.155 and add an AMC to ARA.MED.155 covering the relevant details of transfer described in the draft ARA.GEN.320 and AMC1 ARA.GEN.320.

response: Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment: *361* comment by: *European Helicopter Association (EHA)*

the expression "existing licensing" should be replaced by "actual licensing authority"

response: Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment: *383* comment by: *René Meier, Europe Air Sports*

ARA.MED.155(a)
page 12/55

Ambiguity in wording: It is not clear what is meant by “medical report holders”.

Proposal:
Please add a definition or an explanation.

Rationale:
A clarification will help readers to understand the text properly.

response: Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment: *384* comment by: *René Meier, Europe Air Sports*

ARA.MED.155(a)(3)
page 12/55

(3) is difficult to understand, it leaves room for interpretation.

Proposal: add the word “and" between ECG and audiometry.
Replace “and” at the end of the sentence by "as well as...".

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	Rationale: Our modification makes the (3) easier to understand.
response	Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

comment	*409* comment by: *marina vanbrabant* Medical report holders should not be included in this rule.
response	Noted– ARA.MED.155 is no longer needed as ARA.GEN.360 has been adopted instead

ARA.MED.200 p. 13

comment	*14* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*90* comment by: *Aivars PRIEKULIS* (b) ... and the appropriate procedures are in place to perform aero-medical examinations... *AME is not an organisation, therefore AME do not have to write procedures for him-(her-)self* *Proposal - to delete this requirement.*
response	Not Accepted – The AMEs should have procedures in place allowing the other staff to perform their tasks in compliance with the requirements and to ensure equal treatment of all applicants

comment	*104* comment by: *AESA* b) we understand that multiple AME practice locations above 2 might complicate the oversight procedures and in fact jeopardize the good medical practice of the AME. Our experience showed a number of mistakes, errors due to the fact of being in multiple locations.
response	Noted

comment	*205* comment by: *Luftfahrt-Bundesamt* **ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate** The term “aero-medical competency” under ARA.MED.200 (a) is a legal term that is not defined within the scope of the regulation. In order to avoid any legal disputes with the AMEs and findings with the aviation authorities during the performance of audits, a definition of the term is absolutely necessary. It must be found out whether the requirement would be

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	already fulfilled, if the AME had undergone training in accordance with the requirements of a revalidation of the approval or if an additional examination of the practical and theoretical knowledge is necessary. Taking into account a standardization among the EU Member States, the definition of this term should be laid down. It should be defined which minimum requirements are to be fulfilled within the scope of the examination of the "aero-medical competency".
response	Noted

comment	*230* comment by: *The Norwegian Civil Aviation Authority*
	ARA.MED.200 (a) AMEs areo-medical competence should be demonstrated by a competency test before a revalidation or renewal. This is the best and easiest measure to secure the correct competence.
response	Noted

comment	*255* comment by: *German NSA (BAF)*
	ARA.MED.200 (a) The AMC states that the AME has to have evidence of completion of the relevant training courses or refresher training. This ensures their aero-medical competency in accordance with Part MED/ ATCO-MED. This paragraph duplicates the content of ARA.GEN 315 (a) which is not good legal practice. The paragraph is not applicable to AMEs class 3 as they are not required to comply with Part-MED. <u>Proposal</u>: Delete (or move with changes to GM material): GM1 ARA.MED.200 (a) a) The competent authority ~~shall~~ should 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~~ the applicable rules.
response	Not Accepted – the requirement mirrors the requirement of MED.D.0303

comment	*256* comment by: *German NSA (BAF)*
	ARA.MED.200 (~~a~~b) Unnecessary and legally dubious changes. If there is an urgent wish to keep it, move to GM.

	ARA.GEN 315 is a paragraph that applies to all persons who are issued with a certificate by the competent authority. Insofar, medical is not different from licensing (e.g. individual instructors) or persons with a certificate under the OPS rules. The paragraph contains the rules for certification of persons, ARA.GEN.200 (a)(1) requires the authority to have a procedure in place to achieve compliance with the Basic regulation and its implementing rules. Therefore this new paragraph is a duplication with regard to the authority procedure. A person (as opposed to an organisation) who receives a certificate has to follow the rules but cannot be obliged to create procedures. This is one of the main differences between a person holding a certificate and an organisation. An AME practice has to be fully equipped (ARA.MED.200 (a)), and a second or third location is also an AME practice and therefore has to be fully equipped. Proposal: Revert to the original text (or move with changes to GM material): GM1 ARA.MED.200 (b) The competent authority should have a procedure in place to ensure that, before issuing the AME certificate, evidence has been provided that the AME practice is fully equipped ~~and the appropriate procedures are in place~~ for the AME to perform aero-medical examinations within the scope of the AME certificate applied for.
response	Not Accepted – the requirement is needed to clarify the requirements of ARA.GEN.315 and comes as a result of the issues identified during the standardisation inspections

comment	*262* comment by: *French DGAC* In ARA.MED.200 (b), the wording that requires : « a procedure in place… to ensure that the appropriate procedures are in place” sounds awkward. We suggest a simpler phrase : “The competent authority shall ensure that the appropriate procedures are in place …”
response	Noted

comment	*308* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** ARA.MED.200(b) **Comment**: The first sentence is unnecessarily long and complicated. To be consistent with ARA.MED.200(a), the requirements for a procedure and ‘having the evidence’ could be deleted without changing the meaning of the text. Also, in the amended text regarding the equipment of the AME practice, the word ‘fully’ has been deleted, which makes the requirement incomplete and illogical. Some specification of the equipment needs to be added, preferably ‘appropriately’ or ‘adequately’. **Proposal**:

An agency of the European Union
TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Amend ARA.MED.200(b):
'The competent authority shall ensure that, before issuing the AME certificate, the AME practice is appropriately equipped …'

response

Not Accepted – the requirement is needed to clarify the requirements of ARA.GEN.315 and comes as a result of the issues identified during the standardisation inspections

comment

385 comment by: *René Meier, Europe Air Sports*

ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate. page 13/52

Complexity of the the procedure for the issue, revalidation, reneval or change: In general, the procedure is complex and bureaucratic. Although for class 1 assessments it is necessary to prevent all sorts of fraud and inconsistencies, for class 2 and LAPL the procedure can be less extended.

Proposal:
Please reduce the bureaucratic work load for class 2/LAPL AMEs.

Rationale:
For the sports and recreational activities within General Aviation, public and pilot interest is less critical because of the low number of pax and masses of the aircraft involved.

response

Noted

comment

386 comment by: *René Meier, Europe Air Sports*

ARA.MED.200 (a)
page 13/52

The first line of (a) is not clear, we think a comma is missing between "issue" and "revalidation". As alternative "the" could be inserted ahead of "issue", "revalidation", "renewal", "extension".

Proposal:
Apply one of the proposals stated above.

Rationale:
The wording will become clearer, easier to understand.

esponse

Accepted

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment	*387* comment by: *René Meier, Europe Air Sports* ARA.MED.200(c) page 13/52 Duration of period of validity of an AME certificate: The duration of validity is 3 years (with a minimum of 10 assessments /year). For a number of class 2/LAPL AMEs, this period is too short, it can be difficult to perform the required assessments within this short time period. Proposal: We propose to extend the period of validity to at least 4 years. Rationale: A 4-years period reflects better todays' licencing environment, fits better with the activities of the licence-holders.
response	Not Accepted – the requirement mirrors the requirement of MED.D.030 which is not in the scope of this update.

ARA.MED.240 p. 13

comment	*15* comment by: *CAA.CZ* I have no comments
response	Noted

ARA.MED.245 p. 13

comment	*131* comment by: *AESA* It is not clear the oversight responsabilities and programme by the competent authority towards the AME´s who are exercising priviledges in a different territory and under the responsability of another authority.
response	Noted – the responsibilities have to be defined in agreement by the two authorities involved depending on the tasks to be performed by each authority in accordance with ARA.MED.246.

comment	*231* comment by: *The Norwegian Civil Aviation Authority* ARA.MED.245 (3) When basing the oversight programme on a risk based system, there should be no need for the MS to visit all the AMEs every three year. Instead the oversight programme

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

should focus on the AMEs with the highest risks, to make sure aviation security does not suffer.

response

Noted – However, the requirement to visit each AME every 3 years is intended as the minimum, while using a risk based system may highlight the need to visit some AMEs more often than that – once/year or every 6 months if the continuous monitoring does not show any improvements

ARA.MED.246 p. 13

comment *16* comment by: *CAA.CZ*

I have no comments

response Noted

comment *219* comment by: *European Transport Workers Federation - ETF*

Page 13 : 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.	ETF does not think that i twill be convenient for competent authorities to comply with this requirement and we therefore fear that it will not be properly implemented. It seems likely that most combination will be needed and that a more pratical approach would be to have a centralised cooperation method.

response Noted

comment *257* comment by: *German NSA (BAF)*

This paragraph is not referenced in Reg (EU) 2015/340, ATCO.AR.F.001 and is therefore not applicable for the exchange of information regarding AMEs class 3. However, as this is

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	basically a duplication of ARA.GEN an exchange of information will take place according to the rules.
response	Noted

comment	*258* comment by: *German NSA (BAF)* Definition for 'Secondary place of business' is needed, taking into account that there were years of discussions about what is a 'principle place of business'.
response	Noted

ARA.MED.250 p. 14

comment	*17* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*105* comment by: *AESA* Add to part (a) the following paragraph: (8) Do not meet the procedures in place to comply with IR and Amc´s.
response	Not Accepted – however we will consider clarifying it in the AMC/GM

comment	*232* comment by: *The Norwegian Civil Aviation Authority* ARA.MED.250 (a). A MA should also have the opportunity to limit, suspend or revoke an AME certification when the AME can not demonstrate sufficient aero medical competency or doesn't comply with the requirements in Part-MED and/or national procedures. The most concerning finding during an AME oversight is the lack of competence in aviation medicine or knowledge of the applicable regulations. Thus, the following should be added *8) inadequate competence in aviation medicine or the applicable regulations*
response	Not Accepted – It is included in the second bullet point and can be further clarified in the AMC/GM

comment	*263* comment by: *German NSA (BAF)* **ARA.MED.250 (a) (1)** The addition renders the paragraph unspecific and rules shall always be clear. The expression “not limited to” leads to the fact that an authority could establish more stringent rules to limit, suspend or revoke a certificate which would not be in line with the objective of common European rules.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	Proposal: Delete 'but not limited to' and amend the list of cases in which the certificate can be limited, suspended or revoked.
response	Not Accepted – not all situation are foreseeable, the suspension and revocation of AME certificate can be also a matter of national law, medical condition of AME, criminally record of AME etc. and the competent authority should be able to react to ensure the safety if need be.

comment	*264* comment by: *German NSA (BAF)* **ARA.MED.250 (b)** There is no need to deviate from the rule that 'shall' is the appropriate term in regulations. 'either of' is not needed. Proposal: 'The certificate of an AME ~~is~~ shall be revoked in ~~either of~~ the following circumstances:'
response	Accepted

comment	*265* comment by: *German NSA (BAF)* **ARA.MED.250 (c)** Over-regulation. There should be a list of valid AME certificates and any person (former AME or *any* person) who is not entitled to issue medical certificates this person will not appear on the list. The administrative burden to retrieve revoked AME certificates and to inform 25 or 26 MS is not acceptable. The list of active AMEs will be updated according to ARA.GEN.150 (e) in its present form. The use of the terms 'procedure' and 'process' is confusing. There shall be a 'procedure' to revoke an AME certificate (ARA.MED.126) and in this paragraph a 'process' is required to retrieve it. What is the background for the use of different but very similar terms? Proposal: Delete ARA.MED.250 (c).
response	Not Accepted – based on standardisation experience several member states could not retrieve the revoked AME certificates because they did not have a formal process in place to be used as a legal basis.

comment	*309* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** ARA.MED.250(b) **Comment:**

The revocation of an AME certificate is a legal process requiring a formal decision by the competent authority making the passive wording 'is' inappropriate in conjunction with a revocation.
The intention of this paragraph is to describe that an AME certificate shall not be valid in the situations described in (b)(1) and (b)(2), even when the AME certificate has not been formally revoked by the competent authority. This can be covered by the wording 'shall be rendered invalid'.
For consistency, 'the certificate of an AME' should be changed to 'an AME certificate'.

Proposal:
Amend ARA.MED.250(b):
'An AME certificate shall be rendered invalid in either of the following circumstances:'

response: Partially accepted

ARA.MED.255	p. 14

comment: *18* — comment by: *CAA.CZ*

I have no comments

response: Noted

ARA.MED.315	p. 14

comment: *19* — comment by: *CAA.CZ*

I have no comments

response: Noted

comment: *106* — comment by: *AESA*

Add: (c) Following review, authority must put in place correction measures if appropiate.

response: Accepted

comment: *139* — comment by: *UK CAA*

ARA.MED.315 Review of examination reports

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	Comment: The medical assessor needs oversight of the review of all reports but this task may be delegated or electronically validated in specified circumstances. **Justification:** Many processes can be automated and numerical values checked by an automated process and suitably trained staff can check and verify data with oversight by the medical assessor. **Proposed Text:** The licensing authority shall require the medical assessor to have a process in place ~~for the medical assessor~~ to
response	Not Accepted the development of processes and procedures are the responsibility of the Competent authority not of one individual.

comment	*266* comment by: *German NSA (BAF)* **ARA.MED.315** Licensing authority is not correct. All processes are established by the competent authority. Furthermore, there may be designated staff or even an IT system to review the examination and assessment reports and report any inconsistencies etc. to the MA who will take action as appropriate. Proposal: 'The ~~licensing~~ competent authority shall have a process in place ~~for the medical assessor~~ to:'
response	Not Accepted in this point we are talking about the licensing authority who receive files from their own AMEs and from foreign AMEs performing medicals on the pilots of the respective authority.

comment	*267* comment by: *German NSA (BAF)* **ARA.MED.315 (b)** AMEs are trained and have continuous training to assess medical fitness and make a decision on whether an applicant is medically fit or not. The authority is to perform oversight. While an advice by the medical assessor in contentious cases may be helpful it is not the task of the medical assessor to discuss 'normal' cases. If the AME cannot manage normal cases he should undergo more training.
response	Not Accepted –the AME should be able to ask for support the medical assessor of the licensing authority in case of doubts for a specific applicant.

comment	*281* comment by: *French DGAC* France DGAC supports the new wording that clarifies the medical assessor role in assisting AME and AeMC.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response | Noted

comment | *310* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: ARA.MED.315

Comment:
The review of examination and assessment reports for technical/administrative inconsistencies, mistakes or errors is usually done by other medical staff than the medical assessor, whose task is to review the aero-medical information and aero-medical assessment.
For consistency, this should be reflected in the text by inserting either 'or medical staff designated by…' from ARA.MED.125(a) or 'any duly authorised personnel of the competent authority responsible for the oversight of AMEs or AeMCs conducting aero-medical assessments of those applicants or holders' from the already adopted ARA.MED.160(b)(3).

Proposal:
Amend ARA.MED.315 to include other medical staff beyond the medical assessor.

response | Not Accepted – the medical assessor is the only one responsible for the review of medical data and could identify errors or mistakes in the medical assessment

comment | *311* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: ARA.MED.315(b)

Comment:
The last words 'in contentious cases' are proposed to be deleted. However, a similar but better expression has been added in AMC2 ARA.MED.120(f).

For consistency, the wording in ARA.MED.315(b) and AMC2 ARA.MED.120(f) should be the same, excluding 'their' before 'decision' and using 'in borderline and difficult cases'.

Proposal:
Amend ARA.MED.315(b):
'to assist AMEs and AeMCs on their request regarding decisions on aero-medical fitness in borderline and difficult cases or those not regulated in Part-MED.'

response | Partially accepted

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

ARA.MED.325 p. 14

comment | *140* comment by: *UK CAA*

ARA.MED.325 Secondary review procedure

Comment: The proposed text does not necessarily require medical involvement which is essential for decision making.

Justification: This should be a medical review with medical and operational experts as necessary.

Proposed Text: 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 and accredited medical conclusion.

response | Accepted

comment | *207* comment by: *Luftfahrt-Bundesamt*

In Germany the medical assessors are appointed by the LBA.

"The *aero-medical section of the* licensing authority shall establish a procedure for the review of borderline and contentious cases and cases where an applicant requests a review in accordance with the applicable medical requirements."

response | Not Accepted – the procedures should be adopted by the competent authority not by individuals or parts of the authorities. How the adoption of procedures is delegated within each competent authority is for each authority to decide.

comment | *220* comment by: *European Transport Workers Federation - ETF*

Page 14 : 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 +page 45 : the related AMC to this IR	ETF fears that the changes introduced will alter the independence of the secondary review. We think it should be an independent process and ask for re-introduction of the independence requirement.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response

Not Accepted – in some cases it proved difficult to find independent medical advisors with appropriate experience willing to participate. The authority may select appropriate medical and technical experts in order to ensure aviation safety

comment

_274_ comment by: _German NSA (BAF)_

The procedures are established by competent authorities only.

The present wording of this paragraph is not very clear, but the amended version is also unclear. This is what the paragraph should say:

Reason to start secondary review procedure (SRP): only on request of an applicant.
In which cases is a request for a SRP possible: unfit assessment by an AME according to MED.A.025 (b)(3) or the medical assessor after a referral because the applicant was not assessed as unfit by the AME who referred the case so that MED.A.025 (b)(3) could not be applied.
AMC material:
Who is in the lead of an SRP: the medical assessor of the competent authority.
Who should participate in the evaluation of fitness:
1) Medical assessor
2) Independent medical advisor (e.g. medical specialist who may not have knowledge in aviation medicine) to ensure an independent review of the case. The result(s) of eventual examinations or tests by the medical advisor will have to be put into the context of aviation medicine by the medical assessor.
3. Technical expert in the field of the privileges of the licence of the applicant to provide advice with regard to MED.B.001 (c)(1)(2).
(eventually 4. one AME.)
Who determines the result: The medical assessor, taking the advice from the specialists into account.
How often can an applicant request a SRV: Only once within a certain time limit (e.g. 4 weeks) after he has been assessed as unfit. One repetition should be possible but only if new and better results can be presented.

Proposal:
'The ~~competent~~ ~~licensing~~ competent authority shall establish a secondary review procedure for applicants who were assessed as unfit and request a review in accordance with the applicable medical requirements.'

response

Not Accepted – the secondary review is not only intended upon request of the applicants in case of unfit assessment, it is also for contentious cases where a fit assessment was issued by the AMEs and where the medical assessor did not agree with during the review process.

comment

_299_ comment by: _French DGAC_

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	France DGAC supports the proposed wording, which will clarify the secondary review procedure, and warmly thanks EASA for it.
response	Noted

comment	*362* comment by: *European Helicopter Association (EHA)* Keep the strikethrough text. It is explanatory of how to do the secondary review.
response	Not Accepted – further details are provided in the AMC

comment	*367* comment by: *ATCEUC* ATCEUC concern is to maintain the independence of the secondary review process. In our opinion this process should be granted to be an independent one so ATCEUC is strongly pushing to highlight and strenghten all the independence requirement.
response	Not Accepted – in some cases it proved difficult to find independent medical advisors with appropriate experience willing to participate. The authority may select appropriate medical and technical experts in order to ensure aviation safety

ARA.MED.330 p. 15

comment	*20* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*82* comment by: *dr roland vermeiren eurocontrol* I see this rule as potentially very dangerous. It allows for all conditions outside the normal regulations to be accepted as special medical circumstances. If new scientific evidence or research exists to allow those conditions to be accepted, this must follow the normal rulemaking procedure to be reflected in an update of the normal rules. Especially now EASA has foreseen a new rulemaking task for a regular update of part MED there is no need for such a way of escaping the actually discussed and accepted rules by specialists in aviation medicine. Especially clearly unacceptable conditions (such as epilepsy and others) in the actual rules must be excluded from such a bypass !
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*107* comment by: *AESA* Concerns about ARA.MED.330. Open window to certification. It will be nice to provide examples where the protocol applied for. Ground research it will be another tool to consider. This part needs more clarification and focus. May be a possibility for applied research and

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

protocol to be done is to use the same procedure that for Age limitation. Consider national ethical issues that might not be complient with ARA MED 330.

response — Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment — _135_ — comment by: _AMABEL_

AMABEL has some concerns with regard to the **ARA.MED.330** about Special Medical Circumstances. The aim of the overall document is to organize the medical certification of applicants. The aero-medical specialists are educated to advice and decide on the "fit to fly status" of an applicant. If somebody's medical condition doesn't comply with the prescribed regulations, he or she should be declared unfit to fly. A review board can take other conditions into account to declare somebody fit to fly with some limitations. The purpose of this Part-Med should not be the foreseeing of rules which would even allow to lower medical criteria in order to implement new medical developments (new treatment, special fly conditions, etc.). It is quite obvious that the 'WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects' should be respected and that the safety of the passengers and the crews should not be impacted by special medical circumstances. But Research doesn't belong to the scope of this document.

response — Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment — _149_ — comment by: _UK CAA_

Paragraph No: ARA.MED.330 (b)

Comment: It is more important to have an appropriate protocol than a set number of participating licensing authorities.

