FEDERAL REGISTER

Vol. 81 Tuesday,
No. 100 May 24, 2016

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Parts 1, 11, 121, et al.
Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 1, 11, 121, 125, and 135

Office of the Secretary

14 CFR Part 382

[Docket No.: FAA–2014–0554; Amdt. Nos. 1–69, 11–59, 121–374, 125–65, and 135–133]

RIN 2120–AK32

Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft

AGENCY: Federal Aviation Administration (FAA) and Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule replaces the existing process by which the Federal Aviation Administration (Agency or FAA) approves portable oxygen concentrators (POC) for use on board aircraft in air carrier operations, commercial operations, and certain other operations using large aircraft. The FAA currently assesses each POC make and model on a case-by-case basis and if the FAA determines that a particular POC is safe for use on board an aircraft, the FAA conducts rulemaking to identify the specific POC model in an FAA regulation. This final rule replaces the current process and allows passengers to use a POC on board an aircraft if the POC satisfies certain acceptance criteria and bears a label indicating conformance with the acceptance criteria. The labeling requirement only affects POCs intended for use on board aircraft that were not previously approved for use on aircraft by the FAA. Additionally, this rulemaking will eliminate redundant operational requirements and paperwork requirements related to the physician's statement. As a result, this rulemaking will reduce burdens for POC manufacturers, passengers who use POCs while traveling, and affected aircraft operators. This final rule also makes conforming amendments to the Department of Transportation's (Department or DOT) rule implementing the Air Carrier Access Act (ACAA) to require carriers to accept all POC models that meet FAA acceptance criteria as detailed in this rule.

DATES: The amendments to 14 CFR 1.1, 1.2, 121.574, 125.219, and 135.91 are effective June 23, 2016. The amendments to 14 CFR 11.201, 121.306, 125.204, 135.144, 382,27, and 382.133, and the removal of Special Federal Aviation Regulation No. 106 are effective August 22, 2016.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see ''How to Obtain Additional Information'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact DK Deaderick, 121 Air Carrier Operations Branch, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, AFS–220, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–7480; email *dk.deaderick@faa.gov.* For questions regarding the Department's disability regulation (14 CFR part 382), contact Clereece Kroha, Senior Attorney, Office of Aviation Enforcement and Proceedings, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9041; email *clereece.kroha@dot.gov.*

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A. Overview of Final Rule

This final rule affects the use of POCs on board aircraft in operations conducted under title 14 of the Code of Federal Regulations (14 CFR) parts 121, 125, and 135, by replacing the existing FAA case-by-case approval process for each make and model of POC in Special Federal Aviation Regulation (SFAR) No. 106, with FAA acceptance criteria. Under SFAR No. 106, each time the FAA approves a specific model of POC for use on board aircraft, the agency updates the list of approved POCs in the SFAR.[1]

This final rule removes SFAR No. 106 and replaces it with POC acceptance criteria and specific labeling requirements to identify POCs that conform to the acceptance criteria. POCs that conform to the final rule acceptance criteria will be allowed on board aircraft without additional FAA review and rulemaking.

As with existing requirements for FAA approval of POCs that may be used on aircraft, the final rule acceptance criteria and labeling requirement only apply to POCs intended for use on board aircraft. Table 1 provides a comparison of the final rule acceptance criteria and

[1] POCs identified in the SFAR are referred to in this preamble as SFAR-approved POCs or SFAR-approved devices.

labeling requirement with related SFAR No. 106.

TABLE 1—COMPARISON OF FINAL RULE ACCEPTANCE CRITERIA AND LABELING REQUIREMENT WITH RELATED SFAR NO. 106 REQUIREMENTS

	Related SFAR No. 106 requirements	Final rule acceptance criteria and labeling requirement
Food and Drug Administration (FDA) clearance to market the device.	The POC must be regulated by the FDA (section 2(2)) *Note:* To satisfy this requirement, manufacturers provide the FAA with the FDA letter granting approval to market the device (the FDA response to a manufacturer's 510(k) submission).	The POC manufacturer has received FDA clearance to legally market the device in the United States.
Hazardous materials	The POC may not contain hazardous materials as determined by the Pipeline and Hazardous Materials Safety Administration (section 2(1)). *Note:* To satisfy this requirement, manufacturers currently provide the FAA with a Pipeline and Hazardous Materials Safety Administration (PHMSA) determination letter stating that the POC is not subject to the Hazardous Materials Regulations (HMR) (49 CFR parts 171–180).	The POC must not contain any hazardous materials subject to the HMR, except as provided for batteries in the exceptions for crewmembers and passengers (49 CFR 175.10). The maximum oxygen pressure generated by the POC must fall below the threshold for the definition of a compressed gas as per the HMR.
Radio frequency (RF) emissions.	Operator must determine that POC does not cause interference with the electrical, navigation or communication equipment on the aircraft on which the device is to be used (section 3(a)(1)). *Note:* To satisfy this requirement, it is current practice for operators to use testing data provided by POC manufacturers regarding the RF emissions of a specific POC model. Manufacturers currently complete testing in accordance with RTCA standard 160G, Section 21, Category M.	The POC's RF emissions do not interfere with aircraft systems.
Identification of POCs safe for use on board aircraft.	POC model must be identified in SFAR No. 106 as approved for use on board aircraft prior to use on board aircraft in part 121, 125, and 135 operations (sections 2, 3(a)). *Note:* Specific POCs approved for use on board aircraft are identified in SFAR No. 106 by manufacturer and model name. Although some POC manufacturers affix a label indicating FAA approval for use on board aircraft, there is no current FAA requirement for a label indicating this approval.	In order to be used on aircraft, a label must be affixed to the POC indicating compliance with acceptance criteria pertaining to FDA clearance to market the device, hazardous materials, and RF emission limits. POC models identified in existing SFAR No. 106 satisfy the acceptance criteria and will be exempt from the labeling requirement. These POC models will continue to be identified in the regulatory text.

This final rule requires all POC models to conform to the acceptance criteria.[2] Further, any POC model that was not previously identified in SFAR No. 106 as approved for use on aircraft must also bear a label indicating conformance with the acceptance criteria before it may be used on board an aircraft. This label will facilitate passenger and crew recognition of POCs that may be used in the cabin during all phases of flight.

SFAR-approved POC models need not bear a label. The final rule regulatory text includes a list of POCs approved in accordance with SFAR No. 106 so that passengers and crewmembers can continue to identify these POCs as approved for use on board aircraft.

In addition, this final rule eliminates SFAR No. 106 requirements related to POC use on board aircraft that are addressed elsewhere in titles 14 or 49 of the CFR. This final rule also eliminates specific SFAR No. 106 requirements applicable to passengers that are not necessary for safe POC use on board aircraft, and impose an unnecessary and unreasonable paperwork burden on POC-using passengers and their physicians as well as crewmembers and aircraft operators. This final rule also increases accessibility in air travel for passengers who require oxygen therapy during flight. Table 2 summarizes the final rule disposition of all SFAR No. 106 provisions.

TABLE 2—SUMMARY OF SFAR NO. 106 PROVISIONS AND DISPOSITION IN FINAL RULE

Summary of SFAR No. 106 provision	Description of disposition in final rule
• Requirement that the POC is legally marketed in the United States in accordance with FDA requirements (section 2(2)). • Requirement for operator to determine that POC does not cause interference with the electrical, navigation or communication equipment on the aircraft on which the device is to be used (section 3(a)(1)).	SFAR No. 106 Provisions Reflected in Acceptance Criteria and Labeling Requirement.

[2] POC models previously listed as approved for use on board aircraft in SFAR No. 106 received approval because they satisfied the criteria set forth in SFAR No. 106. The POC acceptance criteria identified in this final rule are based on existing SFAR No. 106 requirements that must be satisfied before the FAA identifies a POC in SFAR No. 106 as approved for use on aircraft. Thus, a POC model identified in SFAR No. 106 satisfies the acceptance criteria.

TABLE 2—SUMMARY OF SFAR NO. 106 PROVISIONS AND DISPOSITION IN FINAL RULE—Continued

Summary of SFAR No. 106 provision	Description of disposition in final rule
• Prohibition on POCs containing hazardous materials as determined by the Pipeline and Hazardous Materials Safety Administration (section 2(1)). • POC model must be identified in SFAR No. 106 prior to use in part 121, 125, and 135 operations (sections 2, 3(a))*. • Prohibition on smoking or open flame near POC (section 3(a)(2)) ..... • Prohibition on seating a passenger using a POC in an exit seat (section 3(a)(4)). ..... • Requirement to stow POC during movement on the surface, takeoff, and landing (section 3(a)(3)). • POC model must be identified in SFAR No. 106 prior to use in part 121, 125, and 135 operations (sections 2, 3(a))*.	SFAR No. 106 Provisions Retained.
• ''Whenever the pilot in command turns off the ''Fasten Seat Belt'' sign, or otherwise signifies that permission is granted to move about the passenger cabin, passengers operating their portable oxygen concentrator may continue to operate it while moving about the cabin.'' (section 3(a)(6)). • Requirement for POC user to ensure that POC batteries in carry-on baggage are protected from short circuit and are packaged in a manner that protects them from physical damage (section 3(b)(6)).	SFAR No. 106 Provisions Eliminated Because Addressed in Other Existing Regulations.
• ''Whenever the pilot in command turns off the ''Fasten Seat Belt'' sign, or otherwise signifies that permission is granted to move about the passenger cabin, passengers operating their portable oxygen concentrator may continue to operate it while moving about the cabin.'' (section 3(a)(6)). • Requirement for POC user to ensure that POC batteries in carry-on baggage are protected from short circuit and are packaged in a manner that protects them from physical damage (section 3(b)(6)).	SFAR No. 106 Provisions Eliminated Because Addressed in Other Existing Regulations.
• Requirements for POC user to obtain a physician's statement and provide notice to pilot and aircraft operator regarding POC use and contents of physician statement (sections 3(a)(5) and 3(b)(3)). • Requirement for POC user to be capable of responding to alarms or to travel with a person who can perform these functions (section 3(b)(1)). • Requirement for POC user to ensure that the POC is free of petroleum products or signs of excessive wear or abuse (section 3(b)(2)). • Prohibition on use of salves and lotions unless ''oxygen approved'' (section 3(b)(4)) • Requirement for passenger to carry a sufficient number of batteries for duration of flight (section 3(b)(5))**.	SFAR No. 106 Provisions Eliminated in Their Entirety.

