

## Annex VIII to ED Decision 2025/002/R

### ‘AMC and GM to Part-SPA — Issue 1, Amendment 15’

The text of the amendment is arranged to show deleted, new and unchanged text as follows:

- deleted text is ~~struck through~~;
- new or amended text is highlighted in **blue**;
- an ellipsis ‘[...]’ indicates that the rest of the text is unchanged.

#### **Note to the reader**

*In amended, and in particular in existing (that is, unchanged) text, ‘Agency’ is used interchangeably with ‘EASA’. The interchangeable use of these two terms is more apparent in the consolidated versions. Therefore, please note that both terms refer to the ‘European Union Aviation Safety Agency (EASA)’.*

The Annex to Decision 2012/019/R of the Executive Director of the Agency of 24 October 2012 is amended as follows:

## SUBPART J – HELICOPTER EMERGENCY MEDICAL SERVICE OPERATIONS

### AMC1 SPA.HEMS.130(g)(1) Crew requirements

Operators should identify, as part of their safety risk assessment process, additional risks for flight crew members who have attained the age of 60 years and who perform single-pilot HEMS operations in accordance with point FCL.065(a) of Annex I (Part-FCL) to Regulation (EU) No 1178/2011, including the negative effects of fatigue as a cardiovascular and cerebrovascular risk factor, and take appropriate action to effectively mitigate those risks.

#### Rationale

RMT.0287

With the alleviation of the age limits for the pilots involved in HEMS operations, certain mitigating measures have been put in place to reduce the risk level. Consequently, the rulemaking group and EASA experts recommended to add an AMC clarifying the need for the operators employing pilots over the age of 60 to perform single-pilot HEMS operations to include the risks related to age into their risk assessment and mitigation process within their SMS to ensure that certain work-related conditions such as long shifts do not increase the risk of incapacitation for these pilots over the age of 60.

As a result, this AMC is introduced to highlight the importance of a proper risk assessment and mitigation.

### GM1 SPA.HEMS.130(g)(1) Crew requirements

#### BEST PRACTICES FOR FLIGHT CREW MEMBERS ABOVE THE AGE OF 60 PERFORMING SINGLE-PILOT HEMS OPERATIONS

Several studies have found that, in general, the frequent exposure of working population to long working hours ( $\geq 55$  hours per week), frequent overtime work (3-4 hours overtime) or shift work is associated with increased risk of cardiovascular disease (CVD) — including of fatal and non-fatal coronary heart disease (CHD) and atrial fibrillation — and cerebrovascular disease such as stroke.

In the context of the association of long work hours, overtime work and shift work with an increased CVD risk, some authors recommend for general population countermeasures such as a limit of operation time to 40 hrs/week and working time up to 10 hours within 24 hours (Virtanen et al., 2018). Although such operational limitations might be considered to apply for pilots from the age of 60 onwards, it is not clear, due to lack of dedicated studies, how that will affect the cumulative CVD risk after numerous years of exposure to long and irregular working hours before their 60th birthday. However, by limiting the working hours the risk for CVD and cerebrovascular disease will not be further increased due to fatigue and, with time passing, this risk is expected to gradually reduce. A working hour limitation could also lead to a reduction in fatigue and an increase in the recovery of older pilots.

With regard to the above-mentioned considerations, it should be emphasised that sufficient sleep of good quality is the key factor in preventing fatigue and maintaining optimal performance and good health. Ideally, a pilot should have a continuous 8-hour sleep opportunity per 24 hours. Sleep should be facilitated in a dark and quiet environment allowing horizontal rest. Where the ideal 8-hour continuous rest is not possible due to operational constraints, the operator could consider additional mitigating measures within their FRMS/SMS. The operators should also give proper consideration to the period of the day when this rest period is scheduled in relation to the circadian rhythm of the flight crew members.

Operators could consider implementing an FRMS tailored to the specific operational demands of the company. Pilots and managers should be educated to stimulate awareness of the safety implications of fatigue, recognise the signs of fatigue, and how to prevent fatigue by sufficient sleep and strategic naps.

Basic principles to consider for HEMS operators:

- (a) Form a fatigue safety action group including manager/head of flight operations, planner, pilot(s)
- (b) Identify potential fatigue hazards, including accumulation of fatigue
- (c) Assess fatiguing rosters (e.g. this can simply be done using the Karolinska Sleepiness Scale or the Samn-Perelli Fatigue Scale in conjunction with an assessment of the sleep duration and quality using a simple scale)
- (d) Estimate risk associated with an identifiable hazard
- (e) Redesign rosters/rotations in coordination with stakeholders
- (f) Monitor reduction of risk (e.g. using the Karolinska Sleepiness Scale or the Samn-Perelli Fatigue Scale in conjunction with an assessment of the sleep duration and quality using a simple scale)
- (g) Provide procedures and training (if necessary, this might be done by (an) external expert(s) and online)
- (h) Make use of the continuous improvement plan-do-check-act principle of the SMS

**Rationale**

RMT.0287

With the alleviation of the age limits for the pilots involved in HEMS operations certain mitigating measures have been put in place to reduce the risk level. Consequently, the rulemaking group and EASA experts recommended to provide guidance on the potential risks related to age into the operator risk assessment and mitigation process within their SMS to ensure that certain work-related conditions such as long shifts do not increase the risk of incapacitation for these pilots over the age of 60.

