European Union Aviation Safety Agency

GUIDELINES

FOR THE TRANSPORT OF COVID-19 INFECTED PATIENTS USING CONTAINMENT DEVICES- EXEMPTIONS UNDER ARTICLE 71(1) OF THE BASIC REGULATION

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1. Purpose of these Guidelines

This document provides guidance for national competent authorities (NCAs) to consider when granting exemptions under Art. 71(1) of Regulation (EU) 2018/1139 (hereinafter, the Basic Regulation) allowing the installation of equipment on aircraft for the transport of Highly Infectious Desease (HID) patients. Such equipment, hereafter called patient isolation device (PID), shall reduce the risk of contamination of crews and medical teams.

The transportation of COVID-19 infected patients, and of patients suspected of being infected, is vital for the efficiency of European health services and for the patients themselves. Avoiding the contamination of the flight crews and medical teams is vital to ensure the continuity of essential medical services, including medical transportation services.

This document addresses installed equipment, and focuses on the following:

1. Combinations of stretchers and PID;
2. Standalone-installation of PID;
3. Partitioning devices used to separate the cockpit area from the cabin.

The guidelines are not addressing personal protective equipment, which are not subject to airworthiness requirements. Air Medical Services installations without PID or Partitioning Devices are not covered by these guidelines.

EASA proposes 2 ways of enabling an immediate installation of devices that reduce the risk of contamination:

1. An exemption process, for which further guidance is provided below.
2. An accelerated process for design change approvals using the 'minor change' classification, described in chapter 4.

2. Scope of exemptions

2.1. When using Article 71(1) of the Basic Regulation (BR) to exempt operators from certain requirements of Regulation 748/2012[1], Regulation 1321/2014[2] and Regulation 965/2012,[3] the NCAs should specify the following:

1) The period of exemption: the period should refer to the duration of the COVID-19 outbreak in the Member State, but in any case should be less than 8 months.
2) The scope of exemption: as applicable.
3) The exempted provisions should be limited to the following, as applicable:
   a) Articles 21.A.181(a)(1) of the Annex I (Part 21) of Regulation (EU) n° 748/2012;
   b) Articles M.A.304, M.A.501 M.A.902(b)(2), M.A.902(b)(5) of the Annex I (Part M) of Regulation (EU) n° 1321/2014

[1] COMMISSION REGULATION (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations

[2] COMMISSION REGULATION (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks

[3] 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).

c) Article 145.A.42 of Annex II (Part 145) of Regulation (EU) n° 1321/2014
d) Articles SPA.HEMS.110 of the Annex V (Part SPA) of Regulation (EU) n° 965/2012and
e) Stretchers and isolation devices: CAT.IDE.A&H.100(a) in association with CAT.IDE.A&H.205 of the Annex IV (Part CAT) of Regulation (EU) n° 965/2012
f) Partition systems : CAT.IDE.H.100(b)(2) of the Annex IV (Part CAT) of Regulation (EU) n° 965/2012

2.2. The exemption should allow, on a temporary basis and as applicable or necessary:

a) the installation on aircraft of non-approved equipment for the purpose of reducing the risk of contamination of crews and medical teams;
b) The use of the aircraft and its equipment.

2.3. Such exemptions should be limited to those cases where no approved equipment installation (including approved hardware) is available.

3. Mitigations (Focus areas for the competent authorities) –

Exemptions should be granted

- for the time needed to obtain an airworthiness approval or
- for the time to bridge any production, reception, or installation delays of an approved device or
- in case when an installation cannot meet all airworthiness requirements or
- in case when no permant approval is sought

provided that mitigations can be established.

Mitigations for consideration in the frame of Art. 71.1 can comprise a combination of the below listed elements.

In particular the temporary nature of the Exemption provides for mitigation when certain airworthiness requirements/essential requirements cannot or only partially be met.

For permanent use, a design change approval is required.

3.1. Installation pre-requisites

1) For the patient isolation device:
   a) An approved EMS installation / cabin layout including a stretcher installation is advantageous, otherwise an adequate alternative installation needs to be demonstrated/established
   b) The isolation device / stretcher combination should provide adequate restraints for the patient under normal flight conditions.
   c) The isolation device / stretcher combination should be capable of adequate attachment to the approved EMS installation. Indivividual components/accessories of the isolation device can be attached separately.
2) For the partitioning device:
   a) Adequate access to emergency exit shall remain available to all occupants.
   b) Communication of the Pilot-in-Command with crew in the cabin must be ensured.
   c) Adequate attachment of partitioning device materials and fittings, to reduce loose item risk internally and externally.

3.2. Airworthiness mitigation aspects

The temporary nature of the Exemption is an element of mitigation.

In addition, in case a piece of equipment had not been approved, the following airworthiness criteria may not be fully demonstrated but should nonetheless be optimised as much as possible in the available time frame.

1. Flammability requirements of compartment interiors

   The patient may use oxygen for medical needs. The quantity of oxygen transported in the cabin should be limited to the quantity required to support the needs of the transported patients for the given transport. For no other reason should an oxygen enriched atmosphere exist, when full compliance to flammability criteria is not achieved.

2. Value of loads on the approved stretcher compared to the maximum demonstrated loads, when adding the mass of the isolation device to that of the patient:

   The additional mass of the isolation device on the approved stretcher shall be assessed, design safety factors for wear and tear and maintenance intervals can be considered for mitigation.

