

Opinion No 08/2022

Helicopter emergency medical service performance and public interest sites

RELATED NPA/CRD: 2018-04 — RMT.0325 (OPS.057(a)) & RMT.0326 (OPS.057(b))

EXECUTIVE SUMMARY

The objective of this Opinion is to modernise the European Union's (EU) aviation regulatory framework applicable to helicopter emergency services and medical services.

The Opinion proposes revised requirements with regard to the following:

- flights to/from public interest sites (PISs) located in congested areas;
- helicopter emergency medical service (HEMS) flights by day or by night in relation to equipment, training, operating minima, and operating site/hospital site features;
- HEMS requirements for high-altitude operations; and
- a new HEMS concept to cover mountain operations and rescue operations, other than search and rescue (SAR) operations.

The proposals put forward in this Opinion are expected to increase safety, and foster efficiency and proportionality while keeping the economic impact on HEMS operators at a minimum.

Domain:	Helicopter operators		
Related rules:	Annex I (Definitions), Annex II (Part-ARO), Annex III (Part-ORO), Anne IV (Part-CAT), Annex V (Part-		
	SPA), Annex VII (Part-NCO) and Annex VIII (Part-SPO) to Commission Regulation (EU) No 965/2012		
Affected stakeholders:	Helicopter operators		
Driver:	Level playing field	Rulemaking group:	No
Impact assessment:	Light		

Start Terms of Reference	Public consultation NPA 2018-04	Proposal to the Commission Opinion No 08/2022	Adoption by the Commission Implementing act	Decision Certification Specifications, Acceptable Means of Compliance, Guidance Material
21.11.2016	18.6.2018 (Focused consultation with experts in 2021 as part of the comment-review phase)	23.9.2022	Q2/2023	Q4/2023



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1. About this Opinion

1.1. How this Opinion was developed

The European Union Aviation Safety Agency (EASA) developed this Opinion in line with Regulation (EU) 2018/1139¹ ('Basic Regulation') and the Rulemaking Procedure².

This rulemaking activity is included in Volume II of the European Plan for Aviation Safety (EPAS) for $2022-2026^3$ under rulemaking tasks RMT.0325 (OPS.057(a) & RMT.0326 (OPS.057(b)). The scope and timescales of the tasks were defined in the related ToR RMT.0325 (OPS.057(a)) & RMT.0326 (OPS.057(b)) Issue 3^4 .

The *draft* text of this Opinion has been developed by EASA with the support of experts from industry and Member States.

All interested parties were consulted⁵ through NPA 2018-04 *Helicopter emergency medical services performance and public interest sites*⁶.

The *final* text of this Opinion and the draft Commission Implementing Regulation have been developed by EASA considering the input received during the public consultation of NPA 2018-04 and the comment review that followed.

Several comments received to NPA 2019-09 *All-weather operations* — *Helicopters and specialised operations*⁷ also addressed the VFR operating minima proposed in NPA 2018-04 and were also taken into account.

The resulting final draft Opinion was discussed with the MAB during a plenary MAB meeting on 9 February 2022, where EASA presented the outcome of the consultation and an overview of the proposed amendments.

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

⁷ NPA 2019-09 - All-weather operations — Helicopters and specialised operations | EASA (europa.eu)



¹ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (<u>https://eurlex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri=CELEX:32018R1139</u>).

² EASA is bound to follow a structured rulemaking process as required by Article 115(1) of Regulation (EU) 2018/1139. Such a process has been adopted by the EASA Management Board (MB) and is referred to as the 'Rulemaking Procedure'. See MB Decision No 01-2022 of 2 May 2022 on the procedure to be applied by EASA for the issuing of opinions, certification specifications and other detailed specifications, acceptable means of compliance and guidance material ('Rulemaking Procedure'), and repealing Management Board Decision No 18-2015 (<u>EASA MB Decision No 01-2022 on the Rulemaking Procedure</u>, repealing MB Decision 18-2015 (by written procedure) | EASA (europa.eu)).

³ European Plan for Aviation Safety 2022 - 2026 | EASA (europa.eu)

⁴ <u>RMT.0325 (OPS.057(a)) & RMT.0326 (OPS.057(b)) - Helicopter emergency medical services performance and public interest site | EASA (europa.eu)</u>

⁵ In accordance with Article 115 of Regulation (EU) 2018/1139 and Articles 6(3) and 7 of the Rulemaking Procedure applicable at the time of publication of the NPA, as defined in MB Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by EASA for the issuing of opinions, certification specifications and guidance material (<u>http://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-18-2015-rulemaking-procedure</u>).

⁶ <u>NPA 2018-04 - Helicopter emergency medical services performance and public interest sites | EASA (europa.eu)</u>

1.2. The next steps

This Opinion proposes amendments to Regulation (EU) No 965/2012⁸ (the Air OPS Regulation), having assessed their potential impacts. It is submitted to the European Commission, which will use it as a technical basis to prepare an implementing act.

The Opinion proposes also a deferred applicability date in order to provide HEMS operators with sufficient time to implement the amended Air OPS Regulation. Further transitional periods are proposed for some new requirements as regards equipment.

The Decision with the related acceptable means of compliance (AMC) and guidance material (GM) to support the application of the implementing act will be published by EASA once the related implementing act is adopted by the European Commission.

Furthermore, EASA publishes separately with this Opinion, for information purposes only, the draft AMC and GM to the proposed amendments.

⁸ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1) (<u>http://eur-lex.europa.eu/legalcontent/EN/TXT/?qid=1494235623593&uri=CELEX:32012R0965</u>).



2. HEMS: in summary — why and what

This chapter provides the rationale behind the proposed amendments to the Air OPS Regulation.

2.1. Why we need to amend the Air OPS Regulation — issue/rationale

Overview

The main issues for EASA to propose amendments to the HEMS requirements in the Air OPS Regulation are the following:

To implement JAA Temporary Guidance Leaflet (TGL) 43 and adapt the HEMS performance requirements to mountain operations

Currently, the HEMS performance requirements do not cater for the specificities of mountain operations, including mountain rescue operations and rescue operations other than search and rescue (SAR) operations.

In the JAA framework, the performance requirements for HEMS were contained in JAR-OPS 3 Subparts F, G, H and I, with specific mitigation measures provided in Appendix 1 to JAR-OPS 3.005(d) *Helicopter Emergency Medical Service* and in Appendix 1 to JAR-OPS 3.005(i) *Helicopter operations at a public interest site*. These performance requirements were transposed into the Air OPS Regulation, and specifically in Annex IV (Part-CAT) Subpart C *AIRCRAFT PERFORMANCE AND OPERATING LIMITATIONS*

Section 2 *Helicopters*, and in Annex V (Part-SPA) point SPA.HEMS.125 *Performance requirements for HEMS operations*, and in the related AMC and GM.

In addition, the JAA framework was complemented by TGL 43, which included material relevant for the performance of HEMS operations in mountain areas. TGL 43 was not initially transposed into the EASA framework.

To better address mountain operations

Implementation experience has shown that mountain operations are currently not adequately covered. An example is HEMS operations with a cargo sling. When the EASA framework for HEMS was initially developed, it was not foreseen that sling load operations would be used in HEMS, and that Member States (MSs) would operate mountain rescue according to national rules. However, experience has shown that these assumptions were not correct, and that MSs have been conducting these operations under the EASA framework. However, since the requirements were initially not developed with these operations in mind, they did not fully cover all relevant aspects. Several MSs used alternative means of compliance (AltMoC) that addressed sling load operations in mountain HEMS. The review of these AltMoC supported the conclusion that some elements of the implementing rules applicable to HEMS needed to be amended to adequately cover some aspects of mountain HEMS operations.



To modernise the regulations with regard to HEMS performance requirements at public interest sites (PISs)

The regulations regarding PISs needed to be reassessed to determine whether they were still appropriate and whether the derogations under Article 6(6) of the Air OPS Regulation were still necessary.

To better address the risks associated with emergency flights conducted in a degraded visual environment

The update of the HEMS safety requirements is necessary to better reflect and address the risks associated with emergency flights conducted in a degraded visual environment, and which risks are specific to HEMS operations as shown through previous experience, which led to the immediate reaction of one MS to a safety issue and to an AltMoC used by another MS.