As a result, this GM is introduced to highlight the importance of a proper risk assessment for the most common risks and provide best practice advice on the potential mitigating measures.

**AMC1 SPA.HEMS.130(g)(2) Crew requirements****TRAINING AND CHECKING OF PILOTS ABOVE THE AGE OF 60 PERFORMING SINGLE-PILOT HEMS OPERATIONS**

(a) Initial training for the personnel providing the training and checking for pilots above the age of 60 performing single-pilot HEMS operations should aim to raise their awareness regarding the signs and operational impact of mild cognitive decline, as well as the reporting process to the medical assessor of the licensing authority, and the confidentiality principles to be considered.

In developing such training, proper consideration should be given to the information provided in GM1 SPA.HEMS.130(g)(2) and GM2 SPA.HEMS.130(g)(2).

The duration of the training should not exceed 6 hours.

Recurrent training may be considered based on the operator's assessment.

(b) The training should ensure that personnel providing training and checking for this category of pilots are able to perform the following tasks:

- detect and document, to the best of their abilities, any signs of cognitive decline;
- consider essential cognitive factors contributing to flight performance when conducting regular mandatory operator proficiency checks (OPCs). In order to do this, attention should be focused in particular on the ability to function under highly stressful demands, such as, but not limited to, abnormal and emergency procedures under high time pressure;
- discuss their concerns with the pilot in question encouraging them to self-report the problems to their AME/AeMC or to a peer support programme, and when any signs of cognitive decline have been identified or are suspected, share, without undue delay, the report with the medical assessor of the licensing authority, as defined in Part-MED, for further assessment, in accordance with principles of medical confidentiality.

**Rationale**

RMT.0287

The rulemaking group and the discussions in the MEG regarding the alleviation to pilot age limits for HEMS pilots highlighted the importance of including among the mitigating measures an assessment of the cognitive function in order to be able to detect early signs of cognitive decline.

In addition to the cognitive assessment included in the regular medical assessment, the discussions within the rulemaking group and during the MEG meeting highlighted the difficulties to identify the mild cognitive decline during the regular medical assessment, and the fact that the operational relevance should also be considered. This also revealed that mild cognitive decline is more likely to manifest in high-stress situations such as emergency manoeuvres which are exercised during the simulator checks.

However, in order to be able to detect signs of cognitive decline, the instructors/examiners should be trained on what they should look for.

Furthermore, as all medical data, aspects related to the cognitive function should be treated in a confidential manner.

Consequently, this AMC is introduced to clarify how the requirement to observe the cognitive function during the simulator checks should be complied with.

## GM1 SPA.HEMS.130(g)(2) Crew requirements

### (a) Information for examiners about operational signs of cognitive performance deficits

Cognition encompasses many aspects of intellectual functions and processes such as perception, attention, thought, the formation of knowledge, memory and working memory, judgement and evaluation, reasoning and computation, problem-solving and decision-making, comprehension and production of language. Cognitive processes use existing knowledge and discover new knowledge.

Cognitive decline is considered to begin from 40 years of age. There is large variation in the extent and functional effects of age-related impairment between people of the same age. The most important changes in cognition with normal ageing are declines in performance of cognitive tasks that require one to quickly process or transform information to make a decision, including measures of speed of processing, working memory and executive cognitive function.

### (b) Cognitive functions and aviation

The cognitive functions that are generally assumed to impair with increasing age and considered important for the proper performance of all flying tasks are:

- (1) problem-solving and decision-making (e.g. diagnosis of faults and defects and taking action);
- (2) information processing within a required time frame (e.g. process the information of flight, navigation and engine instruments, primary flight displays, radar, TCAS, radio voice communications, data-link, direct vision, crew member communication, vibrations, noises and smells). With tasks involving both speed and accuracy, older people tend to attach greater importance to accuracy, thereby slowing their speed of response;
- (3) perception (e.g. instrument monitoring);
- (4) memory (e.g. recall information given by air traffic control);
- (5) psychomotor coordination (e.g. flight control).

Signs of cognitive impairment can relate to any or all of the five functions listed above. It is generally accepted that experience can counter cognitive decline in active pilots up to a certain level.

When assessing cognitive function in relation to flight performance during the regular OPCs, the examiner may consider the List of competency elements and performance criteria described in points (g) through (o) of GM1 to Appendix 5 to Annex I (Part-FCL) to Regulation (EU) 1178/2011 with particular focus on the following points:

- attitudes and behaviours appropriate to the safe conduct of flight, including recognising and managing potential threats and errors;
- management of abnormal and emergency situations;

- communication with ATC, ground personnel and crew, and HEMS crew.

