



Explanatory Note to ED Decision 2023/007/R

Helicopter emergency medical service performance and public interest sites

RMT.0325 (OPS.057(A)) & RMT.0326 (OPS.057(B))

EXECUTIVE SUMMARY

The objective of this Decision is to facilitate the implementation of the new requirements introduced into Regulation (EU) No 965/2012 (the ‘Air OPS Regulation’) by Commission Implementing Regulation (EU) 2023/1020 (the ‘HEMS Regulation’).

The amendments introduced by the HEMS Regulation and the acceptable means of compliance (AMC) and guidance material (GM) introduced in this Decision will modernise the European Union (EU) aviation regulatory framework applicable to helicopter emergency medical services, and are expected to increase safety and foster efficiency and proportionality, while keeping the economic impact on HEMS operators at a minimum.

REGULATION(S) TO BE AMENDED/ISSUED

N/A

ED DECISIONS TO BE AMENDED

- ED Decision 2014/025/R — AMC/GM to Part-ARO
- ED Decision 2014/017/R — AMC/GM to Part-ORO
- ED Decision 2014/015/R — AMC/GM to Part-CAT
- ED Decision 2012/019/Directorate R — AMC/GM to Part-SPA
- ED Decision 2013/021/Directorate R — AMC/GM to Part-NCC
- ED Decision 2014/016/R — AMC/GM to Part-NCO
- ED Decision 2014/018/R — AMC/GM to Part-SPO

AFFECTED STAKEHOLDERS

Helicopter operators, national competent authorities, flight crew members, technical crew members.

WORKING METHOD(S)

Development

By EASA with external support

Impact assessment(s)

Light

Consultation

NPA — Public

Related documents / information

- ToR RMT .0325 (OPS.057(a)) & RMT.0326 (OPS.057(b)) Issue 3, published on 21.11.20161
- NPA 2018-04²
- CRD 2018-04³
- Opinion No 08/2022⁴

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

¹ [RMT.0325 \(OPS.057\(a\)\) & RMT.0326 \(OPS.057\(b\)\) - Helicopter emergency medical services performance and public interest site | EASA \(europa.eu\)](#)

² [NPA 2018-04 - Helicopter emergency medical services performance and public interest sites | EASA \(europa.eu\)](#)

³ [CRD 2018-04 - Helicopter emergency medical services performance and public interest sites | EASA \(europa.eu\)](#)

⁴ [Opinion No 08/2022 - Helicopter emergency medical service performance and public interest sites | EASA \(europa.eu\)](#)



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1. About this Decision

1.1. How this regulatory material was developed

This rulemaking activity is included in the 2023 edition of Volume II of the European Plan for Aviation Safety (EPAS) for 2023-2025⁵ under Rulemaking Task (RMT).0325.

EASA developed the regulatory material in question in line with Regulation (EU) 2018/1139⁶ (the Basic Regulation) and the Rulemaking Procedure⁷, as well as in accordance with the objectives and working methods described in the Terms of Reference (ToR) for this RMT⁸.

EASA developed the draft text of this Decision with the support of experts from industry and Member States and published it for public consultation through NPA 2018-04⁹. Comments were received from interested parties, including operators, aircraft manufacturers, national competent authorities (NCAs), and pilot unions. EASA reviewed the comments received and duly considered them. For further information on the NPA published, on the comments received, and the methodology employed for their revision, please refer to Section 1.1 of Opinion No 08/2022¹⁰.

The comments received and EASA's responses to them are presented in Comment-Response Document (CRD) 2018-04¹¹.

Based on the input from the consultation, EASA published Opinion No 08/2022 on 26 September 2022, proposing amendments to the Air OPS Regulation¹², based on which the European Commission adopted the HEMS Regulation¹³ amending the Air OPS Regulation.

EASA developed the final text of this Decision based on the input received during the consultation of the NPA with the support of experts from industry and Member States, as well as based on the input

⁵ [European Plan for Aviation Safety \(EPAS\) 2023-2025 | EASA \(europa.eu\)](#)

⁶ 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) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri=CELEX:32018R1139>).

⁷ 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 (<https://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-01-2022-rulemaking-procedure-repealing-mb>).

⁸ [RMT.0325 \(OPS.057\(a\)\) & RMT.0326 \(OPS.057\(b\)\) - Helicopter emergency medical services performance and public interest site | EASA \(europa.eu\)](#)

⁹ [NPA 2018-04 - Helicopter emergency medical services performance and public interest sites | EASA \(europa.eu\)](#)

¹⁰ [Opinion No 08/2022 - Helicopter emergency medical service performance and public interest sites | EASA \(europa.eu\)](#)

¹¹ [CRD 2018-04 - Helicopter emergency medical services performance and public interest sites | EASA \(europa.eu\)](#)

¹² 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) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494235623593&uri=CELEX:32012R0965>).

¹³ Commission Implementing Regulation (EU) 2023/1020 of 24 May 2023 amending Regulation (EU) No 965/2012 as regards helicopter emergency medical service operations (OJ L 137, 25.5.2023, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1020&qid=1685092396216>).

received during the adoption procedure for the HEMS Regulation, and published the Decision on the Official Publication of EASA.



2. In summary — why and what

2.1. Why we need to act — issue/rationale

Helicopter emergency medical services are specific commercial air transport operations which provide an essential service to European citizens. The Air OPS Regulation contains requirements that apply to these operations at European Union level.

EASA identified the need to amend the requirements applicable to HEMS to address the following issues¹⁴:

- To implement JAA temporary Guidance Leaflet (TGL) 43 and adapt the HEMS performance requirements to mountain operations;
- To better address mountain operations;
- To modernise the requirements on HEMS performance at public interest sites (PISs);
- To better address the risks associated with emergency flights conducted in a degraded visual environment;
- To address safety issues identified through implementation.

Accordingly, EASA issued Opinion No 08/2022, with proposed amendments to the Air OPS Regulation. The proposals that were contained in the Opinion were adopted by the HEMS Regulation.

It is necessary to facilitate the implementation of the HEMS Regulation.