* The list of POCs currently identified in SFAR No. 106 will be maintained in parts 121, 125 and 135. A detailed discussion regarding the identification of POCs that conform to the acceptance criteria is provided in the preamble discussion, ''Manufacturer Label.''

** Air carriers may require passengers using a POC to bring an adequate number of batteries to power a POC. *See* 14 CFR 382.133.

This final rule also includes several conforming changes to 14 CFR part 382 to ensure that the Department's rule requiring carriers to accommodate passengers with disabilities who are traveling with POCs is consistent with the FAA changes to POC carriage and use on aircraft.

Finally, the amendments provided in this final rule are consistent with the retrospective regulatory review requirements of Executive Order 13563. On January 18, 2011, the President signed Executive Order 13563, Improving Regulation and Regulatory Review. Among other things, Section 6 of that Executive Order directs agencies to conduct a retrospective analysis of existing rules. Specifically, Executive Order 13563 provides that ''[t]o facilitate the periodic review of existing significant regulations, agencies shall consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.''

Consistent with Executive Order 13563, the FAA routinely evaluates existing regulations and other requirements. The FAA works to identify unnecessary, duplicative, or ineffective regulations and to mitigate the impacts of those regulations, where possible, without compromising safety.

As part of the FAA's continuing obligation to review its regulations, the agency conducted an analysis of SFAR No. 106 and determined that it involves several unnecessary burdens. As a result of this determination and the resulting final rule amendments, the final rule will provide relief to POC manufacturers, passengers who use a POC, aircraft operators and the FAA. The final rule will provide relief to POC manufacturers and the FAA by eliminating the SFAR No. 106 POC approval process, to passengers who use a POC by eliminating the FAA requirement to obtain a physician's statement, and to aircraft operators by eliminating the requirements for crewmember review of the physician's statement and pilot in command (PIC) notification. The quantification of benefits follows the same methodology as the proposed rule as the agency did not receive negative comments on this methodology. The agency presents cost savings in Table 3 below.

The total cost savings from this final rule is $39.5 million ($27.6 million at 7% present value and $33.6 million at 3% present value). The largest cost savings of $39 million occurs from the reduction of crew time to review the physician's statement. These are the same estimated benefits and costs as presented for the proposed rule and since the FAA received no comments regarding these estimates, there are no changes to this final rule.

B. Summary of Cost Savings

The FAA estimates that manufacturers will save $108,000 over ten years because they will no longer have to petition the FAA for rulemaking with each new device they want to add to the list of POCs approved for use

during flight on board aircraft. These cost savings will be reduced slightly because manufacturers will incur an estimated total one-time cost of $22,000 to comply with the labeling requirement. The FAA estimated additional cost savings because of the discontinuation of certain requirements from SFAR No. 106. Table 3 presents total estimated cost savings.

TABLE 3—TOTAL ESTIMATED COST SAVINGS

	Cost savings	7% Present value savings	3% Present value savings
FAA Savings—No SFAR	$91,644	$68,871	$80,519
Manufacturer Savings—No petition for rulemaking	108,000	75,853	92,126
Removal of FAA requirement for user to obtain a physician's statement for POC use on aircraft	569,961	401,645	486,914
Removal of FAA requirement for crew review of physician's statement and PIC notification	38,726,085	27,083,677	32,972,652
Total Cost Savings	39,495,690	27,630,045	33,632,212

II. Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. 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.

This rulemaking is promulgated under the authority described in 49 U.S.C. 106(f), which vests final authority in the Administrator for carrying out all functions, powers, and duties of the administration relating to the promulgation of regulations and rules, and section 44701(a)(5), which requires the Administrator to promulgate regulations and minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security. Further, 49 U.S.C. 41705 provides the Secretary of Transportation the authority to prohibit discrimination against a qualified individual with a disability in air travel.

III. Background

A. Statement of the Problem

On July 12, 2005, the FAA published a final rule adding SFAR No. 106 to part 121 of title 14 (70 FR 40156). The final rule adding SFAR No. 106 permitted the use of POCs identified in the SFAR to address the needs of passengers requiring oxygen therapy while traveling on board aircraft.

Prior to SFAR No. 106, passengers could carry and operate equipment generating, storing or dispensing medical oxygen on board an aircraft only if the equipment was furnished by the certificate holder and certain other conditions prescribed in 14 CFR 121.547, 125.219 and 135.91 were satisfied. In 2005, only a limited number of air carriers provided compressed medical oxygen, for a fee, to passengers who required medical oxygen therapy during flight. Because compressed oxygen is considered a hazardous material, it was an expensive and logistically challenging exercise for air carriers to provide medical oxygen. Today, virtually no certificate holders conducting part 121 operations provide in-flight medical oxygen for a fee to passengers.

Further, passengers requiring oxygen therapy during travel also faced difficulty coordinating service between the carrier and the medical oxygen supplier to ensure coverage at the terminal, on board the aircraft, and gate-to-gate. Sometimes, passengers would spend at least part of the time travelling without medical oxygen due to service problems with the oxygen supplier.

In 2002, POCs were brought to the attention of the FAA as a new portable technology for dispensing medical oxygen for purposes of oxygen therapy. POCs work by filtering nitrogen from the air and providing the POC user with oxygen at a concentration of approximately 90 percent. Thus, POCs do not require the same level of special handling as compressed oxygen. However, due to existing FAA regulations applicable to the use of devices that dispense oxygen (§§ 121.574, 125.219, and 135.91), including POCs, the FAA informed the POC community that an exemption would be required for a passenger to carry on and operate a POC that the passenger supplied for his or her own use (*i.e.,* not furnished by the aircraft operator).

Rather than wait for petitions for exemption from the existing regulations (§§ 121.574, 125.219, and 135.91), the FAA completed rulemaking to address the issue of passenger-supplied POCs by adding SFAR No. 106 to title 14. *See* 69 FR 42324 (July 14, 2004) and 70 FR 40156 (July 12, 2005). SFAR No. 106 allows passengers to carry and operate their own POC on board an aircraft if the FAA has approved the specific POC model for use on board aircraft and identified the POC model in the SFAR.[3] As a result of SFAR No. 106, the FAA has mitigated the challenges faced by passengers requiring oxygen therapy during travel and has increased the accessibility to air travel for many passengers requiring oxygen therapy by allowing passengers to supply their own POCs for use during air travel.

Passengers may not use a POC on board an aircraft in part 121, 125, or 135 operations unless the FAA has identified the device they wish to use in SFAR No. 106 as approved for use in such operations. In 2005, SFAR No. 106 identified the first specific POC models approved for use on board aircraft. Although the agency intended SFAR No. 106 to serve as a special, temporary regulation, until POC performance standards (acceptance criteria) could be developed, it has remained in place for the last decade. *See* 70 FR at 40158–40159. During this time, the FAA has amended SFAR No. 106 seven times to identify additional POC models that may be used on board aircraft.[4] This process is time-consuming for POC manufacturers because they must petition the FAA for rulemaking to add their POC model to the SFAR list if they want their POC to be approved for use on board aircraft. Together with a petition for rulemaking, manufacturers provide the FAA with documentation required for the FAA to make a determination whether the POC satisfies the requirements of the SFAR. This process is also time-consuming for the FAA because each time the FAA

[3] Initially, SFAR No. 106 applied to part 119 certificate holders conducting operations under part 121. In a technical amendment published January 12, 2007 (72 FR 1442), the FAA extended the requirements of SFAR No. 106 to part 119 certificate holders conducting operations under parts 125 and 135.

[4] 71 FR 53956 (Sept. 12, 2006); 74 FR 2354 (Jan. 15, 2009); 75 FR 742 (Jan. 6, 2010); 75 FR 39632 (July 12, 2010); 77 FR 4220 (Jan. 27, 2012); 77 FR 63221 (Oct. 16, 2012); and 79 FR 6018 (Feb. 3, 2014).

approves a new POC for use on board aircraft, the FAA must complete rulemaking to add the newly approved POC model to SFAR No. 106.

Over the last ten years, FAA regulations and guidance regarding the use of POCs on aircraft, POC technology itself, and air carrier programs concerning the use of POCs on board their aircraft have rapidly evolved. The combined result of these initiatives is an increase in accessibility to air travel for many passengers who require oxygen therapy during flight. In keeping with the Department's ongoing commitment to increase accessibility to air travel, this final rule removes certain burdensome and time-consuming requirements that were put in place to ensure safety when POC technology was first introduced for use on board aircraft but are no longer necessary.

B. Summary of the NPRM

On September 19, 2014, the FAA published an NPRM entitled ''Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft'' in which the FAA proposed to replace SFAR No. 106 with acceptance criteria for POCs to be used by passengers on board aircraft in operations conducted under parts 121, 125 and 135. *See* 79 FR 56288. In the NPRM, the FAA proposed to replace the burdensome SFAR No. 106 POC approval process with acceptance criteria based on SFAR No. 106 requirements, and an additional requirement for POCs (carried and used on board aircraft) to bear a label indicating compliance with these acceptance criteria. The FAA proposed, however, that all SFAR-approved POCs would be excluded from the labeling requirement. Further, the proposed acceptance criteria and labeling requirements would only affect POCs intended for use on board aircraft. The FAA also proposed to eliminate several redundant operational requirements as well as paperwork requirements related to the physician's statement, which are not necessary for aviation safety.

