Federal Aviation Administration

Memorandum

Date:	November 20, 2015
To:	Manager, Boeing Aviation Safety Oversight Office, ANM-100B
From:	Manager, Transport Airplane Directorate, ANM-100
Prepared by:	Jim Voytilla, ANM-100B
Subject:	INFORMATION: Equivalent Level of Safety (ELOS) Finding for the Passenger Oxygen System for Boeing Model 787-8/-9/-10 (Project Nos. TC6918SE-T, PS06-0496, PS06-0497, PS13-0546 and PS14-1031)
ELOS Memo#.:	TC6918SE-T-ES-16
Reg. Ref.:	§ 25.1443(c)

The purpose of this memorandum is to inform the certificate management aircraft certification office of an evaluation made by the Transport Airplane Directorate (TAD) on the establishment of an equivalent level of safety (ELOS) finding for the Boeing Model 787-8 airplane.

This memo was subsequently revised to extend this ELOS to the Boeing Model 787-9 and 787-10 airplanes.

Background

Boeing has submitted a request for an Equivalent Safety Finding to Title 14, Code of Federal Regulations (CFR) section 25.1443(c) for the Model 787. Section 25.1443(c) specifies minimum mass flow requirements for passenger supplemental oxygen systems in terms of mean tracheal partial pressure, breathing rate, and tidal volume per breath. The § 25.1443(c) requirements correspond to constant flow oxygen systems and test methodologies available at the inception of the rule forty years ago, and do not specifically correspond to how human subjects would respond if actually subjected to decompression conditions

Boeing plans to install a pulse oxygen system on the 787. The system will be designed to deliver a high concentration of oxygen to each passenger at the start of his/her inhalation

cycle that will travel deep into his/her lungs where physiologically it is most efficiently absorbed by the alveoli. After the initial high oxygen concentration provided at the start of inhalation, the remainder of the breathing cycle will consist of ambient air. The system will not deliver oxygen per the minimum mass flow performance parameters specified in § 25.1443(c).

Applicable regulation(s)
§ 25.1443(c)

Regulation(s) requiring an ELOS finding
§ 25.1443(c), Minimum mass flow of supplemental oxygen.

Description of compensating design features or alternative standards which allow the granting of the ELOS (including design changes, limitations or equipment need for equivalency)

The FAA finds the following criteria would provide an equivalent level of safety to § 25.1443(c):

1) If testing is accomplished in accordance with established industry practices, and the evaluation of the pulse oxygen system performance must include an agreed to number of masks and randomly selected novice human subjects. If new and novel test methods are used which increase the test variability, statistical justification must be provided for the quantity of test subjects used.
2) While using the pulse oxygen system each test subject shall be exposed to the range of altitudes for which the system is certificated for use. The SaO_2 levels must be agreed to with the FAA.
3) The process for developing baseline SaO_2 levels must be supported by experienced members of the medical community and must be approved by the Seattle ACO who will use the FAA's Civil Aeromedical Institute (CAMI) for review and comment.
4) The equipment is designed to supply a specified dosage of oxygen for each breath. To address the increased breathing rate of an anxious person, the equipment must deliver this specified dosage of oxygen under the § 25.1443(c) specified tidal volume and breathing rate.
5) Boeing will test the 787 pulse oxygen system per procedures that include human subject testing. Seattle ACO review may include providing the proposed test procedures and results to CAMI for review and comment.

Explanation of how design features or alternative standards provide an equivalent level of safety to the level of safety intended by the regulation

The requirements of § 25.1443(c) provide protection to cabin occupants from the effects of hypoxia by requiring physiological breathing environments (mean tracheal oxygen partial pressures) equivalent to those at 10,000 or 14,000 feet depending on the actual cabin pressure altitude. Human subject testing in an altitude chamber will show that an

equivalent level of protection from hypoxia is provided to cabin occupants while utilizing the pulse oxygen system.

FAA approval and documentation of the ELOS finding

The FAA has approved the aforementioned equivalent level of safety finding in project issue paper ES-16 or Administrative Collector Issue Paper G-6. This memorandum provides standardized documentation of the ELOS that is non-proprietary and can be made available to the public. The TAD has assigned a unique ELOS Memorandum number (see front page) to facilitate archiving and retrieval of this ELOS. This ELOS Memorandum number should be listed in the type certificate data sheet under the Certification Basis section. An example of an appropriate statement is provided below.

Equivalent Level of Safety Findings have been made for the following regulation(s):
§ 25.1443(c), Minimum mass flow of supplemental oxygen
(documented in TAD ELOS Memo TC6918SE-T-ES-16)

Christopher Parker

Transport Airplane Directorate,
Aircraft Certification Service

12/3/2015
Date

ELOS Originated by Seattle ACO:	Project Engineer Robert Hettman	Routing Symbol ANM-150S