2.2. Who is affected by the issue

Helicopter operators conducting HEMS, Member States' NCAs, flight crew members and technical crew members (TCMs) involved in HEMS.

2.3. What we want to achieve — objectives

The main objective of this Decision is to facilitate the implementation of the HEMS Regulation by introducing the relevant AMC and GM to the amended Air OPS Regulation.

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

Introduction

This Decision addresses the following topics:

Topic	Associated AMC and GM
Public interest sites ¹⁵	All AMC and GM to Part-ARO except for the deletion of GM4 ARO.OPS.200. AMC1 CAT.POL.H.225 and GM1 CAT.POL.H.225; GM1 SPA.HEMS.100(a)
Extension of the scope of HEMS ¹⁶	GM1 SPA.HEMS.100(a)

¹⁴ A full description of these issues can be found in Section 2.1 of EASA [Opinion No 08/2022](#).

¹⁵ See Section 2.3.1 of Opinion No 08/2022 for more information on this topic.

¹⁶ See Section 2.3.2 of Opinion No 08/2022 for more information on this topic.



HEMS operations using the cargo sling ¹⁷	AMC1 SPA.HEMS.105(b), GM1 SPA.HEMS.105(b), AMC1 SPA.HEMS.105(b)(2)
Oxygen ¹⁸	GM1 ORO.GEN.130(b); AMC2 CAT.IDE.H.240; All AMC and GM to SPA.HEMS.110(d).
Helicopter performance for mountain operations ¹⁹	AMC1 SPA.HEMS.125(a)(3); AMC1 SPA.HEMS.125(a) and GM1 SPA.HEMS.125(a).
NVIS ²⁰	AMC1 SPA.NVIS.110(e); GM1 SPA.NVIS.110(e); GM1 SPA.HEMS.100(c).
HEMS VFR operating minima ²¹	GM1 CAT.POL.H.215(a)(3); All AMC and GM to SPA.HEMS.120.
Obstacle awareness and avoidance ²²	AMC1 SPA.HEMS.110(b) and GM1 SPA.HEMS.110(b); All AMC and GM to SPA.HEMS.125(c)(4); AMC1 CAT.OP.MPA.105.
Crew composition, seating of the technical crew member, crew member training, checking and experience ²³	All AMC to Subpart ORO.TC; All AMC and GM to SPA.HEMS.130.
Enabling helicopter operations under IFR ²⁴	AMC1 CAT.POL.H.215(a)(1);(a)(2)
Auto-pilots and stability augmentation systems ²⁵	AMC1 SPA.HEMS.110(e)(1) and AMC1 SPA.HEMS.110(e)(2)
Other changes in relation to HEMS operations: aircraft tracking, ground personnel, and risk assessments, information and documentation ²⁶	GM1 SPA.HEMS.125(c)(3); The deletion of AMC1 SPA.HEMS.130(e)(2)(ii)(B); new AMC1 SPA.HEMS.151; AMC1 SPA.HEMS.135(b) and GM1 SPA.HEMS.135(b); AMC2 SPA.HEMS.140 and GM1 SPA.HEMS.140(b).
Editorial changes related to all weather operations	The deletion of GM4 ARO.OPS.200; All AMC and GM to Section CAT.OP except AMC1 CAT.OP.MPA.105; All AMC and GM to Section CAT.POL.A; GM1 ORO.GEN.160;

¹⁷ Section 2.3.3 of Opinion No 08/2022 for more information on this topic.

¹⁸ See Section 2.3.4 of Opinion No 08/2022 for more information on this topic.

¹⁹ See Section 2.3.5 of Opinion No 08/2022 for more information on this topic.

²⁰ See Section 2.3.6 of Opinion No 08/2022 for more information on this topic.

²¹ See Section 2.3.7 of Opinion No 08/2022 for more information on this topic.

²² See Section 2.3.8 of Opinion No 08/2022 for more information on this topic.

²³ See Sections 2.3.9, 2.3.10, 2.3.12 and 2.3.13 of Opinion No 08/2022 for more information on this topic.

²⁴ See Section 2.3.11 of Opinion No 08/2022 for more information on this topic.

²⁵ See Section 2.3.12 of Opinion No 08/2022 for more information on this topic.

²⁶ See Section 2.3.14 of Opinion No 08/2022 for more information on this topic.

	All AMC and GM to Subpart SPA.LVO; All AMC and GM to Parts NCC, NCO and SPO.
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AMC and GM to Part-ARO

GM4 ARO.OPS.200 has been deleted since it is not needed following the amendment of Appendix II to Part-ARO (Operations Specifications form).

The changes to **AMC2 ARO.OPS.215** and the new **GM1 ARO.OPS.215** are necessary to fully implement the new text of SPA.HEMS.125(a)(2)(iv) and (a)(3)(v), which requires the operator to have been granted an approval by the competent authority under CATL.POL.H.420. ARO.OPS.215 contains the requirements to be followed by the competent authority when granting such approvals. The changes made to point (a)(1) of AMC2 ARO.OPS.215 and the new GM1 ARO.OPS.215 support MSs in ensuring that the safety assessment performed by the operator is appropriate to the area overflown, considering the type of operations (HEMS, non-medical HEMS, or CAT other than HEMS). This allows MSs to have different safety targets for different kinds of operations on their territory.

In **AMC2 ARO.OPS.220**, a new point (c) has been added to ensure that the competent authority of the State where the approved public interest site is located notifies the competent authority of the State of the operator in case they are aware of a change in the obstacle environment.

AMC3 ARO.OPS.220 establishes that MSs should maintain a directory of approved public interest sites in their territory, to support the fulfilment of the requirements in ARO.OPS.220.

The new **GM1 ARO.OPS.220** provides guidance to MSs in the case of temporary changes to the obstacle environment at an approved public interest site and in the case of changes to the obstacle environment at an approved public interest site in one MS that affects an operator of another MS.

AMC and GM to Part-ORO

GM1 ORO.GEN.130(b) has been amended to reflect the amendments to CAT.POL.H.420, SPA.HEMS.125(a), CAT.POL.H.225, and SPA.HEMS.110(d).

