Will publish in Part 5. of the Federal Register on July 14, 2004.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121, 125, and 135

[Docket No. FAA-2004-18596 SFAR No.;XX Notice No.

RIN 2120-AI30

Use of Certain Portable Oxygen Concentrator Devices onboard Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to address the traveling needs of persons on oxygen therapy by permitting the use of certain portable oxygen concentrator devices on aircraft, providing certain conditions are satisfied.

DATES: Send your comments on or before [~~Insert date 30 days after date of publication in the Federal Register~~] August 13, 2004.

ADDRESSES:

Address your comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590-0001. You must identify the docket number FAA-2004-18596 at the beginning of your comments, and you should submit two copies of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to http://dms.dot.gov. You may review the public docket containing comments to these proposed regulations in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal

holidays. The Dockets Office is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: James W. Whitlow, Office of the Chief Counsel, AGC-2, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267-3222; facsimile (202) 267-3227.

SUPPLEMENTARY INFORMATION:

Comments Invited: Interested persons are invited to participate in the making of the proposed action by submitting such written data, views, or arguments as they may desire. Comments relating to the environmental, energy, federalism, or economic impact that might result from adopting the proposals in this document also are invited. Substantive comments should be accompanied by cost estimates. Comments must identify the regulatory docket or notice number and be submitted in duplicate to the DOT Rules Docket address specified above.

All comments received, as well as a report summarizing each substantive public contact with DOT personnel concerning this proposed rulemaking, will be filed in the docket. The docket is available for public inspection before and after the comment closing date.

All comments received, on or before the closing date, will be considered by FAA before taking action on this proposed rulemaking. Comments filed late will be considered as far as possible without incurring expense or delay. The proposals in this document may be changed in light of the comments received.

Commenters wishing FAA to acknowledge receipt of their comments submitted in response to this document must include a pre-addressed, stamped postcard with those comments on which the following statement is made: "Comments to Docket No. FAA-2004-18596."

The postcard will be date stamped and mailed to the commenter.

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by taking the following steps:

(1) Go to the search function of the Department of Transportation's electronic Docket Management System (DMS) web page (http://dms.dot.gov/search).

(2) On the search page type in the last four digits of the Docket number shown at the beginning of this notice. Click on "search."

(3) On the next page, which contains the Docket summary information for the Docket you selected, click on the document number of the item you wish to view.

Background

The FAA is proposing this Special Federal Aviation Regulation (SFAR) to address the traveling needs of persons on oxygen therapy. The FAA has been made aware of the critical need for improved service to passengers who must travel with oxygen while on the aircraft. Consequently, the FAA is proposing this SFAR to permit the use of certain portable oxygen concentrator devices on aircraft, provided certain conditions are satisfied. The NPRM proposes to limit the SFAR to the AirSep LifeStyle Portable Oxygen Concentrator because this is the only device of this type the FAA has evaluated and determined to be safe. Other devices may be added to the SFAR after the FAA has been satisfied that they can be safely used on board aircraft. The FAA seeks comments, particularly technical information about other assistive devices which may be of benefit to users of medical oxygen delivery systems, to enable the FAA to evaluate the safety of these devices and the feasibility of including these devices in the SFAR. In order for an oxygen delivery system to be considered safe by the FAA for use onboard an aircraft, at a minimum the Research and Special Programs Administration (RSPA) must first

determine that the device does not contain hazardous materials and is not subject to its hazardous materials regulations.

Currently, 14 CFR 121.574, 125.219, and 135.91 allow a passenger to carry and operate equipment generating, storing or dispensing medical oxygen on board an aircraft only if the equipment is furnished by the certificate holder and certain other conditions are satisfied. The oxygen furnished in compliance with these regulations is compressed oxygen, which is regulated as a hazardous material in transportation by the RSPA. Several of the conditions contained in sections 121.574, 125.219, and 135.91 are designed to ensure that the oxygen cylinder is in compliance with RSPA's hazardous materials regulations. Other conditions are designed to ensure that the oxygen is dispensed safely while in use on the aircraft. Currently, air carriers are not required to provide medical oxygen and many regional carriers and some larger carriers do not provide this service. Those carriers that do allow passengers to use the medical oxygen typically provide the compressed oxygen themselves and charge a fee for this service.

Over the last two years, a new portability technology for dispensing medical oxygen to users has been brought to the FAA's attention – (1) the AirSep Corporation's LifeStyle Portable Oxygen Concentrator (POC), which is the first unit to be evaluated by the FAA; and (2) the Inogen, Inc.'s Inogen One POC, which is currently being evaluated by the FAA. The FAA has reviewed the documentation on both these products and had several discussions with their manufacturers regarding the use of these units on board aircraft. Based on information received to date, the FAA believes that the AirSep POC unit warrants special consideration for use on aircraft. The FAA currently is reviewing the Inogen One POC to determine if it too warrants such special consideration. Therefore, this proposed rule only pertains to the AirSep POC.