The comment period for this NPRM closed November 18, 2014.

C. Differences Between Notice of Proposed Rulemaking and Final Rule

The final rule differs from the NPRM as follows:

- Replaces the proposed prescriptive requirement for radio frequency (RF) emissions evaluation with a performance-based standard that allows POC manufacturers to determine the means by which to assess whether its POC will radiate RF emissions that interfere with aircraft systems.
- Modifies verbiage for required label text.
- Retains the SFAR No. 106 prohibition on exit row seating for passengers using a POC and the SFAR No. 106 requirements pertaining to POC stowage.
- Amends 14 CFR part 382 to ensure that it is consistent with the FAA changes to POC carriage and use on aircraft.

D. General Overview of Comments

The FAA received 33 comments on the NPRM. Commenters included 21 individuals or anonymous commenters, the Airline Pilots Association (ALPA), Airlines for America (A4A), the Association of Flight Attendants (AFA), American Airlines, Delta Air Lines, Main Clinic Supply, Phillips Respironics, BPR Medical Limited, Oxygen to Go (OTG), the Mayo Clinic, and one commenter identified as the past president of the Airlines Medical Directors Association (AMDA).

Although the FAA received general support for the NPRM from many commenters, some commenters recommended modifications to the proposed acceptance criteria, POC labeling requirements, and issues related to the identification of POCs that may be used on board aircraft. Other commenters did not support the elimination of certain SFAR No. 106 provisions, including those pertaining to exit row seating for passengers using a POC, POC stowage, the physician's statement and passenger notification of intended POC use to the PIC and aircraft operator. Comments are addressed in the preamble discussion entitled, ''Discussion of Public Comments and Final Rule.''

The agency also received a request from OTG to reopen the comment period. The agency denied this request, because the agency satisfied the requirement of the Administrative Procedure Act to publish a general notice of a proposed rule in the **Federal Register**. *See* 5 U.S.C. 553. Both the request to reopen the comment period and the agency's response to this request can be found in the docket for this rulemaking.

IV. Discussion of Public Comments and Final Rule

A. Applicability, Effective Dates and Compliance

Currently, SFAR No. 106 applies only to those POC models intended for use on board aircraft in operations conducted under parts 121, 125, and 135 of title 14 of the Code of Federal Regulations. SFAR No. 106 authorizes the use of specific POCs on board aircraft in operations conducted under parts 121, 125, or 135, if the conditions in the SFAR are satisfied.

Consistent with SFAR No. 106 and the NPRM, this final rule applies only to those POC models intended for use on board aircraft in part 121, 125, and 135 operations, and like SFAR No. 106 it does not create a requirement for operators to allow POC use. The Department's requirements for air carriers to allow the use of a POC on board an aircraft (designed to have a maximum capacity of more than 19 passenger seats) continue to be found in 14 CFR 382.133.

In the NPRM, the agency proposed an effective date of 90 days after publication of the final rule in the **Federal Register**. Because the agency did not propose a separate compliance date, compliance would also be required 90 days after publication in the **Federal Register**.

The agency seeks to allow compliance with this final rule as soon as possible. The agency recognizes, however, that affected aircraft operators may need to revise operating manuals and training programs, and expects these revisions to occur within the normal course of business. Accordingly, the SFAR will remain in place until August 22, 2016 and compliance with the new rule will be permitted beginning on August 22, 2016 to allow a sufficient amount of time for operating manuals and training programs to be amended in the normal course of business.

B. Definition of Portable Oxygen Concentrator

As proposed, this final rule defines ''portable oxygen concentrator'' in 14 CFR 1.1 as a medical device that separates oxygen from other gasses in ambient air and dispenses this concentrated oxygen to the user. This definition is consistent with the description of POCs in existing SFAR No. 106. The § 1.1 definition of a POC added by this final rule is also consistent with Advisory Circular (AC) 120–95, Portable Oxygen Concentrators,[5] as well as the device description used by POC manufacturers and the Food and Drug Administration (FDA) (the federal agency with primary regulatory authority over POCs for medical use).[6]

[5] AC 120–95B defines POCs as ''small, portable devices that work by separating oxygen from nitrogen and other gasses in the air and providing the user with oxygen at a concentration of more than 90 percent . . .''

[6] Portable oxygen concentrators are a subset of portable oxygen generators defined by the FDA in 21 CFR 868.5440.

By including this definition in § 1.1, the FAA distinguishes POCs from portable oxygen generators and other medical devices that use compressed or liquid oxygen for medical oxygen therapy. Devices that use compressed or liquid oxygen must satisfy separate and more rigorous requirements to mitigate the risks they present.

C. Portable Oxygen Concentrator Acceptance Criteria

Under SFAR No. 106, the FAA allows the carriage and use of specific POC models only if they are identified in the SFAR as approved for use on board aircraft. A POC may be identified in the SFAR only after the POC manufacturer has petitioned the FAA for rulemaking (to add the POC to the SFAR) and has demonstrated to the FAA that the specific POC model satisfies the requirements of the SFAR (*i.e.,* the POC must be regulated by the FDA and the POC may not contain hazardous materials as determined by PHMSA).

Each time the FAA approves a specific model of POC for use on board an aircraft, the agency must update the list of POCs in the SFAR through rulemaking. Additionally, the aircraft operator is responsible for determining that the POC does not cause interference with aircraft equipment. The FAA notes that in practice, aircraft operators use data supplied by POC manufacturers to the FAA to determine compliance with the requirement to ensure that a POC will not interfere with aircraft equipment.

In the NPRM, the agency proposed to replace the SFAR No. 106 case-by-case POC approval and rulemaking with requirements for POCs used on board aircraft to conform to specified acceptance criteria and to bear a label indicating that the device conforms to these criteria. The proposal further stated that POCs conforming to the acceptance criteria and bearing the appropriate label would be allowed on board aircraft without further rulemaking. The proposed acceptance criteria are summarized as follows:

- The POC manufacturer complies with all FDA requirements to legally market the device in the United States.
- The POC does not contain any hazardous materials subject to the HMR except as provided for in the exceptions for crewmembers and passengers in 49 CFR 175.10 for batteries used to power electronic devices when operator approval is not required.
- The maximum oxygen pressure generated by the POC must fall below the threshold for the definition of a compressed gas per the HMR.
- The POC radio frequency (RF) emissions must fall below the threshold permitted in RTCA standard 160G, Section 21, Category M.

As addressed in more detail in this section of the preamble discussion, this final rule adopts the proposal with modifications to the RF emissions acceptance criterion and labeling requirement.

1. Food and Drug Administration Clearance or Approval

POCs are medical devices regulated by the FDA in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), and title 21 of the CFR. Accordingly, manufacturers must obtain FDA clearance or approval prior to marketing a POC within the United States, and must comply with certain provisions in title 21 of the CFR, including but not limited to device registration and listing (21 CFR part 807), labeling (21 CFR part 801), adverse event reporting (21 CFR part 803), and good manufacturing practice requirements (21 CFR part 820).

SFAR No. 106 requires all POCs used on board aircraft in operations conducted under 14 CFR parts 121, 125, and 135 to be legally marketed as a POC, in compliance with FDA regulations. The purpose of this requirement is to ensure the device is actually what the manufacturer holds it out to be—a POC. To demonstrate compliance with this requirement, POC manufacturers submit evidence that the device has been cleared or approved by the FDA for marketing in the United States. The FAA accepts FDA premarket clearance in response to a 510(k) submission as evidence the device may be marketed in the United States.[7]

In the NPRM, the agency proposed to continue to require any POC used on board an aircraft to be cleared or approved by the FDA for marketing in the United States prior to such use. However, given that FDA requirements for legal marketing of a POC in the United States already apply to POCs, independent of the SFAR, manufacturers would no longer need to submit evidence of this clearance or approval to the FAA to demonstrate compliance because it would be unnecessarily burdensome. Rather, the FAA proposed that POCs conforming to the proposed acceptance criteria, including the manufacturer's authority to legally market the device as a POC, would be identified by a label affixed to the device. This final rule adopts this proposed acceptance criterion without change.

2. Radio Frequency Emissions

Sections 121.306, 125.204, and 135.144 place responsibility on the aircraft operator for determining which portable electronic devices (PED) may be safely used on its aircraft. Although the agency recognizes POCs as a type of PED, SFAR No. 106, includes a requirement for an aircraft operator to make a determination that the device does not cause interference with the electrical, navigation, or communication system of the aircraft in which the device will be used. The SFAR No. 106, section 3(a)(1) requirement pertaining to POC interference with aircraft equipment has the same effect as the requirements in §§ 121.306, 125.204, and 135.144 pertaining to all PEDs.

Each operator may establish a method to make a determination regarding the effects of PEDs on its aircraft's avionics systems. Historically, FAA guidance material (*i.e.,* AC 91.21–1 and AC 120–95) identified one method of compliance with the SFAR and §§ 121.306, 125.204, and 135.144 by recommending the operator complete device-by-device evaluations of RF emissions.[8] These evaluations involve comparing the device's RF emissions against the current RTCA DO–160 standards for installed airborne equipment. The FAA identified RTCA DO–160, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21, Category M in guidance material for medical PEDs (including POCs intended for use on aircraft) because it established safe and conservative RF emissions limits for installed aircraft systems.

Consistent with the historical device-by-device approach to RF emissions evaluation and agency guidance, it is current practice for POC manufacturers to provide the RTCA test compliance statements to the FAA.[9] Although

[7] A 510(k) submission is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to premarket approval. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. If FDA makes a finding of substantial equivalence, the device is considered ''cleared.'' Additional information regarding the 510(k) process is available at *www.fda.gov.*

[8] The term EMC was used throughout the NPRM however, EMC is a broad term used for installed aircraft electrical systems. Where appropriate, the FAA has replaced the term EMC with RF emissions in this final rule preamble because when a device-by-device examination of a PED is conducted, the operator would consider the RF emissions of that device.