GM1 ORO.GEN.160 has been amended to correct an editorial mistake.

GM1 ORO.TC.105 has been changed into **AMC1 ORO.TC.105**, considering its content and purpose, and following comments received during the NPA consultation. In addition, some additional criteria have been introduced regarding the medical assessment of TCMs.

The new **AMC2 ORO.TC.110** has been introduced to address the validity period for the recurrent checking of TCMs.

AMC1 ORO.TC.115 has been amended to include some specifications applicable to CRM training of TCMs.

Small amendments to increase clarity have been introduced to **AMC1 ORO.TC.135**.

AMC and GM to Part-CAT

The new **AMC1 CAT.POL.H.215(a)(1);(a)(2)** has been introduced following the deletion of the prescriptive distance of 5 Nm from the implementing rule and its replacement by 'the relevant terrain and obstacles'. Under IFR in the en-route phase, the horizontal distances to obstacles should be in



relation to the navigation performance of the helicopter, irrespective of an engine failure. Conventional routes are designed to provide 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 because they are unlikely to be certified 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.

The new **GM1 CAT.POL.H.215(a)(3)** clarifies that, under VFR in the en-route phase, the horizontal distances to obstacles should be defined by the rules of the air irrespective of an engine failure.

The new **AMC1 CAT.POL.H.225** has been introduced to ensure that any change to the obstacle environment at an approved public interest site is adequately processed by the operator.

GM1 CAT.POL.H.225 has been amended to reflect the changes introduced to CAT.POL.H.225 related to approved public interest sites.

The new **AMC2 CAT.IDE.H.240** has been introduced, mirroring the AMC applicable to aeroplanes. Operators will need to install certified oxygen systems for flights above 10 000 ft at night. Nasal cannulas and oxygen hose systems are likely to be the most practical option up to 18 000 ft. A [proposed special condition on auxiliary oxygen system as a supplemental oxygen source](#) has been published for the purpose of the certification of such systems. It can be re-published and consulted and a final version of the special condition can be adopted. There is therefore no obstacle to the certification of oxygen systems based on nasal cannulas. Oxygen bottles may be portable and certified under a European technical standard order (ETSO).

In addition, the following AMC and GM have been amended to introduce small editorial adjustments:

- **AMC5 CAT.OP.MPA.110.** The amendments clarify the provisions for runways without runway touchdown zone lights (RTZL) and/or runway centre line lights (RCLL) both for head-up displays and for autopilots /flight directors. The clarification ensures the use of this provision either when the RTZL are out of service or when the RCLL are out of service.
- **AMC11 CAT.OP.MPA.110.** The amendments ensure firstly that Table 17 uses the latest naming convention (deletion of ILS and introduction of CAT I) and secondly full alignment with Table 6 of AMC3 SPA.LVO.100(b), as both tables deal with the same topic.
- **AMC2 CAT.OP.MPA.182.** The amendment introduces the symbol '+', to clarify that the ceiling at the destination aerodrome should be at least 2 000 ft above the aerodrome or circling minima plus 500 ft, whichever is greater. This corrects a mistake introduced when moving the old provision of AMC1 CAT.OP.MPA.150 to AMC2 CAT.OP.MPA.182.
- **AMC8 CAT.OP.MPA.182** and **AMC9 CAT.OP.MPA.182.** The asterisks (*) have been deleted as they are not applicable for single runways.
- **GM1 CAT.OP.MPA.305.** The amendments introduce missing references applicable to helicopters. Thus, the new text provides the reference for aeroplanes as originally stated: Table 1 in AMC1 SPA.LVO.100(a) and provides a new reference for helicopter: Table 3 in AMC2 SPA.LVO.100(a).

Further small adjustments have been made to:

- AMC1 CAT.OP.MPA.105



- GM8 CAT.OP.MPA.110
- GM1 CAT.OP.MPA.185
- AMC1 CAT.OP.MPA.192(d)
- AMC2 CAT.OP.MPA.312(a)(3)
- AMC2 CAT.POL.A.235

AMC and GM to Part-SPA

The new **AMC1 SPA.NVIS.110(e)** has been introduced to provide a means of compliance for operators to demonstrate equivalent visual acuity, following the change to SPA.NVIS.110(e).

NVG from different manufacturers typically have an equivalent level of performance if designed at the same period to meet a certain military standard and bid for a given military tender. However, it is often difficult to relate a civilian pair of NVG to a given military standard. The only standard for civilian NVG is ETSO-C164 / TSO-C164a and therefore DO-275. On rare occasions the generation of NVG is known, however this is not enough. Most civilian NVG are generation 3 and the provided visual acuity can be very different.

Another item of specification available is typically the figure of merit. This specification itself does not define visual acuity, which varies with many other parameters. However, it is likely that the other parameters (e.g. image intensification) will have improved in parallel with the figure of merit.

Therefore, if two NVG are of the same generation and have a sufficiently similar figure of merit, it is accepted that no operational demonstration takes place.

In all other cases, an operational demonstration is needed to define whether the visual acuity of the NVG intended to be used is sufficiently similar. Following the operational demonstration, a risk assessment is needed for the operator to conclude whether the two different NVG can be used together on board the same helicopter, with or without operating limitations or conditions. The benefit of upgrading to a better model of NVG can be considered as part of this risk assessment.

It is already possible today that a pilot changes from one NVG make and model to another. It is expected that this becomes more often the case as the rules become performance based. This is taken into account as part of the operator's risk assessment. In any case, familiarisation or differences training apply.

The new **GM1 SPA.NVIS.110(e)** has been also introduced to support the understanding of generations of NVG and refers to other military standards that may be used for the same purpose as the generation. It also defines the figure of merit.

GM1 SPA.HEMS.100(a) has been amended to reflect the changes in the scope of HEMS introduced at implementing rule level and to reflect the changes in performance requirements.

Following the change to SPA.NVIS.100(c), requiring night operations to non-pre-surveyed HEMS operating sites to be conducted under SPA.NVIS.100, the new **GM1 SPA.HEMS.100(c)** has been introduced to provide some explanations when pre-surveyed sites are used and NVIS is therefore not required.



