EASA European Union Aviation Safety Agency	**Consultation paper** **Equivalent Safety Finding**	Doc. No.: ESF-F25.1443-01 Issue : 1 Date : 8 February 2023 Proposed ☒ Final ☐ Deadline for comments: 1 MARCH 2023

SUBJECT	:	Passenger Breathable Gas Mix Supplemental System
REQUIREMENTS incl. Amdt.	:	CS 25.1441(b), 25.1443(c) at Amdt. 26
ASSOCIATED IM/MoC	:	Yes☒ / No ☐
ADVISORY MATERIAL	:	

Table of Content

INTRODUCTORY NOTE:

The following Equivalent Safety Finding (ESF) has been classified as important and as such shall be subject to public consultation in accordance with EASA Management Board decision 12/2007 dated 11 September 2007, Article 3 (2.) which states:

"*2. Deviations from the applicable airworthiness codes, environmental protection certification specifications and/or acceptable means of compliance with Part 21, as well as important special conditions and equivalent safety findings, shall be submitted to the panel of experts and be subject to a public consultation of at least 3 weeks, except if they have been previously agreed and published in the Official Publication of the Agency. The final decision shall be published in the Official Publication of the Agency.*"

ABBREVIATIONS:

COPD	Chronic Obstructive Pulmonary Disease
SpO_2	Peripheral Blood Oxygen Saturation Level
$VO_{2(rest)}$	Resting volumetric Oxygen consumption

IDENTIFICATION OF ISSUE:

EASA received an application for the certification of a passenger oxygen system, replacing the existing Cabin Supplemental oxygen system in B777-300ER aeroplanes.

The applicant has submitted a request for an Equivalent Level of Safety to CS 25.1443(c) for the B777-300ER. CS 25.1443(c) specifies minimum mass flow requirements for passenger and cabin crew supplemental oxygen systems in terms of mean tracheal partial pressure, breathing rate, and tidal volume per breath.

The system proposed is not designed to deliver oxygen per the minimum mass flow performance parameters specified in CS 25.1443(c).

The system uses a breathable gas mix based on oxygen and carbon dioxide. The carbon dioxide allows to improve the oxygen processing by blood and lungs and increases the cerebral blood flow. These physiological effects help to maintain a high blood oxygen saturation and allow a reduction in the oxygen flow below the values specified in the CS 25.1443(c).

On the other hand, the carbon dioxide is known to be a harmful contaminant when present in the air at high concentration. The CS 25.831(b) requires the carbon dioxide concentration during flight in the compartments normally occupied by passengers or crew members, to never exceed harmful/hazardous levels such as 0.5% by volume sea level equivalent.

The JAR 25.831(b) at Change 15 or before defined in the past a carbon dioxide concentration greater than 3% by volume sea level equivalent as hazardous.

This document records the proposed Equivalent Safety Finding as an alternative to compliance with CS 25.1443(c) and CS 25.1441(b) based on a strategy to demonstrate that raised concentration of carbon dioxide beyond CS 25.831(b) level and mixed with oxygen is safe for the cabin supplemental oxygen system's

users. It provides compensating factors allowing to reach an equivalent level of safety per point 21.B.80(a)2 of Part-21 (Annex I to Regulation (EU) No 748/2012).

Note: paragraphs 3.a) and 3.b) of the below Equivalent Safety Finding, dealing with an alternative to compliance with CS 25.1443(c), have already been used in a previously consulted ESF on "*Minimum Mass Flow Supplemental Oxygen*" that was published by EASA in February 2011:

https://www.easa.europa.eu/sites/default/files/dfu/Special%20Condition%20F-18.pdf

Considering all the above, the following Equivalent Safety Finding is proposed.

ESF-F25.1443-01

Equivalent Safety Finding

Passenger Breathable Gas Mix Supplemental System

1. APPLICABILITY

This ESF is applicable to Large Aeroplanes with passenger breathable gas supplemental systems installed that provide a gas mix based on oxygen and carbon dioxide.

1.1 AFFECTED CS

CS 25.1441(b) at Amendment 26
CS 25.1443(c) at Amendment 26

2. SCOPE

In lieu of direct compliance with CS 25.1443(c) and associated standards of TSO C64a/SAE AS 8025, and provided that the below compensating factors are complied with, passenger breathable supplemental systems providing a gas mix based on oxygen and carbon dioxide might be used even if the minimum mass flow requirements for passenger and cabin crew supplemental oxygen systems in terms of mean tracheal partial pressure, breathing rate, and tidal volume per breath are not fulfilled.