[9] Currently, POC manufacturers provide the RTCA DO–160 Section 21 test qualification statements to the FAA; the FAA then makes the

Continued

section 3(a)(1) of SFAR No. 106 places the burden upon the aircraft operator to assess the impact of a POC on the aircraft, the FAA has accepted as proof of non-interference, RF emissions test qualification statements (provided by POC manufacturers) that show a specific POC does not exceed certain maximum RF emissions thresholds established by RTCA in DO–160, Environmental Conditions and Test Procedures for Airborne Equipment.[10]

On October 31, 2013, the agency announced a new means of compliance with §§ 121.306, 125.204, and 135.144, allowing operators to expand the use of passenger supplied and operated PEDs throughout all phases of flight, based on a determination by the operator that the aircraft systems themselves are PED tolerant (*i.e.,* aircraft systems safety risk assessment showing the systems meet the requirements of RTCA DO–307 or another PED tolerance assessment). *See* Information for Operators (InFO) 13010 and InFO 13010SUP.[11] The agency does not, however, require aircraft systems safety risk assessment of PED tolerance in accordance with InFO13010 and InFO 13010SUP. These assessment methods provide one means for airplane operators to demonstrate compliance with §§ 121.306, 125.204, and 135.144 and allow PEDs to be used on board aircraft. It is up to each aircraft operator to determine whether to expand the use of passenger supplied and operated PEDs via a determination of PED tolerance for certain aircraft types. The FAA estimates that eighty percent of part 121 air carriers (which comprise an estimated 98% of total part 121 passenger enplanements in 2013) and several of the largest part 135 air carriers have expanded PED use according to InFO 13010 and InFO 13010SUP. The remaining operators continue to rely on individual PED evaluations.

In the NPRM, the agency proposed to require the RF emissions for each POC intended for use on board aircraft to be tested in accordance with RTCA DO–160G, Section 21, Category M. The agency also proposed to add POCs to the list of devices excepted from the general PED non-interference requirements in §§ 121.306, 125.204, and 135.144 to eliminate redundancy with the POC-specific non-interference requirements.

This final rule retains a POC-specific non-interference requirement, modified to reflect a performance-based standard. The Agency recognizes that the majority of operators conducting part 121 operations and several of the larger operators conducting part 135 operations have already conducted aircraft systems safety risk assessments for PED tolerance in accordance with InFO 13010 and InFO 13010SUP with results allowing for continuous use of PEDs from gate to gate. A determination that an aircraft is ''PED tolerant'' would make an independent assessment of RF emissions for any PED used on that aircraft unnecessary. Nevertheless, because of the need to ensure service for passengers who require oxygen therapy during air travel, the FAA believes it is necessary to maintain a regulatory structure to ensure that passengers may continue to use POCs on board aircraft even if the aircraft operator has not determined that the aircraft is ''PED tolerant.'' Therefore, consistent with the SFAR and the NPRM, this final rule retains a requirement to assess POC RF emissions as one of the POC acceptance criteria. (The agency notes that POCs previously approved by the FAA for use on aircraft in accordance with SFAR No. 106 that demonstrated RF emissions below the maximum emissions threshold in DO–160G, Section 21, Category M would not need to be retested or reassessed by the operators prior to use on board aircraft because those prior assessments remain valid.)

Delta Air Lines generally supported inclusion of RTCA DO–160, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21, Category M, in the proposed acceptance criteria. Recognizing, however, that FDA may require RF emissions assessments that may test to standards that could be used to demonstrate compliance with the FAA prohibition on PEDs interference with aircraft systems, the agency sought comment on whether POC manufacturers complete RF emissions assessments in accordance with requirements by other federal agencies that could also be used to demonstrate compliance with the generally applicable PED requirements. The agency did not receive any comments related to this specific issue except as provided by Delta. After further review of the proposal and other RF emissions assessments that POC manufacturers may conduct (*e.g.,* International Standards Organization (ISO) 7137 and the FDA recognized EMC standards for Class II medical devices in IEC 60601–1–2 edition 4.0), the agency has determined that the proposed requirement to use RTCA DO–160 as the only means by which to evaluate POC RF emissions was overly prescriptive.

Historically, the FAA identified RTCA DO–160 Section 21, Category M in guidance material for medical portable electronic devices intended for use on board aircraft. Although POCs are not installed aircraft systems, the agency identified RTCA DO–160 as one method to demonstrate compliance with the PED non-interference requirement because RTCA DO–160 establishes safe and conservative RF emissions limits for installed aircraft systems. The agency recognizes, however, that there are other methods to assess POC RF emissions and ensure that POC use will not cause interference with aircraft systems. Thus, this final rule includes a performance-based RF emissions acceptance criterion that allows POC manufacturers to determine how to assess whether their POC meets the aircraft system non-interference requirement before they affix a label to the device confirming that this criterion has been satisfied.

Guidance material in AC 91.21–1C identifies examples of methods appropriate to ensure compliance with this requirement, including RTCA DO–160 and other industry EMC standards identified in the AC. The FAA emphasizes, however, that FDA approval or clearance to market a POC does not necessarily mean that the POC complies with the FAA's aircraft system non-interference requirement.

In addition to Delta's comment, an individual commented that the POC manufacturer should include the electromagnetic interference test results on the POC label, eliminating the need for the air carrier to test the device. The agency clarifies that the purpose of the label is to identify those devices that conform to the FAA acceptance criteria. One of those criteria prohibits the POC from radiating radio frequency emissions that interfere with aircraft systems. Therefore, a device that bears the required label must also not radiate RF emissions such that it causes interference with aircraft systems. The POC manufacturer identifies devices that meet this and other criteria by affixing a label. In this way, the label indicates that the device will not radiate RF emissions that cause interference with aircraft systems and does not need to be retested by the aircraft operator. Thus, adding specific test results to the label would be unnecessary.

RTCA test qualification statements available on its Web site for aircraft operators to use to demonstrate compliance with section 3(a)(1) of the SFAR. The RTCA compliance statements may be viewed at *http://www.faa.gov/about/initiatives/cabin_safety/portable_oxygen/.*

[10] *See* AC 120–95, Portable Oxygen Concentrators. The FAA notes that while RTCA made significant changes to DO–160 since edition E was issued (December 9, 2004) and cited in agency guidance, Section 21, Category M (applicable to POCs) was not revised in either DO–160F or DO–160G.

[11] All InFOs can be found at *http://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/info/all_infos/.*

3. Hazardous Materials

SFAR No. 106 allows passengers to use one of the specific POCs identified in the SFAR only if the POC does not contain hazardous materials as determined by PHMSA.[12] *See* SFAR No. 106, section 2(1). The PHMSA determination required by SFAR No. 106 is one of the prerequisites that must be satisfied for the FAA to identify a POC in the SFAR. PHMSA issues this determination via a letter, at the request of the POC manufacturer and after PHMSA reviews manufacturer-supplied information regarding the POC.

POCs typically operate using either rechargeable batteries (usually lithium ion) or AC/DC electrical power via an external power cord. Although the POC units themselves are not considered hazardous materials, the lithium ion batteries typically used to power POCs are hazardous materials.[13] *See* 49 CFR 172.101, Hazardous Materials Table. However, lithium ion batteries are conditionally excepted from certain requirements of the HMR (*e.g.* UN specification packaging and labeling) if they meet certain size limitations (100 Wh), package limitations, and comply with package marking and battery testing conditions of the HMR. *See* 49 CFR 173.185(c). These exceptions only apply when the POC units are transported as cargo.[14]

Other HMR exceptions are provided in 49 CFR 175.10 that apply to POC units containing lithium ion batteries and associated spare batteries when carried on board aircraft by passengers and crewmembers. *See* 49 CFR 175.10(a)(18). In accordance with the exceptions in § 175.10(a)(18), passengers may bring an unlimited number of lithium ion batteries up to 100 Wh per battery to power their POC. Further, as a result of recent amendments, § 175.10(a)(18) also authorizes the aircraft operator to allow passengers and crewmembers to carry on board as spares up to two batteries that are larger than 100 Wh but do not exceed 160 Wh only if certain criteria are met.[15]

The PHMSA determination letters required by the SFAR were limited to a determination regarding the HMR exceptions for a POC unit containing small lithium ion batteries (*i.e.,* 100 Wh or 8g equivalent lithium content or less) for transportation as cargo as these are the exceptions that would apply to a manufacturer for transportation of a POC unit from the point of manufacture to the point of retail sale (although the size limits that distinguish a small lithium ion battery are the same for both the transportation of such batteries as cargo as well as for the passenger and crewmember exceptions). Existing PHMSA determinations for SFAR-approved POCs, however, do not include an assessment of each individual air carrier's policies pertaining to the allowance for larger batteries carried as spares.

Consistent with the proposal in the NPRM, this final rule eliminates the SFAR No. 106 provision requiring a PHMSA determination that the POC does not contain hazardous materials. Instead, this final rule prohibits POCs used on board aircraft from containing hazardous materials subject to the HMR and references the HMR. Further, as noted above, POC users may carry an unlimited number of small spare lithium ion batteries (*i.e.,* lithium ion batteries up to 100 Wh per battery) and up to two larger spare lithium ion batteries (*i.e.,* batteries larger than 100 Wh but that do not exceed 160 Wh) in accordance with the exceptions for hazardous materials carried by aircraft passengers and crewmembers as is the case today.[16] *See* 49 CFR 175.10(a)(18).

There is no safety basis for requiring the PHMSA ''no hazardous materials'' determination letter as a prerequisite to the use of a POC on board an aircraft. The HMR conditional exceptions provided in §§ 175.10 and 173.185 apply to passengers, crew and the POC manufacturer, respectively, independent of the SFAR and this final rule. Further, the FAA does not require a PHMSA determination letter prior to passenger carriage of any other PED that may contain hazardous materials and POCs do not present any unique hazardous materials safety issues that would be mitigated by the requirement to obtain a PHMSA determination letter.