The new **AMC1 SPA.HEMS.105(b)** defines relevant criteria to meet the objectives of the implementing rule, regarding crews, equipment, training and standard operating procedures (SOPs) for HEMS HEC operations with the cargo sling.

Regarding crew and ground personnel, point (a) defines the tasks that require a sling TCM. Point (b) covers tasks that can be considered as ground operations, and do not require a crew member. For such tasks, training and checking is defined with reference to ORO.GEN.110. It is expected that in some cases, an operator may rely on a large number of mountain technicians from a defined organisation to perform such tasks. Further reference is made to ORO.GEN.205 to cover such cases. Point (c) describes the case where the sling TCM is also the HEMS TCM.

Regarding equipment, point (e) ensures that the sling TCM and any additional ground personnel involved are equipped at least to the same level as a task specialist involved in SPO.SPEC.HEC operations. Point (f) introduces a recommendation for the helicopter equipment that mirrors an equivalent recommendation in AMC1 SPO.SPEC.HEC.100.

In relation to training, point (d) ensures that the sling TCM and any additional ground personnel involved are trained, briefed and checked at least to the same level as a task specialist involved in SPO.SPEC.HEC operations.

The initial training of the pilot is defined in point (g) to be at least to the same level as that of a pilot involved in SPO.SPEC.HEC operations. It is complemented with point (h) for the recurrent training and checking and (i) for recency. Points (j) and (k) are aligned on HHO criteria. Such recurrent training and checking and experience criteria are deemed necessary to meet CAT standards and to cover the needs of HEMS pilots that may not be involved in HEC or HESLO daily. Alignment with HHO also ensures that the AMC does not create a decision bias towards HHO or towards the use of the cargo sling.

Point (j) introduces validity periods until the end of the month and 3 calendar months' revalidation windows for the training, checking and recency in relation to HEMS HEC cargo sling operations.

Finally, point (k) covers the operator's SOPs.

The new **GM1 SPA.HEMS.105(b)** and **GM3 SPA.HEMS.130(f)(1)** have been introduced to clarify that HEMS operating sites can be used for HEMS training and checking. The new **GM2 SPA.HEMS.125(c)(3)** describes how to minimise the risk associated with take-off and landing performance while using relevant HEMS operating sites for training and checking.

In addition, the new **AMC1 SPA.HEMS.105(b)(2)** has been introduced regarding the airworthiness approval of the cargo hook. Most cargo hook installations not meeting the criteria of point (a) but meeting the criteria of point (b) of AMC1 SPO.SPEC.HEC.105(b) are single-cargo hook installations, whereas most but not all dual cargo hook installation would meet the criteria of point (a) of AMC1 SPO.SPEC.HEC.105(b). The new AMC defines airworthiness criteria for the double cargo hook to follow either point (a) or (b) of AMC1 SPO.SPEC.HEC.105(b). Installations other than dual cargo hooks should meet the criteria of AMC1 SPO.SPEC.HEC.105(b) point (a).

Following the changes to SPA.HEMS.110, several new AMC and GM have been introduced. The new **AMC1 SPA.HEMS.110(b)** focuses on moving map displays. Moving maps with own-ship position, terrain database and obstacle database are considered to be essential tools for situational awareness and obstacle avoidance. SPA.HEMS.110(b) makes them mandatory for HEMS operations. The terrain awareness component of HTAWS would meet the new requirements, but it is not the only available



system to do so. The AMC also accepts EFB software applications as a means of compliance since they provide the required function without replacing or duplicating an existing or required one.

As regards the definition of an EFB type B application: In the context of SPA.HEMS.110(b), the EFB type B application is a valid means of compliance because it provides the required function without replacing or duplicating an existing or required one.

The use of non-certified systems, such as EFB applications, comes with many uncertainties compared to certified systems. They do however complement certified systems for terrain and obstacle awareness. A non-certified terrain and obstacle database could be more precise and up-to-date than a certified one. This is partly due to the fewer regulatory obstacles to the data reporting process.

Type B EFB software applications displaying a moving map with own-ship position can be used under VFR. They may display the relative altitude of the available terrain and obstacle data to that of the helicopter. In VFR the primary means of maintaining the desired altitude or height are the visual cues and the baro altimeter. The approximate relative altitudes that can be expected from a Type B EFB software application will not provide such cues. Such feature is therefore compatible with point (d)(3)(iii) of AMC10 SPA.EFB.100(b)(3) and with point (a)(1) of AMC1 CAT.GEN.MPA.141(b) on information displayed.

The new **GM1 SPA.HEMS.110(b)** on moving maps training, points at existing training requirements and reminds that they include the training towards the limitations of the systems. This part of the training is essential as regards the awareness of terrain and obstacles, because the (certified or non-certified) databases will never include all obstacles.

The new **AMC1 SPA.HEMS.110(d)(3)** focuses on short excursions above 13 000 ft without oxygen. Ongoing research programmes featuring cognitive tests taken by HEMS pilots in hypobaric chambers at altitudes up to 5 000 m (16 400 ft) show promising results. They tend to validate that HEMS pilots do not need oxygen up to 13 000 ft and should be able to sustain up to 30 minutes of flight above 10 000 ft and up to 16 000 ft.

Nevertheless, the research conditions may not be representative of mission temperatures and stress, nor of the real cognitive and psycho-motricity needs of a helicopter pilot. More research is scheduled to take place in 2023 on real helicopter missions. It is also known that HEMS pilots make more mistakes at high altitudes without oxygen. Hypoxia onset can be irreversible and become catastrophic because a single pilot or a whole crew subject to hypoxia will believe that all is well.

Therefore, pending the final results of these research programmes, AMC1 SPA.HEMS.110(d)(3) is based on the following:

- Operations up to 30 minutes above 10 000 ft at altitudes not exceeding 14 000 ft are deemed to be acceptable based on previous oxygen regulations and on sufficient operational experience.
- For operations above 13 000 ft and up to 16 000 ft, the current rule of thumb is never to exceed 10 minutes above 13 000 ft without oxygen. This is consistent with 15 minutes above 10 000 ft when considering the climb and descent time from 10 000 ft to 13 000 ft.