3. COMPENSATING FACTORS

For passengers and cabin crew members, it shall be shown, that the passenger breathable gas mix (oxygen and carbon dioxide) system provides an equivalent level of protection from hypoxia as detailed below:

a) Between 10,000 ft and 18,500 ft cabin pressure altitude, the supplemental breathable gas mix system for the passenger and cabin crew shall provide a blood oxygenation level that is equivalent with the blood oxygenation level reached at 10,000 ft cabin pressure altitude when breathing standard air. Breathing standard air at 10,000 ft cabin pressure altitude provides a mean tracheal oxygen partial pressure of 100 mmHg as required by CS 25.1443(c).

b) Between 18,500 ft and 40,000 ft cabin pressure altitude, the supplemental breathable gas mix system for the passenger and cabin crew shall provide a blood oxygenation level that is equivalent with the blood oxygenation level reached at 14,000 ft cabin pressure altitude when breathing standard air. Breathing standard air at 14,000 ft cabin pressure altitude provides a mean tracheal oxygen partial pressure of 83.8 mmHg as required by CS 25.1443(c).

c) During an actual decompression event and sudden exposure to high cabin pressure altitudes, it is likely that cabin occupants may begin to experience symptoms of hypoxia with decreasing SpO_2 levels for many reasons, such as delays in donning the new supplemental system masks. In order to provide an equivalent level of protection, the breathable gas mix system should allow the user to recover from lowered SpO_2 levels at a rate equal to or better than they would using an oxygen system where the oxygen flow was determined by using traditional test methods and assuming delivery of a homogeneous gas mixture to comply with CS 25.1443(c). This could be accomplished by ensuring that a high flow rate of oxygen is available when the new system mask is first donned such that the users SpO_2 levels would fully recover to baseline values before using a lower flow of oxygen intended to sustain the user at the baseline value. As an alternative, comparative data should be provided to demonstrate that the time to return from lowered SpO_2 levels to baseline or greater values using a

breathable gas mix flow is either unchanged or medically insignificant compared to the use of systems where the minimum flow rate was determined assuming that a homogeneous gas mixture is delivered to the user.

d) The addition of carbon dioxide into the breathable gas mixture shall be assessed in terms of physiological effects to passengers for the maximum time of use during long depressurized diversion.

e) The range of the population with a possible reduced response to the positive carbon dioxide effect and allowed to travel by flight without any additional medical oxygen equipment, shall be adequately identified, and it shall be demonstrated that this population is still adequately protected by the new system.

Means of Compliance to Equivalent Safety Finding ESF-F25.1443-01

Based on the novelty of the proposed design, EASA is exceptionally publishing these Means of Compliance for comments and invite medical experts to provide any comments or concerns on the proposed text below.

TEST SET UP

The following testing activities are proposed to show the adequate implementation of the compensating factors by demonstrating an equivalent level of protection from hypoxia and without any adverse effects on targeted users during the complete operation of the system.

(a) The blood oxygenation level in human bodies is characterised by the stabilised peripheral blood oxygen saturation level (SpO_2). The purpose of the test should be to demonstrate that the supplemental breathable gas mix (oxygen and carbon dioxide) dispensing equipment ensures test subjects SpO_2 levels, which are sufficient or at least as high as the applicable baseline SpO_2:

(1) 10,000 feet baseline: At 10,000 ft cabin pressure altitude, the "10,000 ft baseline" SpO_2 of test subjects should be measured while breathing standard air. In the next step, the cabin pressure should be reduced in steps up to 18,500 ft cabin pressure altitude while the test subjects are breathing supplemental breathable gas mix at a flow rate sufficient to meet or exceed their individual "10,000 ft baseline" SpO_2 level.

(2) 14,000 feet baseline: At 14,000 ft cabin pressure altitude, the "14,000 ft baseline" SpO_2 of test subjects should be measured while breathing standard air. In the next step, the cabin pressure should be reduced in steps up to 40,000 ft cabin pressure altitude while the test subjects are breathing supplemental breathable gas mix at a flow rate sufficient to meet or exceed their individual "14,000 ft baseline" SpO2 level.