Pursuant to 49 CFR 175.10(a)(18), passengers seeking to use a POC powered by a spare lithium ion battery that is over 100 Wh but less than 160 Wh are permitted to do so only with the approval of the operator. Given that the POC manufacturer cannot assume knowledge of and approval by each carrier regarding passenger and crewmember carriage of larger batteries, under this final rule, a POC manufacturer will be unable to label a POC as conforming to the final rule acceptance criteria if the POC has an installed lithium battery larger than 100 Wh. The final rule regulatory text clarifies the conditions under which POCs used on aircraft may contain batteries as a power source, including this limitation. Nonetheless, the passenger is ultimately responsible for compliance with the exceptions in § 175.10(a)(18) for spare batteries used to power a POC. For example, if a passenger wants to bring a spare lithium ion battery larger than 100 Wh into the aircraft cabin to power a POC unit, the passenger is responsible for compliance with § 175.10(a)(18) and reviewing airline acceptance policies.

A manufacturer must only affix a label to a POC powered by an installed lithium ion battery that does not exceed 100 Wh because the manufacturer cannot ensure compliance with the 49 CFR 175.10(a)(18) condition under which a passenger may carry and use a battery that exceeds 100 Wh (*i.e.,* approval by an aircraft operator with which a passenger may choose to fly). Adhering to this limitation will facilitate passenger carriage and use of POCs on board aircraft and ensure that there are no restrictions on the number of spare lithium ion batteries less than 100 Wh that can be carried on board the aircraft for full operability of the POC throughout the duration of the flight(s).

[12] PHMSA is responsible for regulating and ensuring the safe and secure movement of hazardous materials by all modes of transportation, including aviation. To minimize threats to life, property or the environment due to hazardous materials related incidents, PHMSA's Office of Hazardous Materials Safety develops the HMR and standards for classifying, handling and packaging shipments of hazardous materials within the United States.

[13] 49 CFR 105.5 defines a hazardous material as a substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and has been designated as hazardous under section 5103 of Federal hazardous materials transportation law (49 U.S.C. 5103). The term includes hazardous substances, hazardous wastes, marine pollutants, elevated temperature materials, materials designated as hazardous in the Hazardous Materials Table (see 49 CFR 172.101), and materials that meet the defining criteria for hazard classes and divisions in part 173 of subchapter C of this chapter.

[14] The PHMSA final rule, Hazardous Materials: Transportation of Lithium Batteries, recently removed 49 CFR 172.102(c)(1), *Code/Special Provision* 188 and relocated it, in part to 173.185. *See* (79 FR 46012, (August 6, 2014)). Currently, conditional exceptions for the transportation of small batteries as cargo can be found in 49 CFR 173.185.

[15] The revisions to the HMR exceptions for hazardous materials carried by aircraft passengers and crewmembers have resulted in a more conservative approach to the carriage of lithium ion batteries used to power PEDs than the previous requirements under 49 CFR 175.10(a)(18)(2014 ed.). The current passenger and crewmember exceptions include a new requirement for approval by the air operator for the carriage of spare lithium ion batteries larger than 100 Wh (approximately 8 grams) and have reduced the maximum Watt-hours for spare lithium ion batteries from 300 Wh (approximately 25 grams) to 160 Wh.

[16] The NPRM discussion regarding the SFAR limitation on hazardous materials took an overly conservative approach in the discussion pertaining to limitations on spare batteries carried by aircraft passengers and crewmembers.

Finally, although the FAA did not receive any comments regarding its proposal to remove the requirement for a PHMSA determination of no hazardous materials, the agency notes that an individual commented that the rules pertaining to lithium ion batteries must be updated, citing potential lithium ion battery hazards. The agency finds that revisions to the requirements applicable to passenger carriage of lithium ion batteries generally, are outside of the scope of the proposal because the proposal was narrowly tailored to address only POC carriage and use on aircraft. Further, PHMSA recently updated the requirements applicable to lithium ion batteries as part of a comprehensive rulemaking addressing the transportation of lithium batteries. *See* 79 FR 46012 (August 6, 2014). As a result of this update, PHMSA regulations pertaining to lithium ion batteries are now harmonized with the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transportation of Dangerous Goods by Air. Through the rulemaking process, PHMSA determined that harmonization with the ICAO Technical Instructions pertaining to lithium ion batteries used to power PEDs carried by passengers and crewmembers on aircraft provides an appropriate level of safety.

4. Maximum Oxygen Pressure

As previously discussed, the SFAR No. 106 approval process requires POC manufacturers to obtain a PHMSA determination letter stating the POC device does not contain any hazardous materials. As part of this determination, PHMSA reviews information provided by the POC manufacturer regarding the oxygen pressure generated by a POC. If the POC generates oxygen pressure of 200 kPa gauge (29.0 psig/43.8 psia) or greater at 20 °C (68 °F), PHMSA would classify the POC as an article containing Hazard Class 2, Division 2.2 (non-flammable, non-poisonous compressed gas) and the POC would be subject to the applicable HMR (49 CFR 173.115). However, a POC does not contain a compressed gas subject to the HMR if it generates an oxygen pressure below this threshold.

In the NPRM, the agency proposed to include as a POC acceptance criterion a design limitation that would restrict POCs used on aircraft from generating a maximum oxygen pressure of 200 kPa gauge (29.0 psig/43.8 psia) at 20 °C (68 °F), or more. The agency did not receive any comments on this proposal.

The final rule includes the proposed POC design limitation as one of the POC acceptance criterion so as to ensure that newly manufactured POCs used on board aircraft will continue to incorporate this existing design limitation, thus ensuring that POCs will not present the hazards associated with devices that generate compressed oxygen. Accordingly, as proposed, the final rule establishes a maximum oxygen pressure allowed for POCs intended for use on board aircraft.

A POC designed to generate a maximum oxygen pressure of 200 kPa gauge (29.0 psig/43.8 psia) at 20 °C (68 °F), or more, would constitute a hazardous material and thus be subject to the HMR. As such, it must not be labeled as meeting the standards for use on board aircraft.

The agency has determined that inclusion of the requirement regarding oxygen pressurization does not overlap with 49 CFR 173.115 or the general prohibition on hazardous materials in this final rule, because it applies a design standard regarding the operation of the device. Further, it addresses concentrated oxygen that falls below the pressure threshold for the definition of compressed gasses subject to 49 CFR 173.115.

D. Manufacturer Label

The FAA does not currently require POCs to bear a label indicating FAA approval and compliance with the SFAR. Aircraft operators, crewmembers, and passengers must identify POCs approved for use on aircraft by reviewing the list of FAA-approved devices in the SFAR.

In the NPRM, the FAA proposed to require POCs that satisfied the proposed acceptance criteria and were intended for use on aircraft to bear a label indicating that the device satisfies these criteria as a condition of its carriage and use on aircraft. However, the NPRM excluded SFAR-approved POCs from the labeling requirement.

The FAA also proposed specific label attributes. The proposed label would be required to contain the following statement in red text: ''The manufacturer of this portable oxygen concentrator has determined this device conforms to all applicable FAA requirements for portable oxygen concentrator carriage and use on board aircraft.'' Finally, the agency proposed that the label would have to be applied in a manner to ensure it remains affixed for the life of the POC.

Identification of POCs that satisfy acceptance criteria: The agency sought comment on the potential safety benefits and associated burdens of extending the proposed labeling requirement to all POC models currently identified in SFAR No. 106—existing and newly manufactured or just newly manufactured. Several commenters expressed concern regarding the exclusion of existing SFAR-approved POCs from the proposed POC labeling requirement. A4A, the Mayo Clinic and two individuals commented that the labeling requirement should extend to all POC models that may be used on board aircraft (those that are currently identified in SFAR No. 106 and those subsequently determined by their manufacturers to satisfy the proposed acceptance criteria).

The individuals cited concern regarding potential confusion due to the two methods (*i.e.,* review label and review list of SFAR-approved POCs) by which to identify POCs that may be used on aircraft as the basis for requiring all POCs to be labeled. The Mayo Clinic suggested that POC manufacturers could retrofit existing SFAR-approved devices through an inexpensive labeling method such as a sticker to resolve its concerns about potential health care provider confusion regarding which POCs may be used on aircraft.

A4A noted that air carrier employees with responsibility for determining device acceptability should be able to make this determination efficiently, without having to refer to the CFR. A4A also stated that its comments on extending the labeling requirement to POCs approved under the SFAR should only be applied to newly manufactured POCs because retrofitting existing devices would be unreasonably burdensome.

Philips Respironics objected to the extension of the labeling requirement to existing SFAR-approved POCs citing a significant burden and stating that passengers and aircraft operators would have sufficient means by which to identify POCs that may be used on board aircraft.

The final rule retains the proposal to label POCs that have not been previously identified in SFAR No. 106 as approved for use on aircraft. SFAR-approved POCs will continue to be identified in §§ 121.574, 125.219, and 135.91.

The labeling requirement provides a simple, efficient and effective method by which to identify POCs that may be used on aircraft. In order to determine whether a POC may be used on an aircraft, a POC user or an aircraft operator need only examine the POC to determine whether it bears the label required by this final rule. As is the case today, for those POCs that do not bear the required label, a POC user and aircraft operator need only verify that the model is identified in the regulatory

text—the same process that is currently used to identify SFAR-approved POCs.

The FAA maintains that it is not necessary or practical to require POC manufacturers to label POCs previously identified in SFAR No. 106 as approved for use on board aircraft. POC models previously identified in SFAR No. 106 as approved for use on board aircraft have satisfied the SFAR No. 106 criteria and would also satisfy the proposed acceptance criteria. Further, the FAA expects that the use of SFAR-approved POC models will lessen over time as those POCs age and their users replace those older models with newer ones, obviating the need to retrofit existing SFAR-approved POC models with a label.

