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14 CFR Part 121

Use of Additional Portable Oxygen Concentrator Devices Onboard Aircraft; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. FAA–2004–18596; SFAR 106]

RIN 2120–AI81

Use of Additional Portable Oxygen Concentrator Devices Onboard Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Special Federal Aviation Regulation 106 (SFAR 106), Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft, to allow for the use of the *AirSep Corporation's FreeStyle, SeQual Technologies' Eclipse,* and *Respironics Inc.'s EverGo* portable oxygen concentrator (POC) devices onboard aircraft, provided certain conditions in the SFAR are met. This action is necessary to allow all POC devices deemed acceptable by the FAA to be available to the traveling public in need of oxygen therapy for use in air commerce. When this rule becomes effective, there will be a total of five different POC devices the FAA finds acceptable for use onboard aircraft during travel, and passengers will be able to carry these devices onboard the aircraft and use them with the approval of the aircraft operator.

DATES: This final rule amending SFAR 106 will become effective on September 12, 2006.

FOR FURTHER INFORMATION CONTACT: David Catey, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. Telephone: (202) 267–3732.

SUPPLEMENTARY INFORMATION:

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page (*http://dms.dot.gov/search*);

(2) Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies/*; or

(3) Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html*.

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the amendment number or docket number of this rulemaking.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact their local FAA official, or the person listed under **FOR FURTHER INFORMATION CONTACT**. You can find out more about SBRFA on the Internet at our site, *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/*.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code (49 U.S.C.). Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

The FAA is authorized to issue this final rule pursuant to 49 U.S.C. 44701. Under that section, the FAA is authorized to establish regulations and minimum standards for ''other practices methods and procedure the Administrator finds necessary for air commerce and national security.''

Background

On July 12, 2005, the FAA published Special Federal Aviation Regulation 106 (SFAR 106) entitled, ''Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft'' (70 FR 40156). SFAR 106 is the result of a notice the FAA published in July 2004 (69 FR 42324) to address the needs of passengers who must travel with medical oxygen. Prior to publication of SFAR 106, passengers in need of medical oxygen during air transportation faced many obstacles when requesting service. Many carriers did not provide medical oxygen service aboard flights, and those that did often provided service at a price that travelers could not afford. Coordinating service between air carriers and suppliers at airports was also difficult, and passengers frequently chose not to fly because of these difficulties.

Recently, new medical oxygen technologies approved by the Food and Drug Administration (FDA) reduce the risks typically associated with compressed oxygen. Several manufacturers have developed small portable oxygen concentrators (POC) that work by separating oxygen from nitrogen and other gases contained in ambient air and dispensing it in concentrated form to the user with an oxygen concentration of about 90%. The POCs operate using either rechargeable batteries or, if the aircraft operator obtains approval from the FAA, aircraft electrical power.

In addition, the Pipeline and Hazardous Materials Safety Administration (PHMSA) has determined that the POCs covered by this amendment are not hazardous materials. Thus, they do not require the same level of special handling as compressed oxygen, and are safe for use onboard aircraft, provided certain conditions for their use are met.

SFAR 106 permits passengers to carry on and use certain POCs onboard aircraft if the aircraft operator ensures that the conditions specified in the SFAR for their use are met. The devices initially determined acceptable for use in SFAR 106 are the *AirSep LifeStyle* and the *Inogen One* POCs. Aircraft operators can now offer medical oxygen service as they did before SFAR 106 was enacted, or they can arrange for passengers to carry on and use one of the devices covered in SFAR 106. SFAR 106 is an enabling rule, which means that no aircraft operator is required to allow passengers to operate these devices onboard, but they may allow them to be operated onboard. If one of these devices is allowed by the aircraft operator to be carried on board, the conditions in the SFAR must be met.

When SFAR 106 was published, the FAA committed to establishing a single standard for all POCs so that regulations wouldn't apply to specific manufacturers and models of device. Whenever possible, the FAA tries to regulate by creating standards rather than approving by manufacturer. In the case of SFAR 106, the quickest and easiest way to serve both the customer and the air carrier was to allow the use of the devices determined to be acceptable by the FAA in SFAR 106 in a special, temporary regulation. As we stated in the preamble discussion in SFAR 106 ''while we are committed to developing a performance-based standard for all future POC devices, we do not want to prematurely develop standards that have the effect of stifling new technology of which we are unaware.'' We developed SFAR 106 and published it so that passengers who otherwise could not fly could do so with an affordable alternative to what existed before SFAR 106 was published.