(b) The cabin altitude dependant breathable gas mix flow rates and oxygen/carbon dioxide concentrations should be recorded and later used to specify the cabin altitude dependant breathable gas mix flow performance of the supplemental breathable gas mix dispensing equipment. The test results from the 10,000 feet baseline should be used for the cabin pressure altitude range of 10,000 to 18,500 ft, whereas the 14,000 feet baseline should be used for the cabin pressure altitude range of 18,500 to 40,000 ft.

(c) The testing should be accomplished in accordance with established industry practices. The evaluation of the passenger supplemental breathable gas mix system performance should include an agreed number of masks and randomly selected novice human subjects. If new and novel test methods are used, statistical means should be provided to justify the quantity of test subjects.

(d) The test subjects should be exposed to the full range of altitudes for which the system will be certified. A series of exposures at maximum increments of 7,500 feet pressure altitude is acceptable for compliance demonstration.

(e) To address the increased breathing rate of a panicking person, the equipment should deliver in the above mentioned paragraph (a)(1) and (a)(2) the specified breathable gas mix flow rate under the CS 25.1443(c) specified tidal volume and breathing rate, which may be demonstrated by tests using a breathing machine with performance as specified in SAE ARP 1109B. Any alternate breathing machine performance standard should be presented and agreed with EASA and complemented by the use of a validated model for system response aspects which could be not evaluated with a breathing machine.

(f) For a subset of the test runs, the altitude chamber may be simulated on ground by using hypoxic gas mixtures.

(g) In order to validate that prolonged breathing of raised carbon dioxide concentration mixed with supplemental oxygen, does not result in any unacceptable adverse effect on cabin users, the test subjects should be exposed to the representative supply and ambient conditions as well as the longest exposure time of the targeted operational use. The Modified BORG scale[1] and the Lake Louise mountain sickness Self questionnaire[2] will be used to assess the presence and severity of symptoms during the test.

(h) As required in paragraph 3.e) of ESF-F25.1443-01, it is under the applicants responsibility to identify the range of the population with a possible reduced or adverse response to the positive carbon dioxide effect. Therefore, it should also be confirmed by test that the system operation principle and use of novel gas mixture (Oxygen/Carbon Dioxide) remain compatible with a range of flying public suffering from medical conditions (such as Chronic Obstructive Pulmonary Disease (COPD), but not limited to COPD), whereby the nature of their condition allows flight travel without any supplemental medical oxygen. It should be demonstrated that the carbon dioxide addition still offers relatively positive benefit compared to healthy passengers.

It is acknowledged that it might be difficult and/or not ethical to expose unhealthy test subjects to high altitude depressurized conditions. Consequently, the applicant might propose alternate test means or conditions to try to replicate the physiological response of a person suffering from COPD (or any other identified health issue) with healthy test subjects.

When simulating the conditions for chronic obstructive pulmonary disease, the following aspects should be considered:

- COPD patients might suffer from gas exchange inefficiency, have reduced ventilatory response and have reduced ability to exhale carbon dioxide.
- Limit Criteria for COPD patient allowed to fly without supplemental medical oxygen would be equivalent to a SpO_2 greater than 95% at sea level (blood arterial partial pressure P_aO_2 greater than 70 mmHg) or 85% at 8,000 ft (blood arterial partial pressure P_aO_2 greater than 50 mmHg).

For example, this could be accomplished by the following method:

- From the participant cohort used for testing as described in paragraph (a) to (d), a subset of participants who meet the following conditions, should be asked to return for further testing:
  - A 14,000 ft SpO_2 nominal baseline between 80% and 83%;
  - A $VO_{2(rest)}$ within the nominal range as that of an elderly passenger or COPD patient deemed fit to fly.

  Note: if the subset of participants meeting the above criteria is insufficient, then the use of new participants meeting these criteria would be acceptable.

[1] The Borg rating of perceived exertion scale is especially used in clinical diagnosis and severity assessment of breathlessness and dyspnea.
[2] The Lake Louise score has provided a robust and practical tool for researchers to diagnose and to score the severity of acute mountain sickness (AMS).

