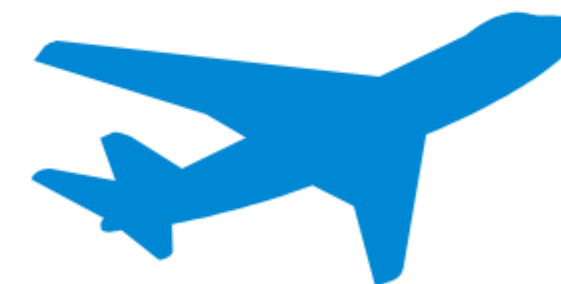


SMART SKIES, LEGAL HORIZONS

«Impact of the New European Regulation on HEMS Operations in Italy»

Rome June 12-13 2025



- Air Operations**
(IR + AMC/GM & CS/GM)

Sharing EU Safety Standard Pillars

HEMS Regulation: How ENAC exercises implementation and oversight duties



EASA
European Union Aviation Safety Agency

**HEMS
REGULATION**
(EU) 2023/1020

HEMS scope extension including mountain rescue	Operations on PIS (Public Interest Site)	HEMS operations using cargo hooks and sling
Oxygen requirements for mountain operations at high altitudes	Helicopter performance for mountain operations	Night vision imaging systems (NVISs) operations
Simplification of the HEMS VFR operating minima and Obstacle awareness and avoidance	Crew composition and HEMS technical crew member (TCM) seating position	Operative Procedures and Risk Assessment





Numero: 2024/01-ONO
Ed. n. 1 del 21 maggio 2024

Le Indicazioni Tecniche e Operative contengono elementi di carattere generale relativi a specifici domini dell'aviazione civile. I criteri interpretativi/procedurali/metodologici sono forniti senza alcuna indicazione preferenziale da parte dell'ENAC e tra di essi il richiedente può identificare il possibile modo per soddisfare il requisito, o il complesso dei requisiti, che meglio si adatta alla propria realtà. Le Indicazioni Tecniche e Operative possono essere pubblicate come documento autonomo da utilizzare quale complesso di indicazioni tecniche e procedurali per l'attuazione di processi di certificazione/approvazione di tipo sperimentale in attesa dell'emissione di Regolamenti.

INDICAZIONI TECNICHE E OPERATIVE
OPERAZIONI HEMS SECONDO IL NUOVO
REGOLAMENTO EU 2023/1020



ITO



REGOLAMENTO

OPERAZIONI CAT CON ELICOTTERI IN AMBIENTE OSTILE
AL DI FUORI DI AREE CONGESTIONATE

Ad HOC Regulations

(eg. 26/07/2022
or 13/06/2023)



FAQ

FAQ

The HEMS operations in Italy



EU Safety Standards in Italy

- The operations are **extremely heterogeneous** driven by the **specific local environment** and **medical requirements** including:
 - **Extended overwater operations**
 - **High mountain operations**
 - **Hoist operations including night hoist operations in unknown sites**
- The system is well established and developed with an historical pedigree dating back to the the **14th of June 1986** when the first rescue mission took place in Emilia Romagna region
- Since its introduction the service has evolved from pure daylight scoop&run to **24/7 with special operations and intensive care transportation**



EU Safety Standards in Italy

- Because of its peculiar geographical characteristics **Italy requires an extensive use of hoist operations**
- Out of 52 bases performing hoist operations in Europe 41 are located in Italy alone, accounting for **almost 80% of the entire European civil hoist operations market**
- Compared to the rest of Europe, **the Italian HEMS cabin** is typically **more loaded**, hosting on average a significant number of people on-board (1/2 pilots + 3 to 5 people in cabin)



Who is affected by the new Amendment IR (EU) 2023/1020

Certified Operator SPA-
HEMS



NCA National Competent
Authority

Flight Crew Members



Technical Crew Members

Contractors services
HEMS (Asl-Asp-Regioni-
Università)



Ente Nazionale per l'Aviazione Civile
Italian Civil Aviation Authority



Legal and technical aspects

HEMS PHILOSOPHY by EASA

ACCEPTABLE RISK concept iaw
EASA Guidance Material

Who needs to be protected?