This AMC is a means of compliance to point (d)(3) of the implementing rule only. Individual factors or limitations are covered at implementing rule level, points (d)(6), (d)(7) and (d)(9), and may result in personal limitations of a given crew member irrespective of this AMC.



The new **GM1 SPA.HEMS.110(d)(3)** is a reminder of the requirements in the implementing rules. It ensures that the duration of the excursion above 10 000 ft without oxygen is well understood and not exceeded.

The new **AMC1 SPA.HEMS.110(d)(6);(d)(7)** has been introduced to enable operators and individuals to progressively gain experience in high altitude operations without oxygen.

The new **AMC1 SPA.HEMS.110(d)(8)** introduces detailed criteria for hypoxia training, to meet the objectives of the rules that crews are trained to:

- know their individual body response and early signs of hypoxia,
- recognise early signs of hypoxia in other crew members.

The objective is to ensure that the potentially catastrophic scenario caused by crew members not recognising hypoxia does not materialise.

The training objectives and conditions described in the AMC are applicable to all crew members.

The new **AMC1 SPA.HEMS.110(e)(1)** and **AMC1 SPA.HEMS.110(e)(2)** describe the minimum characteristics of a stabilisation system and auto-pilot, as required by the related rule.

SPA.HEMS.120 has been amended to remove the detailed minima from the rule level. Those details have now been transferred to **AMC1 SPA.HEMS.120(a)**, which at the same time improves and simplifies the previous VFR minima.

In the new Table 1, by day, the 499–400 and 399–300 ft cloud base categories are merged for simplification purposes. It was simply not practical for visibility minima to vary every 100 ft.

The new Table 1 no longer makes a distinction between single-pilot operations with TCMs and two-pilot operations. The distinction was considered not adequate, especially when the TCM is sufficiently trained. On average, this leads to a reduction of the HEMS minima by day, and to a slight increase in the weather minima at night. At night, the visibility is increased from 2 500–3 000 to 3 000 m visibility with NVIS, and from 2 500–3 000 to 5 000 m visibility without NVIS. 5 000 m visibility is higher than the visibility minimum that is sometimes accepted in special VFR (3 000 m), but this is justified since HEMS without NVIS is a more demanding operation than reaching an aerodrome in a control zone. Also, the 5 000 m visibility minimum is applicable in combination with a lower ceiling minimum (1 200 instead of 1 500 ft). When the ceiling is higher than 1 500 ft, the visibility minima can be reduced to 3 000 m. The aim is not to give operational credit to NVIS operations, but to allow reduced visibility in HEMS operations only if sufficient mitigation measures are in place. By day, the VFR minimum visibility is averaged out at 1 500 m for dispatch, starting from values of 1 000, 2 000 and 3 000 m. The reduced VFR minima for day and night can be applied in single-pilot operations provided the HEMS TCM receives sufficient training. The option for the commander to decide to continue a day flight if the visibility is temporarily reduced, but not below 800 m, is maintained.

The word ‘cloud base’ is kept in Table 1 for night HEMS VFR minima. However, a footnote is introduced to describe the cases where ‘ceiling’ can be used in lieu of ‘cloud base’. This footnote is deemed useful for weather conditions where FEW clouds would be present at known locations (coastline, hill tops) without interfering with the flight.

In addition, dispatch conditions should be described in the operations manual as per SPA.HEMS.120(a) and SPA.HEMS.140(a). Therefore, operators should define precisely in which cases they wish to use



cloud ceiling of cloud base without increasing the risk. The requirement to remain clear of clouds when flying VFR is unchanged.

Point (b) and Tables 2 and 3 of the new AMC reduce VFR minima for HEMS operations under IFR using PinS approaches and departures to an IDF, when the instrument chart instructs the pilot to 'proceed VFR'.

Depending on the class of airspace and time of day, the 'proceed VFR' minima can mean anything from visibilities of 800 to 5 000 m. When the missed approach point (MAPt) of the PinS approach and the IDF are very close to the heliport or operating site, the VFR minima may be much higher than needed for the purpose of achieving a landing or a go-around, especially at night.

The new visibility minima ensure that, at the MAPt on a PinS approach, the destination is in sight (with a 500-m margin by night which will help avoid visual illusions), or the minima are per Table 1.

The new visibility minima ensure that by night the MCA is visible from take-off, or the minima are per Table 1. By day, the minimum visibility is 800 m or 1 500 m depending on the distance from departure to the MCA.

The new ceilings are sufficient for the VFR segment of the flight.

The new VFR operating minima are valid for all classes of airspace and are based only on the capability of the pilots to fly and navigate visually, because they do not need to take into account traffic deconfliction.

At altitudes close to the MDH and within a 5-km radius of the MAPt or IDF, there should be no conflicting IFR traffic, because any IFR traffic will be much higher.

It is expected that if there is a low-level flying IFR traffic nearby, IFR/IFR deconfliction should exist for the following phases which are far more critical than the VFR segment of the flight:

- once the departing VFR helicopter reaches the IDF, it transitions to IFR and climbs;
- or if the approaching IFR helicopter goes around at or before the MAPt instead of flying the VFR segment.

If in use, the weather conditions will be IMC except for helicopters that use this specific approval. No conflicting VFR traffic should exist.

Only in case a helicopter transitions to VFR near the MAPt while another helicopter departs VFR to an IDF under the same specific approval, and the IDF is close to or co-located with the MAPt, can a traffic conflict exist. Considering the very short distances and durations of the VFR segments of flight, the traffic should already be deconflicted for the purpose of the IFR segments.

Point (c) of the new AMC focuses on vertical distance to obstacles. HEMS vertical clearance from obstacles in the en-route phase cannot remain as per the rules of the air. They should be reduced and made compatible with Table 1. An overcast ceiling of 300 ft should be compatible with a HEMS flight by day despite some obstacles. A vertical obstacle clearance of 200 ft is the minimum vertical clearance that can realistically be introduced.