Justification: Having a specified minimum number of licensing authorities does not fulfil the safety aim of the regulation. There is no justification to increase the number of participating licensing authorities required.

Proposed Text: ~~In order to undertake research,~~ ~~a~~A ~~competent~~ licensing authority~~, in cooperation with at least one two other competent licensing authorityies,~~ may develop and evaluate a medical ~~assessment~~ certification protocol, based on which the~~se competent~~ licensing authority~~ies~~ may issue a defined number of pilot medical certificates with appropriate limitations.

response — Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment | *182* comment by: *AeMC PERCY FRANCE*

Dear Colleagues,

I have the honor as the representative of the Aemedical Center of Percy Military Hospital to make some comments about the NPA.
As expected, the most important and sensitive topic is the ARA.MED.330, which had also been previously introduced and discussed in the Part-ARA of June 2016 as *Special medical circumstances*. However, despite its rewording, this specific point is a unique case in the Part-MED which allows continuous modifications of the rules, with a very few Authorities concerned and finally a dynamic process (which may be a good idea) not so structured to be compatible with ethics and science. This process is unlikely to be compatible with the current European laws as we will develop below.

I.

The flight surgeons and the aeromedical examiners (AME) are obviously favourable and familiar with novelty. Every treatment or technique that is likely to improve the health and thus to discuss positively fitness for pilots, is a real great victory for these practitioners. Furthermore, many pilots are involved in protocols of treatment, particularly in the field of haematology and oncology. However, these protocols are deciding when grounding, with a unique objective for the aircrew which is the health, and the fitness assessment does not include specific intervention (especially during flying duties). To summarize, the fitness assessment is performed previously to the flight, on a medical, aeromedical and scientific basis, by respecting the regulations edited by the EASA. We should notice the following point: if the EASA regulations include check-lists and specific pathologies that theoretically do not allow aircrews to fly, there is for the AME a significant adaptability to assume some structured decisions with specific and legitimate limitations, without any protocol, with the acceptance of their respective aeromedical Authority.

II.

In this context of aeromedical assessment, is there a place for research and protocols of certification (we will discuss these terms below)?
One should argue that the true question is: on a physiological point of view, is there an interest to test a medical condition of a patient during a commercial flight with passengers, when not closely in relation to specific constraints (such as for the aerotoxic syndrome for instance)? Simulation in aeronautics and in medicine is more and more developed and can actually reproduce all the situations of a commercial (or other) flight. Aeronautics has become a model for medical simulation (« CRM » in trauma room...) Furthermore, “Crew Resource Management” can be tested before flying, with competent researchers (of the Human Factor) and protocols, and they should not be tested during a flight. In this way, in the military environment, different techniques and protocols such as the human centrifuge machine or the hypobaric chamber are used to test fighter or transport pilots before they return to flying duties after some medical conditions (e.g. AF, PVB or pneumothorax). Thus, why should a medical condition be tested during a commercial or other professional flight? Why should a certification be tested through a protocol, all the more as the TML, OML, OSL, SSL (…) limitations are somewhere a way “to test the compatibility” of some medical conditions with flying activities?

III.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Special medical circumstances and “medical research”, “protocol”, “protocol of certification”…

1. We have seen the process of correction: research has become protocol of certification, perhaps medical…

In June 2016, it had been stated in the part-ARA that: “*…when the terms ‘medical assessment protocol’, ‘research protocol’ and ‘protocol’ are used, they all refer to a medical assessment protocol*”. Then, it is very clear that we are in the field of Medicine (this is ARA-MED and not ARA-FCL or FSTD….)
As a consequence, the principles of ethics are to be respected, and all the rules which are listed below are to be applied:

- WMA Declaration of Helsinki - Ethical principles for medical research involving human subjects. 64th WMA General Assembly, October 2013;
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

- International ethical guidelines for health-related research involving humans. WHO / CIOMS, Genève 2016;
https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

- A practical guide for health researcher. WHO/Regional Office for the Eastern Mediterranean, Cairo 2004;
http://apps.who.int/iris/handle/10665/119703

- European textbook on ethics in research. European Commission, Directorate -General for research – Science, economy and society, Brussels 2010.
https://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf.

2. It is not useful to describe point by point all the principles that must be respected in the field of Medicine. However, we would like to emphasize four points:

- “*…Ethics are principles of right conduct. There are generally no disagreements on the ethical principles in themselves, since they represent basic human values. There can however, be differences on how they are interpreted and implemented in specific cases…*” (ref 3) So, basically there is no reason not to apply medical ethics in the regulations of aeronautical and aerospace medicine.

- Definition of human research (ref 4): ”*…Research aims to generate (new) information, knowledge, understanding, or some other relevant cognitive good and does so by means of a systematic investigation….* “So, we are in the ARA.MED.330 in the field of medical (human) research.

- Obviously, the “agreement” (between the licensing Authorities and the Agency) looks like an ethical committee but is not one…: “*an independent body in a Member State, consisting of healthcare professionals and nonmedical members, whose responsibility is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	assurance of that protection by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent." (ref 4) Why these basic principles should be denied in our regulations? - We are also in the field of commercial aviation and the passengers should be included in the process even if it seems impossible to do… In conclusion: Every practitioner knows that, if we are doing some "arrangements" with the medical principles during our daily activity (which concerns safety moreover flight safety), this is or will be a matter of problem. We are not talking about the law even if we can unfortunately imagine an airline crash with a pilot on command involved in a protocol and so the reactions of the lawyers of the families of victims. We are also highlighting the truly substance of our work as medical Doctors. We are acting in the 21th century in Europe and not in another time or location. The ARA.MED.330 in this NPA has to be removed as it is written and, if this idea is not given up, it has to be structured more precisely by including a large panel of physicians, researchers, specialists of ethics and specialists of the law. Eric Perrier, MD, Prof., General Professor of Aviation Medicine and Internal Medicine – French Military Health Service Academy Head of the Aeromedical Center of Percy Military Hospital "Attaché" Cardiology and aeromedicine unit Percy Military Hospital HIA Percy – DEA/CPEMPN 101 Avenue Henri Barbusse – 92140 Clamart – FRANCE
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*184* comment by: *FAA* Regarding paragraph (d): Article 39 of the Chicago Convention provides that either an attachment to or an endorsement on a license is sufficient: **"**Any person holding a license who does not satisfy in full the conditions laid down in the international standard relating to the class of license or certificate which he holds shall have endorsed on or attached to his license a complete enumeration of the particulars in which he does not satisfy such conditions." Due to privacy, confidentiality, and other litigious concerns, the United States is limited to using certain functional or operational endorsements only, and only on FAA second- and third-class medical certificates. For all classes, medical limitations are specified in an

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	attachment to the medical certificate (i.e., a letter of authorization issued with the medical certificate that sets forth the medical limitations).
response	Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*187* comment by: *Head of the aeromedical center - Bordeaux - France* - Is it really ethical to allow the realization of research study on in flight pilots without asking for the consent of the passengers? -This new paragraph makes it possible to dispense with European standards under medical research argument. - When it exist a risk for flight safety, should we not prefer studies in flight simulator? - Is it possibility to set up a european supervisory group to analyse the protocol and permit to start study? In my opinion, this ARA MED 330 raises too many problems to be validated without an real discussion of the different Member States and a strict definition of the study protocol limits. flight safety first ! This comment represents the opinion of all flight surgeons of the AeMC of Bordeaux.
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*193* comment by: *Philippe CIBOULET* - it is legitimate to have the possibility of re-examining and arranging regulations according to the evolution of knowledge. - Normally, only the data validated by therapeutic tests published on the registers of pharmacovigilance should be considered. - But can one consider such protocols linked to special medical circumstances on inevitably small populations of pilots, that may run an in-flight risk, and whose conclusions could be erroneous because of the low number of pilots included and thus of the low power of the study? Perhaps these protocols of special circumstances could give an answer to the question, specific to the aeronautics justifying test -flight. These situations seem to me very rare in civil aviation and likely in general to be solved in a simulator which would not jeopardize safety. In fact, my opinion is to set safety regulations: - systematical taking into account the results on a large scale for a pathology or a given molecule a priori guaranteeing an experimentation without risk for the crew and passengers (absence of notorious undesirable effects impacting the safety of the flights, tiny proportion of minor undesirable effects not impacting the safety of the flights) - Do not start a protocol without the opinion of the totality of the licensing authorities. - Bring the systematic proof that the protocol considered is in adequacy with the ethical charters of the therapeutic tests - Bring the proof that the protocols considered are not likely to worsen the health status of the pilots - Bring the statistical proof that the protocol is efficient enough to draw some valid conclusions

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

	- Final discussion considering the results with the totality of the licensing authorities about the possible decision to make an amendment to the regulation.
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*196* comment by: *Deputy Departmental Head Aeromedical Center of Toulon* This paragraph has obviously been deeply reworked. It opens up the possibility of evaluating in aeronautical practice new treatments or procedures in flight crews who otherwise would be unfit. This is an evolution that can be interesting and can be conceived. But it would be necessary to return more in the details in particular concerning the imposed limits (TML max 6 months, OML / OSL, re-evaluation at the end of the protocol of the results in particular of the balance effectiveness / tolerance ...) and to envisage the compulsory diffusion with the whole national authorities of EASA countries of the findings. Finally, a maximum limit of experimentation of these possible experimental protocols (2 years) should be set
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*209* comment by: *Luftfahrt-Bundesamt* **ARA.MED.330 Special medical circumstances** The definition under ARA.MED.330 (a) already makes clear that the tasks comprise some kind of development or research activities. The meaning of the term 'certification protocol' is not explained in more detail, obviously a 'certification protocol' is a study in this context. If the participating authorities and EASA are sure that there is no increased safety risk, the pilots concerned can fly in all Member States. The planned procedure foresees that applicants, who are generally not in compliance with the regulation, will become medically fit in certain Member States although having diseases. These Member States will issue the licences and the pilots will be able to fly in all Member States that, due to understandable reasons, have not established such a procedure. There is reason to fear that pilots having certain diagnoses will take advantage of those Member States where a 'protocol' for their disease exists. We wish more transparency in this matter, in particular, with reference to (d): 'The protocol shall be agreed between the licensing authorities concerned and the Agency and shall include as a minimum:' We would support a procedure with the intention to inform all Member States because not only the participating states, but more or less all Member States could be involved. A further step could then be the consultation of the Member States to finally take a decision on the part of EASA. In any case, this could help to define an acceptable level for all Member States thus reducing or avoiding risks to aviation safety.
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment | *224* comment by: *French main military Aeromedical Center (CPEMPN)*

Attachment #2

Centre universitaire des Saints Pères Université Paris Descartes N° SIRET : 478085350 00013	SOCIETE FRANÇAISE DE MEDECINE AEROSPATIALE -------- Président : Professeur Eric PERRIER Vice-Président : Professeur Brigitte GUIDEZ -------- Information : http://www.soframas.asso.fr

March 19th 2018,

We are presenting the thinking of the Working Group of Medicine of the French Society of Aerospace Medicine (SOFRAMAS). To do so, a presentation about the NPA 2017-22 was exposed during a scientific session then a call for comments and opinions to the French Aeromedical Examiners (AMEs) was organized before this synthesis.

The most sensitive topic in the NPA 2017-22 / Updating part-MED and related AMC and GM is the ARA.MED.330 *Special medical circumstances* that needs to be discussed. This ARA.MED.330 is expected to apply for commercial flights particularly.

Every practitioner (MD), particularly as an AME, would agree that the decision-making process is in relation with the progress in medicine. We could add that one major point of the philosophy in clinical aviation medicine is to adapt all the time our aeromedical decisions to the (new) data in care medicine. One old but demonstrative example of this evolution was coronary heart disease, and a more recent one is anticoagulation.

I. We should wonder why such an ARA.MED.330 is proposed.

This ARA.MED is more in relation to the evolution of the regulations than to the progress in medicine. Indeed, when the regulations were previously expressed with national rules which did not go into details for each pathology, most decisions could be taken by the AMEs or the licensing authorities by considering the data of science only, as far as these rules were "open to discussion". The wording of the JAR-FCL then the EASA regulations has changed the power of these rules, because an adverse effect of very precise regulations was a possibility of "no-discussion" for some medical conditions (e.g. aneurysm of the thoracic aorta) with no consideration for medical progress (e.g. anticoagulation reduced to vitamin-K antagonists). This wording of the present rules needs these texts to be changed when a new significant medical situation is identified, and the objective of the ARA.MED.330 is too help for these changes.

II. In this context, why is the ARA.MED.330 disturbing the AMEs and the Aeromedical centers (AeMCs)?

- By using the expression "*medical certification protocol*", it is a new concept to declare fit to fly a pilot who is at the same time unfit, having regard to the present regulations which may change in the future… i.e. perhaps and later: obviously this is strange for the AMEs.

- A pilot of one nation, whose licensing authority of this nation and of two others such as EASA will have validated a certification protocol, will be able to fly in aircrafts registered in the member states but… in all countries… And so, a nation which will not be involved in a protocol, or which would disagree with it, all the same will see such pilots included in protocols flying quite freely in its airspace regularly.

- A certification protocol supposes that the final conclusion will be positive and so the regulations will be changed. But it should be considered that a protocol may lead to a negative conclusion with no change in the regulations. In this possible situation, what to think about all favourable decisions and flying activities for aircrews during the protocol, as far as retrospectively they should not have been issued and authorized?

- There are a number of inaccuracies in this ARA.MED.330: What is a "risk assessment"? Does it refer to the flight safety or to the health of pilots? What does a "cooperation" between the three licensing authorities consist of? EASA should consider that all European countries have not exactly the same philosophy of aeromedical expertise: the possibility of sanction or not in case of a voluntary omission has an impact on the value of anamnesis; consideration to the flights and the professional conditions as factors which should not worsen a medical condition is not universal…

- There is no mention of a maximum duration for a certification protocol, and then aircrews may be involved in a protocol during many years before analysis and conclusion is done.

- In a participating member state, the competent authority shall provide the AMEs/AeMCs within their jurisdiction with details of the protocol. But can an AME or AeMC disagree with a certification protocol and ask not to participate?

- For the final evaluation of the protocol, there is no expected feed-back to all the nations but to the participating nations only and yet, conclusions and changes in the regulations shall apply to all of them. It should be recommended a collegial discussion of the accuracy and pertinence of the final conclusion for each experiment, by involving all the nations or the one which would like to give their opinion (all the more as they may have never heard about this protocol).

III. Many AMEs or AeMCs are thinking that the principles of aeromedical expertise are calling into question with the ARA.MED.330.

- The job of AMEs and AeMCs is to assess the medical risk of in-flight incapacitation. Two elements are part of this assessment: the medical condition and the real daily flying activity. The medical condition refers to pathologies i.e. their evolution and complications including the efficiency and iatrogenicity of the required therapeutics. Data of the literature are accurate and reliable because they are based on studies carried out in large populations and long durations, with patients who had no interest to hide adverse effects or technical problems to respect a treatment or protocol. Aeromedical decisions are taken on the basis of this knowledge which has been collected scientifically prior to aeromedical concerns, and that explains an initial period of grounding is frequently required.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

- What can a certification protocol bring along? In theory nothing, because if the initial risk of a pilot is assessed as unacceptable by the AME, and the pilot is included in a protocol, the report of no event during a number of flights will not question the previous medical thinking of the AME. Basically, we do not prove we were right to let a pilot fly safely when nothing happened to this airman during flights. Moreover, a scientific evidence of a low risk requires statistical analyses. However, all certification protocols during flights will include few pilots (with a poor value of anamnesis in this context), and so the statistical power of these protocols will inevitably be very low, and any extrapolation of the results in these small populations will not be possible for all the aircrews depending on EASA regulations.

- To the contrary of a certification protocol, every AME and AeMC would agree that an in-flight test is useful in some situations where this test is necessary to check or to confirm the fitness decision: e.g. prostheses of the lower limbs and hand controls, incapacitating tinnitus and cockpit environment, recurrence of primitive pneumothorax and atmospheric pressure or +Gz accelerations (hypobaric chamber, human centrifuge machine) … When the aeronautical environment leads to a specific risk in aircrews, what is rarely observed in professional commercial civil aviation, an in-flight test is strongly justified and encouraged.

- Any protocol which includes monitoring procedures during flights is difficult to consider: first because it is the demonstration that a significant medical risk does exist on board (and so medical parameters are to be checked), and second because it looks like everything should be done to make a pilot work and/or fly despite this risk.

- Furthermore, an aeromedical prognosis for a following period is made by the AMEs on the basis of a medical condition at a present time (e.g. having regard to the prognostic value of a negative ischemic test); in a certification protocol, the AMEs will have to certify that a pilot who has correctly followed the monitoring procedures in the last period will do it again in the next period. That is difficult to forecast for the AMEs, and so a more acceptable protocol should include live monitoring procedures (it means telemedicine with “MD as controllers” watching their monitoring screens as if they were working in Intensive Care Units).

IV. In spite of the evolution of the wording of the medical terms since 2016, the ARA.MED.330 is about medical research.

- Medical research is well organized in many European countries, with specific regulations, then it is difficult to imagine a medical protocol becoming a reference in one country whereas it has been developed and signed in others by aeromedical committees which are not official medical committees (e.g. ethical committee).

- As it is written in the NPA 2017-22, the protocol shall be compliant with relevant ethical principles. But is it in accordance with the ethical principles to imagine a certification protocol without passengers’ knowledge, with a final objective “to fly and work at any price”? Again, the EASA and licensing authorities cannot substitute for ethical committees.

Finally, the insulin problematic for diabetic pilots illustrates very well how difficult it is to accept a certification medical protocol and its following implications despite a publication in a famous journal (see *Mitchell SJ et al. A UK Civil Aviation Authority protocol to allow pilots*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

with insulin-treated diabetes to fly commercial aircraft. Lancet Diabetes Endocrinol 2017 Sep; 5(9): 677-9):
- Insulin treatment is not compatible with Class 1 and Class 2 fitness as it is worded in the EASA regulations.
- The risk of mild and severe hypoglycemia episodes is well known (and high) in all the studies performed in the general population and the real life (with reliable value of anamnesis).
- In the UK CAA series, 26 Class 1 pilots were followed during 19.5 months only; 10 did not fly during the period, and the 16 others flew one third as much as they should have performed in the real life for the same duration; many data were missing or were not published in this study (blood glucose values of the operational and non-operational periods, HbA1C curve). The statistical power of this study was hopeless; there was no possibility of a scientific conclusion, except to claim that blood glucose controls are possible during flights (but we had already known that, and if not, it could have been tested in a flight simulator).
- Ethics was called into question in this study for at least three reasons: HbA1C raised 0.2% within this short period; no passengers' knowledge of the protocol; and implication of the copilot in the monitoring procedures.

In this context, we should be aware that the ARA.MED.330 may lead some countries to imagine certification protocols in numerous medical situations, with no limits. As examples:
- Severe renal insufficiency and blood parameters
- Chronic pulmonary insufficiency and SaO2 monitoring
- Epilepsy and blood dosage of the treatment and EEG monitoring
- Psychological disturbances and pre-flight assessment by a consultation
- Severe ventricular arrhythmias and implantable cardiac monitoring
- Hypertrophic cardiomyopathy, Implantable Cardioverter Defibrillator, and in-flight ECG monitoring
- …

Everything becomes possible to propose… what is dangerous for the flight safety.