Although the agency appreciates the intent of the Mayo Clinic's comment regarding a ''bridging strategy'' by which adhesive stickers could be used to identify previously manufactured SFAR-approved POCs, a label used to satisfy the requirements of this final rule must be sufficiently durable so as to remain affixed to the POC for the life of the device and prevent the transfer to another type of oxygen dispensing device, such as a device that uses compressed oxygen.

In comments related to the identification of SFAR-approved POCs, Delta Air Lines suggested that the list of SFAR-approved POCs provided in the proposed regulatory text was incomplete because it did not identify all devices that the FAA previously approved in accordance with the SFAR. The list of SFAR-approved POCs identified in the proposed and final rule regulatory text is identical to the list of POCs identified in SFAR No. 106. The agency stresses that SFAR approval is device-specific. For instance, while the SFAR identifies the SeQual Eclipse as approved for use on aircraft, the approval does not extend to any other variants of SeQual Eclipse models that were not specifically reviewed and approved for use on aircraft by the FAA and identified in the SFAR. Thus, only those specific POCs identified in the SFAR by manufacturer and model name are currently approved for use on aircraft. This final rule continues to identify those SFAR-approved devices as they appear in the SFAR, since those SFAR-approved POCs need not bear a label as a condition of their use on aircraft.

Delta Air Lines further commented that the FAA should update the list of POCs approved under SFAR No. 106 with the names of all POCs currently under review by the FAA, in accordance with the SFAR prior to publication of the final rule. This final rule includes a list of all POCs approved by the FAA under the SFAR.

FAA identification of POCs that satisfy acceptance criteria: Several commenters raised issues related to the FAA listing of POCs that satisfy the FAA acceptance criteria. A4A suggested that the FAA maintain a list of POC devices that meet the FAA's proposed acceptance criteria to keep industry and the public updated with compliant POCs. A4A further explained that the FAA should maintain a list of POCs that meet the acceptance criteria because of challenges for aircraft operators in determining whether a POC satisfies the acceptance criteria, especially in the instance in which a manufacturer incorrectly labels a device.

The FAA disagrees with A4A's comment that unless the FAA maintains a list of POCs that satisfy the acceptance criteria, POC identification will be unnecessarily burdensome. The process of examining a POC to determine whether it bears a label is less burdensome than the existing process of examining a POC to identify the model name and then verifying that the model is identified in the SFAR. In either case, a crewmember of an aircraft operator must examine the POC.

A4A also recommended that the FAA maintain a list of POCs that are labeled as conforming to FAA requirements for POC use on board aircraft to track POCs that are subsequently determined to be non-compliant. However, the FAA has alternate appropriate methods by which to notify aircraft operators in the unlikely event that a POC intended for use on aircraft is no longer compliant with FAA requirements. For example, the FAA can provide such notice through a Safety Alert for Operators (SAFO) or an InFO, as appropriate. All SAFOs and InFOs are made available on the agency's Web site.

Label attributes: The final rule requires the label to contain the following statement in red text: ''The manufacturer of this POC has determined this device conforms to all applicable FAA requirements for POC carriage and use on board aircraft.'' The purpose of this verbiage is to facilitate identification of devices that conform to the acceptance criteria and the red color is expected to draw attention to the text.

Consistent with the NPRM, this final rule also requires a labeling method that ensures the label remains affixed to the POC for the life of the device. The purpose of this requirement is to ensure the label is durable and cannot be transferred to another type of oxygen dispensing device (such as a device that uses compressed oxygen).

Several commenters suggested changes related to the proposed label that would standardize label features in addition to the proposed required text and color. A4A commented that the FAA should mandate additional specific label attributes so that labels are identical and can be easily recognized by gate agents.

Philips Respironics commented that the proposed label text is overly burdensome due to the length of the text and the color requirement. This commenter proposed an alternate label that states, ''Complies with FAA requirements for airline use'' and includes an airplane graphic. Together with this alternate label, Philips Respironics suggested a POC manual update to further describe the label. Main Clinic Supply supported the label example included in the Philips Respironics comment.

The agency has considered comments regarding additional standard label features but has determined that it is unnecessary to require standardized features beyond the proposed label verbiage and text color. The use of red text is sufficient to draw attention to the label identifying a POC that may be carried and used on board an aircraft.

The specific label language proposed in the NPRM and included in this final rule is necessary to facilitate the identification of the device as a POC that satisfies the acceptance criteria for POCs intended for use on board aircraft. A more generic or general label such as the label proposed by Philips Respironics and supported by Main Clinic Supply would not effectively serve this purpose. The agency is aware that manufacturers of some POC models approved under SFAR No. 106 may have voluntarily applied labels similar to the label recommended by Philips Respironics and Main Clinic Supply. The FAA determined, however, that the label proposed by commenters could hinder a passenger's ability to use an SFAR-approved POC by introducing confusion into the POC identification process due to multiple similar labels (*i.e.,* labels currently affixed to some SFAR-approved POCs and the label proposed by commenters). The only label that may be used to determine compliance with this final rule and to ascertain whether a POC may be used on board an aircraft is a label that exhibits the verbiage and color criteria specifically provided in this final rule.

Further, the FAA analyzed the costs associated with the NPRM labeling requirement and estimated that the requirement would not result in a significant burden. Commenters did not challenge the FAA assumptions that

provide a basis for the estimate of the labeling costs in the NPRM. Given that the final rule label verbiage includes only minimal changes from the proposed label verbiage, the final rule is not expected to result in a significant burden to POC manufacturers.

Additionally, the FAA notes that, although the agency supports the Philips Respironics comment regarding POC manufacturer manual updates to describe the label, it would reach beyond the scope of the proposal for the FAA to require POC manufacturers to include additional information in the POC user manual. However, the FAA encourages manufacturers to inform POC users of issues pertaining to POC use on board aircraft.

Finally, A4A commented that if the POC acceptance criteria were to change, the FAA should change the label requirements to distinguish those POCs that meet the new acceptance criteria from those that do not meet the new acceptance criteria. The agency will consider this comment if it finds that a future rulemaking is required to revise POC acceptance criteria.

E. Manufacturer Determination of Conformance to Acceptance Criteria

Two individuals questioned whether the FAA should rely on POC manufacturers to determine that a POC is safe and fits within the regulatory requirements. One of the individual commenters recommended that POC manufacturers demonstrate compliance with the acceptance criteria to the FAA before labeling the device as satisfying those criteria. In a related comment, Delta Airlines recommended that the FAA should require POC manufacturers to provide airlines with the data that demonstrates compliance with the acceptance criteria at the airlines' request.

The FAA employs a range of oversight approaches throughout title 14. The process in this final rule that allows manufacturers to self-certify that their POC conforms to all applicable requirements for use on board aircraft and to affix a label that can be reviewed by aircraft operators and passengers is consistent with other existing agency oversight practices. For example, child restraint system (CRS) manufacturers self-certify (via a label) that their CRS meets all applicable performance criteria and is approved for use on aircraft. In another example, the Technical Standard Order (TSO) program involves a process where a manufacturer makes statements of conformance to the standards in a particular TSO for many different types of articles used on aircraft.

In the case of POCs, the FAA has determined that the devices present minimal risk to aircraft operations. Additionally, the proposed and final rule acceptance criteria for POCs leverage existing regulatory requirements that are applicable to POCs and relevant to the safe carriage and use of POCs, including the use of POCs on board aircraft. The purpose of the label applied by POC manufacturers is to facilitate aircraft operator and passenger identification of devices that meet the acceptance criteria required for POCs intended for use on board aircraft.

Accordingly, a case-by-case POC approval process is unnecessarily burdensome to mitigate any potential risk presented by POCs. An aircraft operator seeking specific information regarding a POC may reach out to a POC manufacturer without FAA regulation. The agency also notes that POC user manuals and POC manufacturer Web sites also provide information pertaining to the attributes and functions of the associated POCs.

F. Prohibition on Smoking or Open Flame

SFAR No. 106 prohibits smoking or open flame within 10 feet of any person using a POC. In the NPRM, the agency proposed to retain this restriction. The agency did not receive any comments on the proposal to retain the SFAR prohibition on smoking or open flame near a person using a POC. Accordingly, the final rule includes this proposal without change.

Although the risk posed by concentrated oxygen is minimal when generated at a pressure below that which would trigger the application of the HMR, given the unique environment of an aircraft, the agency has determined that it is reasonable to provide an additional margin of safety by prohibiting smoking or open flame in the vicinity of a person using a POC. Accordingly, the agency will maintain the existing prohibition on smoking or open flame within 10 feet of a person using a POC by extending the smoking prohibitions in existing §§ 121.574, 125.219, and 135.91 to POCs and adding language to specifically prohibit an open flame.

The smoking prohibition in existing §§ 121.574, 125.219, and 135.91 effectively results in a prohibition on an open flame. However, given the risks created by smoking near a person using medical oxygen and the storage of such oxygen, in this final rule the agency will ensure that this restriction is clear by explicitly prohibiting an open flame in addition to smoking.

Finally, as proposed, this final rule amends the regulatory text in § 125.219(b) to prohibit smoking not only within 10 feet of where medical oxygen is being used but also within 10 feet of where it is stored. This amendment is consistent with the preamble for the final rule issuing § 125.219 as well as the prohibitions on smoking within 10 feet of the location of medical oxygen storage or use in §§ 121.574 and 135.91. *See* 45 FR 67214, 67230 (October 9, 1980).

G. Operational Requirements

1. Exit Seats

Section 3(a)(4) of SFAR No. 106 prohibits a person using a POC from sitting in an exit row. The FAA proposed to eliminate this SFAR No. 106 provision from the final rule.

