

[4910-13]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. FAA-2008-1227; SFAR 106]

RIN 2120-AJ40

Use of Additional Portable Oxygen Concentrator Devices On Board 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 On Board Aircraft, to allow for the use of the Delphi Medical Systems' RS-00400 and Invacare Corporation's XPO2 portable oxygen concentrator (POC) devices on board aircraft, provided certain conditions in the SFAR are met. SFAR 106 was previously amended to add three additional POC devices to the original SFAR. Today's action is necessary to allow all POC devices deemed acceptable by the FAA to be available for use in air commerce to the traveling public in need of oxygen therapy,. With this Final Rule, there will be a total of seven different POC devices the FAA finds acceptable for use on board aircraft, and passengers will be able to carry these devices on board the aircraft and use them with the approval of the aircraft operator.

DATES: This final rule amending SFAR 106 will become effective on [INSERT DATE OF PUBLICATION].

FOR FURTHER INFORMATION CONTACT: David Catey, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW, Washington, D.C. 20591. Telephone: (202) 267-8166.

SUPPLEMENTARY INFORMATION:

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

- (1) Searching the Federal eRulemaking Portal at <http://www.regulations.gov>;
- (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 SBREFA 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 USC). 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 USC Section 44701. Under that section, the FAA is authorized to establish regulations and minimum standards for other practices, methods, and procedures 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 On Board Aircraft" (70 FR 40156). SFAR 106 is the result of a notice of proposed rulemaking (NPRM) 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 aircraft operators 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 operators and suppliers at airports was also difficult, and passengers frequently chose not to fly because of these difficulties.

New medical oxygen technologies approved by the Food and Drug Administration (FDA) reduce the risks typically associated with compressed oxygen and provide a safe alternative for passengers who need oxygen therapy. Several manufacturers have

developed small portable oxygen concentrator (POC) devices 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 POC devices 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 POC devices 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 on board aircraft, provided certain conditions for their use are met.

SFAR 106 permits passengers to carry on and use certain POC devices on board 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, published July 12, 2005, were the AirSep Corporation's LifeStyle and the Inogen, Inc.'s Inogen One POCs. SFAR 106 was amended on September 12, 2006 (71 FR 53954) to add three additional POC devices, AirSep Corporation's FreeStyle, SeQual Technologies' Eclipse, and Repironics Inc.'s EverGo, to the original SFAR. This final rule adds two additional POC devices, Delphi Medical Systems' RS-00400 and Invacare Corporation's XPO2, that may be carried on and used by a passenger on board an aircraft.

Aircraft operators can now offer medical oxygen service as they did before SFAR 106 was enacted, or they can meet certain conditions and allow passengers to carry on and use one of the POC 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

POC devices on board its aircraft, but it may allow them to be operated on board. If the aircraft operator allows one of these devices to be carried on board, the conditions in the SFAR must be met.

When SFAR 106 was originally published, the FAA committed to establishing a single standard for all POC devices so that regulations would not apply to specific manufacturers and models of devices. Whenever possible, the FAA tries to regulate by creating performance-based standards rather than approving specific devices by manufacturer. In the case of SFAR 106, the quickest and easiest way to serve both the passenger and the aircraft operator 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 of the final rule that established 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 and published SFAR 106 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 POC devices. 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 POC devices, and several have requested that their product also be included as an acceptable device in SFAR 106. These new manufacturers include Delphi Medical Systems and Invacare Corporation. Each of these companies has formally petitioned the FAA for inclusion in SFAR 106 by

submitting documentation of the devices to the Federal Docket Management System.

That documentation is available at <http://www.regulations.gov> under the following

docket numbers:

1. Delphi Medical Systems – FAA-2008-0261; and
2. Invacare Corporation – FAA-2008-0278.

As stated in Section 2 of SFAR 106, no covered device may contain hazardous materials as determined by PHMSA (written documentation necessary), and each device 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. Delphi Medical Systems', Model RS-00400; and
2. Invacare Corporation's, Model XPO2.

The Rule

This amendment to SFAR 106 will include the Delphi Medical Systems' RS-00400 and Invacare Corporation's XPO2 devices in the list of POC devices authorized for use in air commerce. The FAA has reviewed each individual device and accepted the documentation provided by the two 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 two devices were determined by the FAA to be acceptable for use in air commerce.