As a conclusion, we would say that the idea to include the medical progress in a specific paragraph of the current regulations is attractive at the first look. However, after thinking about the practical considerations and ethical concerns of the process, the proposal ARA.MED.330 of the NPA 2017-22 is not acceptable as it is worded.
A last argument could be: What would happen in case of a crash involving a plane of an airline company with a pilot in-command who was at the same time included in a certification protocol? The lawyers should take delight in defending the victims' families, and no AME or AeMC would assume responsibility to say it was a comfortable situation… We should also think about it three years after the Germanwings tragedy.

Olivier MANEN, MD, Prof.
Chair of the Advisory Board Committee of the French Society of Aerospace Medicine
Chair of the Working Group of Medicine of the French Society of Aerospace Medicine

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	_268_ comment by: _German NSA (BAF)_ This paragraph is not referenced in Regulation 2015/340, ATCO.AR.F.001 and is therefore not applicable to class 3 applicants.
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	_269_ comment by: _German NSA (BAF)_ **ARA.MED.330** General: In the case of new medical technology, medication, or procedures a risk assessment can be made and the rules can be amended as long as the new rules comply with ICAO Annex 1. Presently, ATCO.MED.B.001 provides for the necessary flexibility in most of these cases. <u>Proposal</u>: Remove ARA.MED.330.
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	_270_ comment by: _German NSA (BAF)_ **ARA.ME.330 (b), (d) (5) anf (f)** The term 'licensing authority' is not correct. Procedures – and this protocol is a kind of procedure – are established by competent authorities only. Same applies to subparagraphs (d), (d) (5) and (f) <u>Proposal</u>: Replace 'licensing authority' by 'competent authority'.
response	Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

An agency of the European Union

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment	282 comment by: *French DGAC*
	We strongly believe that this provision should be removed, for the reasons mentioned below. **At the very least, the member States over which a pilot under an ARA.MED.330 protocol flies should be informed and should have the possibility of refusing the flight over its territory.** **I) Medical protocol** 1) Members of rulemaking task 0287 b) as indicated in page 4 para 3 of this NPA have proposed, with the majority of votes, to delete this paragraph. 2) This article allows modifications of the medical rules, with the collaboration of two or three Authorities without the approbation of the others. 3) Such a provision is unduly flexible. In any other aviation matters, when an exemption to the rules is planned, the exemption process entails informing other member States and, in some cases, a vote. On the contrary, this provision makes it possible for some States to let a pilot fly in exemption of part of the medical rules, without notifying the Member states over which the pilot may fly. We believe that this provision is not compatible with the spirit of article 14 of regulation 216/2008. 4) Currently EASA has published on October 9 2017 TORs of RMT 0424 “Regular update of part MED” which will work with a group composed with different experts from NAA’s and stakeholders. Sub groups will be composed of high specialists in different topics as cardiology, psychiatry, ophthalmology etc... This group will work soon (May 2018). The progression will be in line with EASA normal process and will produce new rules in conformity with evolution of medicine and technics. This is the reason why it is not necessary to let initiative of changes to two or three authorities without concertation of the others. 5) Aeromedical centers (AeMCs) and aeromedical examiners (AME’s) of course support rules changes in order to follow the evolution of medicine. But all proposed changes should be initially analyzed on ground and simulator to ensure that they are compatible with real flights. All innovation (e.g. electronic equipment linked to treatment or medication) could jeopardize flight safety. Improvisation is not appropriate and this is the reason why, to make a technical analogy, pilots’ rigorous procedures are tested first on the ground to guarantee flight safety in case of failure. As far as medicine is concerned, we know that before utilization of a medication, several tests phases are necessary before dual marketing approach. However, these tests are practiced with patients duly informed of risks; there is no possible comparison with a pilot under an ARA.MED.330 protocol who exposes not only his own safety but also the safety of his passengers and third parties on ground. Considering that the current and future rules open a lot of possibilities of fitness, why should some States be allowed to conduct experimentations, sometimes far from the accepted rules, which could be very controversial at each level (NAA’s, stakeholders), sometimes below ICAO regulations, and without real information of the public and passengers involved? In

aeronautics like in medicine we have a lot of possibilities of simulation before flying with passengers, possibilities which should not be neglected.

6) Special medical circumstances and “medical research”, “protocol”, “protocol of certification”…

(We thank Prof Perrier, Percy Paris Aeromedical center, and his team for their contribution to this paragraph).

The principles of ethics have to be respected, and all the rules which are listed below have to be applied:
Ref 1 WMA Declaration of Helsinki - Ethical principles for medical research involving human subjects. 64th WMA General Assembly, October 2013;
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
Ref 2 International ethical guidelines for health-related research involving humans. WHO / CIOMS, Genève 2016;
https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
Ref 3 A practical guide for health researcher. WHO/Regional Office for the Eastern Mediterranean, Cairo 2004;
http://apps.who.int/iris/handle/10665/119703
Ref 4 European textbook on ethics in research. European Commission, Directorate -General for research – Science, economy and society, Brussels 2010.
https://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf.
It is not useful to describe point by point all the principles that must be respected in the field of medicine. However, we would like to emphasize some points:

- “…*Ethics are principles of right conduct. There are generally no disagreements on the ethical principles in themselves, since they represent basic human values. There can however, be differences on how they are interpreted and implemented in specific cases*…” (Ref 3 chap 2.2))
So, basically there is no reason not to apply medical ethics in the regulations of aeronautical and aerospace medicine.

- Definition of human research (Ref 4 page 14):”…*Research aims to generate (new) information, knowledge, understanding, or some other relevant cognitive good and does so by means of a systematic investigation…*. “So, we are in the ARA.MED.330 in the field of medical (human) research.

- Obviously, the “agreement” (between the licensing Authorities and the Agency) looks like an ethical committee but is not one…: “*an independent body in a Member State, consisting of healthcare professionals and nonmedical members, whose responsibility is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent*.” (Ref 4 page 30) Why should these basic principles be denied in our regulations?

To conclude

ARA.MED.330 in this NPA has to be removed as it is written and, if this idea is not given up, it has to be structured more precisely by including a large panel of physicians, researchers, specialists of ethics and lawyers.
We think that this article opens the door to different "experiences" without consensus of other member states.

5) Finally DGAC asks the Agency whether this protocol is compatible with ICAO convention (art.39 and 40) and its annexes. Shouldn't a pilot who flies under ARA MED 330 be restricted to fly only in his country?

II) Is this provision meant to be applicable to ATCOs?

Although ARA.MED.330 isn't in the list of Aircrew provisions that are applicable to ATCOs per ATCO.AR.F.001 (Regulation 2015/340), yet, in the first paragraph on page 7 of the NPA, ATCOs are mentioned as being within the scope of this provision.

This seems worrisome to us, as, even when working in pairs, ATCO do not have dual controls and are complementary but not interchangeable, meaning the incapacitation of an ATCO can have consequences on flight safety.
Will AESA please clarify the scope of this provision and, if applicable to ATCO, amend ATCO.AR.F.001 in regulation 2015/340.

response

Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment

312 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: ARA.MED.330

Comment:
The original concept of this paragraph, introduced in 2015 through Regulation (EU) 2015/445, has been used as an open door to deviate from any requirement laid down in Part-MED. This might be regarded as a deviation from basic EU principles requiring uniform levels of competition based on fair and equal terms and conditions.

The original concept is not compatible with basic research principles, which is also commented in the explanatory notes. However, the changes made in the proposed text is mainly to exchange 'research' with 'certification protocol', keeping the rest of prerequisites for 'research' unchanged.

This paragraph, even with the amended text, might result in serious flight safety issues, which is unacceptable.

The conclusions of the rulemaking group to delete ARA.MED.330 is strongly supported.

Proposal:

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Delete ARA.MED.330.

response

Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment

313 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: ARA.MED.330(a)

Comment:
If ARA.MED.330 is not deleted, it should be clearly stated that it may only be applied for conditions on the verge to be accepted for an amendment of the requirements with support from the majority of member states.

Proposal:
Amend ARA.MED.330(a):
'When new medical technology, medication, or procedures with broad consensus are identified that may justify fit assessment of applicants …'

response

Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment

314 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: ARA.MED.330(b)

Comment:
If ARA.MED.330 is not deleted, it should be clearly stated that before acceptance or approval of the protocol, the protocol requirements shall be fulfilled, including the defined number of applicants to be included.

Proposal:
Amend ARA.MED.330(b):

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	'Before acceptance of the protocol all protocol requirements shall be fulfilled, including the defined number of applicants to be included.'
response	Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*315* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*
	Section: ARA.MED.330(c)
	Comment: If ARA.MED.330 is not deleted, all cases based on this paragraph should be referred to the medical assessor of the licensing authority in accordance with the requirements for several borderline medical conditions. The medical assessor should be responsible for the aero-medical assessment and issuance of medical certificates based on this paragraph.
	Proposal: Amend ARA.MED.330(c): **'All cases where ARA.MED.330 is applied shall be referred to the medical assessor of the licensing authority. Medical certificates based on ARA.MED.330 shall only be issued by the medical assessor.'**
response	Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*316* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*
	Section: ARA.MED.330(d)
	Comment: If ARA.MED.330 is not deleted, it should be clearly stated that the protocol shall not only be agreed between the agency and the licensing authorities concerned, but also approved by the agency. The protocol should also require an acceptance by the majority of member states as an implementation might create a higher risk also to other member states.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Proposal:
Amend ARA.MED.330(d):
'The protocol shall be agreed between the licensing authorities of all member states and approved by the Agency and shall include as a minimum:'

response

Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment

_317_ comment by: _Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)_

Section: ARA.MED.330(d)(2)

Comment:
If ARA.MED.330 is not deleted, improvements of ARA.MED.330(d) are required.
For clarity, it should be required that the evidence shall corroborate the conclusion. Also, it is recommended to insert 'suggested' before certification protocol.

Proposal:
Amend ARA.MED.330(d)(2):
'a literature review and evaluation of the existing evidence corroborating that issuing a medical certificate based on the suggested certification protocol …'

response

Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment

_318_ comment by: _Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)_

Section: ARA.MED.330(e)

Comment:
If ARA.MED.330 is not deleted, ARA.MED.330(e) can be questioned, as it refers to ethical principles for research which will no longer be relevant.

Proposal:

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Delete ARA.MED.330(e).

response

Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment

319 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: ARA.MED.330(f)

Comment:
If ARA.MED.330 is not deleted, ARA.MED.330(f) should for clarity be amended using a better wording. 'License holders belonging to a licensing authority' should be changed to 'holders of a license issued by a licensing authority involved …'.

Proposal:
Amend ARA.MED.330(f):
' … holders of a license issued by a licensing authority involved …'

response

Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment

360 comment by: *Head of AeMC Roissy (France)*

I don't agree with the implementation of certification protocols. I think that the european guidelines are the best guides for licensing authorities to accept or refuse a new technology or a new medication. during flight.
A certification protocol would consider a too small sample of pilots to conclude.
Endly, in case of an accident or a crash, what would be the responsability of an AME after having declare fit a pilot in a certification protocol ?

response

Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment

388 comment by: *René Meier, Europe Air Sports*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

ARA.MED.330(f)
page 15/32

Inconsistency in the wording applied: No consistent use of "applicants" and/or "licence holders".

Proposal:
Please use “applicants/medical licence holder”.

Rationale:
This prevents confusion with Part-FCL licences.

response — Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts’ Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment — *402* — comment by: *European Cockpit Association*

ARA.MED.330 Special medical circumstances
AMC1 ARA.MED.330 Special medical circumstances
AMC1 ARA.MED.330(b)(c) Special medical circumstances
GM1 ARA.MED.330 Special medical circumstances

ECA Comment:
ECA definitely wants to keep the ARA.MED 330 and the related AMCs. Currently, the development in the field of medicine is very fast, and there will be treatments or medications that could be perfectly safe in aviation environment, but are not allowed within current regulation. To gain experience in aviation environment, it is important to have a regulated protocol for to study these new options in a safe way.

In addition, pilots should be able to receive the best treatment for their medical condition, and sometimes if this results in grounding, pilot may not take that treatment or medication. This protocol will allow faster evaluation of such treatment and may also benefit pilots’ health.

response — Noted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts’ Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment — *434* — comment by: *DidierDELAITRE*

First Comment :
The text does not provide for consultation of the protocol with other Member States, nor what happens if they raise objections. Does the Protocol make it possible to circumvent controversies between certain Member States on certain diseases?

response — Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts’ Group representing Member States and

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment *435* comment by: *DidierDELAITRE*

Second Comment :
"(b) In order to undertake research, a competent licensing authority, in cooperation with at least one two other competent licensing authorities, ..."
Is this article consistent with :
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 "Whereas: (1)A high and uniform level of protection of the European citizen should at all times be ensured in civil aviation, by the adoption of common safety rules and by measures ensuring that products, persons and organisations in the Community comply with such rules and with those adopted to protect the environment."?

response Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment *436* comment by: *DidierDELAITRE*

Third Comment :
"(f) The exercise of licence privileges shall be restricted to licence holders belonging to a licensing authority involved in the certification protocol and to flights in aircraft registered in Member States involved in the certification protocol. This restriction shall be indicated on the medical certificate."
- Is this article consistent with the principle of free movement?
- What happens if an accident/a diversion - occurs in/to a country which is not involved in the protocol ?

response Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment *437* comment by: *DidierDELAITRE*

Fourth Comment :
"(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;"
Medical data from accidents and incidents are partial and insufficient, in particular due to professional secrecy and the lack of doctors involved in investigations. The scientific evidence, which favours positive "publishable" results, is a fragile and insufficient basis.

response Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*438* comment by: *DidierDELAITRE* Fifth Comment : "(4) the limitations that will be endorsed on the medical certificate;..." Have the socio-economic consequences of the medical decision been taken into account? The cost of training and its financing? The accountability of airline service in case of the pilote would be declared unfit soon or late? These two factors were present in the occurrence of GermanWings. The decision of fitness opens rights from a socio-economical point of view, well beyond the fact of piloting.
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*439* comment by: *DidierDELAITRE* Sixth Comment "(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,..." Safety may justify, new medical issues may enable. This article is based on a reverse reasoning, where the medical examination is used to make a pilot fit at all costs. That is what has been done in the case of GermanWings accident. The purpuse of performing medical examinations must be for safety.
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

comment	*440* comment by: *DidierDELAITRE* Seventh & Final Comment : "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..." EASA supports ARA.MED.330 despite the fact that the process is not relevant from a medical point of view. EASA should develop more clearly the reasons why "EASA considers that these requirements should be kept in an improved version".
response	Accepted – As a result to the comments received an additional focused consultation on this topic with the member of the Medical Experts' Group representing Member States and industry was performed. The focused consultation concluded with the vast majority in favour of deleting ARA.MED.330. Consequently, ARA.MED.330 was proposed to be deleted.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

Appendix V to Part-ARA – Certificate for AeMCs	p. 16-17

comment	*21* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*150* comment by: *UK CAA* **Paragraph No:** **APPENDIX V TO ANNEX VI PART-ARA** - CERTIFICATE FOR AERO-MEDICAL CENTRES (AeMCs) **Comment:** All certificates and attachments should be AMC material. **Justification:** Formats may need to vary according applicable national law and available IT systems, taking account of future developments where certificate information may be available electronically negating the need to hold a physical certificate. **Proposed Text:** No change but move to AMC
response	Not Accepted

comment	*152* comment by: *UK CAA* **Page No:** 17 **Paragraph No:** **APPENDIX V TO ANNEX VI PART-ARA** - CERTIFICATE FOR AERO-MEDICAL CENTRES (AeMCs) **Comment:** The information in attachments should be part of the certificate **Justification:** No need to have separate documents **Proposed Text:** Merge certificate and attachment
response	Not Accepted – they are already one document, just different pages

comment	*218* comment by: *AESA/DSANA* Comment The certificate for aero-medical centres as well as the one for aero-medical examiners should be eliminated from Regulation (EU) No 2015/340 in order to avoid duplication. Justification These certificates appear in Regulation (EU) No 2015/340, but they only refer to class 3 medical certificates and that same Regulation.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

response	Noted – however amending Regulation (EU) No 2015/340 is not in the scope of the current RMT

comment	*271* comment by: *German NSA (BAF)* Presently it is not possible to include the AeMC certificate with class 3 privileges in Reg (EU) No 1178/2011 as this is covered in Reg (EU) 2015/340. Proposal: Delete reference to class 3
response	Not Accepted

comment	*283* comment by: *French DGAC* In France, the department in charge of class 3 AME certificates is distinct from the department in charge of other classes' certificates; and merging both departments is not considered. As a consequence, there are no obvious benefits for France to merge certificate templates, since an AeMC certified both for pilots and ATCO will still hold two different certificates, no matter what. As mentioned in ARA.MED.130 Medical Certificate Format above, amending the certificates comes at a cost. We suggest rendering this modification optional, for example by adding the phrase 'if applicable'.
response	Noted

comment	*375* comment by: *Croatian Civil Aviation Agency* **Appendix V to Annex VI Part-ARA – AeMC certificate** On the proposed AeMC certificate is the same revision number of EASA Form 146 Issue 1 as in Commission Regulation 290/2012, even though it was revised in Commission Regulation 245/2014 and in Commission Regulation 2015/340.
response	Accepted

comment	*389* comment by: *René Meier, Europe Air Sports* Appendix V to Annex VI Part-ARA page 16/52 Certificate for aero-medical centres: Inconsistency in the format of certificates. Proposal: Please delete: "Date of Issue ..." and "Signed..." Insert: "Date of issue: dd/mm/yyyy" and "Signature of Competent Authority" Rationala:

	To be consistent with other certificates.
response	Accepted

Appendix VII to Part-ARA – Certificate for AMEs	p. 18-19

comment	*22* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*23* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*151* comment by: *UK CAA* **Paragraph No:** **APPENDIX VII TO ANNEX VI PART-ARA** **Comment:** All certificates and attachments should be AMC material. **Justification:** Formats may need to vary according applicable national law and available IT systems, taking account of future developments where certificate information may be available electronically negating the need to hold a physical certificate. **Proposed Text:** No change but move to AMC
response	Not Accepted – for consistency with other areas they shall remain as appendix to part ARA

comment	*153* comment by: *UK CAA* **Paragraph No:** **APPENDIX VII TO ANNEX VI PART-ARA** **Comment:** The information in attachments should be part of the certificate **Justification:** No need to have separate documents **Proposed Text:** Merge certificate and attachment
response	Not Accepted – they are already one document, just different pages

comment	*218* ❖ comment by: *AESA/DSANA* Comment The certificate for aero-medical centres as well as the one for aero-medical examiners should be eliminated from Regulation (EU) No 2015/340 in order to avoid duplication.