AFA and an anonymous commenter recommended that the FAA retain the provision in SFAR No. 106 prohibiting a passenger from using a POC while sitting in an exit row. Both commenters noted that POC tubing would create obstacles in the exit row. AFA stated that generally, certificate holders should have the responsibility for determining the suitability of passengers who occupy exit seats; however, they maintained that an explicit restriction on exit row seating would eliminate any ambiguity about a POC user's ability to assist in an emergency.

The FAA agrees with commenters in that a passenger's ability to perform exit row functions could be impeded by the presence of the device, possibly creating a tripping hazard and an obstacle to egress. Thus, although §§ 121.585 and 135.129 require the certificate holder to determine the suitability for passengers it permits to occupy exit seats, the final rule retains the SFAR No. 106 provision prohibiting passengers using a POC from sitting in exit seats to eliminate any potential ambiguity pertaining to whether a passenger using a POC may occupy an exit seat.

2. Stowage of Portable Oxygen Concentrators

SFAR No. 106, section 3(a)(3) states that during movement on the surface, takeoff, and landing, the POC must either be stowed under the seat in front of the user, or in another approved stowage location, so as not to block the aisle way or entryway into a row. Further, SFAR No. 106 limits the location of POC use to a seat location that does not restrict any passenger's access to, or use of, any required emergency or regular exit, or the aisle(s) in the passenger compartment. However, FAA regulations in parts 121,

125, and 135, also address the stowage of carry-on items and carriage of cargo in the passenger cabin to ensure an appropriate stowage location and that emergency exit row access is not hindered by carry-on items or cargo. *See* §§ 121.285, 121.589, 125.183, and 135.87. Thus, the FAA proposed to eliminate the POC stowage requirement in SFAR No. 106.

AFA recommended that the FAA retain the requirements in section 3(a)(3) of SFAR No. 106 that pertain to POC stowage. AFA stated that, for consistency with existing medical oxygen rules that require certificate-holder provided equipment to be ''appropriately secured,'' (§§ 121.574, 125.219 and 135.91) the final rule regulatory text should continue to address stowage requirements for passengers' POCs. The commenter stated that some operators might conclude that only devices furnished by the certificate holder are required to be secured or stowed unless POC stowage is specifically addressed.

Although the FAA continues to expect that POC stowage will be addressed in an operator's carry-on baggage program in accordance with the requirements of 14 CFR 121.285, 121.589, 125.183 and 135.87, the FAA agrees with the commenter that retaining and specifically addressing POC stowage (and thereby reinforcing POC stowage requirements) could increase the likelihood of safe stowage of passenger supplied POCs. Accordingly, as found in SFAR No. 106, this final rule includes a specific requirement for POCs to be stowed during movement on the surface, takeoff, and landing.

Notably, the user manuals for 18 of the POC models currently approved under SFAR No. 106 specify oxygen tube length. Every manual specifying oxygen tube length indicates the associated POC has at least 7 feet of tubing, which is long enough to allow a passenger to use a device stowed under a seat.

H. Discussion of Special Federal Aviation Regulation No. 106 Requirements Excluded From Final Rule

The FAA has determined that many of the requirements included in SFAR No. 106 are overly prescriptive or redundant with existing rules and are therefore not necessary. Accordingly, the FAA has not retained them in this final rule. A discussion of the SFAR No. 106 requirements excluded from this final rule follows.

1. Special Federal Aviation Regulation No. 106 Requirements Addressed in Existing Regulations

a. Passenger Movement About the Cabin While Using a Portable Oxygen Concentrator

SFAR No. 106, section 3(a)(6) states that when the PIC turns off the ''Fasten Seat Belt Sign,'' or otherwise grants permission to move about the passenger cabin, passengers may continue to use their POC while moving about the cabin. The agency included this provision in SFAR No. 106 in response to commenters' concerns that the agency should allow passengers using a POC to operate the device for the entirety of the flight, if necessary. Therefore, in the final rule implementing SFAR No. 106, the agency stated that passengers are allowed to use a POC for the duration of the flight, including during movement on the surface, takeoff, and landing. The agency also stated that once passengers were allowed to move about the cabin of the aircraft, they would be allowed to bring the POC with them. *See* 70 FR at 40159.

In the NPRM, the agency proposed to remove section 3(a)(6) of the SFAR. Section 3(a)(6) of the SFAR is unnecessary because there are no regulations directed at passengers using a POC that would limit their movement about the cabin when passenger movement is permitted by the PIC. Accordingly, as proposed in the NPRM, the final rule does not include a provision similar to section 3(a)(6) of the SFAR. The agency did not receive any comments on the proposed elimination of this SFAR No. 106 provision.

b. Protection of Batteries From Short Circuit

SFAR No. 106, section 3(b)(6) requires passengers to ensure all POC batteries carried on board the aircraft in carry-on baggage are protected from short circuit and packaged in a manner that protects them from physical damage. Batteries protected from short circuit include: (1) Those designed with recessed battery terminals; or (2) those packaged so that the battery terminals do not contact metal objects (including the battery terminals of other batteries). Additionally, when a passenger carries a POC on board an aircraft as carry-on baggage, and does not intend to use the POC during the flight, the passenger must remove the battery and package it separately unless the POC contains at least two effective protective features to prevent accidental operation and potential overheating of the battery within the POC during transport.

The FAA proposed to eliminate the SFAR No. 106 provisions applicable to spare batteries carried by passengers on board aircraft for use in POCs because they are unnecessary. The portion of SFAR No. 106, section 3(b)(6) addressing spare batteries is redundant with PHMSA regulations applicable to spare lithium batteries carried by passengers on board aircraft. *See* 49 CFR 175.10(a)(18).

A4A commented that the FAA should strongly recommend that POC manufacturers include a carrying case for spare lithium battery packs to ensure battery isolation and insulation. The FAA supports any action a POC manufacturer takes to facilitate passenger, crewmember, and operator compliance with the requirements for the safe carriage of lithium ion batteries on board aircraft, including spares. However, the agency does not agree that the commenter's recommendation is necessary because PHMSA has identified the requirements for safe carriage of spare lithium batteries used to power all PEDs carried by aircraft passengers or crewmembers. *See* 49 CFR 175.10(a)(18).

PHMSA requires all lithium batteries to be of a type proven to meet the requirements of each test, including Test T.7 (Overcharge), in Part III, Sub-section 38.3 of the UN Manual of Tests and Criteria. *See* 49 CFR 173.185 and 175.10(a)(18). Additionally, PHMSA requires spare lithium batteries carried on board aircraft to be carried in the cabin in carry-on baggage and individually protected from short circuit to mitigate the risk of a fire during flight (*e.g.,* by placement in original retail packaging, by otherwise insulating terminals by taping over exposed terminals, or by placing each battery in a separate plastic bag or protective pouch). *See* 49 CFR 175.10(a)(18).

The agency notes that the SFAR diverges from PHMSA requirements pertaining to installed batteries. *See* 49 CFR 175.10(a)(18). The SFAR requires a passenger to remove a POC battery if the device does not have at least two features that prevent accidental operation. The HMR, however, do not require an installed battery to be removed from any PED, which would include a POC that is not in use. *See* 49 CFR 175.10(a)(18).

Based on the analysis of currently approved POCs and PHMSA requirements applicable to lithium ion batteries carried by passengers and crewmembers to power PEDs, an independent FAA requirement for two protective features as a prerequisite to leaving an installed battery in a POC is unnecessary. The agency reviewed the

24 SFAR-approved POCs and determined those POCs all have at least two design features preventing inadvertent or accidental operation. Thus, batteries may remain in SFAR-approved POCs while those POCs are not in use.

In addition, current PHMSA regulations address the safe transportation of lithium ion batteries as well as passenger carriage of lithium ion batteries. Lithium batteries must be of a type proven to meet the requirements of each test, including Test T.7 (Overcharge), in Section 38.3 of the UN Manual of Tests and Criteria. *See* 49 CFR 173.185.

Based on the analysis of SFAR-approved POCs and the applicable HMR, an independent FAA requirement for two protective features as a prerequisite to leaving an installed battery in a POC is unnecessary. All POCs currently used on board aircraft are equipped with two protective features and all lithium ion batteries must be designed to satisfy the overcharge test protection, therefore, the risk of a fire originating from the battery is minimal. Accordingly, this final rule eliminates SFAR No. 106, section 3(b)(6) from title 14.

2. Special Federal Aviation Regulation No. 106 Requirements Excluded in Their Entirety

a. Physician Statement and Pilot in Command and Aircraft Operator Notification Requirements

Section 3(b)(3) of SFAR No. 106 requires passengers intending to use a POC to have a written statement signed by a licensed physician, and kept in that person's possession that states whether the user of the device has the physical and cognitive ability to see, hear, and understand the device's aural and visual cautions and warnings and is able, without assistance, to take the appropriate action in response to those cautions and warnings; states whether or not oxygen use is medically necessary for all or a portion of the duration of the trip; and specifies the maximum oxygen flow rate corresponding to the pressure in the cabin of the aircraft under normal operating conditions.

Section 3(b)(3) of SFAR No. 106 further requires a passenger to inform the aircraft operator that he or she intends to use a POC on board the aircraft and to allow the crew of the aircraft to review the contents of the physician's statement. Similarly, section 3(a)(5) of SFAR No. 106 requires PIC notification whenever a passenger brings and intends to use a POC on board the aircraft. The PIC must be apprised of the physician's written statement required by section 3(b)(3) of the SFAR including the nature of the passenger's oxygen needs and the passenger's ability to understand operational and warning information presented by the POC.

As proposed, the FAA will no longer require POC-using passengers to present a physician's statement, to notify the aircraft operator and PIC of their intended POC use, to inform the PIC of the contents of their physician's statement, and, to allow the crew of the aircraft to review the content of their physician's statement. The FAA received comments related to these proposals from two POC suppliers (Main Clinic Supply and OTG), the Mayo Clinic, AMDA, and a number of individuals. The FAA has reviewed and considered all comments regarding the physician's statement and pre-flight notification of POC use.