The AirSep POC, which does not contain hazardous materials, operates by separating oxygen from nitrogen and other gases comprising ambient air and dispensing it in concentrated form to the user at a purity level of approximately 90% (+- 3%). The AirSep units deliver five oxygen flow rates of 1 to 5 liters per minute. The AirSep units must have their filters changed by an authorized equipment distributer every 3000 hours. There is an hour meter on the device that notifies the user how many hours have gone by since the last maintenance check. The AirSep units may be operated either from an aircraft electrical outlet (if installed) or by a rechargeable battery with a duration of 50 minutes fully charged.

RSPA has reviewed and evaluated both the AirSep POC and the Inogen POC and determined that these devices are not regulated as hazardous materials in transportation. RSPA issued letters to the manufacturers stating this conclusion in May 2003 (AirSep POC) and March 2004 (Inogen POC).

While the RSPA determination is an important step for the FAA's review of the POCs, the FAA must still make an independent determination whether the devices pose a hazard in aviation. If there is no hazard, then the FAA could grant an exemption to petitioners from either section 121.574, 125.219, or 135.91, as applicable, allowing the use of the POCs because the FAA's regulations apply to devices that dispense oxygen. The FAA informed the portable oxygen community that an exemption would be needed in order for a passenger to carry on and operate a POC not furnished by the aircraft operator via a letter issued through the Department of Transportation's Office of the Secretary in November 2002. To date, the FAA has not yet received any petitions for exemption. The FAA has been informed that several air carriers are interested in this technology and are in the process of evaluating whether these devices interfere with the electrical, navigation or communication equipment on board its aircraft. Rather than

waiting for a carrier to apply to the FAA for an exemption under the existing regulatory structure, the FAA has decided to propose an amendment to its regulations to permit passengers to carry on and operate their own POC on board an aircraft as long as certain conditions are met.

Section-by-Section Discussion of the Proposals

Section 1 of the SFAR would indicate that this SFAR prescribes special operating rules for the AirSep POC. It also establishes that the SFAR would apply to both the aircraft operator and the passenger using the POC. Section 2 would then define the AirSep POC.

Section 3 would establish the requirements for operating this device on board an aircraft. Section 3(a)(1) specifies that the aircraft operator is responsible for determining whether the device would interfere with the electrical, navigation or communication equipment aboard each aircraft on which the device is used. The operator is responsible for making this determination pursuant to 14 CFR 91.21, 121.306, 125.204, or 135.144. Given the broad array of aircraft and equipment combinations, only the operator can be responsible for making such a determination.

Section 3(a)(2) would mirror a safety warning contained in the AirSep Patient User Manual. In this Manual, AirSep states that leaving the nasal cannula under bed coverings or chair cushions while the POC is turned on but not in use could result in the oxygen "mak[ing] the material flammable." However, the FAA has also been informed by AirSep that if the nasal cannula is not positioned to sense inhalation , no oxygen will flow from the cannula. The FAA seeks comments regarding risks associated with the POC being turned on but not in use.

Section 3(a)(3), would require the operator to assure that the user is capable of hearing the unit's various alarms, seeing the alarm light indicators, and taking the appropriate action in response to the alarm, or travel with someone who is capable of performing those functions. This proposed condition also mirrors several warning statements in the AirSep Patient User

Manual. The POC is equipped with an alarm that will sound in the event that the unit fails to sense user breathing, overheats, or otherwise malfunctions. Section 3(b)(1) requires that the operator assure that the user turns off the unit in the event that the alarm sounds indicating a general malfunction of the unit while in use on the aircraft.

Section 3(a)(4) would prohibit the operator from allowing smoking or open flame within 10 feet of any person using a POC. The FAA's regulations at 121.574, 125.219, and 135.91 require no less than 10 feet between a person smoking and a passenger using oxygen. Given the unique environment of an aircraft, and the devastating consequences that can occur in the event oxygen is used too close to someone who is smoking, the FAA is proposing a limit of at least 10 feet. While smoking is no longer allowed on scheduled flights, it may be permitted on non-scheduled flights.

Section 3(a)(5) requires that the operator prevent the air intake/gross particle filter and air outlet from being blocked while in use. The FAA believes it is important to include this statement in its conditions because blocking off the filter or outlet could result in the unit malfunctioning and having to be turned off.

Section 3(a)(6) & (7) would require that the device be stowed either underneath the seat in front of the user, or in another approved stowage location, and that the user is seated, so as not to restrict access to or use of any required emergency, or regular exit or of the aisle in the passenger compartment. These two conditions are consistent with the FAA's existing regulations and are necessary to ensure safe movement within the cabin, prevent injury from loose objects within the cabin and, if necessary, not obstruct evacuation of the aircraft.