An agency of the European Union

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	Justification These certificates appear in Regulation (EU) No 2015/340, but they only refer to class 3 medical certificates and that same Regulation.
response	Noted – however amending Regulation (EU) No 2015/340 is not in the scope of the current RMT

comment	*272* comment by: *German NSA (BAF)* Presently, it is not possible to include the AME certificate for class 3 privileges in Reg (EU) No 1178/2011 as this is covered in Reg (EU) 2015/340. Proposal: Delete references to class 3.
response	Not Accepted

comment	*320* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** Appendix VII, Certificate for Aero-Medical Examiners **Comment**: In the conditions, no 3 should be amended, as 'not exceeding three years' will be interpreted as any unspecified period from one day to three years which is not acceptable. 'A period not exceeding three years' is regulated in ARA.MED.200(c) and should not be mentioned here. Instead, the specified expiry date (within the three year period) decided by the competent authority shall be stated here, as the competent authority sometimes may have a justified reason to choose a shorter validity period. In addition, the situations described in ARA.MED.250(b), where an AME certificate is rendered invalid when the licence to practice has been revoked, should be covered by adding 'or otherwise rendered invalid'. **Proposal**: Amend Appendix VII, Condition No 3: **'This certificate shall remain valid until [dd/mm/yyyy] subject to compliance with the requirements of Part-MED/Part ATCO.MED unless it has been surrendered, superseded, suspended, revoked or otherwise rendered invalid.'**
response	Partially accepted

comment	*376* comment by: *Croatian Civil Aviation Agency* **Appendix VII to Annex VI Part-ARA – AME certificate**

	On the proposed AME certificate is the same revision number of EASA Form 148 Issue 1 as in Commission Regulation 290/2012, even thought it was revised in Commission Regulation 2015/340.
response	Accepted

Proposed amendments to Part-ORA – ORA.AeMC.105 p. 20

comment	*2* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*24* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*222* comment by: *AESA/DSANA* Comment Caution should be taken when adding 'class 3' to the requisites ORA.AeMC. The amendment of Regulation (EU) No 2015/340 is necessary for the sake of coherence. Justification Regulation (EU) No 2015/340 ATCO.OR.E.001 states that: Aero-medical centres (AeMCs) shall apply the provisions of Subparts ORA.GEN and ORA.AeMC of Annex VII to Commission Regulation (EU) No 290/2012 (1), with: (a) all references to class 1 to be replaced with class 3; and (b) all references to Part MED to be replaced with Part ATCO.MED Point (a) wouldn't be logical if 'class 3' is added to ORA.AeMC. Therefore, point (a) should be restricted to ORA.GEN.
response	Noted

comment	*273* comment by: *German NSA (BAF)* The term 'an organisation' is not clear, could by a training organisation. Delete the addition 'or class 3' as this is covered by Reg (EU) 2015/340, ATCO.OR.E.001 (a). Delete 'in accordance with the privileges defined in the terms of approval attached to the AeMC's certificate'. Reason: This paragraph is to define the possible scope of 'an' AeMC. It does not deal with the scope of an individual AeMC which is defined by terms of approval provided as an attachment to the certificate. Proposal:

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	'(a) 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). (b) The scope of an AeMC is (1) to issue medical certificates, including initial class 1 medical certificates, (2) to issue cabin crew medical reports; (3) to provide aero-medical expertise and practical training for AMEs.
response	Noted

ORA.AeMC.115 p. 20

comment	_25_ comment by: _CAA.CZ_ I have no comments
response	Noted

comment	_275_ comment by: _German NSA (BAF)_ **ORA.AeMC.115 (b)** The term “contracted activity” could be replaced by “contract”. Specialist medical examinations are performed in hospitals or specialised doctors offices. Neither of them is an organisation as defined in Regulation 1178/2011. Depending on the case, the examinations may be performed at different institutions other than the designated hospital or medical institute, e.g. follow-up of cancer or pace maker, or any case of endocrinology, or ... It is not possible that the competent authority gets access to the premises of a hospital to determine compliance. The provider of these specialist examinations gets the right to perform the examinations in their field by the national Medical Boards. It is not possible to impose aviation requirements on these institutions. The AME sends pilots and ATCOs to eye specialists and ENT specialists. Regulation 1178/2011 does not provide for persons to contract activities. This means that AMEs can send applicants to any specialist without entering into contracted activities. The consequence may be that an AeMC has to refer an applicant to an AME for him to send the applicant to a hospital for specialist medical examinations. Proposal: Revert to original text, or '[...] provide details of a contract with designated hospitals [...]'
response	Not Accepted – subcontractors should allow access to the competent authority.

ORA.AeMC.120 p. 20

comment	_26_ comment by: _CAA.CZ_

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	I have no comments
response	Noted

comment	*113* comment by: *AESA* Add (4) Experience in Aviation Medicine fully demonstrate in appropiate CV
response	Not Accepted – how the experience has to be demonstrated is left for the competent authorities to decide allowing the flexibility for each individual Member State

comment	*276* comment by: *German NSA (BAF)* It is not possible to meet this requirement if the competent authority responsible for the implementation of Reg (EU) No 1178/2011 differs from the competent authority responsible for the implementation of Reg (EU) 2015/340. Proposal: An aero-medical centre shall not hold more than one AeMC certificate within an specific area of competence.
response	Accepted

comment	*285* comment by: *French DGAC* This provision only makes sense in a context where the same authority is in charge of the certification of Aicrew and Class 3 AeMC certification. As mentioned before, in France, when approved both for pilots and ATCO, AeMC will keep holding two different certificates delivered by two different Authority departments. We suggest removing this provision, as it might lead to an EASA finding against authorities with an organisation similar to ours, without any safety reasons.
response	Partially accepted

ORA.AeMC.135 p. 20

comment	*27* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*108* comment by: *AESA* (b) do not distinguish between initials and periodicals. "Adequate" it is very "abstract term", numbers should be included, takeing into account the total number of licences issues in the country.

response	Not Accepted – EASA cannot propose a number to be usable in all member states, however the competent authorities may define in the national procedures their understanding of what an adequate number is based also on the size of their industry.

comment	*188* comment by: *German Military Aviation Authority* Many facilities perform joint assessments for civil and military aviation together. Although military aviation is exempted from direct influence of EU regulation 216/2008, military aviation ensures that they act with due regard as far as practicable to the objectives of that Regulation, to fulfill article 1 section 2 of that regulation. Furthermore, military requirements exceed those of civil aviation regularly. I propose to enable the acknowledgement of military aviation medicine experiance where practical. ORA.AeMC.135 (b) should be supplemented as follows or similar: ensuring their continued experience by performing an adequate number of class 1 or class 3 **or equivalent military** aviation medical examinations, as appropriate, every year
response	Accepted

comment	*222* ❖ comment by: *AESA/DSANA* Comment Caution should be taken when adding 'class 3' to the requisites ORA.AeMC. The amendment of Regulation (EU) No 2015/340 is necessary for the sake of coherence. Justification Regulation (EU) No 2015/340 ATCO.OR.E.001 states that: Aero-medical centres (AeMCs) shall apply the provisions of Subparts ORA.GEN and ORA.AeMC of Annex VII to Commission Regulation (EU) No 290/2012 (1), with: (a) all references to class 1 to be replaced with class 3; and (b) all references to Part MED to be replaced with Part ATCO.MED Point (a) wouldn't be logical if 'class 3' is added to ORA.AeMC. Therefore, point (a) should be restricted to ORA.GEN.
response	Noted

comment	*277* comment by: *German NSA (BAF)* **ORA.AeMC.135 (b)** Delete the addition 'or class 3' as this is covered by Reg (EU) 2015/340, ATCO.OR.E.001 (a).
response	Not Accepted -

comment	*284* comment by: *French DGAC*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	To complete the updating of this requirement regarding ATCO, we suggest adding, after "MED.D.030", "or ATCO.MED.C.025 as appropriate".
response	Accepted

ORA.AeMC.160 p. 20

comment	*28* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*91* comment by: *Aivars PRIEKULIS* reports of the … alcohol screening… *- Alcohol screening is not the AeMC`s, but the operator`s/police responsibility* *Proposal to delete this reporting part requirement*
response	Not Accepted – in accordance with MED.B.055 (b) Drugs and alcohol screening shall form part of the initial class 1 aero-medical examination

comment	*154* comment by: *UK CAA* **Paragraph No: ORA.AeMC.160 Reporting** **Comment:** Not clear what is meant by "risk factors" – does this mean data from the analysis of the AeMCs (safety) management activities? **Justification:** Clarify meaning of text **Proposed Text:** 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~~safety management activities.
response	Not Accepted – the text refers to health risk factors and trends identified during the aero-medical examinations

comment	*183* comment by: *FAA* To clarify the meaning of this provision, a definition for what is intended by "screening" would be helpful. It is not clear whether the intent is for each applicant to submit to drug and alcohol *testing* during medical examination or for the examiner to conduct specific *screening* of the applicant for risk factors.

response	Not Accepted – in accordance with MED.B.055 (b) Drugs and alcohol screening shall form part of the initial class 1 aero-medical examination

comment	*286* comment by: *French DGAC* Reports of the drugs and alcohol screening are subject to the publication of the related regulation. We suggest adding, after 'drug and alcohol screening', the phrase '**if applicable'**.
response	Partially accepted – wording clarified

comment	*390* comment by: *René Meier, Europe Air Sports* ORA.AeMC.160.Reporting page 20/52 Drugs and alcohol screening and risk factors identified: the background and procedure is not clear. Proposal: Please identify and clarify the rules to be applied. Rationale: We have to know and to understand the rules on which this paragraph is based. Question: Would it not be helpful to draw a distinct line between "drug" and "medication" throughout the NPA and all future provisions?
response	Partially accepted – with the adoption of the updates to MED.B.055 the intent is clarified

comment	*418* comment by: *NATS* **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. Issue Clarify who this applies to. Understand the intention is for D&A screening for initial Class 1 applicants, post Germanwings. This leads to increased cost/time with questionable benefit. Not included as requirement for initial Class 3. Within NATS we have random D&A testing anyway. This allows more flexibility. Suggested Resolution The AeMC shall provide the competent authority with statistical reports regarding the aero-medical assessments of applicants, including for initial Class 1 applicants, reports of the drugs and alcohol screening and risk factors identified.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Partially accepted – with the adoption of the updates to MED.B.055 the intent is clarified

ORA.AeMC.200	p. 21

comment	*29* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*155* comment by: *UK CAA* **Paragraph No: ORA.AeMC.200 Management system (b)** **Comment:** Not clear why this text has been added or why it is needed.
response	Noted – the intent is to ensure the AeMC is working as a team and the AMEs cooperate with other medical experts in the AeMC

ORA.AeMC.205	p. 21

comment	*30* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*109* comment by: *AESA* (a) Concept of "Minimum", again very abstract, must be defined the minimum number.
response	Partially accepted – the word minimum refers to the basic examinations that are required by Part-MED/ Part ATCO>MED for initial class 1 . Minimum was replaced by the word “Standard”

comment	*156* comment by: *UK CAA* **Paragraph No: ORA.AeMC.205 Contracted activities** **Comment:** Current text is not clear concerning what tests must be performed within the organisation and what can be contracted out and how. **Justification:** Edited for clarity **Proposed Text:** Notwithstanding ORA.GEN.205:

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	(a) ~~Minimum~~ The mandatory required aero-medical test and examinations for the issue of a class 1 or 3 medical certificate 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)* If the mandatory requirements performed are not performed within the organisation and are contracted out, the organisation shall ensure the contracted service or product conforms to the applicable requirements. (c) Additional medical examinations and investigations may be performed by other ~~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.~~
response	Partially accepted – the word minimum refers to the basic examinations that are required by Part-MED/ Part ATCO>MED for initial class 1 . Minimum was replaced by the word "Standard"

comment	*278* comment by: *German NSA (BAF)* **ORA.AeMC 205 (a)** The new paragraph (a) does not match the header. This paragraph will lead to many discussions between AeMCs and competent authorities and the level playing field is in danger. Proposal: Either define the minimum or delete the paragraph. The pertaining AMC is not helpful in this case as it does not mention the clinical examination of the applicant.
response	Partially accepted – the word minimum refers to the basic examinations that are required by Part-MED/ Part ATCO>MED for initial class 1 . Minimum was replaced by the word "Standard"

comment	*279* comment by: *German NSA (BAF)* **ORA.AeMC.205 (b)** Contracted activities are not possible. See comment to ORA.AeMC.115(b). In addition: A person (individual expert) cannot perform contracted activities because ORA.GEN.205 only allows organisations to perform contracted activities. There may be examinations or tests that will be done only rarely and by specialists who will not have a contract with an AeMC. The way out for the AeMC then is to ask an individual AME to send the applicant to a specialist. Proposal: Delete ORA.AeMC.205 (b)
response	Not Accepted – subcontractors should allow access to the competent authority.

ORA.AeMC.210	p. 21

comment	*31* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*110* comment by: *AESA* (2) .... in the terms of approval attached to the AeMc´s certificate priviledges and other **specialist** or technical staff.
response	Partially accepted – medical experts have been added as a separate point 3.

comment	*111* comment by: *AESA* (b) Add (3) In absence of head AeMC, the additional qualified AME will be in charge of (2)
response	Not Accepted – Delegation to a second AME can be done by adding it in the AeMC management system, it does not require a mandate in the requirements

comment	*157* comment by: *UK CAA* **Paragraph No: ORA.AeMC.210 Personnel requirements (a)(3)** **Comment:** Not clear why this text has been added or why it is needed
response	Noted

comment	*178* comment by: *EAAP* **EAAP comment to ORA.AeMC.210 (a)(3):** We propose the following text: "(3) have available medical experts and experts from the clinical psychology profession for the cooperation mentioned in ORA.AeMC.200(b)"
response	Not Accepted – medical experts include all relevant experts including all mental health specialists. There is no need to further detail all categories.

comment	*189* comment by: *German Military Aviation Authority* As an AeMC is an organisation by definition, the head should be able to delegate his tasks, particularly when he is out of office, not only for vacation but for the required professional activities like visiting conferences or train his own professional skills. ORA.AeMC.210 subparagraph (b) should be supplemented by an additional sentence: The head of the AeMC can nominate a deputy for these tasks, providing the deputy fulfills the requirements to head an AeMC

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response

Not Accepted – Delegation to a second AME can be done by adding it in the AeMC management system, it does not require a mandate in the requirements

comment

_222_ ❖ comment by: _AESA/DSANA_

Comment
Caution should be taken when adding 'class 3' to the requisites ORA.AeMC. The amendment of Regulation (EU) No 2015/340 is necessary for the sake of coherence.

Justification
Regulation (EU) No 2015/340 ATCO.OR.E.001 states that:
Aero-medical centres (AeMCs) shall apply the provisions of Subparts ORA.GEN and ORA.AeMC of Annex VII to Commission Regulation (EU) No 290/2012 (1), with:
(a) all references to class 1 to be replaced with class 3; and
(b) all references to Part MED to be replaced with Part ATCO.MED

Point (a) wouldn't be logical if 'class 3' is added to ORA.AeMC. Therefore, point (a) should be restricted to ORA.GEN.

response

Noted – however, for clarity reasons the rulemaking group proposed to clearly specify class 3 as well.

comment

_280_ comment by: _German NSA (BAF)_

ORA.AeMC.210 (a) (1)

Delete the addition 'or class 3' in the text as this is covered by Reg (EU) 2015/340, ATCO.OR.E.001 (a).

The words 'attached to the AeMC's certificate' are not needed because there are no terms of approval which are not attached to the certificate.

Proposal:

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

response

Not Accepted – for clarity reasons the rulemaking group proposed to clearly specify class 3.

comment

_287_ comment by: _German NSA (BAF)_

ORA.AeMC.210 (a) (2)

Delete the addition 'or class 3' as this is covered by Reg (EU) 2015/340, ATCO.OR.E.001 (a).

There is no reason for a second AME at an AeMC if the head of an AeMC is highly qualified, has continuous experience as required, and has access to other medical expertise as required

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

	(liaison with hospitals or clinical institutes). 'adequate number' of staff may be zero depending on how many applicants visit the AeMC. Proposal: '(2) have on staff an adequate number of AMEs in accordance with the scope of the AeMC approval.'
response	Not Accepted – an AeMC concept has a prerequisite a higher standard of knowledge and experience being attributed the examination of initial class 1 and initial class 3 applicants as well as HEMS pilots over the age of 60 years old involved in single pilot HEMS operations. For this reason, having at least 2 fully qualified AMEs allows a higher standard and peer consultation in dealing with difficult cases.

comment	*289* comment by: *German NSA (BAF)* **ORA.AeMC.210 (b) (2)** Delete the term 'class 3' as this is covered by Reg (EU) 2015/340, ATCO.OR.E.001 (a).
response	Not Accepted – for clarity reasons the rulemaking group proposed to clearly specify class 3.

comment	*338* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** ORA.AeMC.210(a)(2) **Comment:** The sentence needs a linguistic improvement, at present it requires an AME to hold a class 1 or class 3 medical certificate. **Proposal:** Amend ORA.AeMC.210(a)(2): **'have on staff at least one additional certified AME with privileges to issue class 1 or class 3 medical certificates, as applicable, in accordance with the privileges and scope as listed in the terms of approval attached to the AeMC certificate, and other technical staff;'**
response	Accepted – the wording was updated

comment	*339* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** ORA.AeMC.210(a)(2) **Comment:**

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

The sentence needs a linguistic improvement, at present it requires an AME to hold a class 1 or class 3 medical certificate.

Proposal:
Amend ORA.AeMC.210(a)(2):
'have on staff at least one additional certified AME with privileges to issue class 1 or class 3 medical certificates, as applicable, in accordance with the privileges and scope as listed in the terms of approval attached to the AeMC certificate, and other technical staff;'

response Accepted – the wording was updated

comment _391_ comment by: _René Meier, Europe Air Sports_

ORA.AeMC.210(a)(2)
page 21/52

Confusing wording: "...one additional qualified AME with a class 1 or class 3 medical certificate, as applicable..."

Proposal:
We invite you to change the sentence to "...one additional qualified AME with privileges to issue class 1 or class 3 medical certificates, as applicable...".

Rationale:
According to the present wording the AME does not need to have a class 1 or 3 medical certificate.

response Accepted – the wording was updated

comment _392_ comment by: _René Meier, Europe Air Sports_

ORA.AeMC.210(b)
page 21/52

Confusing wording presented.

Proposal:
(b) The head of the AeMC shall be responsible for:
(1) coordinating the assessments of examination results
(2) signing reports, certificates etc...

Rationale:
Our text is easier to understand and better structured.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response | Accepted – the wording was updated

comment | *417* comment by: *NATS*

ORA.AeMC.210 Personnel requirements
(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.

Issue

Clarify the ability to delegate the of signing of certificates to AMEs by Head of AeMC. This is already approved by UK CAA and outlined within NATS SMS.

Suggested Resolution

(b) The head of the AeMC shall be responsible for coordinating and delegating as appropriate: 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.

response | Not Accepted – Delegation to a second AME can be done by adding it in the AeMC management system, it does not require a mandate in the requirements

AMC/GM to Part-ARA – AMC1 ARA.MED.1 p. 22

comment | *33* comment by: *CAA.CZ*

I have no comments

response | Noted

comment | *78* comment by: *dr roland vermeiren eurocontrol*

I strongly support this rulemaking part about the medical assessors.
They are a corner stone of the safety circle for the medical assessment of applicants, and thus should have a very high level of aviation medicine competence and thus a good training and a lot of experience , especially on difficult cases . They cannot be replaced by experts without specialist medicine training.

response | Noted

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment | *158* comment by: *UK CAA*

Paragraph No: AMC1 ARA.MED.120 (a)

Comment: The text should not be changed.

Justification: Rule should be competency and not time based. The AMC should not adversely impact doctors training in the medical specialty of Aviation Medicine in countries where this is recognised. This may adversely impact doctors in countries with a low availability of suitably qualified doctors.