We continue to pursue the performance-based standard for all POCs. This process is time-consuming

and we intend to publish a notice in the **Federal Register** and offer the public a chance to comment on the proposal when it is complete. In the meantime, manufacturers continue to create new and better POCs, and several have requested that their product also be included as an acceptable device in SFAR 106. These new manufacturers include SeQual Technologies, Inc., and Respironics, Inc. AirSep Corporation, which manufactures the *LifeStyle* POC authorized for use under SFAR 106, has asked the FAA to authorize the use of its *FreeStyle* POC under SFAR 106 also. Each of these companies has formally petitioned the FAA for inclusion in SFAR 106 by submitting documentation of the devices to the Department of Transportation's Docket Management System. That documentation is available at *http://dmes.dot.gov* under the following docket numbers:

1. SeQual Technologies—FAA–2005–22574.

2. Respironics Inc., formerly OxyTec Medical Corporation—FAA–2006–23678.

3. AirSep Corporation—FAA–2006–24912.

As stated in Section 2 of SFAR 106, each covered device must not contain hazardous materials as determined by PHMSA (written documentation necessary), and must also be regulated by the FDA. Each petitioner included technical specifications for the devices in their request for approval, along with the required documentation from PHMSA and the FDA. The petitioners provided the FAA with the required documentation for the following POC devices:

1. SeQual Technologies' *Eclipse* Oxygen System;

2. Respironics *EverGo* System; and

3. AirSep Corporation's *FreeStyle* Portable Oxygen Concentrator.

The Rule

This amendment to SFAR 106 will include the *SeQual Eclipse, Respironics EverGo,* and *AirSep FreeStyle* devices in the list of POCs authorized for use in air commerce. The FAA has reviewed each individual device and accepted the documentation provided by the three manufacturers. That documentation includes letters provided to the manufacturer by PHMSA and the FDA affirming the status of each device as it pertains to the requisites stated in SFAR 106.

After reviewing the applicable FDA safety standards and the PHMSA findings, these three devices were determined by the FAA to be acceptable for use in air commerce.

Along with the inclusion of these three new devices in Section 2 of the SFAR, we amend the rule by removing the requirement that a POC provide oxygen therapy solely through the use of pulse technology. It was only after publication of SFAR 106 that we learned about a continuous flow feature of the SeQual Technologies Eclipse POC. The Eclipse POC features pulse delivery in addition to its continuous flow feature. Therefore, we find there is no safety reason for limiting POC acceptance to those POCs having only the pulse delivery feature. That requirement was formerly included in Section 2 of the SFAR and has been removed.

Good Cause for Adoption of This Final Rule Without Notice and Comment

As stated above, SFAR 106 was published on July 12, 2005. We stated in the preamble of that final rule that the *AirSep LifeStyle* and *Inogen One* POC devices were the only known acceptable devices when the rule was published. We also stated in that final rule that ''we cannot predict how future products may be developed and work.'' We initiated a notice and comment period for the use of POC devices onboard aircraft on July 14, 2004 (69 FR 42324) and responded to the comments received in response to that NPRM in the final rule published in 2005. Therefore, it is not in the public interest to publish a notice to request comments on this amendment because all issues related to the use of POC devices onboard an aircraft have already been discussed. Further notice and comment would unnecessarily delay the acceptance of the *AirSep FreeStyle*, *SeQual Eclipse*, and *Respironics EverGo* POC devices as authorized for use onboard aircraft and included in SFAR 106.

Therefore, I find that notice and public comment under 5 U.S.C. 553(b) are impracticable and contrary to the public interest. Further, I find that good cause exists for making this rule effective immediately upon publication.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA determined that there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations. I find that this action is fully consistent with my obligations under 49 U.S.C. 40105(b)(1)(A) to ensure that I exercise my duties consistently with the obligations of the United States under international agreements.

Paperwork Reduction Act

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA submitted a copy of the new information collection requirements in this final rule to the Office of Management and Budget for its review. OMB approved the collection of this information and assigned OMB Control Number 2120–0702.

This final rule requires that if a passenger carries a POC on board the aircraft with the intent to use it during the flight, he or she must inform the pilot in command of that flight. Additionally, the passenger who plans to use the device must provide a written statement signed by a licensed physician that verifies the passenger's ability to operate the device, respond to any alarms, the extent to which the passenger must use the POC (all or a portion of the flight), and prescribes the maximum oxygen flow rate.