An overcast ceiling of 1 200 ft should be compatible with a HEMS flight by night despite some obstacles. The 1 200 ft should include:



- more obstacles and greater obstacles than by day, because the horizontal distance to obstacles greatly increases by day;
- a vertical clearance to obstacles;
- but also, a vertical margin from the clouds, to avoid inadvertent entry into IMC.

A vertical obstacle clearance of 500 ft may result in heights of 700-800 ft above ground, reducing the vertical margin from clouds to 400 ft. It is the minimum vertical clearance that can realistically be introduced. Operator SOPs should define greater obstacle margins if the ceiling is greater than 1 200 ft, or if the conclusions of their risk assessments command a greater obstacle-margin and a lesser margin from clouds.

The new **GM1 SPA.HEMS.120(a)** clarifies that the VFR operating minima that are not discussed in AMC1 SPA.HEMS.120(a) remain as defined in the applicable rules of the air.

The new **AMC1 SPA.HEMS.120(d)** defines the minimum tasks to be allocated to the HEMS TCM, together with the minimum training, to mitigate the risks associated with lower minima.

Editorial changes are introduced to **GM1 SPA.HEMS.120** following the transfer of the HEMS operating minima from implementing rule to AMC level.

The new **GM2 SPA.HEMS.120** introduces additional guidance to clarify that HEMS operating minima are applicable to HEMS training flights. This is deemed useful, if only to enable training towards such minima.

The new **AMC1 SPA.HEMS.125(a)(3)** transposes some of the requirements of TGL 43:

- Point (a) derives from TGL 43 and is consistent with the changes to SPA.HEMS.130 on the crew composition.
- Point (b) refers to the limitations associated with performance class 3 included in CAT.POL.H.400, and adds a provision that the mission is completed 30 minutes before night, or at sunset, adding a time margin at planning stage.
- Point (c) ensures that the operator has contingency options if the HEMS mission can no longer be completed with the helicopter that was planned at dispatch stage, considering the limitations referred to in (b).
- Point (d) describes means of compliance for the recording requirement in SPA.HEMS.125(a)(3)(vi).

The following elements of TGL-43 were not considered relevant to be included in AMC or GM:

- a detailed description of a 'rendez-vous' system;
- descriptive elements;
- impact assessment.



The new **AMC1 SPA.HEMS.125(a)** and **GM1 SPA.HEMS.125(a)** describe the applicable specifications for crash-resistant seats and crash-resistant fuel systems, which are based on the final analysis report of the Rotorcraft Occupant Protection Working Group (ROPWG)²⁷.

GM1 SPA.HEMS.125(b)(3) has been renumbered **GM1 SPA.HEMS.125(c)(3)** to reflect the renumbering of the points in the implementing rule.

AMC1 SPA.HEMS.125(b)(4) has been renumbered **AMC1 SPA.HEMS.125(c)(4)** to reflect the renumbering of the points in the implementing rule and amended. While the minimum site dimensions of 2xD by day and 2xD by 4xD by night at non-pre-surveyed sites remain the means of compliance by default, the operator is now allowed to define other criteria, based on a risk assessment. The criteria can be below 2xD if mitigated with operating procedures and training. This includes no minimum dimensions based on the use of the hoist or cargo sling (the previous AMC defined minimum dimensions of 2xD also for the hoisting site). The operator may also define 3-dimensional obstacle protection volumes at the operating site. The operator may define criteria for slope landings, one-skid landings, or tolerate e.g. small obstacles within parts of the 2xD distance that are well in sight and do not interfere with the helicopter or its rotors.

By night, for operations other than HEC, the minimum dimensions always remain 2xD by 4xD.

The landing technique should remain the commander's decision based on the conditions of the day.

Finally, for un-surveyed sites, the commander should estimate from the air whether the defined criteria are met, and whether a safe landing can take place.

The new **AMC2 SPA.HEMS.125(c)(4)** has been introduced, upgrading the previous GM1 SPA.HEMS.130(e)(3) to AMC level and clarifying it. The helicopter should provide minimum illumination. The new **GM1 SPA.HEMS.125(c)(4)** clarifies that any additional illumination from the ground can help, but it might also blind the crew or make the identification of cables more difficult, if not well designed.

The new **AMC1 SPA.HEMS.130** has been introduced to define the validity of all expiry dates at the end of the month. A 3-month revalidation window has been introduced for both flight crew and technical crew, with reference to an existing AMC.

The new **AMC1 SPA.HEMS.130(a)** includes provisions on the minimum experience of the HEMS commander, which were removed from the rule level. The AMC also provides for increased pilot experience with night HEMS operations. Newly recruited HEMS pilots typically lack night flight experience. Unfortunately, helicopter night experience can mainly be gained by flying HEMS. An additional 30 hours of night experience and 10 approaches, landings and take-offs are introduced for those pilots required to land at night at HEMS operating sites. Credit is given in case of a structured night HEMS training programme.

AMC1 SPA.HEMS.130(b)(2) has been deleted since its content does not add anything to the already existing requirements in ORO.FC.105 and related AMC.

AMC1 SPA.HEMS.130(d) has been amended to reflect the changes to the rule. The new text introduces improved IMC training for pilots that do not hold a current instrument rating. The previous requirements on recency were deemed insufficient to achieve pilot proficiency in dealing with a loss

²⁷ Rotorcraft Occupant Protection Working Group (ROPWG) task 6 final analysis report to the Aviation Rulemaking Advisory Committee (ARAC) of 27 September 2018,

of visual references during a flight. The previous 30-minute instrument flight recency has been replaced by a structured training session with a minimum duration of 45 minutes and several training elements to be successfully covered during each session.

The use of the auto-pilot including upper modes, if fitted, can take place every other session. If a single type or variant is fitted with such systems, the training may alternate between a generic IFR trainer that can be a helicopter FNPT, and an FSTD that is fully representative of the type. For operations on two different types or variants, the training can alternate between the variants.

AMC1 SPA.HEMS.130(e) has been also amended, and some of the changes made come from the discussions with the MSs during the adoption of the related rules.

Point (a) defines that the standard seating of a TCM is in a forward-facing front seat.