Proposed Text: No change to original:
"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;"

response | Not Accepted – the 5 years of experience in the medical domain was removed from the IR as it had limited relevance. However, the medical assessors are expected to assess the referrals and secondary reviews, meaning the most difficult cases, consequently their knowledge and experience in aero-medical assessments is essential to ensure flight safety. For this reason the Rulemaking Group recommended the a certain level of previous experience in class 1 aeromedical assessments. The current wording of this AMC explains what can be considered as "*specific knowledge and experience in aviation medicine and aero-medical practice*" as required by ARA.MED.120(b)

comment | *200* comment by: *Luftfahrt-Bundesamt*

AMC1 ARA.MED.120 Medical assessors
The amendments proposed in AMC1 ARA.MED.120 under (a) aggravate the requirements for medical assessors in an unnecessary and exaggerated way and are not in compliance with the requirements according to ARA.MED.120. Implementing this requirement, a medical assessor should first complete a specialist medical training, then successfully complete a training as an AME and at least have five years of experience before he could work as a medical assessor. It is certainly necessary for a medical assessor to have an aero-medical training like an AME, however, it is not necessary that he carried out the tasks of an AME to carry out the tasks of a medical assessor correctly. The requirements specified under ARA.MED.120 (a) and AMC1 ARA.MED.120 (a) contradict each other in their intention. An alignment is absolutely necessary.
The amendment proposed under (a) directly leads to a further aggravation of a recruiting of staff within the aviation authorities, since medical staff can only be recruited among existing AMEs, i.e. in Germany among a group of 450 doctors. This requirement is superfluous and counterproductive regarding the authority requirements. Provided that the amendment proposed under AMC1 ARA.MED.120 (a) is not withdrawn, the development of different AltMOCs with the resulting consequences of a lacking standardization within the EU Member States is to be expected.
ARA.MED120 (a) should include the requirement of a "medical specialist" to ensure a sufficient specialist qualification of the medical assessors. The requirements under AMC1 ARA.MED.120 (a) should not be amended.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

response	Not Accepted – the 5 years of experience in the medical domain was removed from the IR as it had limited relevance. However, the medical assessors are expected to assess the referrals and secondary reviews, meaning the most difficult cases, consequently their knowledge and experience in aero-medical assessments is essential to ensure flight safety. For this reason the Rulemaking Group recommended the a certain level of previous experience in class 1 aeromedical assessments. The current wording of this AMC explains what can be considered as "*specific knowledge and experience in aviation medicine and aero-medical practice*" as required by ARA.MED.120(b)

comment	*233* comment by: *The Norwegian Civil Aviation Authority* AMC1 ARA.MED.120 (a) CAA Norway does not find it necessary to have held class 1 privileges for 5 years to become a medical assessor. It is more important to have considerable aeromedical competence and aeromedical experience. A medical assessor is a consultant for all national AMEs and has responsibilities comparable to a senior consultant at the hospital. Thus, specification of minimum experience or competence is reasonable. However, the duration of class 1 privileges is not necessarily an indicator of competence or relevant experience. The results of an annual competence test for Norwegian AMEs actually indicates the opposite, as newly approved AMEs tend to achieve a higher score than the majority of the "veteran AMEs". To achieve a clinical specialty at the hospital and become a consultant the resident is required to practice under direct guidance of a consultant over a period, as well as complete a minimum number of academic courses and procedures. One or two years as a full-time "aeromedical resident" (on-job training) at an AeMC or AMS should be a more relevant requirement than class 1 privileges for 5 years. For countries with a small population there might be difficult to recruit suitable AMEs with 5 years' experience as a class 1 AME. The last 6 years there has been approximately 100 class 1 AMEs in Norway. Most AMEs own their own medical practices or are associated with larger institutions at different locations around the country. Aeromedical certification constitutes a small proportion of their total interests which is mainly based on diagnosis and treatment of patients in general. It is our experience that very few medical doctors with considerable experience and well established as AMEs are interested in an administrative position at a NAA. In 2012, 2013 and 2017 CAA Norway hired three new medical doctors. In 2012 there were only three applicants with more than 5 years' experience and one AME with less experience as a class 1 AME. In 2013 and 2017 there were none. In 2012 the candidate with less than 5 years' experience was chosen for the position. We think that the requirement for 5 years AME practice (or equivalent) will limit the possibilities for recruitment of the right candidate since it might create a situation where a NAA has to exclude applicants in other ways better suited for the task. It is thus our proposal that NAAs are given more flexibility to choose candidates based on an overall assessment and not only by numbers of years as AME. The number of years as AME (5 years could mean as little as 50 class 1 examinations) is anyway overridden by the requirement of 200 examinations. We can't see that the effect of the time lapsing between these examination (whether it is 3, 5 or more years) will make any significance for the job as medical assessor.

response	Not Accepted – the 5 years of experience in the medical domain was removed from the IR as it had limited relevance. However, the medical assessors are expected to assess the referrals and secondary reviews, meaning the most difficult cases, consequently their knowledge and experience in aero-medical assessments is essential to ensure flight safety. For this reason the Rulemaking Group recommended the a certain level of previous experience in class 1 aeromedical assessments. The current wording of this AMC explains what can be considered as "*specific knowledge and experience in aviation medicine and aero-medical practice*" as required by ARA.MED.120(b)

comment	*288* comment by: *French DGAC* **AMC1.ARA.MED.120** Since ARA.MED.120 is applicable to ATCO (per ATCO.AR.F.001, Regulation 2015/340), we understand that AMC1.ARA.MED.120 is also applicable to class 3 medical assessors. A a consequence, (a) should be amended as follows : "(a) have held class 1 **or, if applicable, class 3** privileges for at least 5 years and have undertaken a minimum of 200 class 1 **or, if applicable, class 3** medical examinations, or equivalent,"
response	Accepted

comment	*321* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** Appendix VII, Certificate for Aero-Medical Examiners **Comment**: In the conditions, no 3 should be amended, as 'not exceeding three years' will be interpreted as any unspecified period from one day to three years which is not acceptable. 'A period not exceeding three years' is regulated in ARA.MED.200(c) and should not be mentioned here. Instead, the specified expiry date (within the three year period) decided by the competent authority shall be stated here, as the competent authority sometimes may have a justified reason to choose a shorter validity period. In addition, the situations described in ARA.MED.250(b), where an AME certificate is rendered invalid when the licence to practice has been revoked, should be covered by adding 'or otherwise rendered invalid'. **Proposal**: Amend Appendix VII, Condition No 3: **'This certificate shall remain valid until [dd/mm/yyyy] subject to compliance with the requirements of Part-MED/Part ATCO.MED unless it has been surrendered, superseded, suspended, revoked or otherwise rendered invalid.'**

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response | Not Accepted – the 'A period not exceeding three years' allows to clarify the validity period for AMEs and applicants seeking medical certification.

comment | *322* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: AMC1 ARA.MED.120(a)

Comment:
Today, recruitment of medical assessors is very difficult in most member states. The proposed additional specific requirement 'having held class 1 privileges for at least 5 years' will make this situation even worse. An AME with class 1 privileges performing only the required minimum of 10 examinations per year for 5 years will have gained far less experience than an AME who has performed 100 examinations in 1 year. Thus, the specific requirement of 5 years is inappropriate and would force a number of competent authorities to produce AltMOCs to man the positions as medical assessors.

The existing text gives more flexibility as to how experience is gained and should be retained.

Proposal:
Amend AMC1 ARA.MED.120(a):
'have considerable experience of aero-medical practice …'

response | Not Accepted – the 5 years of experience in the medical domain was removed from the IR as it had limited relevance. However, the medical assessors are expected to assess the referrals and secondary reviews, meaning the most difficult cases, consequently their knowledge and experience in aero-medical assessments is essential to ensure flight safety. For this reason the Rulemaking Group recommended the a certain level of previous experience in class 1 aeromedical assessments. The current wording of this AMC explains what can be considered as "*specific knowledge and experience in aviation medicine and aero-medical practice*" as required by ARA.MED.120(b)

comment | *340* comment by: *German NSA (BAF)*

AMC1 ARA.MED.120

Experience of the medical assessor should include class 3 assessments. 5 years of class 1 experience does not provide experience to assess air traffic controllers.

	Performance based regulations are not based on numbers and hours and the official policy of EASA, as decided by the Management Board, is to introduce performance based rulemaking. Numbers and time periods should therefore be abandoned on a general basis.
response	Partially accepted – text adjusted to add class 3 where applicable.

comment	_411_ comment by: _marina vanbrabant_ AMC1 ARA.MED 120 Proposed text : a) have considerable experience of aero-medical practice for at least five years and ......
response	Accepted

comment	_413_ comment by: _NATS_ **AMC1 ARA.MED.120 Medical assessors** EXPERIENCE AND KNOWLEDGE Medical assessors should: (a) have considerable experience of aero-medical practice held ~~class 1~~ AME privileges for at least 5 years and have undertaken a minimum of 200 class 1 medical examinations, or equivalent _Impact_ At present, requirement to be a civilian Class 1 AME for 5 years has limited NATS Deputy AeMC from being officially recognised as such by previous Head of Oversight, as military experience did not count. NATS would support case to allow military experience as an AME to be included in 5 years requirement. Suggested Resolution Medical assessors should: (a) have considerable experience of aero-medical practice held ~~class 1~~ AME privileges for at least 5 years and have undertaken a minimum of 200 class 1 medical examinations, or equivalent (including military experience);
response	Accepted– military experience is included in equivalent, does not require being states separately.

AMC2 ARA.MED.120	p. 22-23

comment	_32_ comment by: _CAA.CZ_ I have no comments

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Noted

comment	*34* comment by: *CAA.CZ* I have no comments
response	Noted

comment	*79* comment by: *dr roland vermeiren eurocontrol* again my strong support, and this highlights the importance of their tasks and thus the high level of their competence
response	Noted thank you for the support!

comment	*112* comment by: *AESA* Add (4) Experience in Aviation Medicine fully demonstrate in appropiate CV
response	Not Accepted – experience in aviation medicine is already part of AMC1 ARA.MED.120 (a). Furthermore how that experience is demonstrated, namely CV or documented evidence is for the NCA to describe in their national procedures.

comment	*114* comment by: *AESA* (g) Collaborate in Aviation Research Protocols and iniciatives sponsored by EASA or National Authority.
response	Not Accepted – although very important, it is not an essential task attributed under the Basic Regulation or its Implementing Regulations. Nevertheless, where aviation medicine research is undertaken nothing should prevent the medical assessors playing an active role, but rather they should be encouraged to participate and share their expertise. This is enabled by the fact that the fact that the tasks of the medical assessor are not limited to the specific tasks listed in AMC2 ARA.MED.120

comment	*201* comment by: *Luftfahrt-Bundesamt* **AMC2.ARA.MED.120 Medical assessors** (f) to provide technical support to AMEs and AeMCs in borderline and difficult cases. Please specify what you understand by ‘technical’ support.
response	Noted – technical support means in this context specialist advice in performing the aero-medical assessment of such cases.

comment	*234* comment by: *The Norwegian Civil Aviation Authority* (b) A comma is missing after "referral".

response	Accepted – however it is not clear to which provision you are referring to, we presume you are referring to AMC2.ARA.MED.120 (c)

comment	*290* comment by: *French DGAC* We strongly believe **the words 'secondary review or' should be removed.** They are not appropriate, as many authorities have entrusted an independent board with the secondary review, specifically so that the medical assessor is not in charge of both the referral and the appeal, to avoid conflicts of interest. This would be coherent with changes in ARA.MED.325, which recognize that the secondary review procedure can be trusted to a board, instead of remaining the sole responsibility of the medical assessor. Furthermore, the structure of the AMC is confusing, as it is flagged as 'AMC2 ARA.MED.120', while it covers topics from ARA.MED 120, ARA.MED.125 and ARA.MED.126. We suggest dividing this provision in three parts to mirror the regulation's structure.
response	Not Accepted – the fact that secondary review is listed among the tasks of the medical assessor does not forbid the secondary review to be performed by a board of experts, and even in such cases the medical assessor has role in the preparation as well as implementation of the decision.

comment	*323* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** AMC2 ARA.MED.120(c) **Comment**: According to Part-MED, the AeMCs and AMEs shall, for specified conditions, consult the medical assessor before issuing a medical certificate. This should also be reflected as a task in AMC2 ARA.MED.120(c). **Proposal**: Amend AMC2 ARA.MED.120(c) **'… in case of consultation, referral, secondary review or …'**
response	Accepted – text adjusted accordingly

comment	*324* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** AMC2 ARA.MED.120 **Comment**:

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

According to MED.A.040(f), the medical assessor may issue a medical certificate if a case is referred or if corrections to the information of a medical certificate are necessary. Also, ARA.MED.125(c) requires the medical assessor to issue the medical certificate in case of a referral.
The task to issue medical certificates should be inserted as a new point in AMC2 ARA.MED.120.

Proposal:
Amend AMC2 ARA.MED.120:
'(x) to issue a medical certificate if a case is referred or if corrections to the information of a medical certificate are necessary; '

response Accepted – text adjusted accordingly

comment 325 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: AMC2 ARA.MED.120(f)

Comment:
The expression 'technical support' can easily be misunderstood as computer support and should be avoided here. The procedure required is also described in ARA.MED.315(b) using a slightly different wording. A different wording is also used in the text for referral in AMC1 ARA.MED.125(b). For consistency, the wording in ARA.MED.315(b), AMC1 ARA.MED.125(b) and AMC2 ARA.MED.120(f) should be the same.

Proposal:
Amend AMC2 ARA.MED.120(f):
'to assist AMEs and AeMCs on their request regarding decisions on aero-medical fitness in borderline and difficult cases or those not regulated in Part-MED.'

response Accepted – text adjusted accordingly

comment 348 comment by: *German NSA (BAF)*

The legally correct wording for acceptable means of compliance needs to be respected. With this change the Agency is trying to draft implementing rules via the back door. While 'to be' should not be used in rules according to the European rule drafting guidelines, the expressions 'are ... to' still means 'must' or 'shall' if introduced in a legal text

	'Specific' and 'not limited to' are superfluous because the medical assessor will not undertake unspecific tasks and will follow the rules provided in ARA. Additional specifications by individual NAAs which could be introduced via this AMC are against the aim of a level playing field. Propsal: 'MEdical assessors should: (a) [...]'
response	Accepted – text adjusted accordingly

comment	*349* comment by: *German NSA (BAF)* **AMC2 ARA.MED.120 (a)** The medical assessor should provide lectures in training courses in order to keep AMEs informed on changes in certification procedures, authority policies, experience made by the medical assessor during audits, mistakes found in examination and other forms etc., etc. Proposal: '(a) provide, approve and oversee lectures in [...] courses for AMEs and AeMCs.'
response	Partially accepted – We agree with the concept and consider that the second sentence of point (a) capture the essence of your comment.

comment	*350* comment by: *German NSA (BAF)* AMC2 ARA.MED.120 (a) Medical assessors may also deliver lectures during those training courses provided that a procedure is in place to avoid conflict of interest; What kind of conflict of interest could be expected?
response	Noted – We consider that there could be, hypothetically, a preferential treatment in approving a course where the medical assessor is providing lectures or preferential treatment in terms of AME certification for the graduates of the course where the medical assessor is providing lectures

comment	*351* comment by: *German NSA (BAF)* **AMC2 ARA.MED.120 (e)** s. comment to ARA.MED.155 - Transfer of medical files: This paragraph is not referenced in Reg (EU) 2015/340, ATCO.AR.F.001, and will therefore not apply to transfer requests of ATCOs.
response	Noted – however, similar requirements have been included in ATCO.AR.D.003

comment	*352* comment by: *German NSA (BAF)* **AMC2 ARA.MED:120 (f)** What is technical support? Is it IT support?
response	Noted – Technical support means specific assistance in the aero-medical assessment of difficult cases. Wording updated to clarify the meaning.

comment	*393* comment by: *René Meier, Europe Air Sports* AMC2 ARA.MED.120 Medical assessors (f) page 23/52 The cited tasks of of the MA require completion. Proposal: Please amend the text to read "...to provide technical *and aeromedical* support to AMEs and AeMCs in borderline and difficult cases." Rationale: This insert adds to the clarity of the text.
response	Accepted – Wording updated to clarify the meaning.

AMC3 ARA.MED.120 p. 23

comment	*80* comment by: *dr roland vermeiren eurocontrol* sometimes this delegation may be necessary but always under strict supervision of the medical assessor ; a technical or expert delegation without overview of the medical doctor/assessor on the whole process is dangerous for safety
response	Noted – thank you for your comment

comment	*115* comment by: *AESA* .... proper procedure or **regulation** in place to avoid conflict of interest
response	Not Accepted – An AMC cannot require a Regulation to be put in place as means of compliance. At AMC level we can have procedures or documented processes as means of compliance. For AMC2 ARA.MED.120 the rulemaking group proposed to have a procedure in place to avoid conflict of interest. The naming conventions for such procedures at national level are entirely up to the competent authority.

comment	*235* comment by: *The Norwegian Civil Aviation Authority*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	The opportunity to delegate tasks to trained persons is highly important to medical sections with little personal resources.
response	Noted – That is the reason for developing this new AMC 3 and the GM 1 to ARA.MED.120. Thank you for your comment.

comment	_326_ comment by: _Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)_
	Section: AMC3 ARA.MED.120
	Comment: For consistency, the expression 'medical staff designated by the competent authority/medical assessor' used in ARA.MED.125 should be used also here. The responsibility to guarantee the competency of these staff lies with the competent authority, not with the medical assessor. The meaning of the sentence 'the entire process is properly documented' is not understood.
	Proposal: Amend AMC3 ARA.MED.120: **'The medical assessor may delegate certain tasks to other medical staff designated by the competent authority or to contracted agents. The competent authority should ensure that these persons have relevant training and experience for the delegated tasks. The delegation should be properly documented.'**
response	Partially accepted – We agree with the concept that the responsibility to guarantee the competency of these staff lies with the competent authority, not with the medical assessor. Text is amended to reflect the proposal.

comment	_431_ comment by: _German NSA (BAF)_
	Note: The medical assessor himself may be appointed by contract; the competent authority ensures that he has the necessary qualification and training. s. comment on GM to AMC3 ARA.MED 120.
response	Accepted – Wording updated to clarify the meaning.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

GM1 ARA.MED.120	p. 23-25

comment	*35* comment by: *CAA.CZ* I have no comments
response	Noted – thank you for your comment

comment	*36* comment by: *CAA.CZ* I have no comments
response	Noted – thank you for your comment

comment	*37* comment by: *CAA.CZ* I have no comments
response	Noted – thank you for your comment

comment	*81* comment by: *dr roland vermeiren eurocontrol* supported, good guidance for these cases
response	Noted – thank you for your comment

comment	*133* comment by: *AMABEL* With regard to **GM1 ARA.MED.120** concerning the delegation of Medical assessor’s tasks, AMABEL agrees with the proposed text that explains the different considered options of using “appropriately qualified medical assessors and AMEs from pool of experts”, even from other (member) states. However, these options could represent the start of a deeply going rationalization mechanism within member states which will not be able anymore to appoint any qualified Medical Assessor due to financial reasons. These states will prefer to rely on other national aeromedical authorities and maybe in the future to a unique European body assuming the tasks of Medical Assessor for the EASA, if no specific State is willing to invest in his own system “offering” some support to the other member States. Nevertheless, even in those conditions of in- or outsourcing, **AMABEL insists to stick to the requirements for a suitable Medical Assessor that were previously mentioned in ARA.MED.120 and AMC1 ARA.MED.120**.
response	Noted – thank you for your comment. This GM provides several best practices that could be considered and customised by the Member States, but they should not be used to replace the requirements of ARA.MED.120

comment	*159* comment by: *UK CAA* **Page No:** 24-25

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Paragraph No: GM1 ARA.MED.120 (c)

Comment: Text appears unsuitable for guidance material

Justification: This appears to be explanatory text rather than guidance material.

Proposed Text: ~~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~~

response — Noted – thank you for your comment. However this GM is intended to clarify the provisions to which it is attached and to provide some options for implementation.

comment — *236* comment by: *The Norwegian Civil Aviation Authority*

(a) This opportunity is important for MAs with few AMEs qualified or interested in becoming a medical assessor.

response — Noted – That is the reason for developing this new GM 1 to ARA.MED.120. Thank you for your comment.

comment — *327* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Attachment #3

Section: GM1 ARA.MED.120

Comment:
This text is far too extensive and has the nature of an explanatory note rather than a guidance material. Several sections of the text are not applicable in all member states. The whole text has to be revised, and *a proposed condensed text is attached*.

Proposal:
Amend GM1 ARA.MED.120 according to the attached text.

Proposed text for GM1 ARA.MED.120
Swedish Transport Agency
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. The 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 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 recruitment of a fully qualified medical assessor is not possible, there should be a possibility to employ a medical doctor to be trained and nominated as a medical assessor once the training is finalized.
(b) Use of 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 issues should be considered and related risks appropriately mitigated:
• 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 to avoid to permanently rely on the pool
• Data protection issues

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

• Recognition between states, including the right to practice medicine in a different State.