Section 3(a)(8) would require the operator to ensure that the device is free from oil, grease or petroleum products. Again this condition is similar to a warning statement contained in

the AirSep Patient User Manual and to a condition contained in the FAA's current medical oxygen regulations. This condition also obligates the operator to look at the condition of the device and ensure that it is free from damage and other signs of excessive wear or abuse. Section 3(a)(9) would require the operator to verify that the hour meter indicates that the hours will not exceed 3000 hours by the end of the scheduled flight time of that flight leg. Section 3(a)(10) would require the pilot in command to be notified when a passenger is using the portable oxygen concentrator on board the aircraft. This is consistent with current 121.574, 125.219, and 135.91, and ensures that the pilot in command (PIC) is fully informed.

Section 3(b) would impose certain standards and requirements on the unit's user. Section 3(b)(1) would require the user to be capable of hearing the unit's alarms, seeing the alarm light indicators, and taking the appropriate action in response to the various alarms and alarm light indicators, or be traveling with someone who is capable of hearing the unit's alarms, seeing the alarm light indicators, and taking the appropriate action in response to the various alarms and alarm light indicators.

Section 3(b)(2) would obligate the user to turn off the unit if a warning alarm and associated alarm light indicator detects a general malfunction of the unit. However, FAA has received information from AirSep that a warning alarm will sound if the gross particle filter or air outlet is blocked. According to AirSep, once the blockage is removed the alarm sound will stop and the unit does not need to be turned off. The FAA is seeking comments as to the various reasons an alarm may sound and how these situations can be remedied.

Section 3(b)(3) would mandate that the user must have a statement signed by a licensed physician that specifies the use of the POC and establishes the maximum flow rate corresponding to the pressure in the cabin of the aircraft under normal operating conditions.

Section 3(b)(4) would mirror the AirSep Patient User Manual by requiring that the user only use lotions or salves that are approved for use with oxygen.

Section 3(b)(5) stipulates that the user must ascertain from the aircraft operator the duration of the flight (including any anticipated delays) and provide a sufficient number of batteries to power the device for the duration of the flight, including reasonable delays. This proposal is not intended to require that the AirSep portable oxygen concentrator be powered by batteries as a condition of carriage. Rather, this portion of the NPRM proposes that a user have a sufficient number of batteries to potentially serve as a power source during all phases of flight. This condition is consistent with the means for determining the oxygen quantity needed for the duration of a flight contained in 14 CFR 121.574(a)(5).

The FAA seeks comments on the following questions. First, should the aircraft operator be required to inform the user about the availability of electrical outlets suitable for the AirSep portable oxygen concentrator? Second, should the user be required to carry batteries for the duration of the flight including reasonable delays if there are electrical outlets available on the flight? Third, are the meanings of the terms "anticipated delay" and "reasonable delay" sufficiently clear? In a related Office of the Secretary rulemaking under the Air Carrier Access Act, the Department will seek comment on whether carriers must permit users of AirSep portable oxygen concentrator to plug their devices into available on-board power outlets, consistent with FAA safety rules related to electronic devices.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), there are no requirements for information collection associated with this proposal.

Summary of Economic Evaluation, Regulatory Flexibility Determination, International Trade Impact Assessment and Unfunded Mandates Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. section 2531-2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. And fourth, the Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of $100 million or more, in any one year (adjusted for inflation.)

However, for regulations with an expected minimal impact the above-specified regulatory evaluation is not required. The Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis and review of regulations. If it is determined that the expected economic impact is so minimal that the proposal does not warrant a full evaluation, a statement to that effect and the basis for it is included in the proposed regulation.

This proposed SFAR would permit the use of certain portable oxygen concentrator (POC) devices on aircraft, provided certain conditions are satisfied. These conditions are described

elsewhere in this document and would impose some costs on aircraft operators who choose to allow FAA approved POCs on board their aircraft. This proposal does not require operators to allow their use, however, and therefore it imposes no costs. The FAA assumes that operators who choose to allow POC use would voluntarily decide to take this action only if it were advantageous for them to do so. Since this proposal imposes no required costs, no economic evaluation was proposed.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to the regulation." To achieve that principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis as described in the Act. However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 act provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

Since meeting the requirements of this proposed SFAR is entirely voluntary on the part of the aircraft operators, t imposes no economic burden. Consequently, the FAA certifies that the rule would not have a significant economic impact on a substantial number of small entities.

International Trade Impact Analysis

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create any unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. In addition, consistent with the Administration's belief in the general superiority and desirability of free trade, it is the policy of the Administration to remove or diminish to the extent feasible, barriers to international trade, including both barriers affecting the export of American goods and services to foreign countries and barriers affecting the import of foreign goods and services to the United States.