However, for day operations only, in the case where the TCM can conduct their primary tasks from the cabin as efficiently as from the front seat, and to facilitate the conduct of HEMS HEC including hoist operations, it can make sense that the TCM is seated in the cabin for the whole flight.

For day and night operations, it was found possible for the HEMS TCM to move from the cockpit to the cabin and back during the hover phase, also to facilitate the conduct of HEMS HEC including hoist operations. The AMC develops the necessary conditions for safe operations.

As required in SPA.HEMS.120, the HEMS VFR operating minima can only apply if the HEMS TCM is seated in the front seat, and non-primary aviation tasks may not be possible from the cabin. The seating of the TCM should therefore be the commander's decision. Point (b) to (d) define the primary tasks that the HEMS TCM should be tasked with, and the other aviation tasks that the HEMS TCM may be tasked with, with minor changes. The reading of checklists is a primary task whenever possible, in accordance with the implementing rules.

Only editorial changes have been introduced in points (e) and (f).

The new points (g) to (i) introduce conditions so that an inexperienced HEMS TCM is not crewed with an inexperienced commander. The conditions apply in the case of newly recruited TCM that have just completed their initial training for the first time at their first HEMS operator.

The HEMS TCM should be considered inexperienced until they have completed 50 HEMS missions. During this time the HEMS TCM should not be crewed with a HEMS commander that is considered inexperienced on the type under the same criteria as the current AMC1 ORO.FC.200(a). Alleviations are introduced under the same criteria as in the current AMC1 ORO.FC.200(a). The HEMS TCM remains experienced when changing operators.

The new **AMC1 SPA.HEMS.130(e)(1)(ii)** ensures that the pilot can decide that the TCM is needed in the crew or if they can be relieved from flight duties to meet medical needs. Collisions with obstacles on take-off remain a non-negligible risk. It is important that the TCM always takes part in the briefing that reminds of relevant obstacles and threats before take-off.

GM1 SPA.HEMS.130(e)(2)(ii) has been deleted following the deletion of the requirement for 'specific geographic areas' at implementing rule level.

The **AMC1 SPA.HEMS.130(e)(2)(ii)(B)** has been deleted and replaced by the new **AMC1 SPA.HEMS.151** following changes at implementing rule level.

GM1 SPA.HEMS.130(e) defines the crew concept and adds guidance on how to ensure its continuity.



The amended **AMC1 SPA.HEMS.130(f)(1)** introduces initial and annual recurrent helicopter/FSTD training focusing on crew cooperation with the TCM. The initial training is not required if the pilot has had MCC training or if the pilot has sufficient experience of multi-pilot or multi-crew operations. The experience of the trainer is aligned with the experience required to teach multi-pilot operations.

The new **AMC2 SPA.HEMS.130(f)(1)** restructures the training and checking of HEMS crew members, considering any prior aviation knowledge they might have, and includes details in the following aspects of the training and checking programme:

- initial and recurrent training covering the primary tasks of the HEMS crew member;
- additional training and checking reflecting any additional tasks the HEMS crew member may be assigned, in addition to their primary tasks;
- conversion course ground training and checking when changing helicopter types or when changing operators;
- initial and recurrent aircraft/FSTD training;
- operator proficiency checks;
- line flying under supervision;
- line checks.

Point (a) includes a description of the minimum theoretical training towards the primary tasks of the TCM. Only the main topics are described, and the detailed structure and sub-topics are included in GM.

Points (b) to (f) include a description of the minimum theoretical training towards the optional tasks of the TCM. Only the main topics are described, and the detailed structure and sub-topics are included in GM.

Points (g) and (h) describe the theoretical training needed for a conversion course, when changing operators or changing type within an operator.

Points (i) and (k) include elements on initial and recurrent aircraft/FSTD training focusing on crew cooperation with the pilot for new HEMS TCMs. Experienced HEMS crew members at the time of entry into force of the new AMC need not perform the initial training. The initial training may be combined with line flying under supervision and needs not be repeated when changing operators.

Point (j) focusses on line flying under supervision.

Points (l) and (m) describe the content of line checks and operator proficiency checks. Both checks are necessary, but they do not need to overlap.

Point (n) describes the use of FSTDs and enables the use of the FSTD for most of the line check.

Points (o) and (p) describe the use of other training devices for other parts of the training.

Point (q) ensures that all training and checking that takes place in the aircraft/FSTD takes place with a crew composition that is the same as during normal operations.

Points (r) and (s) define that the trainer and checker of the HEMS TCM should be a suitably qualified commander or, for tasks conducted in the cabin where crew cooperation is not essential, a suitably



qualified TCM. For the training that focuses on crew cooperation, the suitably qualified commander should have at least 350 hours of experience in multi-crew operations, as for the pilot training.

Point (t) focuses on the CRM assessment of the TCM.

The new **GM1 SPA.HEMS.130(f)(1)** includes a detailed structure for the theoretical part of the training described in AMC2 SPA.HEMS.130(f)(1). It describes the training credit that is granted to holders of PPL(A) and PPL(H) or people who have successfully completed the theoretical knowledge examination for these licences.

The new **GM2 SPA.HEMS.130(f)(1)** provides guidance for the TCM to participate in observation flights once the initial ground training is completed, and prior to the first aircraft/FSTD training under VFR by day or by night, or under IFR.

The amendment to **AMC1 SPA.HEMS.135(b)** recognises the use of software applications to familiarise ground operations personnel with their tasks.

The new **GM1 SPA.HEMS.135(b)** provides a list of topics that ground operations personnel could be familiarised with.

AMC1 SPA.HEMS.140 has been amended to include additional elements in the operations manual, in addition to the current content, following other changes to the SPA.HEMS requirements and related AMC.

AMC2 SPA.HEMS.140 describes a minimum number of elements to be considered in the operator's HEMS risk assessment:

- Some elements that were previously included in SPA.HEMS.130(e)(2)(ii) have been moved to AMC level, and extended to day and night and single-pilot and multi-pilot operations.
- Crew composition and equipment aspects that were previously included in SPA.HEMS.140 have been moved to AMC level;
- Flight time limitations and crew fatigue have been added.