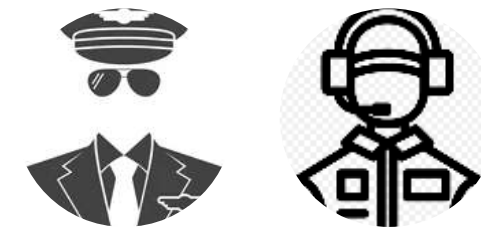
Third parties (people and things).
HIGH PROTECTION



Passengers, patients, doctors
LOWER PROTECTION



Crew Members
LOWEST PROTECTION



RISK

$$\text{Risk} = \text{Probability} \times \text{Severity}$$



Risk Matrix

Risk Probability	Risk Severity				
	Catastrophic A	Critical B	Moderate C	Minor D	Negligible E
5 - Frequent	5A	5B	5C	5D	5E
4 - Likely	4A	4B	4C	4D	4E
3 - Occasional	3A	3B	3C	3D	3E
2 - Seldom	2A	2B	2C	2D	2E
1- improbable	1A	1B	1C	1D	1E

Legal and technical aspects

THE HEMS PHILOSOPHY GM1 SPA. HEMS.100(a)

The following principles of responsibility shall be adopted:

It is for the medical professional to decide between HEMS or air ambulance – not the pilot.

For that reason, medical staff who undertake to task medical sorties should be fully aware of the additional risks that are (potentially) present under HEMS operations (and the pre-requisite for the operator to hold a HEMS approval). (e.g. in some countries, hospitals have principal and alternative sites).

The patient may be landed at the safer alternative site (usually in the grounds of the hospital) thus eliminating risk – against the small inconvenience of a short ambulance transfer from the site to the hospital).



- Once the decision between HEMS or air ambulance has been taken by the medical professional, the commander makes an operational judgement over the conduct of the flight.

The ENAC Mission: Flight Safety Priority

SPA.HEMS.125 Performance requirements for HEMS operations



Helicopter **performances for mountain operations** never approved before (**PC3**) might now be accepted according to SPA.HEMS under following conditions:

- HEMS operating site located above 7.000 ft, using a helicopter certified under **Category A** or
- Using helicopters certified under **Category B** for missions not involving transport of patients or other pax or if Category A helicopters are not available due to involvement in other contemporary HEMS missions. The operator is approved according to CAT-POL-H.420 (therefore such operations shall be



Currently CAT.POL.H.420 HEMS Ops are not allowed in Italy: ENAC is not ignoring the new alleviation provided by EASA regulation, but at the same time cannot ignore hazards posed by the Italian hostile environment and operations at high altitude where a

SPA.HEMS.100

Entry into force and applicability

- **1 STEP 25-MAJ-2024**

- Major amendments and AMC, GM

- **2 STEP 25-MAJ-2026**

- Only AMC1 SPA.HEMS.145(b); GM1 SPA.HEMS.100(c))

- Night operations on **HEMS Operating Sites outside congested areas with sufficient lighting.**

- (GM1 SPA.HEMS.100(c)

- Operations on HEMS Operating Bases. **New weather information network.**

- AMC1 SPA.HEMS.145(b)

- **3 STEP 25-MAJ-2028**

- Only AMC1 SPA.HEMS.110(e)(1); AMC1 SPA.HEMS.110(e)(2))

- Minimum equipment (VFR DAY) CAT IDE.H130 (**Radio-altimeters with warning and autopilot systems with HDG**)

- Minimum SAS stabilisation equipment and autopilot

Conclusions

- ENAC is Responsible for **implementing and overseeing** EASA regulations at the National level, adapting them to **peculiar Italy's environment**
- The **Italian HEMS service** is **complex** and **extremely developed**
- ENAC mission is to **minimize risk exposure without compromising HEMS effectiveness**
- Within its perimeter, ENAC is **entitled to provide technical and operative instructions** or **FAQ** to tailor EASA regulations in accordance with Italian specific environment

Thank you for your attention