In accordance with the above statute and policy, the FAA has assessed the potential effect of this proposed SFAR to be minimal and therefore has determined that this proposal will not result in an impact on international trade by companies doing business in or with the United States.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any one year by State,

local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action." The FAA currently uses an inflation-adjusted value of $120.7 million in lieu of $100 million.

This proposed SFAR does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Executive Order 13132, Federalism

FAA analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. It determined that this action would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, FAA has concluded that this notice of proposed rulemaking does not have federalism implications.

Energy Impact

The energy impact of the proposed rule has been assessed in accordance with the Energy Policy and Conservation Act (EPCA), Public Law 94-163, as amended (42 U.S.C. 6362). FAA has determined that the proposed rule is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 14 CFR Parts 121, 125, and 135

Air carriers, Aircraft, Airmen, Aviation safety, Charter flights, Safety, Transportation, Air taxis.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to add SFAR No. _____ to Chapter II of Title 14, Code of Federal Regulations, as follows:

1. The authority citation for this SFAR shall read as follows:

Authority: 49 U.S.C. 106(g), 1153, 40101, 40102, 40103, 40113, 41721, 44105, 44106, 44111, 44701-44717, 44722, 44901, 44903, 44904, 44906, 44912, 44914, 44936, 44938, 46103, 46105.

2. Special Federal Aviation Regulation No.XX is added to read as follows:

SPECIAL FEDERAL AVIATION REGULATON NO. XX RULES FOR USE OF PORTABLE OXYGEN CONCENTRATOR SYSTEMS ON BOARD AIRCRAFT.

Section 1. Applicability – This rule prescribes special operating rules for the use of portable oxygen concentrator units on board civil aircraft. This rule applies to both the aircraft operator and the passenger using the portable oxygen concentrator on board the aircraft.

Section 2. Definitions – For the purposes of this SFAR the following definitions apply: AirSep LifeStyle Portable Oxygen Concentrator units are medical devices that: (1) do not contain hazardous materials as determined by the Research and Special Programs Administration; (2) are regulated by the Food and Drug Administration; (3) provide oxygen therapy through pulse technology; and (4) assists a user of medical oxygen under a doctor's care. These units perform by separating oxygen from nitrogen and other gases comprising ambient air and dispenses it in concentrated form to the user.

Section 3. Operating requirements – (a) The AirSep LifeStyle Portable Oxygen Concentrator unit may be used by a passenger on board an aircraft provided the operator ensures that the following conditions are satisfied:

(1) The device does not cause interference with the electrical, navigation or communication equipment on the aircraft on which the device is to be used;

(2) The unit must be turned off if the nasal cannula is not positioned for oxygen delivery to the user;

(3) The user must be capable of seeing the alarm indicator lights, hearing the various warning alarms, and taking the appropriate action should the unit fail to detect the user's breathing or a general malfunction occurs, or is traveling with someone who is capable of performing those functions for the user ;

(4) No smoking or open flame is permitted within 10 feet of any person using a portable oxygen concentrator;

(5) The air intake/gross particle filter or the air outlet must not be blocked during use;

(6) The unit must either be stowed under the seat in front of the user, or in another approved stowage location, so that it does not block the aisle way or the entryway into the row;

(7) No person using a portable oxygen concentrator is permitted to be seated in an exit row;

(8) The portable oxygen concentrator must be free from oil, grease or other petroleum products and be in good condition free from damage or other signs of excessive wear or abuse;

(9) The number of hours before maintenance must be below 3,000 at the end of the scheduled flight time for that flight leg; and

(10) The pilot in command must be apprised when a passenger is using a portable oxygen concentrator.

(b) The user of the portable oxygen concentrator must comply with the following conditions to use the device on board the aircraft:

(1) The user must be capable of hearing the unit's alarms, seeing the alarm light indicators, and taking the appropriate action in response to the various alarms and alarm light indicators, or be traveling with someone who is capable of performing those functions;

(2) In the event the warning alarm sounds, the portable oxygen concentrator unit must be turned off if the warning alarm and the associated alarm light indicator detects a general malfunction of the unit;

(3) The passenger must have a statement signed by a licensed physician that specifies the use of the portable oxygen concentrator and establishes the maximum flow rate corresponding to the pressure in the cabin of the aircraft under normal operating conditions;

(4) Only lotions or salves that are oxygen approved may be used by persons using the portable oxygen device; and

(5) The user must obtain from the aircraft operator the duration of the planned flight, including any anticipated delays. The user must provide a sufficient number of batteries to power the device for the duration of the flight, including any reasonable delays.

Issued in Washington, DC, on JUL 8 2004

James W. Whitlow
Deputy Chief Counsel

Certified to be a True Copy