(c) Assignment of a qualified non-medical inspector as a team member when assessing the SMS system of an AeMC.

response

Not Accepted – thank you for your comment. However, this GM is intended to clarify the provisions to which it is attached and to provide some options for implementation.

comment

377 comment by: *Croatian Civil Aviation Agency*

GM1 ARA.MED.120(b)

For the purpose of distinction between non-medical and medical personnel, some authorities also use medical inspectors. Those persons have medical background (for example nurses, radiology engineers, sanitary inspectors, public health specialist, biochemistry technicians, etc.) with medical education and professional experience both in medicine and working in authority. So, they may be able to perform more than just administrative support and paperwork in AeMC/AME certification and oversight process. In this context we suggest deleting "*non-medical*" inspector and replace it with "*qualified*" inspector.

response

Accepted – Wording updated.

comment

432 comment by: *German NSA (BAF)*

The Bundesaufsichtsamt für Flugsicherung (BAF) implemented a well-founded system with contracted medical assessors which follows the ICAO SARPS and EU rules as they stand. (Annex 1, 1.2.4.8 Contracting States shall use the services of medical assessors to evaluate reports submitted to the Licensing Authorities by medical examiners.)

response

Noted

AMC1 ARA.MED.125	p. 25

comment

38 comment by: *CAA.CZ*

I have no comments

response

Noted – thank you for your comment

comment

116 comment by: *AESA*

(c) The AeMC or the AME will provide to the authority all necessary reports & medical information in order to evaluate the aeromedical fitness of the applicant.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response | Not Accepted – Part ARA includes requirements for authorities. The requirements for AMEs and AeMCs are reflected in Part-MED. In particular, the text you are suggesting is already part of the requirements of MED.A.050 Referral

comment | *203* comment by: *Luftfahrt-Bundesamt*

The LBA appoints medical assessors but the Federal States also deal with pilot licensing. Therefore we would prefer the following wording:

“AMC1 ARA.MED.125 Referral to the *aero-medical section* of the licensing authority”
(a) The *aero-medical section of the licensing authority* should supply the AeMC oder AME with all necessary information that led to the decision on aero-medical fitness.
(b) The *aero-medical section of the licensing authority* should ensure that borderline cases or those not regulated in PART-MED are evaluated on a common basis.

response | Accepted – Wording updated.

comment | *328* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: AMC1 ARA.MED.125 (b)

Comment:
ARA.MED.315(b), AMC1 ARA.MED.125(b), and AMC2 ARA.MED.120(f) use slightly different wordings. Consistency should be sought by using the same wording here.

Proposal:
Amend AMC1 ARA.MED.125 (b):
‘The licensing authority should ensure that borderline and difficult cases or those not regulated in Part-MED are evaluated on a common basis.’

response | Accepted – Wording updated.

comment | *353* comment by: *German NSA (BAF)*

AMC1 ARA.MED.125 (a) and (b)

'Licensing authority' is not correct. The authority which issues the AME certificate is the competent authority and this is an exchange of documents between the authority and the AME.

Proposal:
Replace 'licensing authority' by !competent authority'.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Not Accepted – in case of a referral the AME shall send the documentation to the medical assessor of the competent authority that issues the pilot/ATCO licence (named, for the purpose of this regulation, the licensing authority)

comment	_364_ comment by: _European Helicopter Association (EHA)_ At point (b) it is written that “the licensing authority should ensure that borderline cases or those not regulated in Part-MED are evaluated on a common basis”. This should apply not only in PART MED but also in ATCO-MED.
response	Accepted – Wording updated.

AMC1 ARA.MED.128 p. 25

comment	_40_ comment by: _CAA.CZ_ I have no comments
response	Noted – thank you for your comment

comment	_160_ comment by: _UK CAA_ **Paragraph No: AMC 1 ARA.MED.128 Consultation Procedure** **Comment:** The definition of “minutes” implies a formal meeting which is not what is intended. Change from “minutes” to “a record”. **Justification:** Clarity **Proposed Text:** This procedure should include at least a record ~~the minutes~~ of the consultation.
response	Accepted – Wording updated.

AMC1 ARA.MED.130 p. 25-28

comment	_39_ comment by: _CAA.CZ_ I have no comments
response	Noted – thank you for your comment

comment	_41_ comment by: _CAA.CZ_ I have no comments

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response | Noted – thank you for your comment

comment | *42* | comment by: *CAA.CZ*

I have no comments

response | Noted – thank you for your comment

comment | *43* | comment by: *CAA.CZ*

I have no comments

response | Noted – thank you for your comment

comment | *44* | comment by: *CAA.CZ*

I have no comments

response | Noted – thank you for your comment

comment | *161* | comment by: *UK CAA*

Paragraph No: AMC1 ARA.MED.130 IX Expiry dates

Comment: Additional expiry date for Class 2 IR not required as will always be the same as for Class 2 expiry date.

Justification: It is not clear why this has been added. This will create significant software issues and economic burden for NAAs without adding any additional safety or other benefit.

Proposed Text: Delete "~~Class 2 with IR (dd/mm/yyyy or 'N/A')~~"

response | Accepted – Wording updated.

comment | *162* | comment by: *UK CAA*

Paragraph No: AMC1 ARA.MED.130 Medical Certificate Format IX Expiry dates

Comment: Addition of ophthalmological examination is not required.

Justification: The requirement for a comprehensive eye examination varies with degree of refractive error and class of medical certificate. AMEs are required to ensure that an appropriate ophthalmological review has taken place before issuing a medical certificate. Exceeding the next due date may result in a ramp inspector grounding the pilot unnecessarily.

Proposed Text: Delete "Ophthalmological examination"

response | Not Accepted – ophthalmological examination is among the most common regular specialist evaluations performed. Specifically, in accordance with AMC1 MED.B.070 (d) (3)&(4)
(3) An evaluation by an eye specialist should be undertaken 5-yearly if:

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

(i) the refractive error is between –3.0 and –6.0 dioptres or +3 and +5 dioptres;
(ii) astigmatism or anisometropia is between 2.0 and 3.0 dioptres.
(4) An evaluation by an eye specialist should be undertaken 2-yearly if:
(i) the refractive error is greater than –6.0 dioptres or +5.0 dioptres;
(ii) astigmatism or anisometropia exceeds 3.0 dioptres.

comment *163* comment by: *UK CAA*

Paragraph No: AMC1 ARA.MED.130 Medical Certificate Format IX Expiry dates

Comment: The addition of next due dates for audiograms and ECGs has previously caused significant service disruption for airlines

Justification: These dates were originally included on the medical certificate (JAA). They were removed as they caused confusion amongst ramp inspectors who wrongly interpreted these dates as representing certificate expiry dates. Flights have been grounded because ramp inspectors outside Europe have not allowed them to continue with pilots who had a next due date for an ECG or audiogram stated on their medical certificate that had been exceeded. The ramp inspectors have taken the 'next due' dates as absolutes and did not recognise that there was a difference between the next due dates and the certificate expiry dates.

Proposed Text: Delete all "next" due dates for Class 1, 2 and LAPL.

response Not Accepted – dates should be correctly maintained so that due dates are not exceeded.

comment *164* comment by: *UK CAA*

Paragraph No: AMC1 ARA.MED.130 Medical Certificate Format

Comment: Inflight incapacitation should require the medical certificate holder to seek advice from an AeMC, AME or GMP.

Justification: To assure continued fitness of the certificate holder.

Proposed Text:
(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.
(8) have suffered any inflight impairment or incapacitation

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Not Accepted – Although we completely agree with the comment, the text is just a copy of MED.A.020 for the information of the medical certificate holders. To make the addition we need to update the content of MED.A.020 which is not within the scope of this subtask of RMT.0287

comment	*194* comment by: *Philippe CIBOULET* Page 28, at the level of the project of certificate, I agree with the creation of the box class 2 with IR.
response	Noted – thank you for your comment

comment	*237* comment by: *The Norwegian Civil Aviation Authority* XI Is it necessary to stamp the medical certificate, outdated?
response	Noted – A degree of authentication is needed, be that a stamp or electronic seal.

comment	*291* comment by: *French DGAC* We would like to draw the attention of AESA on the fact that MED.A.020, as amended at the bottom of the form, takes on board other amendments to Part MED which are not yet entered into force. See also our comments above on the cost and administrative burden whenever a form changes. For AMC forms, there is an additional cost of translating into the national language.
response	Noted – However, in the meantime the updates to MED.A.020 have entered into force.

comment	*354* comment by: *German NSA (BAF)* Not applicable to ATCOs. The format of the medical certificate of an ATCO is in an AMC to Subpart F of Reg (EU) 2015/340.
response	Noted – Correct, ARA.MED.130 and corresponding AMC is not applicable for class 3 medical certification.

comment	*363* comment by: *European Helicopter Association (EHA)* our comment is related to the Medical certificate format at pag. 28: the text of MED.A.020 included is not the same that in Regulation 1178.
response	Noted – However, in the meantime the updates to MED.A.020 have entered into force.

comment	*412* comment by: *marina vanbrabant* Expiry date Class 2 IR is same as Class 2
response	Accepted – Class 2 IR war removed.

An agency of the European Union
TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

AMC1 ARA.MED.135(a) p. 29-32

comment	*45*	comment by: *CAA.CZ*
	I have no comments	
response	Noted – thank you for your comment	

comment	*46*	comment by: *CAA.CZ*
	I have no comments	
response	Noted – thank you for your comment	

comment	*47*	comment by: *CAA.CZ*
	I have no comments	
response	Noted – thank you for your comment	

comment	*48*	comment by: *CAA.CZ*
	I have no comments	
response	Noted – thank you for your comment	

comment	*92*	comment by: *Aivars PRIEKULIS*
	Application form ..... (13) **Reference number**: Applicant's **EAMR ID number** would be much more necessary to know for AME/AeMC/AMS.	
response	Accepted – the field can encompass both the national reference number and/or EAMR ID number	

comment	*127*	comment by: *AESA*
	Replace item 126 Sleep disorder/apnoea syndrome by: History of Sleep Disorder or Apnoea Syndrome	
response	Not Accepted – item 126 has to be consider together with the description of the table provided above the table stating: “*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).*”	

comment	*180*	comment by: *EAAP*
	Comment to AMC1 ARA.MED.135(a) Aero-medical forms	

APPLICATION FORM FOR A MEDICAL CERTIFICATE
The current phrasing of item 118 you suggest ('Psychological/psychiatric trouble of any sort') is misleading and trivialises what might be a serious issue. It would be better if there were two Items:
118a: Diagnosed psychiatric condition(s)
118b: Psychological problems for which treatment has been advised or administered. This draws a distinction between mental illness issues that carry a psychiatric diagnosis under a categorization such as DSM V, and psychological or mental wellbeing issues that may be acute or of a lower level of impact on effective working.

The word “psychiatric” needs to be confined in usage to illness, diagnosis or treatment contexts. The usage of “Psychological problems” refers to issues that, whilst having an impact on day-to-day functioning, may not have a serious impact on safe performance but still require attention such as counselling or therapy (for example short-term anxiety conditions).

(31) **Declaration**, typo in line 5:
..... to the medical assessor of ~~the~~ my licensing authority, other health professionals ... etc.

Comment to "INSTRUCTIONS FOR COMPLETION OF THE APPLICATION FORM FOR A MEDICAL CERTIFICATE":
In chapter "GENERAL AND MEDICAL HISTORY" the **number "30"** is missing.

Also, there is plenty of space in box 30 to give the applicant some instruction about what is meant by item 118. It would be a chance missed if this were not done by giving some examples.

The same applies to instructions for item 119 'Misuse of psychoactive substances'. It should not be assumed that every applicant knows what this designation means, especially the young applicants entering the profession that have not yet received any ATPL-theoretical training and education.

response Noted – thank you for your comment. It will be considered in a future RMT dedicated to mental health.

comment *190* comment by: *German Military Aviation Authority*

In the application form, number 27 asks about alcohol and drugs in one phrase.

The word drug can be misunderstanding, as it can be interpreted as medication, the initial meaning of drug. Of course, it should be understood as illicit drug, and this must be expressed for a definite understanding in a clear manner.

Furthermore, as the draft number 27 is written, the question combines a formerly legal consumption (alcohol), with an illegal consumption (illicit drug).

Therefore I propose to:

Divide number 27 in two and give a clear understanding of talking about illicit drugs, no medications, e.g. "do you consume psychoactive substances like illicit drugs"

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response | Partially accepted – The space on the application form is limited and the form should be completed with the assistance of the AME that should be able to clarify the meaning of point 27 and discuss the reply of the applicant. Additionally, the existence of point 28 on use of medication, clarifies the meaning for the type of drugs referred to in point 27.

comment | *195* comment by: *Philippe CIBOULET*

Page 30, box 27 of the medical questionnaire should differentiate the answers about alcohol and drugs;
alcohol: no-yes weekly consumption no-yes drugs: no-yes
Page 30, box 119: the concept of psycho-active substances is likely to be more or less voluntarily unclear for the pilot. Is it not better to use alcohol, drugs and any other psycho-active substance?

response | Partially accepted

comment | *238* comment by: *The Norwegian Civil Aviation Authority*

Application for a medical certificate

(2) Uppercase C for class 3, but not for class 1 and class 2?
(20) CAA Norway suggest that "or been declared unfit by an AME" should be added. This is considered relevant information.
(27) It is important to include "medical event whilst exercising the privileges of the licence" to make the applicant aware of situations he/she would not have considered relevant otherwise.
(30)(130) Should include "psychologist" in the text, since this is important information for an AME and NAA.

response | Accepted

comment | *292* comment by: *French DGAC*

Section 24, although relevant for pilots, is less pertinent for ATCOs. For ATCO, we suggest adding : “airprox or similar events”.

In section 26, ATC ratings are incomplete.
Pursuant to ATCO.B.010 (Regulation 340/2015), the possible choices should be :

- ADI
- APS
- ACS
- ADV
- APP
- ACP

Section 31: The footnote declaration refers to ARA.MED.130 which, as per ATCO.AR.F.001 (Regulation 2015/340) is not applicable to ATCOs.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	We suggest adding, after "according to ARA.MED.130", the phrase "or ATCO.AR.F.005 if applicable" The footnote also refers to MED.A.035(b)(2)(ii)/(iii). For ATCO's benefit, we suggest adding, after "MED.A.035(b)(2)(ii)/(iii)", the phrase " or ATCO.MED.A. 035(b)(2)(ii)/(iii), if applicable". On the contrary, the footnote reference to ARA.MED.150 is acceptable both for pilots and ATCO, persuant to ATCO.AR.F.001 (Regulation 2015/340).
response	Accepted

comment	*406* comment by: *IATA* *Item 24) on the form: Any aviation accident or reported incident medical event whilst exercising the privileges of the licence since the last medical examination?* - We believe the reported incident medical event here means a medical event in relation with flight operations, otherwise it would just be a repetition of all the tick boxes that follow for medical events since last exam. It could be confusing. We would suggest: Any aviation accident or reported related incident medical event whilst exercising the privileges of the licence since the last medical examination?
response	Noted – we think the meaning is the same and does not required additional changes.

comment	*415* comment by: *marina vanbrabant* Proposed text : APPLICATION FORM FOR A MEDICAL CERTIFICATE CL 1 2 3 LAPL 27) Do you drink alcohol ? NO YES state average weekly amount or use drugs ? NO YES type
response	Accepted

AMC1 ARA.MED.135(b) (c) p. 32-36

comment	*49* comment by: *CAA.CZ* I have no comments
response	Noted – thank you for your comment

comment	*50* comment by: *CAA.CZ* I have no comments
response	Noted – thank you for your comment

comment	_51_	comment by: _CAA.CZ_
	I have no comments	
response	Noted – thank you for your comment	

comment	_52_	comment by: _CAA.CZ_
	I have no comments	
response	Noted – thank you for your comment	

comment	_93_	comment by: _Aivars PRIEKULIS_
	Shaded areas (LAPL examination report) are not practical for use, especially, if you have to scan a document or to make a copy.	
response	Noted – thank you for your comment	

comment	_117_	comment by: _AESA_
	Medical Examination report form excluded Class 2. Wecannot see a form designed for Class 2. In our understanding medical examination report must include Clas 1, 2 & 3. Even LAPL could be included. A single form applicable for all medical certificates will facilitate the computer implementation of the system, just " tic ", the classes apply for.	
response	Noted – the form includes class 1, 2 and 3. The LAPL is separate for the paper version to easily identify the fields that are not applicable, however the numbering of fields is similar so in the electronic version they could use the same form in the background.	

comment	_128_	comment by: _AESA_
	Introduce an additional bloc, following Pulmonary Function with the following headline and four items: **OSA Assessment:** 1. Applicant Not at risk of OSA 2. Applicant at risk of OSA 3. Applicant with diagnosis of OSA without adequate treatment 4. Applicant with diagnosis of OSA with adequate treatment	
response	Accepted– form updated	

comment	_181_	comment by: _EAAP_
	Comment to AMC1 ARA.MED.135(b)(c) "MEDICAL EXAMINATION REPORT FORM FOR CLASS 1,2 & 3 APPLICANTS" Clinical exam, item '(225) Psychiatric' should be renamed (225) 'Mental health'. Explanatory note:	

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

The use of 'psychiatric' in item (225) is not consistent with Opinion No9/2016, 2.1.4.6. Mental Health, which states that:
(a) MED.B.050 'Psychiatry'and MED.B.060 'Psychology' are merged under the new MED.B.055 'Mental health'
(b) The new MED.B.055 'Mental health' introduces a new requirement for a comprehensive mental health assessment as part of initial class 1 medical examination.

The term 'psychiatric' is restrictive and not in line with the new requirements. The aero-medical examination should not be focused exclusively on the existence of 'psychiatric' disorders but be a comprehensive examination of the applicant as to his/her mental health and signs and signals as to possible risky psychological/mental states.

The same applies to item (225) of the MEDICAL EXAMINATION REPORT FORM FOR LAPL APPLICANTS, it should be renamed '(225) Mental Health.'

Comment to AMC1 ARA.MED.135(b)(c) "INSTRUCTIONS FOR COMPLETION OF THE MEDICAL EXAMINATION REPORT FORMS":

'225 PSYCHIATRIC' should be renamed by "225 MENTAL HEALTH"

Comment to text: "To include appearance, appropriate mood/thought, unusual behaviour": This suggested guidance for 225 is insufficient and unsatisfactory. The relevance given to the reporting on Ophthalmology and Otorhinolaryngology specialties, each of both having a detailed special form and full instructions for completion, is in sharp contrast to the relevance and detail given to '225 Mental Health' and this is also not in line with the intention of a *comprehensive mental health assessment*. Mental health has proven to be at least equally relevant in the certification of pilots. Until now, the forms and instructions do not reflect this at all. It is time for a new approach.

For the purpose of much better guiding the AMEs in their mental health assessments, **EAAP proposes a special examination form for Mental Health** as guidance and sort of checklist for the AMEs. Prof Robert Bor, who has done the same for ICAO, and Mrs Cristina Albuquerque, Clinical Psychologist from Portugal, are happy to assist EASA in providing detailed and practical guidance for the AMEs to be included in the instructions for examination form item 225.

response Partially accepted– form updated. The addition of a new form to be discussed in the future rulemaking task dedicated to mental health.

comment *223* comment by: *AESA/DSANA*

Comment
Item (204) and (205) of the "Instructions for completion of the medical examination report forms" should be shaded, to be coherent with the "Medical Examination Report Form for LAPL Applicants".

Justification
Items (204) and (205) are shaded in the "Medical Examination Report Form for LAPL Applicants", as they do not require completion.

response Accepted– form updated

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment	*378*	comment by: *Croatian Civil Aviation Agency*
	Attachment #4 **AMC1 ARA.MED.135(b)** Regarding the changes in Part-MED requirements concerning Mental Health assessment it would be reasonable to incorporate new fields into Medical Examination Report Form, according to example of ICAO recommendation (ICAO Manual of civil Aviation Medicine, Third Edition – recommended fields highlighted in attached document).	
response	Noted – thank you for your comment. Will be discussed on a future rulemaking task dedicated to mental health topics	

comment	*394*	comment by: *René Meier, Europe Air Sports*
	Application form for a medical certificate: page 33/52 (27) Do you drink alcohol or use drugs: We have a problem here: the word "drugs" in English is also used for "medication". Proposal: We propose to delete the word "drugs", to insert: "psychoactive substances" instead as in 119 and throughout the entire document and all accompanying papers, this has also to be changed in the Instructions for completion of the Application Form. Rationale: Unambiguous texts, crystal-clear provisions are required for the sake of flight safety.	
response	Partially accepted– form updated. See also the response to comments 190 and 195.	

comment	*407*	comment by: *IATA*
	Page 33 *Item (205) Colour hair* This item has always been there. Is this information still valid and useful nowadays?	
response	Noted – thank you for your comment. Yes, it is useful for identification during the medical, but more important post-accident.	

comment	*408*	comment by: *IATA*
	Item (313) Colour perception Since this is a new version of the document and we believe that other vision tests are likely to become acceptable by EASA in the near future (e.g. CAD?), why have Ishihara specifically stated in the form?	