- (1) On 15 October 2014, the UK CAA (at the time still part of the EASA system) issued safety directive (SD) No SD–2014/003⁹ addressed to operators conducting night HEMS operations within the UK in accordance with a HEMS approval, and directed them to comply with additional requirements (including an NVIS approval, pilots must hold a valid instrument rating (IR), additional meteorological equipment, risk assessment acceptable to the CAA). Finland also used an AltMoC addressing night HEMS operations along the same line.
- (2) A review of HEMS accidents that occurred during 2005–2014 confirmed that a degraded visual environment is a major contributor to accidents in HEMS operations, not only by night, but also by day.

To address safety issues identified through implementation

Implementation experience, safety recommendations issued by safety investigation authorities and exemptions issued by MSs have shown a number of issues as described in detail in Section 2.1 *Why we need to change the rules — issue/rationale* of NPA 2018-04¹⁰. In addition, since the publication of that NPA, the following additional exemptions and safety recommendations were identified as relevant:

- Article 71 exemption issued by France, which anticipates some measures proposed in NPA 2018-04 and introduces the use of single-engined helicopters for mountain HEMS and mountain rescue operations at national level.
- Article 71 exemption issued by Portugal revealed editorial mistakes in NCO.IDE.H and SPO.IDE.H
 with regard to emergency locator transmitters (ELTs).
- Safety recommendation ANSV-5/66-17/5/A/18 addressed to EASA: The ANSV recommended to evaluate the possibility of providing tools for operators aimed at providing support to the decision-making activity of the commander and to carry out a supervision of the work of the crews, both in real time and after the execution of the HEMS mission.
- Safety recommendation ANSV-1/172-17/1/A/19 addressed to EASA: The ANSV recommended drafting guidance material applicable to daytime flights, conceptually similar to the current

¹⁰ <u>https://www.easa.europa.eu/downloads/47107/en</u>



⁹ <u>https://publicapps.caa.co.uk/docs/33/SafetyDirective2014003.pdf</u>

GM1 SPA.HEMS.130(e)(2)(ii), which provides indications about the advisability of employing two pilots in specific geographical areas where the orography and possible sudden changes in visibility may make the conduct of a flight problematic, requiring, even in advance, the monitoring of controls and instruments.

2.2. What we want to achieve — objectives

The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation. This proposal will contribute to the achievement of the overall objectives by addressing the issues outlined in Section 2.1.

The specific objectives of this proposal are to:

- foster the development of efficient and proportional regulations and rules, more precisely regarding:
 - HEMS requirements for high-altitude operations;
 - a new HEMS concept to cover mountain operations and rescue operations (other than SAR operations);
- maintain a high level of safety for HEMS flights to/from PISs located in congested areas, and to ensure that:
 - derogations remain available at historical sites and proper mitigation measures are in place;
 - the deterioration of the obstacle environment is avoided where derogations are available; and
- maintain a high level of safety for HEMS flights by day or by night, regarding equipment, training, operating minima, and operating site/hospital site illumination.

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

2.3.1. Public interest sites (PISs)

Merger of two different derogation schemes and phasing out PISs that should not have qualified for derogation under Article 6(6)

The term 'public interest site' (PIS) covers two different types of derogation from the helicopter performance requirements: the derogation laid down in Article 6(6) and the derogation in point CAT.POL.H.225 *Helicopter operations to/from a public interest site* of the Air OPS Regulation. Article 6(6) was introduced as a temporary, transitional arrangement to accommodate differing actions taken by some MSs in relation to already existing sites¹¹, but experience has shown that Article 6(6) derogations have been used to cover more than what was initially intended.

It appears that Article 6(6) has not only been used for the continuation of use of existing sites, but also to bring new hospital landing sites into existence after 28 October 2014 (the date of applicability of Article 6(6)) and then to approve these 'newly existing sites' as PISs. This situation is assumed to have

¹¹ Commission Regulation (EU) No 965/2012, which introduced Article 6(6) (was published on 25.10.2012 and has been in force since 28.10.2014).



happened only in a few MSs. Such practice should not be possible and should be discontinued. Moreover, it should be made clear that new hospital landing sites that came into existence after 28 October 2014 do not qualify for a PIS derogation.

EASA proposes that sites that were legitimately granted a PIS derogation under Article 6(6) continue to qualify for a PIS derogation under amended point CAT.POL.H.225.

Such sites belong to the following two categories:

- hospital landing sites that qualify for derogation under existing point CAT.POL.H.225 (i.e. those sites that had been in use before 1 July 2002);
- hospital landing sites that have been operated for the first time between 1 July 2002 and 28 October 2014, and would have qualified for derogation under existing point CAT.POL.H.225 if they had been operated before 1 July 2002; the provisions of Article 6(6) are applicable only to existing sites.

Any new hospital landing site that had not been in use before 28 October 2014 is expected to have been designed taking the Air OPS helicopter performance requirements into consideration. New hospital landing sites do not qualify for any derogation.

In order to achieve this, it is proposed that Article 6(6) remain applicable for 5 years following the publication of the Implementing Regulation amending the Air OPS Regulation. This period should cover the needs created by any sites that were inappropriately approved as PISs through the erroneous implementation of Article 6(6), and whose immediate closure would result in an unacceptable disruption to the provision of health services. This period should be enough for the implementation of any changes needed to render such sites compatible with the needs of the operators and the helicopter performance requirements applicable to them.

The proposals put forward in this Opinion result in three possible situations, taking into account the date on which the approved PIS was established:

Date on which the approved PIS was established	Maximum duration of the PIS approval	Applicable requirements as proposed
Before 1.7.2002	Lalimited duration provided	
Between 1.7.2002 and 28.10.2014	there is no permanent deterioration of the obstacle environment.	Point CAT.POL.H.225 Article 6(6) (applicable until 5 years after the publication)
After 28.10.2014	PIS approval to expire 5 years after the publication of the amending Implementing Regulation	Article 6(6) Conditions determined by the Member States

The result of the proposal is the merger of two different PIS derogation schemes of Article 6(6) and of point CAT.POL.H.225 into a single one, defined in amended point CAT.POL.H.225.



Obstacle management at approved PISs

EASA proposes that no new derogations from the helicopter performance requirements due to new obstacles shall be available under amended point CAT.POL.H.225. If a hospital landing site is currently compatible with the applicable helicopter performance requirements, the obstacle environment around it should be controlled in such a way that helicopter performance requirements are complied with, otherwise the helicopter operations should be discontinued.

The deterioration of the obstacle environment at existing PISs that would require further derogations from the helicopter performance requirements under point CAT.POL.H.225 will also be avoided.

While it is understood that usually national competent authorities (NCAs) have no competence over building restrictions or the growth of trees outside aerodromes, where not covered by safeguarding arrangements, they should monitor the obstacle environment at PISs through the review of operator approvals. The current guidance material already foresees a national directory of PISs where site dimensions and obstacle environment at PISs should be recorded.

NCAs should be capable of monitoring any changes in the obstacle environment at PISs that are subject to derogation from the performance requirements by checking the amendments to the operations manual and ensuring that operators amend their manuals as part of the oversight cycle. In order to support this, this Opinion proposes to introduce an additional requirement for operators to ensure that PIS data in the operations manual remains valid and that any change to this data is notified to the competent authority(ies) responsible for the oversight of the operator and the authority of the State where the PIS is located. This proposal does not preclude NCAs from developing their own obstacle-monitoring activities at hospital sites and heliports.

If the obstacle environment has permanently changed in such a way that exposure time has significantly increased in certain wind conditions, NCAs should reassess and, if necessary, revoke the PIS approval for the particular site. In order to achieve this, this Opinion proposes to introduce a new requirement in Annex II (Part-ARO).

The obstacle-monitoring activities proposed by this Opinion to be performed by NCAs will be required only for the purpose of granting, maintaining, and revoking PIS approvals. The proposal does not prevent authorities from using the results of these activities as well as the directory of PISs for other purposes (such as for aeronautical information services (AIS)), subject to national regulations or requirements.

It would be desirable to reduce the burden associated with the evaluation of performance class 1 (PC1) capability at every hospital site, and the burden associated with obtaining PIS approvals for each individual site. This would be especially useful when an operator is urgently requested to fly outside its usual territory.

The following has been considered:

- The determination of the PC1 capability remains an operator task because it is type specific and may depend on parameters such as cabin configuration and fuel load.
- It is good practice for hospitals and/or MSs to chart the obstacle environment in the vicinity of hospital landing sites. It does help the operator to identify in advance at which sites it can operate in PC1 and at which other sites it can only operate with a prior PIS approval. However, this good practice should not be mandated through operational rules.