3. Ability of the restraint systems to maintain the patient to its seat/stretcher/isolation device in all applicable cases of deceleration.

   Deceleration in the case of emergency landing conditions shall be considered as far as practicable as well as minimizing the likelihood of an emergency to occur, e.g. by operational limitation listed in 3.4.

4. The evacuation capabilities shall be maintained.

   The location of the stretcher with respect to the emergency exits, the volume of the device, and the location and volume of any accessories shall be considered to minimize the risk that occupants have no access to emergenxy exits after an emergency landing. The minimum and the maximum number of occupants may need to be established accordingly. For patient isolation devices, an evacuation procedure shall be provided in line with section 3.3 paragraph 1)d).

3.3. Operational mitigation aspects

1) Kinds of operations:
   Aircraft involved in helicopter emergency medical services (HEMS), helicopter air ambulance services[4], and aeroplane (emergency) medical services.

2) Operating procedures and limitations
   a) Procedures and limitations associated with the use of the device:
      The operator should comply with any conditions or limitations provided in the user's manual of the unapproved equipment.

   b) Mitigation of risk related to unusual loads applying to unapproved equipment:
      i) Avoid abrupt manoeuvers;
      ii) No flights in areas where severe turbulence may be expected.

[4] Air ambulance includes any medical related mission without the urgency that would require the use of HEMS.

c) Mitigation of risk of fire in relation to any lack of fire resistance of unapproved equipment, and compatibility with air conditioning systems:
   i) The cabin temperature and air conditioning should be set to avoid any hot spots and any high-pressure areas on unapproved equipment such as partitioning devices;
   ii) No excessive heat shall be generated by any equipment in the close vicinity of unapproved equipment.

d) Emergency evacuation. An emergency evacuation procedure should be defined :
   i) For any occupant, for which access to the available emergency exits is partially obstructed by an unapproved device;
   ii) For a patient transported in a PID, with the assistance of other occupants. A pre-flight briefing should be delivered to the occupants to define the tasks assigned to them in an emergency evacuation scenario.

3.4. Additional operating limitations for helicopter operations:

Helicopter flights with unapproved devices should be conducted under performance class 1 as far as practicable. The provisions of CAT.POL.H.305 shall apply only in the context of HEMS operating sites and public interest sites.

The reduced operating minima defined under SPA.HEMS.120 do not apply. VFR operating minima defined by Regulation (EU) No 923/2012[5] shall apply.

3.5. Continuing airworthiness

The instructions for installation and removal of the equipment should rely on the best engineering judgement and must be detailed enough to ensure that the equipment is always installed as intended. The instructions must be ultimately approved by the nominated postholder of the CAMO. The release to service following installation must refer to the instructions provided by the CAMO and must be issued by the maintenance organisation.

4. Installation under a design change approval

In order to enable an early availability of a transport solution in the frame of the current COVID-19 situation, EASA supports the use of the provisioning of Article 71.1 of the Basic Regulation 2018/1139, also for on-going projects, through the present guidelines and additional support to NCAs and operators as required.

For a permanent change, a design change approval is required.

4.1. Provisions for Minor Design change classification

In the context of the emergency situation created by the COVID-19 pandemic, Approved Design Organizations with adequate design scope may reclassify modifications

- For installation of PID on an existing approved stretcher installation and compliant to the applicable airworthiness code
- For installation of partitioning devices compliant to the applicable airworthiness code

when introducing aforementioned containment devices as “Minor Change” and to approve them under their DOA-privileges.

[5] 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

Any change in operating procedures have to be addressed taking into account the specific configuration of each aircraft model affected.

Further guidance can be found in chapter 3 and must be taken into account.

4.2. Classification of other changes

Changes not meeting the provisions of 4.1 are classified as "Major Change" respectively as "STC".

For related application please note this information published by EASA: https://www.easa.europa.eu/newsroom-and-events/news/easa-processing-new-aircraft-configurations-medical-transport-high-priority

5. Avoidance of market distortion under article 71 of Regulation 2018/1139

It is expected that some operators are capable of operating on the market of safe transportation of infectious patients and have already responded to the demand of transportation of ebola patients or other highly infectious patients. However, the demand created by the current COVID-19 crisis far exceeds the capability of the market. The exemption is designed to allow all operators of one aircraft type to meet the increased demand without delay, and will be extended to other types as necessary.

1. With regards to DOAs :

   Holders of a supplemental type certificate (STC) are in a better position to meet the demand of the health services and operators in a timely manner, than organisations not holding such STCs.

2. With regards to operators:

   Operators that are already equipped with approved devices have an advantage on this market, because new entrants will need to invest in such approved devices to obtain the exemption.

   The granting of a temporary exemption to an operator already under contract, should be extended to all other operators that may apply for tenders.

In cases where some spare capacity exists and a range of similar aircraft types can be used to provide the service, the considerations of chapter 2.3 should be extended to all such available types.This might be the case for partitioning devices to separate the cockpit area from the cabin of an aeroplane.

Under the above conditions, there is no market distortion.

6. Exemption process

Operational and airworthiness departments of the NCA should work together on such exemptions.

7. Information

For the purpose of notification of exemptions, NCAs are invited to inform EASA of the granted exemptions through EASA Flexi tool.

8. Other applicability

For flights not falling under the scope of the Basic Regulation, the NCA may use these Guidelines with the necessary adaptations.