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response — Noted – The Ishihara is the first screening test, if the applicants fail the Ishihara they are referred for the CAD or anomaloscope.

GM1 ARA.MED.135(b) (c) p. 37-40

comment — *53* comment by: *CAA.CZ*

I have no comments

response — Noted – thank you for your comment.

comment — *54* comment by: *CAA.CZ*

I have no comments

response — Noted – thank you for your comment.

comment — *55* comment by: *CAA.CZ*

I have no comments

response — Noted – thank you for your comment.

comment — *118* comment by: *AESA*

If we stress the need of a Mental Health evaluation of applicants at least in the initial exam (comprehensive exam). We consider that a **Mental Health Examination Report** should be added to the Ophtalmology and otorhinolaringology exams. Even more, from a risk assessment perspective a **Cardiology Examination Report Form** should be consideredWe can provide examples if our proposal is taken into account. It will be consistent with AMC1 ORA.AeMC.205. Contracted activities (1) the minimun required medical examinations should at least encompass the following specialties: ophtalmology including colour vision, otorhinolaryngology, cardiology and mental health.

response — Noted – thank you for your comment. Will be discussed on a future rulemaking task dedicated to menta health topics

comment — *165* comment by: *UK CAA*

Paragraph No: GM1 ARA.MED.135 (b) Ophthalmology Examination Report Form and GM1 ARA.MED.135 (c) Otorhinolaryngology (ENT) Examination Report Form

Comment: Items 301 and 401 respectively

Justification: Consent does not match the changes made to the application form on page 30

Proposed Text:

~~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

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	contained in this report, ~~and any or all~~ its attachments ~~to the AME and, where necessary~~ and all information which are 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 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.
response	Noted – thank you for your comment. We consider that as the application form will accompany the examination forms we do not see the need to duplicate the entire text, especially considering the limited space available

AMC1 ARA.MED.151	p. 42

comment	*329* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*
	Section: AMC1 ARA.MED.151.
	Comment: The proposed text limits the authorisation of other medical staff to the medical assessor only, which affects the organisation and procedures of the competent authority. This is a matter of internal procedures of the competent authority, and should not be regulated by EU. The already adopted ARA.MED.160(b)(3) has the following wording: 'any duly authorised personnel of the competent authority'.
	Proposal: Amend AMC1 ARA.MED.151: **'… restricted to the medical assessor or medical staff designated by the competent authority.'**
response	Noted – However the proposed text mirrors the wording of AMC1 MED.A.015

GM1 ARA.MED.155	p. 43

comment	*56* comment by: *CAA.CZ* I have no comments

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Noted – thank you for your comment.

comment	*166* comment by: *UK CAA* **Paragraph No:** GM1 ARA.MED.155 Transfer of medical files **Comment:** Title is incorrect **Justification:** Clarity. **Proposed Text:** **APPLICATION FORM TO ~~INFORMATION FORM FOR THE~~ TRANSFER AEROMEDICAL RECORDS FOR THE PURPOSE OF A CHANGE OF STATE OF LICENCE ISSUE~~OF A PILOT LICENCE MEDICAL DETAILS, IN CONFIDENCE~~**
response	Noted – thank you for your comment. The proposed GM1 ARA.MED.155 was already adopted as AMC1 ARA.GEN.360(a)(2) in a separate rulemaking task. Consequently, the draft GM1 ARA.MED.155 will be deleted

comment	*167* comment by: *UK CAA* **Paragraph No:** GM1 ARA.MED.155 Transfer of medical files **Comment:** The form does not state the intended recipient of the aeromedical records. **Justification:** Clarity. **Proposed Text:** Divide Item 1 into 1(a) Current state of licence issue and 1(b) Proposed state of licence issue
response	Noted – thank you for your comment. The proposed GM1 ARA.MED.155 was already adopted as AMC1 ARA.GEN.360(a)(2) in a separate rulemaking task. Consequently, the draft GM1 ARA.MED.155 will be deleted

comment	*239* comment by: *The Norwegian Civil Aviation Authority* There should be a box to tick and a signature field for the pilot, where they declare that they accept that their medical license will be transferred and their medical history sent to another MA.
response	Noted – thank you for your comment. The proposed GM1 ARA.MED.155 was already adopted as AMC1 ARA.GEN.360(a)(2) in a separate rulemaking task. Consequently, the draft GM1 ARA.MED.155 will be deleted

comment	*330* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* Attachment #5

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Section: GM1 ARA.MED.155

Comment:
The headline of the form is difficult to understand and needs to be changed. There is also a need for a form for request of transfer of medical files. Today, most member states use the well established form drafted as ARA.GEN.320 by RMT 0412 and 0413, covering all information required in ARA.MED.155. The suggested form in this NPA is a copy of a previously drafted document for licence details, which does not cover the medical information required in ARA.MED.155(a)(2), (a)(3) and (a)(4).

The signature section contains the words 'Certification' and 'certify', which in this context are inappropriate. The correct expression is 'verify' as in ARA.MED.155(a)(1).

The form should be replaced by the form drafted by RMT 0412 and 0413 which is presently in use. The form should be used as a transfer request form with the headline 'Request for transfer of medical files' as a transfer of medical files may occur even before a licence has been issued.

Proposal:
Amend GM1 ARA.MED.155 by using the form drafted by RMT 0412 and 0413, which is presently in use. The Swedish version of *this form is attached.*

response — Noted – thank you for your comment. The proposed GM1 ARA.MED.155 was already adopted as AMC1 ARA.GEN.360(a)(2) in a separate rulemaking task. Consequently, the draft GM1 ARA.MED.155 will be deleted

comment — *356* — comment by: *German NSA (BAF)*

Not applicable to ATCOs as paragraph ARA.MED.155 is not referenced in ATCO.AR.F.001.

response — Noted – thank you for your comment. The proposed GM1 ARA.MED.155 was already adopted as AMC1 ARA.GEN.360(a)(2) in a separate rulemaking task. Consequently, the draft GM1 ARA.MED.155 will be deleted. However, similar requirements have been included in ATCO.AR.D.003 and corresponding AMC/GM which are applicable to ATCOs.

AMC1 ARA.MED.200 — p. 44

comment — *57* — comment by: *CAA.CZ*

I have no comments

response — Noted – thank you for your comment.

comment — *119* — comment by: *AESA*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	~~Before issuing the AME certificate~~, Upon request for issuing, revalidation, renewal or change of an AME certificate, the competent authority ......
response	Accepted– text updated.

comment	*120* comment by: *AESA* For applicants for an AME Certificate to exercise privileges of class 2 medical certification only, a virtual.... , Must be: For applicants for an AME Certificate to exercise privileges of class 2, LAPL & CC medical certification only, a virtual....
response	Not Accepted – class 2 privileges include automatically LAPL and CC, there is no need to specify it. The use of only is intended to exclude AMEs that have privileges for aero-medical assessments of class 1 or class 3.

comment	*168* comment by: *UK CAA* **Paragraph No:** AMC1 ARA.MED.200 Procedure for the issue, revalidation, renewal or change of an AME certificate **Comment:** No need to differentiate between those AMEs with or without extended privileges **Justification:** Following the issue of an AME certificate there is an ongoing process of oversight, including inspections. This should not be affected by an AME extending their privileges. **Proposed Text:** 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~~ 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.
response	Not Accepted – the virtual inspections cannot ensure the full scope of the inspection. For this reason, the rulemaking group consider enabling the virtual inspection for the class 2 AMEs it could be extended to all categories of AMEs in the future.

comment	*240* comment by: *The Norwegian Civil Aviation Authority* Should it be referred to letter (a) instead of (b) in ARA.MED.200? CAA Norway does not agree that it is necessary to inspect an AME practice for initial issue, revalidation, renewal or other changes of the certificate. We consider it only needed on initial issue, and thereafter when indicated. The MAs should be able to decide themselves how to verify compliance with ARA.MED.200(b) (and (a)) before issuing a certificate. This could be done be for example visiting the office, virtually visiting the office, photo evidence, phone meeting, test etc.

	To make the MAs visit the AME practice before every issue of a new certificate + conducting and audit every three years, will lead to audits being carried out just before a revalidation every time, making them easy to anticipate for the AME. When basing the oversight programme on a risk based system, there should be no need for the MS to visit all the AMEs every three years. Instead the oversight programme should focus on the AMEs with the highest risks, to make sure aviation security does not suffer.
response	Not Accepted – this inspection is not intended for oversight purpose but to ensure that the AME practice, equipment and staff are compliant with ARA.MED.200. This should not prevent any competent authority from establishing a performance-based oversight system including audits, inspections and unannounced inspections.

comment	*293* comment by: *French DGAC* France thanks AESA for taking on board the proposal of a virtual inspection of AME premises. This amendment will be very helpful, considering the number of AMEs and their dissemination on all the national territory.
response	Noted – thank you for your comment.

comment	*331* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: AMC1 ARA.MED.200

Comment:
The reference to ARA.MED.200(a) is incorrect, as this text has been moved to (b), which also has been expanded to include the very important aspect of appropriate procedures.

The added text for a virtual inspection for class 2 privileges seems rather inappropriate, as the initial issue of an AME certificate always is for class 2 privileges only. On-site inspections will then only be required when an AME has gained experience and applies for an extension of privileges to class 1 or class 3.

However, when an established AME, also with class 1 or class 3 privileges, only moves to a new practice location, the option for a virtual inspection might be considered.
For a virtual inspection to be reliable, the procedure should be described in detail with a list of items to be covered, preferable as GM.

Proposal:
Amend AMC1 ARA.MED.200:
'… For holders of an AME certificate applying for a change of practice location, a virtual inspection of the new premises may be acceptable. In case of concerns …'
Add a new paragraph (AMC3 or GM1 ARA.MED.200) detailing the procedure for a virtual inspection.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Not Accepted – the virtual inspections cannot ensure the full scope of the inspection. For this reason, the rulemaking group consider enabling the virtual inspection for the class 2 AMEs it could be extended to all categories of AMEs in the future.

comment	*365* comment by: *European Helicopter Association (EHA)* What is a virtual inspection?
response	Noted – an inspection using virtual means rather than going onsite.

AMC2 ARA.MED.200 p. 44

comment	*58* comment by: *CAA.CZ* I have no comments
response	Noted – thank you for your comment.

comment	*241* comment by: *The Norwegian Civil Aviation Authority* (b) It should be specified that "maintenance of aero-medical competence" have to be demonstrated by for example a competence test.
response	Not Accepted – Although a competence test is one of the most common ways of demonstrating competence other alternatives are also possible, such as observation of a number of examinations. Each competent authority should decide which is the most suitable for their national context.

AMC1 ARA.MED.246 p. 44

comment	*59* comment by: *CAA.CZ* I have no comments
response	Noted – thank you for your comment.

comment *219* ❖ comment by: *European Transport Workers Federation - ETF*

Page 13 : 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	ETF does not think that i twill be convenient for competent authorities to comply with this requirement and we therefore fear that it will not be properly implemented. It seems likely that most combination will be needed and that a

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	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.	more pratical approach would be to have a centralised cooperation method.
response	Noted – thank you for your comment.	

comment	*357* comment by: *German NSA (BAF)* Not applicable to ATCOs as paragraph ARA.MED.246 is not referenced in ATCO.AR.F.001.
response	Noted – thank you for your comment.

AMC1 ARA.MED.315(a) p. 44

comment	*121* comment by: *AESA* (a) The process to review examination and assessment reports received from AeMcs, AMEs and GMPs should aim to check ~~all~~ a representative shortage of reports of each class.
response	Not Accepted – the continuous oversight principles suggest that all files should be reviewed. For example, this may be done using electronic means for initial screening and review by the medical assessor for the files where problems have been identified during the initial screening.

comment	*206* comment by: *Luftfahrt-Bundesamt* **AMC1 ARA.MED.315 (a) Review of examination reports** The Federal States do not appoint medical assessors. We therefore suggest the following wording: “The *aero-medical section of the* licensing authority shall have a process in place for the medical assessor to:” “(b) The *aero-medical section of the* licensing authority may develop an assessment process to take account of the proportion of inconsistencies or errors found, adapt the sample size accordingly and consider corrective action.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

(c)The *aero-medical section of 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."

response — Accepted– text updated.

comment — *294* — comment by: *French DGAC*

The articulation between (a) and (b) might not be clear enough, as both provisions seem contradictory.

We suggest adding the word '**Nevertheless'** at the beginning of (b).

response — Partially accepted– text updated for clarity.

comment — *332* — comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: AMC1 ARA.MED.315(b)

Comment:
In point (b) of the AMC text the word 'may' is inappropriate. It should be changed to 'should' or, if kept, point (b) should be moved to GM.

Proposal:
Amend AMC1 ARA.MED.315(b):
'The licensing authority should develop an assessment process to take account of …'

response — Accepted– text updated.

AMC1 ARA.MED.325 — p. 45

comment — *208* — comment by: *Luftfahrt-Bundesamt*

AMC1 ARA.MED.325 Secondary review procedure
In Germany the medical assessors are appointed by the LBA.

(b)The composition of the review board should be decided by the *aero-medical section of the* licensing authority preceded by the advice of the medical assessor and may consist of, but not limited to…:"

response — Accepted– text updated.

comment — *220* ❖ — comment by: *European Transport Workers Federation - ETF*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Page 14 : 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 +page 45 : the related AMC to this IR	ETF fears that the changes introduced will alter the independence of the secondary review. We think it should be an independent process and ask for re-introduction of the independence requirement.

response

Not Accepted – the new wording does not impact the independence of the secondary review, but only clarifies the responsibilities.

comment

_295_ comment by: _French DGAC_

In France, the review board composition for pilots is, by law, independent from the medical assessor who cannot give advice on the board members.

We suggest the following amendment :

'(b) The composition of the review board should be decided by the licensing authority**. It may be** preceded by the advice of the medical assessor and may consist of, but no limited to:'

response

Accepted– text updated.

comment

_358_ comment by: _German NSA (BAF)_

AMC1 ARA.MED.325 (a)

Proposal:'
'The secondary review procedure should specify [...]'

response

Accepted– text updated.

comment

_359_ comment by: _German NSA (BAF)_

AMC1 ARA.MED.325 (b)

'Licensing authority' is not correct This is a procedure and therefore established by the competent authority.

Proposal:
Replace 'licensing authority' by 'competent authority'.

An agency of the European Union
TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Not Accepted – the procedure by which the secondary review will be performed is the one of the competent authority that issues the pilot/ATCO licence (named, for the purpose of this regulation, the licensing authority).

comment	*401* comment by: *European Cockpit Association* **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. ECA comment: The requirements for secondary review procedure are welcomed.
response	Noted – thank you for your comment.

AMC1 ARA.MED.330 p. 45

comment	*60* comment by: *CAA.CZ* I have no comments
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment	*61* comment by: *CAA.CZ* I have no comments
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment	*122* comment by: *AESA* Needs more clarification, provide examples to which apply and major involvement by Research Aeromedical Institutions or Universities.
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment	*296* comment by: *French DGAC* Please see our comment on ARA.MED.330

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response

Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment

333 comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: AMC1 ARA.MED.330

Comment:
The first option is to delete this paragraph together with ARA.MED.330, as proposed in our comment to ARA.MED.330.

If ARA.MED.330 is not deleted, however:

This AMC is not fully compliant with the amended ARA.MED.330.

In point (f) the number of applicants to be included should be determined in advance in order to define an end-point of the protocol.

As 'research' has been deleted from the amended ARA.MED.330, point (h) should be deleted.

Proposal:
Amend AMC1 ARA.MED.330:
(f) **'specify the total number of applicants to be included;'**
Delete (h).

response

Noted – However, as result of the comments received on ARA.MED.330 and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment

403 comment by: *European Cockpit Association*

ARA.MED.330 Special medical circumstances
AMC1 ARA.MED.330 Special medical circumstances
AMC1 ARA.MED.330(b)(c) Special medical circumstances
GM1 ARA.MED.330 Special medical circumstances

ECA Comment:
ECA definitely wants to keep the ARA.MED 330 and the related AMCs. Currently, the development in the field of medicine is very fast, and there will be treatments or medications that could be perfectly safe in aviation environment, but are not allowed within current regulation. To gain experience in aviation environment, it is important to have a regulated protocol for to study these new options in a safe way.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	In addition, pilots should be able to receive the best treatment for their medical condition, and sometimes if this results in grounding, pilot may not take that treatment or medication. This protocol will allow faster evaluation of such treatment and may also benefit pilots' health.
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

AMC1 ARA.MED.330(b) (c) p. 45

comment	*62* comment by: *CAA.CZ* I have no comments
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment	*334* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** AMC1 ARA.MED.330(b)(c) **Comment**: The application of ARA.MED.330 is a deviation from the requirements in Part-MED, which should require thorough follow-up at all examinations. Permitting AeMCs or AMEs to revalidate or renew medical certificates based on ARA.MED.330 does not fulfil the requirements for thorough follow-up and will not guarantee an acceptable level of safety. All assessments for revalidation or renewal need to be referred to the medical assessor of the licensing authority who should also issue all medical certificates based on ARA.MED.330. **Proposal**: Delete AMC1 ARA.MED.330(b)(c).
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

GM1 ARA.MED.330 p. 46

comment	*63* comment by: *CAA.CZ* I have no comments

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment	*169* comment by: *UK CAA* **Paragraph No: GM1 ARA.MED.330 Special medical circumstances (b)** **Comment:** Remove reference to a specific document. **Justification:** The text refers to a document which is outside EASA and the EC control. **Proposed Text:** The protocol and its implementation should comply with medical, ethical ~~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~~.
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment	*185* comment by: *FAA* We notice that paragraph (c) guidance provides medical publication references (to WMA, etc.) Certain ICAO Annex 1 *Notes* also provide such references (e.g., to the World Health Organization). Should these references be normalized and harmonized to accommodate all signatories?
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment	*335* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** GM1 ARA.MED.330 **Comment:** The text should include a declaration that ARA.MED.330 is not intended to be used as a means of making exemptions from current rules. **Proposal:** Amend GM1 ARA.MED.330: **(x) 'ARA.MED.330 is not intended to be used as a means of making exemptions from current rules.'**
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment | *336* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: GM1 ARA.MED.330(a)

Comment:
The text contradicts the amended ARA.MED.330. The second sentence should be deleted.

Proposal:
Delete the second sentence.

response | Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment | *337* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: GM1 ARA.MED.330(c)

Comment:
As the amended ARA.MED.330 no longer refers to research, all references to medical research should be deleted.

Proposal:
Delete GM1 ARA.MED.330(c).

response | Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

comment | *405* comment by: *European Cockpit Association*

ARA.MED.330 Special medical circumstances
AMC1 ARA.MED.330 Special medical circumstances
AMC1 ARA.MED.330(b)(c) Special medical circumstances
GM1 ARA.MED.330 Special medical circumstances

ECA Comment:
ECA definitely wants to keep the ARA.MED 330 and the related AMCs. Currently, the development in the field of medicine is very fast, and there will be treatments or medications that could be perfectly safe in aviation environment, but are not allowed within current regulation. To gain experience in aviation environment, it is important to have a regulated protocol for to study these new options in a safe way.
In addition, pilots should be able to receive the best treatment for their medical condition, and sometimes if this results in grounding, pilot may not take that treatment or medication.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	This protocol will allow faster evaluation of such treatment and may also benefit pilots' health.
response	Noted – However, as result of the comments received and the focused consultation with the MEG members, ARA.MED.330 and its corresponding AMC/GM have been deleted

AMC/GM to Part-ORA – GM1 ORA.AeMC.1 p. 46

comment	*64* comment by: *CAA.CZ* I have no comments
response	Noted – Thank you for your comment.

comment	*341* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** ORA.AeMC.210(a)(2) **Comment:** The sentence needs a linguistic improvement, at present it requires an AME to hold a class 1 or class 3 medical certificate. **Proposal:** Amend ORA.AeMC.210(a)(2): **'have on staff at least one additional certified AME with privileges to issue class 1 or class 3 medical certificates, as applicable, in accordance with the privileges and scope as listed in the terms of approval attached to the AeMC certificate, and other technical staff;'**
response	Accepted

AMC1 ORA.AeMC.115 p. 46

comment	*65* comment by: *CAA.CZ* I have no comments
response	Noted – Thank you for your comment.

comment	*170* comment by: *UK CAA* **Paragraph No: AMC1 ORA.AeMC.115 Application (b)** **Comment:** We do not understand what is meant by this sentence.