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 on board 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 unnecessary to publish a notice to request comments on this amendment because all issues related to the use of POC devices on board an aircraft have already been discussed. Further notice and comment would also delay the acceptance of the Delphi Medical Systems’ RS-00400 and Invacare Corporation’s XPO2 POC devices as authorized for use on board aircraft, which would delay their availability for passengers in need of oxygen therapy.

Therefore, I find that notice and public comment under 5 U.S.C. 553(b) is unnecessary 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 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 SFAR 106 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 device 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 two 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

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 (Public Law 96-354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Public Law 96-39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires agencies to prepare a written assessment of the 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 annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA's analysis of the economic impacts of this final rule.

Department of Transportation Order DOT 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it to be included in the preamble if a full regulatory evaluation of the cost and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows:

This action amends Special Federal Aviation Regulation 106 (SFAR 106), Use of Certain Portable Oxygen Concentrator Devices On Board Aircraft, to allow for the use of the Delphi Medical Systems' RS-00400 and Invacare Corporation's XPO2 portable oxygen concentrator (POC) devices on board aircraft, provided certain conditions in the

SFAR are met. This action is necessary to allow additional 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 seven different POC devices the FAA finds acceptable for use on board aircraft, and passengers will be able to carry these devices on board the aircraft and use them with the approval of the aircraft operator.

The FAA has determined that this final rule is not a “significant regulatory action” as defined in section 3(f) of Executive Order 12866, and is not “significant” as defined in DOT's Regulatory Policies and Procedures.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Public Law 96-354) (RFA) establishes “as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.” The RFA 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 rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA 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.

This final rule adds Delphi Medical Systems' RS-00400 and Invacare Corporation's XPO2 to the list of authorized POC devices in SFAR 106. Its economic impact is minimal. Therefore, as the Acting FAA Administrator, I certify that this action will not have a significant economic impact on a substantial number of small entities.

International Trade Analysis

The Trade Agreements Act of 1979 (Public Law 96-39), as amended by the Uruguay Round Agreements Act (Public Law 103-465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards are not considered unnecessary obstacles to the foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such the protection of safety, and do not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA notes the purpose is to ensure the safety of the American public, and has assessed the effects of this rule to ensure that it does not exclude imports that meet this objective. As a result, this rule is not considered as creating an unnecessary obstacle to foreign commerce.

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 minimal impact 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), enacted as Public Law 104-4 on March 22, 1995, 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 a \$100 million or more expenditure (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 \$136.1 million in lieu of \$100 million.

This final rule 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

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.

Plain Language

In response to the June 1, 1998 Presidential Memorandum regarding the use of plain language, the FAA re-examined the writing style currently used in the development of regulations. The memorandum requires federal agencies to communicate clearly with the public. We are interested in your comments on whether the style of this document is clear, and in any other suggestions you might have to improve the clarity of FAA communications that affect you. You can get more information about the Presidential memorandum and the plain language initiative at <http://www.plainlanguage.gov>.

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 rulemaking action qualifies for the categorical exclusion identified in paragraph 312f 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.

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. Amend SFAR 106 by revising sections 2 and 3(a) introductory text to read as follows:

**Special Federal Aviation Regulation 106—Rules for use of portable oxygen
concentrator systems on board aircraft**

* * * * *

Section 2. Definitions – For the purposes of this SFAR the following definitions apply: Portable Oxygen Concentrator: means the AirSep FreeStyle, AirSep LifeStyle, Delphi RS-00400, Inogen One, Invacare XPO2, Respironics EverGo, and SeQual Eclipse Portable Oxygen Concentrator medical devices as long as those medical devices: (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.

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 FreeStyle, AirSep LifeStyle, Delphi RS-00400, Inogen One, Invacare XPO2, Respironics EverGo, or SeQual Eclipse Portable Oxygen Concentrator devices. These devices 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 January 7, 2009.

Robert Sturgell

Acting Administrator

[FR Doc. 2009-790 Filed 01/14/2009 at 8:45 am; Publication Date: 01/15/2009]