The new **GM1 SPA.HEMS.140(b)** introduces guidance for the commander's HEMS assessment of specific risks associated with the HEMS mission (tactical risk assessment).

The new **AMC1 SPA.HEMS.145(b)** describes minimum meteorological information that should be provided at the operating base in the case of night operations.

The expectation is that most HEMS operating bases will be located outside an aerodrome, and therefore there will be no local meteorological information available from a certified service provider. The AMC therefore provides the following alternatives:

- That such certified meteorological information is available at a location where conditions are likely to be similar to those of the operating base on most nights. A maximum distance from the operating base to that location is not specified, as opposed to AMC1 CAT.OP.MPA.192 that is used under IFR only; or
- That supplementary weather information is provided at the operating base. Criteria for such operator-controlled weather information is described in AMC1 CAT.OP.MPA.192.

This AMC will only become applicable after 3 years, because of its financial and logistical implications. See [Applicability of the AMC and GM](#)



Under night VFR it is not expected that the HEMS helicopter will always return at the base after the mission due to weather uncertainties. However, if the criteria of this new AMC are not met during the period of delayed entry into force, HEMS pilots should not expect to return to base and should be ready to divert.

The new **AMC1 SPA.HEMS.151** has been introduced to ensure the effectiveness of the operator's aircraft tracking system. It should be noted that not all aircraft tracking technologies are able to monitor the HEMS helicopter position from take-off to landing, considering the geography and usually low height of HEMS flights. The AMC does not prescribe one given technology but the performance that is defined should be met.

The following AMC and GM have been amended to introduce small editorial adjustments:

- GM2 SPA.LVO.100
- AMC3 SPA.LVO.100(b)
- GM4 SPA.LVO.100(b)
- AMC1 SPA.LVO.105(g)
- AMC1 SPA.LVO.110
- GM1 SPA.LVO.110
- GM4 SPA.LVO.110
- GM7 SPA.LVO.110
- GM8 SPA.LVO.110
- GM9 SPA.LVO.110
- AMC2 SPA.LVO.120(b)
- AMC4 SPA.LVO.120(b)
- GM1 SPA.LVO.120(b)
- AMC1 SPA.PINS-VFR.100

AMC and GM to Part-NCC

The following AMC and GM have been amended to introduce small editorial adjustments:

- AMC5 NCC.OP.110
- AMC1 NCC.OP.153
- GM2 NCC.OP.153
- GM1 NCC.OP.230
- AMC2 NCC.OP.235(a)(3)



AMC and GM to Part-NCO

The following AMC and GM have been amended to introduce small editorial adjustments:

- AMC2 NCO.OP.110
- GM1 NCO.OP.110
- AMC1 NCO.OP.142(b)(1)
- AMC1 NCO.OP.142(b)(5)
- GM1 NCO.OP.210
- AMC1 NCO.SPEC.115(a)

AMC and GM to Part-SPO

The following AMC and GM have been amended to introduce small editorial adjustments:

- AMC1 SPO.GEN.105(a)
- GM1 SPO.OP.110
- AMC1 SPO.OP.152
- AMC2 SPO.OP.235(a)(3)

Applicability of the AMC and GM

The AMC and GM will apply at the date the related implementing rules will become applicable, except for the following:

- The editorial amendments related to all-weather operations will apply from the date of entry into force of the ED Decision.
- The application of AMC1 SPA.HEMS.145(b) is further delayed, so that the affected operators have the time to upgrade their weather reporting facilities at the HEMS operating base to apply the new AMC. Until it applies, there is no AMC and the means of compliance with SPA.HEMS.145(b) remains the operator's choice.

This means that all AMC and GM will apply on 25 May 2024, with the following exceptions:

- AMC1 SPA.HEMS.145(b) on weather reporting at the HEMS operating base and GM1 SPA.HEMS.100(c) on the alternative to NVIS at night will apply on 25 May 2026.
- AMC1 SPA.HEMS.110(e)(1) on stability augmentation systems and AMC1 SPA.HEMS.110(e)(2) on auto pilots will apply on 25 May 2028.

2.5. What are the stakeholders' views

512 comments were received on NPA 2018-04. 174 comments were submitted by NAAs, 265 comments by helicopter operators and their associations, 10 comments by individuals, 1 comment by an air navigation services provider (ANSP), 21 comments by pilot unions, and 41 comments by manufacturers.



The comments of non-editorial nature were reviewed with the help of a group of experts from helicopter operators, helicopter manufacturers, national competent authorities (NCAs), and pilot unions.

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 AMC and GM.

For the individual responses to the comments received on NPA 2018-04 and more detailed conclusions, please consult Comment-Response Document (CRD) 2018 04²⁸ *Helicopter emergency medical services performance and public interest sites*.

During the comitology procedure for the adoption of the HEMS Regulation, additional comments to AMC1 SPA.HEMS.130(e) were received, which resulted in the following clarifications on the repositioning of the crew member during the flight in the context of HEMS HEC:

- The repositioning procedure should not be used offshore due to insufficient visual cues;
- The operators should develop SOPs for the safe transitioning from aided to unaided vision prior to the hover phase during which the repositioning will take place.

²⁸ [CRD 2018-04 - Helicopter emergency medical services performance and public interest sites | EASA \(europa.eu\)](#)



3. Expected benefits and drawbacks of the regulatory material

The main impact assessment can be found in NPA 2018-04. This impact assessment was further updated in Opinion No 08/2022. The updated impact assessment remains valid for the introduction of the amended AMC and GM.



4. Monitoring and evaluation

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. The monitoring plan proposed by EASA in Opinion No 08/2022 applies to this Decision. For more information, please refer to Chapter 3 of EASA Opinion No 08/2022.



5. Proposed actions to support implementation

Focused communication at meetings of the Advisory Bodies (MAB, SAB, Air OPS TEB, R.COM) took place at the time of publication of the Opinion. No further action to support implementation are foreseen beyond the regular communication with stakeholders.



6. References

Related EU regulation

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 96, 15.10.2012, p 1).