- In those MSs where such practice is not in place, it is for the operators to presurvey the obstacle environment at hospital sites in advance, define whether or not PC1 can be complied with, seek PIS approvals as needed, and define site-specific contingency procedures. Operators have to coordinate with the medical needs of their clients in order to know in advance to which hospital sites they may be requested to fly.
- Since a number of hospital sites may remain PISs in the foreseeable future, it was considered important to keep minimum performance margins when operating to these sites. The required performance level of 8 % climb gradient in the first segment reflects ICAO Annex 14 Volume II in Table 4-3 *Dimensions and slopes of obstacle limitations surfaces* for performance class 2 (PC2) and establishes a means to mitigate performance issues. This requirement is retained because it defines a proportionate mass penalty at PISs, thereby applying an additional performance margin to such operations.

Management of other safety elements at approved PISs

It is expected that if the current fleet of HEMS and air ambulance helicopters is capable of operating in accordance with the helicopter performance requirements and without a PIS derogation, operators will not introduce a new helicopter type if this would compromise safety when flying over congested hostile areas.

However, the proposed amendments would not preclude a fleet change where a new generation of larger helicopters may bring such safety and operational benefits that their need for greater site dimensions or increased lateral separation from obstacles could be accepted.

Amendments to Article 6(6)

The only amendment proposed to Article 6(6) is the inclusion of a cut-off date to implement the amendments described above.

Amendments to point CAT.POL.H.225 Helicopter operations to/from a public interest site

Point (a)(1) is proposed to be amended to include a reference to the derogation in Article 6(6), and to ensure that the approvals granted under point CAT.POL.H.225 are limited to what is intended.

Point (c) is proposed to be amended to mandate the inclusion of further elements into the operations manual.

Point (d) is proposed to be added to ensure that the operator's description of the site and its obstacles remains up to date, and the updated description is notified to the relevant authorities.

Amendments to point ARO.OPS.220 Approval of helicopter operations to or from a public interest site

Point (a) is proposed to be added to clarify the responsibilities or the competent authority when receiving an application for the issue of a CAT.POL.H.225 approval.

The proposed point (b) includes the current content of point ARO.OPS.220. It is slightly amended to ensure that the approval is valid for a given type or list of types, in accordance with point CAT.POL.H.225.



The proposed new point (c) complements the amendments made to Article 6(6) and to point CAT.POL.H.225 in order to implement the merger of the two derogation schemes and to phase out certain PISs, as described above.

New point (d) is proposed to be added to describe the management of changes to the obstacle environment by the competent authority, as described in the point on obstacle management above.

New point (e) is proposed to be added to ensure that at sites operated in performance class 1 (PC1), no performance alleviation is granted following a change to the obstacle environment that makes PC1 no longer possible.

2.3.2. Extension of the scope of HEMS

Amendments to the definition of 'HEMS flight'

EASA proposes to amend the definition of 'HEMS flight' to include mountain rescue and other rescue operations that are not considered search and rescue (SAR) operations.

SAR is one of the activities that are excluded from the scope of the Basic Regulation, under its Article 2(3)(a). SAR operations should, therefore, be covered by national rules. However, the boundaries between SAR, as it is defined by ICAO¹², and some other similar operations that could be considered regular HEMS that fall within the scope of the EASA framework are hard to draw. This has led, in some cases, to regulatory gaps or overlaps between the EASA and the national legal frameworks.

During the development process of this Opinion, some stakeholders expressed the concern that the proposal to extend the definition of HEMS flights in this way would create a conflict with the national definitions of SAR in the MSs, and would create an issue with the implementation of Article 2(3)(a) of the Basic Regulation.

EASA's view is that there is no conflict, and that the proposed amendment will help MSs determine how these operations are conducted, which will determine whether the EU or the national legal framework applies. Article 2(3) of the Basic Regulation excludes SAR from the scope of the EASA framework as well as any other 'similar activities and services' that are carried out 'under the control and responsibility of a Member State, undertaken in the public interest by or on behalf of a body vested with the powers of a public authority [...]'. This means that the way MSs choose to carry out certain activities or services determines whether or not they will fall within the scope of the applicable EU regulations. Amending the definition of 'HEMS flights' in the Air OPS Regulation has no impact on the scope of the EASA framework as defined in Article 2(3) of the Basic Regulation: SAR and any other similar activity or service that fulfils the legal criteria in a MS will remain excluded from the scope and covered by national rules. However, for those activities or services that do fall within the scope of the Basic Regulation, either because they do not fulfil the criteria of Article 2(3) or because a MS decides to opt for Article 2(6), the extension of the definition of HEMS flights, together with other proposals in this Opinion, will improve the completeness and robustness of the EASA framework.

It is an institutional service coordinated by rescue centres, mainly for the purpose of providing assistance to aircraft.



¹² ICAO defines SAR operations as follows:

search: an operation, normally coordinated by a rescue coordination centre or rescue sub-centre, using available
personnel and facilities to locate persons in distress.

rescue: an operation to retrieve persons in distress, provide for their initial medical or other needs and deliver them to a place of safety.

Two types of operations have been particularly identified as relevant to the cases where a person is at an imminent or anticipated future health risk posed by the environment:

- operations where the person at risk needs to be rescued or provided with supplies;
- operations where persons that are neither medical professionals nor the person at risk, animals, or equipment other than medical equipment need to be transported to and/or from a HEMS operating site; the supply of avalanche rescue operations on ground is a typical example of such operations.

Not only the nature of the flights performed is similar to that of HEMS flights as per the current definition, but also the risks involved in such operations were assessed to be equivalent to the risks involved in HEMS operations. This is the case when a non-pre-surveyed operating site needs to be used under time pressure. Therefore, it is proposed that such operations fall under the definition of HEMS flights.

HEMS rules and alleviations are well suited to the complexity of mountain operations. In addition, certain considerations are common to mountain operations and HEMS operations (for example, uncertainties regarding the exact position of the person at risk, their medical condition, transportation of support teams of mountain rescuers, etc). Therefore, it makes sense that common rules apply — not to mention that for safety reasons it is preferable to operate different phases of the same operation under the same regulatory framework.

2.3.3. HEMS operations using cargo hooks and sling

Overview

First of all, it needs to be clarified that the proposals made in this Opinion in relation to HEMS operations using cargo hooks and sling will only apply to HEMS operations conducted in accordance with the Air OPS Regulation. For operations, activities or services that fall within the scope of Article 2(3) of the Basic Regulation, the proposals made in this Opinion will not apply since those operations, activities or services will be covered by national rules, as already explained in Section 2.3.2.

A number of MSs already allow operations that require the use of the cargo hook and the sling under a HEMS approval, even though the current rules do not address this type of operation. In order to allow such operations, those MSs have issued AltMoC setting a number of conditions for such operations and referring to Section 2 of Subpart E of Part-SPO *Human external cargo operations (HEC)*. In order to address this issue, EASA proposes to include this approach in the HEMS requirements.

EASA proposes to accept the use of the cargo hook and the sling as an equivalent method to the use of the hoist to conduct HEMS operations at locations where landing is not a safe option. However, the risks associated to hoist and sling load operations are different; therefore, it is proposed that HEMS sling load operations are subject to risk assessments and specific standard operating procedures.

The decision to use the hoist or the sling should be left to the operator or the health authority that issues HEMS tenders. Decision makers may consider that the use of the helicopter hoist allows the operator to conduct the operation more efficiently, as the helicopter does not always need to land at an intermediate landing site.



Definition of 'HEMS HEC operations'

This Opinion proposes a new definition for 'HEMS HEC operations', which is used in new point SPA.HEMS.105 *HEMS HEC operations*.

HEC stands for 'human external cargo' and includes the carriage of humans outside the helicopter, either with the helicopter hoist or with the cargo sling. HEC is already used with this meaning in Annex VIII (Part-SPO) as well as in CS-27 and CS-29¹³.

Amendments to the definition of 'technical crew member'

The definition is proposed to be extended to include the HEMS sling technical crew member.

Amendments to the definition of 'HEMS operating site'

The current definition already includes hoisting sites. The amendments proposed extend the definition to sites used for operations with the cargo sling.