	Justification: Needs to be clarified
response	Partially accepted – the word minimum refers to the basic examinations that are required by Part-MED/ Part ATCO>MED for initial class 1 or class 3, as applicable. Minimum was replaced by the word "Standard"

comment	*419* comment by: *German NSA (BAF)* **AMC1 ORA.AeMC.115 (a)** There may be AeMCs with the privilege for class 3 only. Change the wording accordingly. Proposal: (a) [...] a list of medical and technical facilities for initial class 1 and class 3 aero-medical examinations as applicable according to the scope of the AeMC approval and of supporting specialist consultants.
response	Accepted– text updated.

comment	*420* comment by: *German NSA (BAF)* **AMC1 ORA.AeMC.115 (b)** There is no clear rule or AMC or GM to clearly state what is considered 'the minimum'. What means 'to cover'? A qualification? Being present? Have the time? Proposal: Amend to clarify or delete
response	Partially accepted – the word minimum refers to the basic examinations that are required by Part-MED/ Part ATCO>MED for initial class 1 . Minimum was replaced by the word "Standard"

comment	*421* comment by: *German NSA (BAF)* **AMC1 ORA.AeMC.115 (d)** The term 'contracted activities' cannot be used in the medical environment because no hospital could tolerate control or inspections by an AeMC or even the competent authority. Proposal: Delete or amend without reference to contracted activities. The term 'contract' could be used.
response	Not Accepted – subcontractors should allow access to the competent authority.

AMC1 ORA.AeMC.135	p. 47

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment	*191* comment by: *German Military Aviation Authority*
	Many facilities perform joint assessments for civil and military aviation together. Although military aviation is exempted from direct influence of EU regulation 216/2008, military aviation ensures that they act with due regard as far as practicable to the objectives of that Regulation, to fulfill article 1 section 2 of that regulation. Furthermore, military requirements exceed those of civil aviation regularly. I propose to enable the acknowledgement of military aviation medicine experience where practical. AMC1 ORA.AeMC.135 (a) should be supplemented as follows or similar: At least a total of 200 class 1 or class 3 **or equivalent military** aero-medical examinations and assessments should be performed at the AeMC every year or At least a total of 200 class 1 or class 3 aero-medical examinations and assessments **or equivalent** should be performed at the AeMC every year With the same rationale, AMC1 ORA.AeMC.210 (a) should be ammended as follows: .... at least 200 aero-medical examinations for a class 1 or class 2 **or equivalent** medical certificate before beeing nominated ....
response	Accepted– text updated.

comment	*342* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*
	Section: AMC1 ORA.AeMC.135(a) **Comment**: A linguistic improvement may be achieved by changing the sequence of the initial words. **Proposal**: Amend AMC1 ORA.AeMC.135(a): **'A total of at least 200 …'**
response	Accepted– text updated.

comment	*343* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*
	Section: AMC1 ORA.AeMC.135(b)

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Comment:
The low number of professional licence holders should not be linked with 'and' but with 'or'.

Proposal:
Amend AMC1 ORA.AeMC.135(b):
'… a low number of professional pilots or ATCOs …'

response Accepted– text updated.

comment 379 comment by: *Croatian Civil Aviation Agency*

AMC1 ORA.AeMC.135(c)(2)
Please consider putting "or equivalent" instead of "as applicable", since the same concept of flexible approach is already used in AMC1 ARA.MED.120(a), as for Medical assessor.

response Accepted– text updated.

comment 396 comment by: *René Meier, Europe Air Sports*

AMC1 Ora.AeMC.135(b)
page 47/52

Missing word?

Proposal:
Please adjust the second sentence to read "....cannot be reached due **to** a low number...."

Rationale:
With this adjustment the sentence is easier to understand.

response Accepted– text updated.

comment 397 comment by: *René Meier, Europe Air Sports*

AMC1 ORA.AeMC.135(c)(1)
page 47/52

We think this portion of the text is not complete.

Proposal:
Please add "class 2 AND/OR LAPL medical certificates...".

Rationale:
By doing so readers will get the full picture.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response | Not Accepted – LAPL and CC medicals cannot be seen as continuing experience at the level

comment | *422* comment by: *German NSA (BAF)*

AMC1 ORA.AeMC.135 (a)

'a total' is not needed. For continued vaidity it may be not sufficient to perform 200 class 3 examinations every year if the terms of approval also cover class 1. In addition, 200 class 3 examinations every year will hardly be possible in any EU country.
Stating these numbers is also against the principle of performance based regulations.

Proposal:
'`(a) At least ~~a total of~~ 200 ~~class 1 or class 3~~ aero-medical examinations and assessments within the scope of approval should be performed at the AeMC every year.'

response | Not Accepted – the word total is intended to clarify the fact that there is no need to have 200 of each classes, but 200 in total.

comment | *423* comment by: *German NSA (BAF)*

AMC1 ORA.AeMC.135 (b)

The wording of the proposal to (a) above makes this paragraph unnecessary.

Proposal:
Delete.

response | Not Accepted – it allows the flexibility for the states where there is a limited number of applicants to accept a lower number of class 1 and/or class 3 examinations while maintaining proportions and mitigating risks.

comment | *424* comment by: *German NSA (BAF)*

AMC1 ORA.AeMC.135 (c)

The wording of the proposal to AMC1 ORA.AeMC.135 (a) makes this paragraph unnecessary.

If it is kept, it should be amended.

Proposal:
'(c) ~~In these cases, t~~The continuing experience ~~of the head of~~ in the AeMC ~~and aero-medical examiners on staff should~~ may also be ensured by ~~them~~ performing aero-medical examinations and assessments for:'

response | Partially accepted– text updated.

comment | *425* comment by: *German NSA (BAF)*

AMC1 ORA.AeMC.135 (c) (2)

	There is a possibility that an AeMC with the privilege for class 1 only also assesses ATCOs of a third country under a certificate of this third country. This should also be accepted as continued experience without regard to the privileges held under EU rules. Proposal: '(2) third country class 1 ~~or~~ and class 3 medical certificates. ~~, as applicable'~~
response	Partially accepted– text updated.

AMC1 ORA.AeMC.200	p. 47

comment	*66* comment by: *CAA.CZ* I have no comments
response	Noted – Thank you for your comment.

comment	*297* comment by: *French DGAC* The words « national medical authority » are not defined in the EU regulations. We suggest replacing : “by a national medical authority” with : “by the medical assessor”
response	Not Accepted – actually the meaning of this is that where a certification process for the medical authorities (medical board) of the medical institutions then that process should be mentioned in the manual of the AeMC and credited by the competent authority in the certification process of the AeMC.

comment	*344* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** AMC1 ORA.AeMC.200(1) **Comment**: The proposed text is mixing up assessment procedures with management system. The paragraph should be clearly addressing only the AeMC management system. **Proposal**: Amend AMC1 ORA.AeMC.200(1): **‘Requirements for a management system by a national medical authority may be included as a part of the AeMC overall management system;’**
response	Accepted– text updated.

comment	*345* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

Section: AMC1 ORA.AeMC.200(2)

Comment:
The proposed text is difficult to interpret and understand. The first sentence is in part contradicted by the second sentence. The intention with this paragraph should be to require all AMEs working at an AeMC to perform a sufficient number of aero-medical assessments to meet the professional standards of an AeMC.

Proposal:
Amend AMC1 ORA.AeMC.200(2):
'… the management system should ensure that each AME performs a sufficient number of aero-medical assessments to meet the professional standards of an AeMC. The required activity of each AME should be specified in the management system.'

response Accepted– text updated.

comment 426 comment by: _German NSA (BAF)_

AMC ORA.AeMC.200 (1)

Editorial: replace (1) by (a).

response Accepted– text updated.

comment 427 comment by: _German NSA (BAF)_

AMC ORA.AeMC.200 (2)

Regulatory overkill and against the rules for AMEs in Part MED /ATCO.MED. The AME has to carry out a certain number of examinations as laid down in these Parts and it is not possible to require something else in AMC material just because the AME works at an AeMC. Performance based regulation is not based in numbers and hours.

Proposal:
Delete.

response Not Accepted – the aim of this AMC is to have the responsibility to perform medicals as part of the AeMC manual. Additional for AMEs working both in an AeMC and in their own practice they should perform some medicals also in the AeMC.

GM2 ORA.AeMC.200	p. 47

comment 67 comment by: _CAA.CZ_

I have no comments

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

response | Noted – Thank you for your comment.

comment | *70* comment by: *CAA.CZ*

I have no comments

response | Noted – Thank you for your comment.

comment | *428* comment by: *German NSA (BAF)*

There is no GM1, why is this GM2?

Proposal:
Rename GM1 or draft a paragraph GM1.

response | Not Accepted – there is a GM1 published by ED Decision 2012/007/R, however as that was not amended it was not included in this NPA.

AMC1 ORA.AeMC.205 p. 47

comment | *68* comment by: *CAA.CZ*

I have no comments

response | Noted – Thank you for your comment.

comment | *71* comment by: *CAA.CZ*

I have no comments

response | Noted – Thank you for your comment.

comment | *171* comment by: *UK CAA*

Paragraph No: AMC1 ORA.AeMC.205 Contracted activities (1)

Comment: The paragraph concerns contracted activities but this is not reflected in the text and correction to spelling of specialties.

Justification: Clarity

Proposed Text: The minimum required medical contracted activities ~~examinations~~ should at least encompass the following special~~i~~ties: ophthalmology including colour vision, otorhinolaryngology, cardiology and mental health

response | Not Accepted – Although the title of ORA.AeMC.205 is Contracted activities, this AMC is linked with the requirements in point (a) of ORA.AeMC.205 regarding the standard examinations to be performed within the centre.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

An agency of the European Union

comment	*172*	comment by: *UK CAA*
	Paragraph No: AMC1 ORA.AeMC.205 Contracted activities (1) **Comment:** Remove reference to an otorhinolaryngology specialist. **Justification:** Reports are very rarely required from an otorhinolaryngology specialist. **Proposed Text:** The minimum required medical contracted activities ~~examinations~~ should at least encompass the following specialities: ophthalmology including colour vision, ~~otorhinolaryngology,~~ cardiology and mental health	
response	Not Accepted – otorhinolaryngology is essential for the initial class 1 and class 3 medical examinations due to the importance of proper hearing and balance for pilots and ATCOs. It is also one of the standard examinations required for the initial aero-medical examination for class 1 and class 3	

comment	*429*	comment by: *German NSA (BAF)*
	AMC1 ORA.AeMC.205 (1) The header does not match the content of the paragraph. 'Contracted acitivities' are not possible in the medical environment. However, a contract may be possible. The paragraph is unclear. The minimum required for a medical examination and assessment for the issue of a medical certificate? The minimum under a contract? The minimum to be performed at the AeMC? Who does the medical history and physical examination? A GMP under contract? **Proposal:** Delete.	
response	Not Accepted – Although the title of ORA.AeMC.205 is Contracted activities, this AMC is linked with the requirements in point (a) of ORA.AeMC.205 regarding the standard examinations to be performed within the centre.	

AMC1 ORA.AeMC.210	p. 47

comment	*69*	comment by: *CAA.CZ*
	I have no comments	
response	Noted – Thank you for your comment.	

comment	*72*	comment by: *CAA.CZ*
	I have no comments	
response	Noted – Thank you for your comment.	

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment | *173* comment by: *UK CAA*

Paragraph No: AMC1 ORA.AeMC.210 Personnel requirements (a)

Comment: The requirements should be competency and not time based.

Justification: The Head of the AeMC should have significant experience in Aviation Medicine and ideally a higher qualification than just the basic and advanced courses.

Proposed Text: 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 and/or class 3 medical certificate before being nominated as head of an AeMC. A higher qualification in Aviation Medicine is preferable.

response | Partially accepted– unfortunately higher qualification in aviation medicine, such as specialist training in aviation medicine, is not broadly available, consequently cannot be added to the AMC.

comment | *346* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

Section: AMC1 ORA.AeMC.210

Comment:
The purpose of this paragraph is to describe the nomination of a head of an AeMC, which is not apparent until the very end of the text. The purpose will be more apparent if 'before being nominated as head of an AeMC …' is moved to the beginning of the paragraph.

Proposal:
Amend AMC1 ORA.AeMC.210:
'Before an AME is nominated as head of an AeMC, he or she should have held AME privileges …'

response | Partially accepted– text updated.

comment | *380* comment by: *Croatian Civil Aviation Agency*

AMC1 ORA.AeMC.210(a)
Please consider adding "or equivalent" on existing text, since the same concept of flexible approach is already used in AMC1 ARA.MED.120(a), as for Medical assessor.

response | Accepted

comment	*414* comment by: *NATS* **AMC1 ORA.AeMC.210 Personnel requirements** GENERAL (a) The aero-medical examiner (AME) should have held ~~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. Issue Continuity. This section should reflect **AMC1 ARA.MED.120 Medical Assessors Experience & Knowledge** - AME to replace Class 1. Suggested Resolution (a) The aero-medical examiner (AME) should have held AME 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.
response	Accepted– text updated

comment	*430* comment by: *German NSA (BAF)* **AMC1 ORA.AeMC.210 (a)** Numbers are not in accordance with performance based regulations. If the hours are to be kept according to a riks assessment that we are not aware of, then they should reflect the fact that there are far less ATCOs than pilots. Proposal: 'In order to be nominated as head of an AeMC, ~~T~~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 of the AeMC ~~attached to the AeMC's certificate~~ for at least 5 years. *(and have performed at least 200 aero-medical examinations for a class 1 AeMC approval or 50 class 3 medical examinations for a class 3 AeMC approval.)* ~~before being nominated as head of an AeMC.'~~
response	Partially accepted– text updated

AMC1 ORA.AeMC.215	p. 48

comment	*73* comment by: *CAA.CZ* I have no comments
response	Noted – Thank you for your comment.

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

comment *123* comment by: *AESA*

(a) Cardiology. Nowdays **Echocardiography** is a current /routine tool in any Cardiological exam.

response Noted – That will be discussed in a separate rulemaking task dedicated to the cardiological requirements.

comment *124* comment by: *AESA*

(b) Ophtalmology: Shoul not include hearing and pure-tone audiometer (possibly typing error).
(b) Ophtalmology: consider also **Optic Coherence Tomography (OCT)** and **Pakimetry,** for better evaluation of the retina and optic nerve and better evaluation of real PIO (Glaucoma).

response Noted – Error corrected.
That will be discussed in a separate rulemaking task dedicated to the ophthalmology requirements.

comment *125* comment by: *AESA*

(d) ENT. Add Verbal Discrimination Testing

response Noted – That will be discussed in a separate rulemaking task dedicated to the cardiological requirements.

comment *126* comment by: *AESA*

(f) (3) Mental Health Evaluation including Psychometric testing.

response Accepted– text updated

comment *174* comment by: *UK CAA*

Paragraph No: AMC1 ORA.AeMC.215 Facility requirements

Comment: Exercise ECGs should be available at the AeMC or arranged with a service provider.

Justification: Exercise ECGs require the immediate availability of an emergency care team which should not be a requirement for AeMCs.

Proposed Text:

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:

An agency of the European Union
TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

(1) 12-lead resting ECG;
~~(2) stress exercise ECG;~~
(3) 24-hour blood pressure monitoring; and
(4) 24-hour heart rhythm monitoring……

…….(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.
(3) exercise ECG

response: Accepted– text updated

comment: *298* comment by: *French DGAC*

In Medical-technical facilities, (a) Cardiology (2) exercise ECG :
By law, exercise ECGs are not allowed in France in facilities where no resuscitation department is available. As a consequence these examinations, when necessary, will need to be contracted.

“(c)Hearing“ should be aligned with other same level headings.

response: Accepted– text updated

comment: *404* comment by: *René Meier, Europe Air Sports*

AMC1 ORA.AeMC.215(a)(2,3 and 4)
page 48/52

The correct interpretation of the results presented by the equipment used requires frequent application.

Proposal:
Please delete (2), (3), (4) under (a), add it under (f).

Rationale:
Exercise ECG, 24-hour blood pressure monitoring and heart rhythm monitoring should be available at a specialist or service provider, as the correct use and interpretation of these equipments require frequent application. This is not under the scope of an AME or AeMC.

response: Accepted– text updated

comment: *416* comment by: *NATS*

AMC1 ORA.AeMC.215 Facility requirements
(a) MEDICAL-TECHNICAL FACILITIES

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

	(a) The medical-technical facilities of an AeMC should consist of the equipment of a general medical practice and, in addition, of equipment for the following: <u>Issue</u> Suggested wording will allow more flexibility for AeMCs re optometry and cardiology requirement, which is onerous, expensive and safer in a cardiology clinical setting. Expense and requirement for optometrist caused considerable delay to NATS reinstatement of AeMC status and is a barrier to other AeMCs. NATS AeMC made a safety case to UK CAA Head of Oversight in May 2017 to allow cardiology to be conducted as a contracted activity externally; impractical and higher risk to conduct heart tests on site at Swanwick. <u>Suggested Resolution</u> (a) The medical-technical facilities of an AeMC should consist of the equipment of a general medical practice and, in addition, of equipment for the following. Alternatively this equipment should be arranged with a service provider with oversight from the AeMC: I
response	Partially accepted– text updated

4. Impact assessment	p. 49

comment	*186* comment by: *FAA* We assume from this Impact Assessment that the intent of "ORA.AeMC.160 Reporting" (pg. 20) is not for specific testing upon examination but to identify screening factors. If testing is intended then that would have significant economic impact.
response	Noted – Thank you for your comment. The actual testing is mandated by Part.MED and an impact assessment for the testing was included in the Opinion 09/2016

comment	*347* comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)* **Section:** 4. Impact assessment, page 49 **Comment**: The proposed changes in this NPA include several important changes creating increased demands and burdens on both competent authorities and AeMCs. It is unacceptable to declare that 'there is no need to develop a regulatory impact assessment'.

An agency of the European Union

	Proposal: The NPA 2017-22 needs to be amended with a thorough RIA.
response	Noted – Thank you for your comment.

5. Proposed actions to support implementation	p. 50

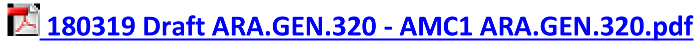
comment	_74_ I have no comments	comment by: _CAA.CZ_
response	Noted – Thank you for your comment.	

6. Referencces	p. 51

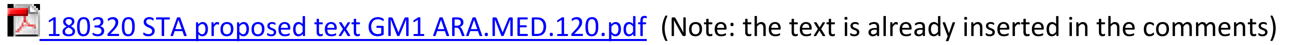
comment	_75_ I have no comments	comment by: _CAA.CZ_
response	Noted – Thank you for your comment.	

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

3. Appendix A – Attachments


180319 Draft ARA.GEN.320 - AMC1 ARA.GEN.320.pdf
Attachment #1 to comment #355

Comment NPA OM.pdf (Note: the text is already inserted in the comments)
Attachment #2 to comment #224


180320 STA proposed text GM1 ARA.MED.120.pdf (Note: the text is already inserted in the comments)
Attachment #3 to comment #327

ICAO_Med.Exam.Report_Mental Health issue.pdf
Attachment #4 to comment #378

180320 STA transfer of SOLI form.pdf
Attachment #5 to comment #330

An agency of the European Union

TE.RPRO.00064-004 © European Aviation Safety Agency. All rights reserved. ISO 9001 certified.
Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.