- In the first step, each test subject SpO_2 should be artificially reduced to a range between 72 and 77%, to simulate an "unhealthy passenger" SpO_2 baseline at 14.000 ft, by breathing ambient air and being exposed to an altitude offset of +3000 ft in addition to the 14.000 ft altitude, i.e., breathing ambient air at 17.000 ft altitude.

  Note 1: Where the individual participant physiology would indicate that they may desaturate below 72%, this altitude offset may be decreased to ensure the safety of the participant.

  Note 2: The 3000 ft altitude offset target has been established according to the following rationales and assumptions:
  - The blood arterial partial pressure P_aO_2 (38.6 mmHg) of a COPD patient at 14.000 ft breathing ambient air has been extrapolated from the limit criteria at 8000 ft for subjects with COPD conditions allowed to travel by flight without medical supplemental oxygen: P_aO_2 (50 mmHg) and SpO_2 (85%).
  - It was also estimated that a healthy subject with a SpO_2 of 80% at 14.000 ft breathing ambient air would replicate an equivalent blood arterial partial pressure of P_aO_2 (38.6 mmHg) (equivalent to a SpO_2 of 72%) when breathing ambient air at an higher altitude (17.000 ft).
  - The extrapolations assumed a linear variation of the blood oxygen partial pressure with the tracheal pressure and were based on the P_aO_2 /SpO_2 oxygen-haemoglobin dissociation curve.

- In the second step, the test mask should be configured to provide the flow normally required at the targeted long exposure diversion altitude (21,000 ft) and each test subject should don the mask and should be exposed to a raised altitude: targeted long exposure diversion + altitude offset established during the first step, i.e 24.000 ft ideally. The goal is to simulate an "unhealthy passenger" SpO_2 response when using the mask during the depressurized diversion.
  - The mask system should ensure that the SpO_2 obtained during the second step, is the same or greater than the "simulated unhealthy passenger" baseline SpO_2 at 14.000ft determined during the first step. This allows to justify that a COPD patient with a remaining ventilatory response to hypercapnia would benefit from the positive carbon dioxide effect.

  - The inhaled oxygen concentration within the mask should be measured or derived with a reasonable accuracy from other measured parameters to be presented and agreed with EASA and should be compared with the oxygen concentration of the Curve B/Figure 1 of AS8025 at the target diversion altitude (21,000 ft). This allows to ultimately justify that a COPD patient with a severely reduced ventilatory response to hypercapnia would still benefit from a large oxygen concentration to ensure hypoxia protection without taking credit of the carbon dioxide effect.

- It should also be justified that a subject with chronic obstructive pulmonary disease (COPD) could not suffer from any significant adverse effect resulting from prolonged carbon dioxide

inhalation (such as severe hypercapnia, excessive hyperventilation or any other distress or physiological disorder).

- Use of analysis and literature to complement the test results might be acceptable.

(i) The leakage through the mask should be measured at ground level for each test subject, prior or after the test described in (a) to (d), (g) and (h).

Further testing on a selection of persons should be also performed independently of the hypobaric trials to determine the facial fit leakage range representative of the facial contour variation of the population of cabin occupants similar to the fit leak test guidance prescribed in the §6.1.7 of AS8025a . It should be demonstrated that the facial fit leakage range would not affect the validity of the results obtained with tests (a) to (d), (g) and (h)

(j) Existing data might also be used such as data from previous qualification tests or compliance findings, provided that the applicant can sufficiently justify the validity of those data.

(k) When testing according to paragraphs (a) to (d),(g) and (h),

(1) Considering the long diversion time (g), the proposed new system should also be demonstrated with light activity of the passenger, such as turning the head, moving on the seat and speaking.
(2) If there is an appreciable cabin temperature decrease further to the depressurization/ diversion and the cabin temperature has any effect on the oxygen consumption characterized through the measured blood oxygen saturation, or on the carbon dioxide tolerance, the testing should be done at the most critical temperature which could be encountered during depressurized operation, or this effect should be accounted for, to determine the equivalent oxygen and carbon dioxide flows/concentrations. Such assessment is limited to failure conditions not shown to be extremely improbable and leading to cabin depressurization in combination with a degraded cabin temperature control.
(3) The tested system should be representative of the serial definition in term of mask leakage, principle of operation and control logics. The differences between the tested system and serial definition should be presented and agreed with EASA before the start of the campaign.