New point SPA.HEMS.105 HEMS HEC operations

The proposed point (a) of point SPA.HEMS.105 introduces HEMS HEC operations and confirms that if the hoist is used, the requirements of Subpart I *HELICOPTER HOIST OPERATIONS (SPA.HHO)* remain applicable without any changes.

The proposed point (b) of point SPA.HEMS.105 defines the conditions for HEMS HEC operations with the cargo sling regarding:

- the helicopter equipment and the equipment to be used by the sling technical crew member;
- the crew composition as well as the training, checking, experience and recency of the crew;
- the need for the operator to perform a risk assessment and develop specific operating procedures.

The proposed rules require the use of an approved double cargo hook, or a cargo hook system approved under a relevant airworthiness standard, considering that the weaknesses of single cargo hook designs cannot be mitigated by uncertified belly band systems.

2.3.4. Oxygen requirements for mountain operations at high altitudes

Overview

Helicopters are unpressurised and are usually not equipped with a fixed oxygen installation. At high altitudes, oxygen supply is required by the Air OPS Regulation. Unlike aeroplanes, HEMS helicopters do not need to fly at high altitudes in the cruise phase. They only fly at high altitudes temporarily for the purpose of landing, taking off, hoisting and sling load operations in the mountains. If the maximum flight altitude and the time spent at high altitudes are not excessive, then the safety benefit of flying with oxygen is very much reduced.

¹³ <u>https://www.easa.europa.eu/document-library/certification-specifications/group/cs-27-small-rotorcraft#group-table</u> <u>https://www.easa.europa.eu/document-library/certification-specifications/group/cs-29-large-rotorcraft#group-table</u>



The current requirements on oxygen for helicopter commercial air transport (CAT) and HEMS operations are based on aeroplane rules and are too restrictive for helicopter operations in mountainous areas.

Therefore, this Opinion proposes to amend points (c) and (d) of point SPA.HEMS.110 to align the oxygen requirements for complex helicopters of the CAT and the HEMS rules with the requirements for non-complex helicopter oxygen requirements and to enable high-altitude HEMS operations without oxygen on the condition that sufficient mitigation measures are in place.

New point (c) of point SPA.HEMS.110 Equipment requirements for HEMS operations

HEMS operations in mountainous areas do not vary significantly with the classification of the helicopter as 'complex' or 'non-complex'. Therefore, EASA proposes that HEMS operations with complex helicopters with a maximum operating passenger seating configuration (MOPSC) of nine or less may be conducted according to the oxygen requirements that are in place for non-complex helicopters.

New point (d) of point SPA.HEMS.110 Equipment requirements for HEMS operations

The current requirements for specialised operations of Annex VIII (Part-SPO) include mitigation measures for high-altitude flights between 13 000 and 16 000 ft for a flight duration of up to 10 minutes.

With regard to CAT HEMS operations, this Opinion proposes a higher safety standard, taking into consideration the characteristics of HEMS missions. It is believed that 10 minutes are not enough to cover the duration of a HEMS mission at high altitudes; therefore, for HEMS operations, the time duration without oxygen above 10 000 ft is proposed to be extended to 30 minutes. Regarding the maximum altitude, it is proposed to be 16 000 ft. Possible ways on how to comply with this will be provided by an AMC.

In addition, new mitigation measures are proposed to further reduce the risk of hypoxia compared to specialised operations':

- The alleviation is restricted to daytime operations only, considering the effects of oxygen deprivation on crew members' night vision.
- All crew members shall be trained in hypoxia in order to know their own limitations, their individual body response and early signs of hypoxia, which might change with age.
- All crew members shall be trained in the recognition of early signs of hypoxia in other crew members.
- All crew members shall be free from any individual medical condition that could lead to hypoxia.

The proposals deviate from the CAT requirements in a controlled manner. The alleviation is proposed to be valid for HEMS only because the justification and assumptions on the mission profile are valid only for HEMS operations.



2.3.5. Helicopter performance for mountain operations

Amendments to point (a) of point SPA.HEMS.125 Performance requirements for HEMS operations

This Opinion proposes substantial amendments to point (a) of point SPA.HEMS.125 to improve the regulation of helicopter performance. Under the proposed rules, helicopter operations under performance class 3 (PC3) over a hostile environment shall be possible in three different cases:

- operations to/from a HEMS operating site located above 7 000 ft, using a helicopter certified under Category A (point SPA.HEMS.125(a)(1));
- operations that do not require the transportation of medical personnel, medical supplies, or ill or injured persons, using a helicopter certified under Category A or that fulfils some specific conditions (point SPA.HEMS.125(a)(2));
- operations to/from a HEMS operating site located above 8 000 ft, under certain conditions (point SPA.HEMS.125(a)(3)).

Helicopter performance requirements for mountain operations at high altitudes — with helicopters certified under Category A

The performance capability of the current fleets of twin-engine helicopters that are used in HEMS operations was reassessed following the comments received on NPA 2018-04. Some helicopter types are capable of operating in PC2, no higher than 7 000 ft altitude, on a summer afternoon (ISA + 15) with a HEMS configuration and payload.

Above this altitude, there are limited phases of flight at HEMS operating sites (during take-off, landing, hovering disembarkation, rescue hoist or sling operations) where it is not always possible for twinengine helicopters to comply with PC1 or PC2 requirements. In this case, the HEMS performance requirements cannot be met and patients' lives still need to be saved.

It is, therefore, proposed to adjust the performance requirements to the reality of high-altitude operations, and enable the use of Category A certified helicopters in PC3 above 7 000 ft for HEMS operations, including HEMS operations at night.

Helicopter performance requirements for non-medical rescue — with helicopters not certified under Category A

Non-medical rescue currently takes place either under Annex IV (Part-CAT) or under national regulations. In both cases, single-engined helicopters may be used.

EASA proposes that non-medical rescue missions may continue to take place with single-engined helicopters under the new point SPA.HEMS.125(a)(2). A CAT.POL.H.420 approval will be needed, and a reference to this point is made, as well as to a minimum altitude of 3 000 ft. This is consistent with the fact that mountainous areas are acceptable for a CAT.POL.H.420 approval, as specifically mentioned in AMC1 CAT.POL.H.420.

From a practical perspective, it is expected that below 3 000 ft, Category A certified helicopters will be available for such non-medical rescue missions.



Helicopter performance requirements for operations that meet the current definition of HEMS — with helicopters not certified under Category A

Above 8 000 ft, most of the current HEMS fleets do not meet PC1 or PC2 criteria and, therefore, operate in PC3, despite Category A certification.

EASA proposes that HEMS may take place with single-engined helicopters above 8 000 ft for the following reasons:

- the safety benefits of a Category A certified helicopter are not that substantial at such high altitudes;
- the demand for HEMS may be very high at certain periods of the year and very low at other times of the year;
- regions with high mountains are more likely to be structurally and economically weaker; they
 may struggle to provide HEMS that match the peak demand of the touristic season with
 Category A certified helicopters.

This proposal effectively transposes the concepts that supported TGL 43.

Since PC3 with a twin-engined helicopter certified as Category A or equivalent is not the same as PC3 with a single-engined helicopter or a helicopter that is not Category A certified, the proposed altitude thresholds are different.

Mitigation measures for HEMS operations in hostile areas — with helicopters not certified under Category A

HEMS operations, being commercial air transport operations, are subject to the requirements of Section 2 *Helicopters* of Subpart C *AIRCRAFT PERFORMANCE AND OPERATING LIMITATIONS* of Annex IV (Part-CAT). The following limitations apply to helicopters that are not certified under Category A:

- only PC3 is available;
- flights are limited to VMC by day;
- flights cannot be operated in congested hostile areas;
- flights may only be operated in non-congested hostile areas with a special approval.

The HEMS requirements also apply and, therefore, there is no alleviation regarding helicopter equipment and crew composition. In particular, cabin layouts where the stretcher installation precludes the technical crew member from seating in the forward-facing front seat are no longer allowed, as explained in Section 2.3.9. This also applies to helicopters not certified as Category A.

Many helicopters in current fleets (single-engined and multi-engined alike) do not comply with the crash-resistant fuel system (CRFS) and crash-resistant seat and structure (CRSS) design specifications adopted in 1989¹⁴ and 1994¹⁵ respectively. Approximately 67 % of the current helicopter fleets meets CRFS design specifications, whereas the implementation rate for CRSS designs is much lower. The mandatory retroactive application of the applicable standards and new fit for helicopters being

¹⁵ FAR 27/29 amendments of 02/11/1994 CRFS, and JAR 27/29 change -0.