Please note that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The Paperwork Reduction Act paragraph in the final rule that established SFAR 106 still applies to this amendment. The availability of three new POC devices will likely increase the availability and options for a passenger in need of oxygen therapy, but the paperwork burden discussed in the original final rule is unchanged. Therefore, the OMB Control Number associated with this collection remains 2120–0702.

Regulatory Analyses

Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866, Regulatory Planning and Review, directs the FAA to assess both the costs and benefits of a regulatory change. We are not allowed to propose or adopt a regulation unless we make a reasoned determination that the benefits of the intended regulation justify its costs. Our assessment of this proposal indicates that its economic impact is minimal. Since its costs and benefits do not make it a ''significant regulatory action'' as defined in the Order, we have not prepared a ''regulatory impact analysis.'' Similarly, we have not prepared a ''regulatory evaluation,'' which is the written cost/benefit analysis ordinarily required for all rulemaking proposals under the DOT

Regulatory and Policies and Procedures. We do not need to do the latter analysis where the economic impact of a proposal is minimal. This final rule amending SFAR 106 has no new costs associated with it because there is no requirement for use of these devices. The regulatory evaluation presented when SFAR 106 was first published is still valid and applicable, and the inclusion of these three devices as options for passengers and operators does not change the cost or benefits assigned in that final rule.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) directs the FAA to fit regulatory requirements to the scale of the business, organizations, and governmental jurisdictions subject to the regulation. We are required to determine whether a proposed or final action will have a ''significant economic impact on a substantial number of small entities'' as they are defined in the Act. If we find that the action will have a significant impact, we must do a ''regulatory flexibility analysis.''

This final rule adds three new devices to the list of authorized POCs in SFAR 106. Its economic impact is minimal. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Trade Impact Assessment

The Trade Agreements Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create 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 into the United States.

In accordance with the above statute and policy, the FAA has assessed the potential effect of this final rule and has determined that it will impose the same costs on domestic and international entities and thus has a neutral trade impact.

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 $128.1 million in lieu of $100 million.

This final rule does not contain such a mandate. The requirements of Title II of the Act, therefore, do not apply.

Executive Order 13132, Federalism

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

Environmental Analysis

FAA Order 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this proposed rulemaking action qualifies for the categorical exclusion identified in paragraph 312d and involves no extraordinary circumstances.

Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA has analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 18, 2001). We have determined that it is not a ''significant energy action'' under the executive order because it is not a ''significant regulatory action'' under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

List of Subjects in 14 CFR Part 121

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

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends SFAR No. 106 to Chapter II of Title 14, Code of Federal Regulations, as follows:

PART 121—OPERATING REQUIREMENTS: DOMESTIC, FLAG, AND SUPPLEMENTAL OPERATIONS

■ 1. The authority citation for part 121 continues to 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. Revise Section 2 of SFAR 106 to read as follows:

* * * * *

Section 2. *Definitions*—For the purposes of this SFAR the following definitions apply: Portable Oxygen Concentrator: means the *AirSep LifeStyle*, *AirSep FreeStyle*, *Inogen One*, *SeQual Eclipse*, or *Respironics EverGo* Portable Oxygen Concentrator medical device units as long as those medical device units: (1) Do not contain hazardous materials as determined by the Pipeline and Hazardous Materials Safety Administration; (2) are also regulated by the Food and Drug Administration; and (3) assist a user of medical oxygen under a doctor's care. These units perform by separating oxygen from nitrogen and other gases contained in ambient air and dispensing it in concentrated form to the user.

* * * * *

■ 3. Revise Section 3(a) introductory text of SFAR 106 to read as follows:

Section 3. Operating Requirements—

(a) No person may use and no aircraft operator may allow the use of any portable oxygen concentrator device, except the *AirSep LifeStyle*, *AirSep FreeStyle*, *Inogen One*, *SeQual Eclipse*, or *Respironics EverGo* Portable Oxygen Concentrator units. These units may be carried on and used by a passenger on board an aircraft provided the aircraft operator ensures that the following conditions are satisfied:

* * * * *

Issued in Washington, DC, on August 18, 2006.

Marion C. Blakey,

Administrator.

[FR Doc. 06–7597 Filed 9–11–06; 8:45 am]

BILLING CODE 4910–13–P