Particular attention on the ability to function under highly stressful demands, such as high time pressure, is expected to allow the examiner to detect deficits and refer the respective case to the medical assessor of the licensing authority.

**Rationale**

RMT.0287

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However, in order to be able to detect signs of cognitive decline, the instructors/examiners should be trained on what they should look for.

Consequently, this GM is introduced to summarise the main points the instructors/examiners should look at.

**GM2 SPA.HEMS.130(g)(2) Crew requirements**

- (a) Considerations concerning confidentiality when reporting possible signs of cognitive performance deficits of a pilot to the licensing authority

EU and national personal data protection regulations should be observed in all cases involving processing of personal data, including transferring of personal data to competent authorities and medical professionals.

Medical confidentiality related to the aero-medical assessments is strictly protected by point MED.A.015 of Annex IV (Part-MED) to Regulation (EU) No 1178/2011. Regardless of the fact that the assessment of cognitive performance is not a medical examination and hence not covered by the provisions of point MED.A.015, the principles of confidentiality should be observed at all times.

Confidentiality of medical records is an important ethical and legal duty of all parties involved and can only be superseded by the requirement to address imminent and high risks of harm to involved or third parties. In the context of the application of point SPA.HEMS.130(g)(2), this means that, when processing information containing health-related data, examiners involved are subject to the requirements of EU and national personal data protection regulations. As a consequence, the information, that the examiner will report to medical assessor of the licensing authority of the pilot concerned, should be clearly described in a privacy notice provided to pilots prior to the proficiency check specified in point (b) of AMC1 SPA.HEM.130(g)(2). When examiners detect a cognitive performance deficit of pilots, the personal data of these pilots should be shared only with the medical assessor of the licensing authority of the pilot

concerned. When such sharing of personal data is needed, the examiner should inform the pilot concerned.

(b) Additional considerations and examples

It is anticipated that in the context of recurrent checking tests examiners may not come in a position where they have to breach confidentiality related to observed signs of neurocognitive performance deficits.

Nevertheless, such situations may take place occasionally. Below we present several best practices to consider in various scenarios:

- (1) If neurocognitive performance deficits (see the report '[Extending age limits of HEMS pilots to 65 years – mental health and cognitive screening](#)') cause failure or partial failure of the proficiency check, the result of the check will be reported to the authority and the pilot will not be allowed to exercise the privileges of their licence/rating pending the results of a new evaluation. While the pilot is grounded, flight safety will not be imminently endangered; nevertheless, the examiner should report the situation to the medical assessor of the licensing authority of the pilot allowing for additional medical investigations. In such a case, the examiner should provide a report based on identifiable factual items explaining why the pilot's performance did not meet the required standards. In case there are signs of a cognitive performance deficit, the medical assessor of the licensing authority may demand a neurophysiological assessment before a re-examination check is to be performed.
- (2) If a result of a check is sufficient only by the narrowest margin and the examiner has found one or more possible sign(s) of cognitive performance deficit, the examiner should explain their concerns to the pilot and seek the consent of the pilot to share the concerns with the medical assessor of the licensing authority in order to discuss monitoring of possible cognitive decline by shortening the interval between the last and the next check and/or a neurophysiological assessment. In such cases, the examiner should describe their concerns in operational terms based on identifiable factual items explaining why the pilot's performance is borderline to meet the required standards such as 'situational assessment and decision-making on engine failures took longer time than commonly needed' (which relates to the cognitive function of problem-solving and decision-making). Where the pilot refuses to give consent regarding the notification to the licensing authority, the examiner performing the proficiency check should consider taking appropriate measures to remove the respective pilot from flying duties in the interest of flight safety, while at the same time reporting the situation to the medical assessor of the licensing authority of the pilot. In that case, the examiner could consider paying special attention to signs of cognitive performance deficit(s) during a next check.
- (3) In the case that a pilot has successfully passed the check, demonstrating that their performance is sufficient to exercise the privileges of the licence/rating, it can be considered that there is no evidence of any cognitive decline that would negatively impact flight safety in the interval before the next check and, consequently, no further measures are needed.

**Rationale**

RMT.0287

The rulemaking group and the discussions in the MEG regarding the alleviation to pilot age limits for HEMS pilots highlighted the importance of including among the mitigating measures an assessment of the cognitive function in order to be able to detect early signs of cognitive decline.

In addition to the cognitive assessment included in the regular medical assessment, the discussions within the rulemaking group and during the MEG meeting highlighted the difficulties to detect the mild cognitive decline during the regular medical assessment, and the fact that the operational relevance should also be considered. This also revealed that mild cognitive decline is more likely to manifest in high-stress situations such as emergency manoeuvres which are exercised during the simulator checks.

However, as all medical data, aspects related to the cognitive function should be treated in a confidential manner.

Consequently, this GM is introduced to provide information and guidance on the medical confidentiality principles that should be considered when handling data related to the cognitive function of the pilots examined.