¹⁴ FAR 27/29 amendments of 13/12/1989 introducing CRSS.

produced under old designs are considered in the context of RMT.0710 *Improvement in the survivability of rotorcraft occupants in the event of a crash*¹⁶. The combination of increased exposure to an engine failure due to the lack of Category A certification, together with the lack of essential features that would help occupants survive an accident may result in casualties and should be avoided. Pending the outcome and conclusions of RMT.0710, it was decided to consider the conclusions of the final analysis report of the Rotorcraft Occupant Protection Working Group (ROPWG)¹⁷, recommending that the retroactive application of seat and fuel bladder crashworthiness standards should become mandatory for helicopters not certified as Category A and involved in HEMS operations.

Amendments to points SPA.HEMS.125(c)(3) *Performance requirements for HEMS operations* and CAT.POL.H.420 *Helicopter operations over a hostile environment located outside a congested area*

Resulting amendments are proposed to points SPA.HEMS.125(c)(3)¹⁸ and CAT.POL.H.420 to reflect the amendments to point SPA.HEMS.125(a), as described above.

2.3.6. Night vision imaging systems (NVISs)

Amendments to point SPA.HEMS.100 Helicopter emergency medical service (HEMS) operations

EASA proposes to add point (c) to point SPA.HEMS.100 to mandate NVISs at night for HEMS operations to non-pre-surveyed sites outside well-lit urban areas.

NVISs, when properly used by appropriately trained crew members in a crew concept, is considered to greatly assist in maintaining situational awareness and in managing risks during night operations. HEMS without NVISs should be restricted to pre-surveyed operating sites and to well-lit urban areas.

Note: 'Crew concept' is discussed in Section 2.3.9 Crew composition.

Amendments to point SPA.NVIS.110 Equipment requirements for NVIS operations

Point (e) of point SPA.NVIS.110 is prescriptive and creates obstacles to the upgrade of the night-vision goggles (NVG) available to an operator, unless it has the financial means to upgrade all its NVG at the same time.

There are many cases where different NVG have been designed to meet given specifications for a given tender. Such NVG may be exchangeable without a perceivable change in the visual acuity.

EASA proposes to replace the prescriptive requirement that all required NVG on an NVIS flight are of the same type, generation and model with a performance-based one: all required NVG shall have the same filter class and shall provide for equivalent visual acuity. Means of compliance to ensure the equivalence of visual acuity provided by the required NVG available on board will be developed in the related AMC.

The requirement that all required NVGs shall be of the same type is proposed to be removed because only two different types of NVG exist:

¹⁸ Currently, point SPA.HEMS.125(b)(3).



¹⁶ <u>https://www.easa.europa.eu/document-library/terms-of-reference-and-group-compositions/tor-rmt0710</u>

¹⁷ Rotorcraft Occupant Protection Working Group (ROPWG) final analysis report to the Aviation Rulemaking Advisory Committee (ARAC) of 27 September 2018

⁽https://www.faa.gov/regulations_policies/rulemaking/committees/documents/media/ROPWG%20Task%206%20Final %20Report%20Revised%202018-09-27.pdf).

- Type I lighting components are those that are compatible with a direct view image NVIS;
- Type II lighting components are those that are compatible with a projected image NVIS.

Currently, only Type I NVG are used in civil aviation (direct view display equipment). A Type II NVG, if it were used in civil aviation, would most probably be uncertifiable as it wouldn't allow a full view of the cockpit instruments underneath the goggles.

Regarding filters, two classes may be certified for civil aviation purposes:

- Class B filter class (with or without HUD modification);
- UK 645 filter class.

The Class B filter class with HUD modification is extremely similar to the Class B filter class. The HUD modification is expected to be very rare in civil aviation operations.

A NVIS-compatible helicopter may be compatible with NVG of both filter classes. However, the NVG will not be compatible with each other as they will filter out different external light. The filter class of the NVG used is expected to be known to the operator.

EASA plans to issue AMC related to the concept of 'equivalent visual acuity'.

2.3.7. Simplification of the HEMS VFR operating minima

Amendments to point SPA.HEMS.120 HEMS operating minima

EASA proposes that the VFR operating minima currently included at regulation level be moved to AMC level for consistency with the IFR operating minima.

This proposed amendment will have no practical impact since it will not affect the provisions of Article 4(3) of Regulation (EU) No 923/2012¹⁹, containing the standardised European rules of the air (SERA), which ensure that helicopter operating minima approved under a Part-SPA approval supersede the VFR operating minima provided in point SERA.5001 *VMC visibility and distance from cloud minima* of the Annex to that Regulation.

It is expected that in the future, technologies such as EFVS may evolve to the point where they can be credited towards reduced VFR minima.

The current requirements of point SPA.HEMS.130(e)(1)(ii) are proposed to be reworded and moved to point SPA.HEMS.120(c) to clarify that the reduced HEMS VFR operating minima apply only in the case of some specific crew configurations (two pilots, or one pilot and one trained technical crew member), ensuring a trained crew of two in the cockpit. The proposal also clarifies that only the ceiling, visibility and distance to the obstacle criteria may be reduced.

¹⁹ Commission implementing Regulation (EU) No 923/2012 of 26 September 2012 laying down the common rules of the air and operational provisions regarding services and procedures in air navigation and amending Implementing Regulation (EU) No 1035/2011 and Regulations (EC) No 1265/2007, (EC) No 1794/2006, (EC) No 730/2006, (EC) No 1033/2006 and (EU) No 255/2010 (OJ L 281, 13.10.2012, p. 1) (<u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0923&qid=1660833722416</u>).



Amendments to point CAT.POL.H.215(a)(3) *En-route — critical engine inoperative*

Under VFR in the en-route phase, the horizontal distances to obstacles are proposed to be defined as per the rules of the air irrespective of engine failure.

Amendments to point SPA.PINS-VFR.100 *Helicopter point-in-space* (*PinS*) approaches and departures with reduced VFR minima

Point (a) of point SPA.PINS-VFR.100 is proposed to be amended to exclude HEMS operations from its scope.

Point SPA.PINS-VFR.100, introduced into the Air OPS Regulation by Implementing Regulation (EU) 2021/2237²⁰, was only expected to be applicable to HEMS operations as a transitional measure until the HEMS VFR minima would be amended.

Under the proposed requirements of point SPA.HEMS.120, if reduced HEMS minima are needed, then the crew should be two pilots or one pilot and one trained technical crew member (TCM) seated in a forward-facing front seat.

The cases where HEMS operations are conducted single-pilot and the TCM is not in a forward-facing front seat are expected to be rare. In such circumstances, standard VFR minima will apply.

2.3.8. Obstacle awareness and avoidance

Addition of point (b) in point SPA.HEMS.110 Equipment requirements for HEMS operations

EASA proposes to add point (b) in point SPA.HEMS.110 to improve the situational awareness of pilots regarding the obstacle environment.

Taking into account that rulemaking task RMT.0708 'Controlled flight into terrain (CFIT) prevention with helicopter terrain avoidance warning systems (HTAWS)'²¹ will reconsider the requirements for HTAWS, moving maps and other situational awareness devices that will be available in the near future, it has been decided not to require certified equipment and accept an electronic flight bag (EFB) application instead.

The proposed requirement is, therefore, limited to VFR, under which Type B EFB applications with own-ship position may be used. With regard to the definition of an EFB Type B application, in the context of point SPA.HEMS.110(b), the EFB Type B application may be used because it provides the required function without replacing or duplicating an existing or required one.

The need for increased situational awareness under IFR will be reassessed under RMT.0708. HTAWS also provides terrain proximity warnings, and some models provide obstacle proximity warnings, in addition to the above-mentioned features. RMT.0708 will assess whether such warnings may play a decisive role in terrain and obstacle avoidance. Considering the amount of nuisance warnings being generated by the current generation of HTAWS, any significant safety improvement may require an amended HTAWS standard.

²¹ https://www.easa.europa.eu/document-library/terms-of-reference-and-group-compositions/tor-rmt0708



²⁰ Commission Implementing Regulation (EU) 2021/2237 of 15 December 2021 amending Regulation (EU) No 965/2012 as regards the requirements for all-weather operations and for flight crew training and checking (OJ L 450, 16.12.2021, p. 21) (<u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R2237&qid=1660833811679</u>).

Amendments to point (c)(4) of point SPA.HEMS.125 Performance requirements for HEMS operations

EASA proposes to reword point (c)(4) of point SPA.HEMS.125²² to provide further clarity.

2.3.9. Crew composition

Amendments to point (e) of point SPA.HEMS.130 Crew requirements

It is proposed to amend point (e) of SPA.HEMS.130 to clarify the minimum crew, the cases where a HEMS flight may take place with one pilot and no technical crew member, and the use of HEMS operating sites with one pilot and no technical crew member.

If the installation of a stretcher precludes the technical crew member from occupying the front seat, HEMS will no longer be possible. This possibility had been used to maintain legacy helicopters in service, but this is no longer considered compatible with the desired safety standards.

The impact of the crew composition on the HEMS operating minima is moved to point SPA.HEMS.120, as already explained in Section 2.3.7 above.

Current point SPA.HEMS.130 restricts the possibility of a crew composition of one pilot and one technical crew member by night to operations in specific geographical areas. Such areas had been defined at national level as 'the whole country', which meant that the safety benefit achieved was negligible, especially when taking into account the existence of other requirements, such as those of point CAT.OP.MPA.105 on the selection of sites, as well as Part C of the operator manuals. It is, therefore, proposed to remove this restriction.

The current considerations to be taken into account for single-pilot operations with technical crew members at night in point SPA.HEMS.130(e)(2)(ii) are considered to be valid also for multi-pilot operations, both by day and by night. EASA proposes the following changes to improve clarity and legal certainty in respect of these conditions:

- The reference to flight following system (current point SPA.HEMS.130(e)(2)(ii)(B)) is moved to new point SPA.HEMS.151 (see further explanations under Section 2.4.14 below).
- The reference to the HEMS minimum equipment list (current point SPA.HEMS.130(e)(2)(ii)(D)) is included in new point (i) to point SPA.HEMS.110.
- The reference to 'continuity of a crew concept' (current point SPA.HEMS.130(e)(2)(ii)(E)) is further clarified and reinforced, and included as new point SPA.HEMS.130(e)(3);

In the context of HEMS, the operator's crew concept is based on either a single-pilot crew with technical crew member or a multi-pilot concept. It includes standard operating procedures and training for the basic crew configuration. It may include deviations to the basic crew, in which case mitigation measures are put in place to ensure continuity.

 Other elements referenced should be part of the HEMS risk assessment required under point SPA.HEMS.140, and will be moved to AMC level.

²² Currently point SPA.HEMS.125(b)(4).



2.3.10. Seating of the HEMS technical crew member (TCM)

Amendments to point (e)(1) of point SPA.HEMS.130 Crew requirements

It is recognised that the HEMS technical crew member should be sitting at the front in order to assist the pilot to the best of their ability. However, in the following cases, this should not be a requirement and EASA proposes to simplify the applicable requirements:

- For HEMS operations with the use of the cargo hook and sling, the technical crew member is no longer needed in the front seat after the in-flight reconnaissance of the HEMS operating site and landing at a nearby intermediate landing site. However, help is needed to deal with the sling and supervise the operation from inside or under the helicopter.
- For HEMS HHO operations, when it is reasonably likely that the hoist is going to be used, the HEMS HHO technical crew member may assist the pilot and check for obstacles from the HHO technical crew member's position in the cabin, and act as the HHO operator.
- After landing at the HEMS operating site, the technical crew member may remain on the ground and assist the medical team while the commander performs a refuelling flight.
- After landing at the HEMS operating site, the technical crew member may remain on the ground to marshal the helicopter for repositioning purposes.

It is, therefore, proposed to use a more performance-based approach as regards the seating of the technical crew member reflected in the text of new point SPA.HEMS.130(e)(1)(iii).

2.3.11. Enabling helicopter operations under instrument flight rules (IFR)

Amendments to points (a)(1), (a)(2) and (c) of point CAT.POL.H.215 *En-route* — *critical engine inoperative*

Conventional routes are designed to provide a 5-NM navigation accuracy or better, but helicopter routes are likely to be designed for RNAV 1 or RNP 0.3 capability. Helicopters are likely to fly close to the minimum altitudes due to the lack of certification for icing conditions. On such routes, it is neither practical nor useful to climb in case of an engine failure, based on an obstacle that is off route and will never be overflown.

In case of an engine failure, point CAT.POL.H.215 defines the obstacles within a certain horizontal distance of the flight path, which should be cleared with sufficient vertical obstacle margin. The current horizontal distance is a defined value based on the 5-NM accuracy of conventional navigation aids, irrespective of the PBN capability of the helicopter. The navigation performance is not affected by an engine failure. EASA proposes to base this horizontal distance on the navigation performance of the helicopter, and for this purpose proposes to amend point CAT.POL.H.215(a)(1) and (a)(2), and to delete existing point (c).

2.3.12. Mitigating the risk of a loss of a visual reference during flight — including pilot training and experience

It is proposed to mitigate the risk of a loss of a visual reference during the flight, considering that most HEMS operations are expected to remain under VFR. The loss of a visual reference during a VFR flight



remains one of the major contributors to fatal accidents in HEMS, which calls for several amendments to the existing requirements.

Addition of point (e) in point SPA.HEMS.110 *Equipment requirements for HEMS operations*, and of Article 3(2)

It is proposed to introduce point (e) in point SPA.HEMS.110 to require all helicopters to be equipped with a basic stability augmentation system or autopilot for single-pilot operations at night.

Higher standards of automation for single-pilot operations at night are desirable but may not be achievable at reasonable costs, whereas the proposal would be sufficiently helpful to the single pilot without excessive disruption to the current HEMS fleets. It is nonetheless expected that some operators will have to either retrofit their helicopters or undertake a fleet change. A sufficient time frame of 5 years following the date of publication of the amending regulation is, therefore, necessary for the successful implementation of this proposed new requirement²³. This deferred applicability is proposed in draft Article 3(2) of the draft implementing act.

Autopilots with altitude and heading hold capability are proposed for newly produced helicopters only. All helicopters manufactured for the HEMS market have such autopilots available, at least as an option.

Amendments to point (b) of point SPA.HEMS.130 Crew requirements

It is proposed to remove the experience requirements currently included in point SPA.HEMS.130(b) and move them to AMC level. This proposed amendment will have no impact since point SPA.HEMS.130(a) already refers to experience requirements in a way that provides for sufficient legal certainty. It is proposed to maintain point (b) with a mention that it is intentionally left blank, to avoid renumbering the remaining points, which would create unnecessary administrative burden and cross-referencing inconsistencies.

Amendments to point (d) of point SPA.HEMS.130 Crew requirements

EASA proposes to amend point (d) of point SPA.HEMS.130 to make it more performance based and to clarify that an instrument rating is not always necessary for HEMS operations.

The proposed new text refers to 'training to proficiency' instead of to 'recency', and introduces the training objective: the trainee needs to have the skills to escape unintended IMC conditions. The validity period of the training remains 6 months. The minimum duration of the training, as well as the manoeuvres to be performed, will be defined at AMC level. As the proposal requires the pilot to be trained to proficiency, the duration of the training will be at least the time needed for each pilot to achieve proficiency.

The title is changed to 'Flight training with sole reference to instruments'.

²³ In early 2018, at the time when NPA 2018-04 was drafted, a deferred implementation period of 10 years had been proposed. However, with the time that has elapsed since then, and taking into account that the adoption of an amending regulation following this Opinion will most likely not take place before 2023, the date of applicability should not be set before 2028, assuming a deferred implementation period of 5 years.



Amendments to point (f) of point SPA.HEMS.130 Crew requirements

It is proposed to amend point (f) of point SPA.HEMS.130 to improve clarity and introduce validity periods for the HEMS specific part of the checking, which were previously implicitly referring to the equivalent validity periods of Subparts ORO.FC and ORO.TC.

For consistency with Subpart ORO.FC, the validity periods of the HEMS checking are introduced at implementing act level. An alleviation to the requirement to implement proficiency and line checks is not yet proposed in point SPA.HEMS.130(f) nor in Subpart ORO.TC, as it currently exists in points ORO.FC.231 *Evidence-based training* and ORO.FC.232 *EBT programme assessment and training topics*. The introduction of such an alleviation at implementing act level would require the development of related AMC material, which can only be developed in the future based on a helicopter EBT data report and training programme. In order to introduce EBT, point SPA.HEMS.130(f) will, therefore, need to be further amended at a later stage.

2.3.13. HEMS crew member training and checking

The HEMS technical crew member is considered essential to the safety of single-pilot operations. The applicable requirements put emphasis on the continuity of the crew concept for which the means of compliance for training and checking will be further developed by means of AMC.

Feedback from stakeholders shows that the HEMS technical crew member training and checking varies significantly among operators. Operators that provide the most advanced training programmes use line flying under supervision, for which amendments to Subpart ORO.TC need to be introduced. Training is essential considering the variety of backgrounds of the HEMS crew members, some of which have no aviation knowledge when recruited.

Amendments to point ORO.TC.130 Familiarisation flights

The proposed amendment introduces two options for the training of technical crew members. Either aircraft/FSTD training (e.g. line flying under supervision) is included as part of the operator conversion training, or familiarisation flights are required. The last part of the current sentence is proposed to be replaced by point (d) of point ORO.TC.110.

Amendments to point (b) of point ORO.TC.110 Training and checking

EASA proposes to amend point (b) of point ORO.TC.110 following the amendments proposed to point ORO.TC.130 and take into account that familiarisation flights are no longer always required. The new proposed text also takes over the content that is proposed to be deleted from point ORO.TC.130, by requiring that technical crew members take a proficiency check before being part of the minimum required crew and, therefore, either:

- immediately after the conversion course, if familiarisation flights are not required; or
- immediately after the familiarisation flights if they are required.

The amendments proposed to point (b) together with the proposed new point (e) ensure that the annual proficiency check takes place every 12 calendar months but does not need to follow the annual recurrent training.



Explanatory note to point (f) of point SPA.HEMS.130 Crew requirements

The proposal is described in Section 2.3.12.

2.3.14. Other minor adjustments to the HEMS requirements

Addition of points (f) and (g) to point SPA.HEMS.110 Equipment requirements for HEMS operations

The proposed new points (f) and (g) require all helicopters involved in HEMS operations to be equipped with an attitude indicator, a stabilised heading indicator and a radio altimeter for cases where the HEMS operation is by day only. Such equipment is needed to fly with reduced HEMS VFR operating minima.

It is proposed to clarify that they are explicitly mandatory for day VFR HEMS operations.

Addition of point (h) in point SPA.HEMS.110 Equipment requirements for HEMS operations

The proposed addition of point (h) clarifies which instruments and equipment are required to be approved in accordance with the applicable airworthiness requirements.

Amendments to point SPA.HEMS.140 Information and documentation

The proposed amendments to point SPA.HEMS.140:

- introduce the operator's HEMS risk assessment with a revised wording, moving certain elements of the risk assessment to AMC level;
- create a link between the risk assessment and the resulting mitigation measures and HEMS operating procedures, and the operations manual;
- introduce a commander's risk assessment of the risks associated with a specific mission (the tactical risk assessment);
- introduce an alleviation to point CAT.OP.MPA.175, considering that it is not possible to timely prepare an operational flight plan in the case of non-pre-surveyed sites.

Insertion of point SPA.HEMS.151 Aircraft tracking system

Currently, point SPA.HEMS.130 requires the operator to consider the use of flight following systems. It is proposed to delete this requirement from point SPA.HEMS.130 (see also explanations under Section 2.3.9 above) and replace it by a dedicated point SPA.HEMS.151 requiring an aircraft tracking system. Aircraft tracking systems are defined in Annex I (Definitions).

The new requirement ensures that the helicopter may be tracked throughout the HEMS mission. The related means of compliance will be provided at AMC level.

Amendments to the definition of 'HEMS operating base'

The definition of the HEMS operating base is proposed to be amended to include multi-pilot operations with no HEMS crew members.

Note: The HEMS crew member is defined as a 'technical crew member' (TCM).



2.3.15. Summary of the proposed transitional measures

EASA proposes a 1-year deferral in the applicability of the proposals put forward in this Opinion (see draft Article 2(1) of the draft implementing act). In addition, EASA proposes transitional periods longer than 1 year in some cases.

EASA proposes a number of additional systems to be fitted to current HEMS helicopter fleets. In some cases, the implementation of the requirement itself will require some time. In other cases, the financial implications are such that operators may not be able to invest in the new systems until their contracts are renewed.

Therefore, EASA proposes specific transitional periods for the following cases:

- Public interest sites: The amendment to Article 6(6) proposes to phase out the derogation provided therein as well as any approved public interest site that had been established as such after October 2014 within 5 years after the date of publication of the amending regulation. Refer also to the explanations in Section 2.3.1. above.
- NVISs: The proposed Article 2(2)(a) defers the applicability of the new requirement in point SPA.HEMS.100(c) to 3 years after the date of publication of the amending regulation. Refer also to the explanations in Section 2.3.6 above.
- Autopilots and stabilisation systems: The proposed Article 2(2)(b) defers the applicability of the new requirement in point SPA.HEMS.110(e) to 5 years after the date of publication of the amending regulation. Refer also to the explanations in Section 2.3.12 above.

2.3.16. Helicopter operations other than HEMS: commercial air transport (CAT) operations

Helicopter CAT operations are affected by the following amendments proposed in this Opinion:

Night vision imaging systems (NVISs)

The proposed amendments to point SPA.NVIS.110(e) replace the prescriptive requirement with a performance-based one, introducing more flexibility. See further explanations in Section 2.3.6 above.

Public interest sites

Air ambulance operations may take place at PISs under the CAT regulations without a HEMS approval. CAT air ambulance operations are affected by the amendments to Article 6(6) and to points CAT.POL.H.225 and ARO.OPS.220. See further explanations in Section 2.3.1 above.

 Enabling helicopter operations under instrument flight rules (IFR) and Simplification of the HEMS VFR operating minima

The proposed amendments to point CAT.POL.H.215 replace the prescriptive requirement with a performance-based one, introducing more flexibility. It affects all CAT operations and is complementary to the amendments previously introduced by RMT.0379 *All-weather operations*²⁴. See further explanations in Sections 2.3.7 and 2.3.11 above.

HEMS crew member training and checking

²⁴ https://www.easa.europa.eu/document-library/terms-of-reference-and-group-compositions/tor-concept-paper-rmt0379



The proposed amendments to points ORO.TC.130 and ORO.TC.110 affect CAT operators involved in NVIS operations or helicopter hoist operations (HHOs) by introducing additional flexibility. See further explanations in Section 2.3.1 above.

2.3.17. Helicopter operations other than HEMS: SPO and NCO operations

Amendments to points SPO.IDE.H.190 *Emergency locator transmitter (ELT)* and NCO.IDE.H.170 *Emergency locator transmitter (ELT)*

The proposal is to amend points SPO.IDE.H.190 and NCO.IDE.H.170 to clarify their intent and achieve consistency.

The current points SPO.IDE.H.190(b) and NCO.IDE.H.170(b) prescriptively require an ELT(S) or a PLB for helicopters with a MOPSC of 6 or less, to be carried by crew members, task specialists or passengers. This means that automatic ELTs do not meet the above requirements, despite meeting all PLB specifications. This was not the intent of the legislator. The proposal is to clarify that having an automatic ELT is sufficient.

For aeroplanes, points SPO.IDE.A.190 and NCO.IDE.A.170 allow the ELT(S) or the PLB to be an alternative to the automatic ELT.

For CAT and non-commercial operations with complex helicopters, points CAT.IDE.H.280 and NCC.IDE.H.215 prescriptively require an automatic ELT. Helicopters are versatile and it is expected that they will be operated in more than one type of operation. If the helicopter equipment complies with the CAT regulations on ELT (and with NCC, if the helicopter is complex), SPO and NCO operations should also be allowed with the same helicopter equipment.

2.3.18. Helicopter operations other than HEMS: point-in-space (PinS) approaches with instructions to 'proceed VFR'

Amendments to Appendix II to Annex II (Part-ARO)

Subpart N *HELICOPTER POINT-IN-SPACE APPROACHES AND DEPARTURES WITH REDUCED VFR MINIMA* (*PINS-VFR*) (*SPA.PINS-VFR*), introduced into the Air OPS Regulation by Implementing Regulation (EU) 2021/2237²⁵, established a new specific approval without explicitly mentioning it in Appendix II to Part-ARO (the 'operations specifications' of the CAT operator). EASA proposes to introduce this specific approval in Appendix II to Annex II (Part-ARO) for consistency.

2.4. What are the stakeholders' views — outcome of the consultation

512 comments were received on NPA 2018-04. The comments of non-editorial nature were reviewed with the help of a group of experts from helicopter operators, helicopter manufacturers, national aviation authorities (NAAs), and pilot unions.

174 comments were submitted by NAAs, 265 comments by helicopter operators and their associations,

²⁵ Commission Implementing Regulation (EU) 2021/2237 of 15 December 2021 amending Regulation (EU) No 965/2012 as regards the requirements for all-weather operations and for flight crew training and checking (OJ L 450, 16.12.2021, p. 21) (<u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R2237&qid=1660833811679</u>).



10 comments by individuals, 1 comment by an air navigation service provider (ANSP), 21 comments by pilot unions, and 41 comments by manufacturers.

The vast majority of the comments received on NPA 2018-04 addressed topics that had already been discussed and thought out during the preparation of the NPA. Most of the comments were constructive and helped fine-tune the draft regulatory proposal.

For the individual responses to the comments received on NPA 2018-04 and more detailed conclusions, please consult Comment-Response Document (CRD) 2018-04 *Helicopter emergency medical services performance and public interest sites*²⁶.

The main change made to the initial proposal following the comments received is in relation to helicopter performance in mountain operations, and is described in Section 2.3.5. Another important change made following the comments received is the introduction of a requirement in pointAddition of point (e) in point SPA.HEMS.110 *Equipment requirements for HEMS operations*, for autopilots instead of stability augmentation systems for new-built helicopters operated in HEMS by night in a single-pilot crew configuration, as described in Section 2.3.12.

The impact of the changes described above is assessed in Section 2.5.

Comments received during the discussion of the final resulting draft Opinion with the MAB showed that some Member States still have reservations on the proposed helicopter performance requirements at high altitude. It was concluded that, given the complexity of the topic, a clear consensus could not be achieved at technical level, and that the discussions would need to continue at EASA Committee level. Some Member States called for more harmonisation in relation to search and rescue (SAR) activities, which are excluded from the scope of the EASA Basic Regulation.

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

Impact assessment

The main impact assessment (IA) may be found in Section 4 of NPA 2018-04²⁷. The assessment is still up to date. Following the changes to the draft regulatory material introduced after the NPA consultation, the IA is complemented as shown below. The overall conclusion of the IA remains unchanged.

Stability augmentation systems

The publication of the Opinion has been delayed by almost 4 years compared to the schedule that was indicated at the time of the publication of the NPA in 2018. EASA proposes that the requirement in point SPA.HEMS.110(e) become applicable 5 years after the date of publication of the amending regulation. The number of helicopters that are not yet equipped with stability augmentation systems and that will not yet be obsolete at that time is reduced compared to the scenario assessed in the NPA. Both the economic cost and the safety benefits are reduced but the overall impact remains positive.

The following data supporting the above conclusions was collected:

²⁷ https://www.easa.europa.eu/downloads/47107/en



TE.RPRO.00036-009 © European Union Aviation Safety Agency. All rights reserved. ISO 9001 certified. Proprietary document. Copies are not controlled. Confirm revision status through the EASA intranet/internet.

²⁶ https://www.easa.europa.eu/document-library/comment-response-documents

- The affected helicopters in the current HEMS fleets were manufactured between 1994 and 2001. Considering the available statistical data on the retirement age of helicopters, only 15 are expected not to retire by 2028, when the proposed requirements will become applicable. This will represent around 2 % of the European Union HEMS fleet.
- The affected helicopters will have to be replaced, retrofitted, or limited to multi-pilot operations by night — whichever option is the best for their operators.
- In case of replacement, the residual value of the helicopter will not be lost because it may be redeployed in the non-HEMS market. The low number of affected helicopters should not distort the market prices for used helicopters.

Autopilot

New point (e)(2) to point SPA.HEMS.110 was not proposed at the time of the NPA. It had, however, been planned for future development and was also suggested by stakeholders in the comments received on the NPA. All helicopters that are currently being manufactured for the HEMS market have an autopilot as an option, which shall comply with the proposed amending regulation. The cost of mounting an autopilot on a new-built helicopter is comparable to that of a retroactive application of a stability augmentation system, but the safety benefit of an autopilot is clearly greater than that of a stability augmentation system.

Further, the option remains to fly a helicopter without an autopilot by day only, or by night provided the crew is composed of 2 pilots.

The overall impact is positive in a comparable way as assessed for the stability augmentation system.

Helicopter performance at high altitude

The option to fly a helicopter that is not certified as Category A is proposed to be introduced in point SPA.HEMS.125(a) in the following specific cases:

- at higher altitudes where the safety benefit of Category A certification exists but is greatly reduced;
- for missions that are currently not within the scope of HEMS operations and may currently be operated with helicopters not certified as Category A.

The potential negative effect of this proposal on safety is mitigated by the introduction of a requirement for a CAT.POL.H.420 approval, as well as the retroactive application of crashworthy fuel bladders and seat belts for the existing HEMS fleets.

The limitations to operations by day under VFR and not to fly in congested hostile areas remain as defined in CAT regulations.

In the rare cases where helicopters are not certified as Category A, the economic cost is greatly reduced and the safety implications are very limited.

The overall impact is positive — with a positive impact being greater than that assessed at the NPA stage.



ELTs

The objective of the proposal regarding ELTs is to clarify the existing regulations, formally introduce a safer alternative for SPO and NCO, and harmonise the different parts of the Air OPS Regulation. It may reduce the cost for operators that are versatile and fly not only SPO or NCO, but also CAT or NCC. The overall impact is positive.



3. How we monitor and evaluate the rules

Monitoring is a continuous and systematic process of data collection and analysis with regard to the implementation/application of a rule/activity. It generates factual information for future possible evaluations and impact assessments, and helps to identify actual implementation issues. EASA proposes the following monitoring plan:

What to monitor	How to monitor it	Who should monitor it	How often
Number and main causes of occurrences (accidents/serious incidents) related to HEMS operations	Reports in ECR and information collected at MS level	EASA and national competent authorities	On a recurrent basis
Relevance of the HEMS rules and regulations	Number of MSs that operate HEMS under national regulations, and range of the variations between HEMS and national regulations	EASA and national competent authorities	On a recurrent basis

Cologne, 23 September 2022

Patrick KY

Executive Director



4. References

4.1. Related EU regulations

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

4.2. Related EASA decisions

- Decision N° 2012/015/ R of the Executive Director of the Agency of 24th October 2012 on Acceptable Means of Compliance and Guidance Material to Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council 'Guidance Material to Annex I — Definitions'
- Decision 2014/025/R of the Executive Director of the Agency of 28 July 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-ARO of Regulation (EU) No 965/2012 and repealing Decision 2014/014/R of the Executive Director of the Agency of 24 April 2014 'AMC and GM to Part-ARO — Issue 3'
- Decision 2014/017/R of the Executive Director of the Agency of 24 April 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-ORO of Regulation (EU) No 965/2012 and repealing Decision 2012/017/R of the Executive Director of the Agency of 24 October 2012 'AMC and GM to Part-ORO Issue 2'
- Decision 2014/015/R of the Executive Director of the Agency of 24 April 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-CAT of Regulation (EU) No 965/2012 and repealing Decision 2012/018/R of the Executive Director of the Agency of 24 October 2012 'AMC and GM to Part-CAT Issue 2'
- Decision N° 2012/019/Directorate R of the Executive Director of the Agency of 24th October 2012 on Acceptable Means of Compliance and Guidance Material to Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council 'Acceptable Means of Compliance and Guidance Material to Part-SPA'
- Decision 2014/016/R of the Executive Director of the Agency of 24 April 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-NCO of Regulation (EU) No 965/2012 and repealing Decision 2013/022/R of the Executive Director of the Agency of 23 August 2013 'AMC and GM to Part-NCO — Issue 2'
- Decision 2014/018/R of the Executive Director of the Agency of 24 April 2014 adopting Acceptable Means of Compliance and Guidance Material to Part-SPO of Regulation (EU) No 965/2012 'AMC and GM to Part-SPO'

4.3. Other reference documents

n/a