Physician statement: Two individual commenters supported the FAA proposal to relieve passengers from obtaining a physician's statement as a condition of their use of a POC on aircraft. Main Clinic Supply supported the proposal to relieve passengers from having to provide a physician statement commenting that the current requirement for a written, signed physician statement for every flight is not practical, causes many delays, and may inhibit POC users' air travel. Main Clinic Supply also stated that physicians and their staff do not have the resources to provide POC training to patients, explaining that the POC user must be responsible for reading the POC operating manual and asking the necessary questions of their oxygen provider.

OTG, AMDA, the Mayo Clinic, and some individual commenters did not support the FAA proposal to remove the requirement for passengers to carry a physician's statement as a condition of POC use on aircraft. OTG, AMDA, and some individual commenters indicated that removal of the existing physician's statement and notification requirements would cause diversions, impact passenger travel, and be costly to the airlines. Generally, commenters asserted that the FAA should retain the SFAR No. 106 requirement for a physician's statement because it ensures that passengers seeking to use a POC on board an aircraft have consulted with a physician regarding POC use in the aircraft environment prior to travel. Commenters also challenged statements in the NPRM regarding POC function in the aircraft environment.

The Mayo Clinic commented that it is particularly important for individuals who have ''poor respiratory reserve'' to have health care provider oversight. In this regard, the physician statement is a form of ''safety net'' to trigger these conversations between passengers and their treating providers. It is critical that these conversations occur prior to air travel since decompensation on board a flight may require urgent response. OTG and some individual commenters commented that additional interaction between a POC user and his or her physician is necessary to educate passengers with limited experience with POC use; to address discrepancies between the POC prescription and the POC provided by a supplier; and to help the POC user account for the effects of cabin pressurization on POC use.

OTG indicated in its comments that the flow rate on a POC prescription may not be appropriate for cabin altitudes. In a related comment, the Mayo Clinic stated, ''[A]lthough a physician or other health care provider with prescribing privileges writes prescriptions for devices to deliver supplemental oxygen, many providers are unfamiliar with the physiology of altitude.'' OTG also commented that, in its experience, a large percentage of physicians and the majority of passengers incorrectly assume aircraft cabins are pressurized to sea level. OTG stated that based on this assumption, physicians do not provide their POC-using patients with recommendations regarding oxygen flow adjustments during air travel when most will require higher flow rates in a pressurized cabin than at sea level. OTG further asserted that the POC will not produce the same percentage of oxygen in a pressurized cabin and the oxygen saturation level of the passenger will be decreased due to the normal physics of the partial pressure of the oxygen on pulmonary tissue.

The agency clarifies that SFAR No. 106 does not specifically require a passenger to obtain a new physician's statement prior to each flight. *See* 70 FR at 40161. Also, SFAR No. 106 does not require the physician's statement to account for the duration of a specific flight, variables that may arise in flight conditions, changes in a patient's oxygen needs over time, or variables that may arise in connection with an individual's medical condition. Further, commenters noted that not all physicians may be familiar with effects of cabin pressure or realize that aircraft are not pressurized to sea level. For these reasons, while the SFAR No. 106 requirement for a physician's statement may result in a one-time conversation about a passenger's POC use on an

aircraft at some point in time, the requirement to obtain such a statement may not provide the POC education and ''safety net'' expected by commenters.

The FAA appreciates and concurs with comments regarding the need for vigilance and understanding of all nuances associated with POC use on aircraft. The agency appreciates and has considered commenters' concerns about the physiology of flight and its relationship to POC use. The FAA emphasizes that pre-flight preparation on the part of the POC-using passenger, working closely with an appropriate medical professional, should always occur when traveling with any medical device. While preparation may differ for each POC-using passenger, depending on the aircraft and kind of operation included in his or her travel plans, passengers may wish to consider such factors with their medical professional such as past experience using a POC, cabin pressurization, layovers, length of flight, and pre-flight activities that could lead to compromised lung function in flight. The FAA also encourages POC-using passengers to carry documentation regarding the device they intend to use including any pertinent documentation provided to them by a medical professional or any medical certificate required by the carriers in accordance with the Department's air travel disability regulation in 14 CFR 382.23.

However, the FAA believes that retaining the SFAR No. 106 requirement for a physician's statement as evidence of this medical consultation is not the most effective education tool in those circumstances in which the physiology of altitude could come to bear on POC use and should not be relied on as the means to address the range of variables potentially affecting passengers using POCs during flight. The FAA has determined that it is more effective to provide reasoned guidance and public outreach to educate POC users and physicians regarding considerations pertaining to POC use during flight in a pressurized cabin. The FAA provides information on passenger health and safety on its Web site (*e.g., http://www.faa.gov/passengers/fly_safe/health/comprehensive/*). The FAA has also updated the POC-specific guidance in AC–120–95B and expects to update its Web site with information a passenger may want to consider when traveling with a POC.

As is the case with in flight use of any medical device, passengers who need to use a POC on board an aircraft should always consult with an appropriate medical professional and their chosen air carrier before traveling. Doing so ensures that passengers are prepared for each flight they take, particularly if, as one commenter noted a prescription may not address adjustments that may be appropriate for POC use on a pressurized aircraft. However, the FAA has determined that the specific, regulatory requirement set forth in the SFAR requiring POC-using passengers to obtain, present, and allow for scrutiny of a physician's statement, as a condition of admission on board an aircraft is particularly burdensome for passengers seeking to use a POC during air travel.

The FAA intended for the SFAR to provide a framework, not previously available, under which persons with a need to use personal oxygen therapy could use their own devices during a flight, thereby increasing accessibility to air travel for POC-using passengers. With more than 10 years of experience with POC technology and POC use on aircraft, the FAA has determined that the requirement for a passenger to provide for aircraft operator, crewmember, and PIC scrutiny, a physician statement pertaining to a medical device that the passenger is solely responsible for during the flight, was an overly conservative addition to the POC oversight framework. Removing the requirement to obtain a physician's statement affects a paperwork requirement; it does not affect passengers' responsibility to be prepared for travel. The purpose of this final rule is to continue to provide POC-using passengers access to air travel, while addressing device safety for aircraft use; it is not intended (and is not within FAA authority) to set forth a standard of medical care for POC-using passengers. Further, the FAA does not require passengers who supply any other medical device for their own use during a flight to provide a physician's statement as a condition of device usage during flight.

Additionally, as mentioned previously, existing DOT requirements in 14 CFR part 382 continue to include a provision to further mitigate the possibility of medical events including those that could result in a diversion. Sections 382.23(b) and 382.133 authorize carriers to require a passenger needing medical oxygen inflight to provide a medical certificate to ensure the passenger can complete the flight safely without requiring extraordinary medical assistance during the flight.

AMDA indicated that the FAA should conduct additional research regarding the potential impact of the elimination of the physician's statement. The FAA has determined that additional research is not necessary at this time because the FAA expects physician consultation to continue as appropriate for the use of any medical device, and that pre-flight notice of POC use on the aircraft will continue in light of the requirement for each aircraft operator to determine whether the POC bears the label required for use on board aircraft.

The purpose of the SFAR and the FAA's action in this final rule is to address continued use of POCs on aircraft without compromising the safety of the aircraft operation. The agency has determined the SFAR No. 106 requirement for a physician statement creates an unnecessary burden that may not ultimately serve the purpose contemplated by commenters. The FAA emphasizes that removing the requirement to obtain a physician's statement affects a paperwork requirement; it does not affect passengers' responsibility to be prepared for travel, including obtaining a medical certificate if the carrier chooses to require one as allowed by 14 CFR 382.23 and 382.133. All passengers using a medical device in an aircraft environment are responsible for preparing for the flight such that they can ensure that the device will function properly during the flight and provide the requisite medical support. Therefore, as proposed, this final rule discontinues the SFAR requirement for a physician statement.

PIC and aircraft operator notification: OTG, AMDA, and several individual commenters did not support the proposal to remove the requirements for pre-flight notification of the aircraft operator and PIC regarding POC use on board an aircraft. These commenters, however, did not provide specific reasons for maintaining the notification requirements. One anonymous commenter asserted that advance notice that a passenger expects to use a POC would allow crewmembers to prioritize actions during multiple cabin events.

Under this final rule, the PIC and aircraft operator (through a crewmember or gate agent) will continue to receive notice of a passenger's POC use during flight as the operator determines during pre-boarding procedures whether the device has the label now required for POC use on the aircraft. Accordingly, as proposed, the FAA discontinues the specific requirement for passengers to notify the aircraft operator and PIC of intended POC use during a flight because a specific notification requirement is unnecessary.

OTG also stated that several POC-related incidents have occurred in flight but did not provide any specific examples, information, or data regarding such diversions or incidents. OTG

further stated that the FAA should have contacted ''air-to-ground'' medical service providers to document POC-related incidents.

The agency reviewed air carrier safety data collected from 2005 through 2014—a period of nearly 10 years—and found no instances of POC malfunction during flight or any related medical incident or diversion. This review included information from several accident, incident, and voluntary reporting databases.[17] Further, no ''air-to-ground'' medical service providers contacted the agency regarding any POC incidents, nor did they provide any comments to the agency in this regard during the open comment period.

Although the FAA is removing the requirement for pre-flight notification, under existing DOT requirements in 14 CFR part 382, carriers continue to be permitted to require individuals who wish to use a POC on aircraft to contact them 48 hours before scheduled departure. Carriers are permitted to require this pre-flight notification so they can ensure that a passenger knows the expected maximum flight duration and can use this information in determining the number of spare batteries that he or she will need to power the POC during the flight.

b. Portable Oxygen Concentrator Alarms

SFAR No. 106, section 3(b)(1) requires a passenger using a POC on board an aircraft to be capable of hearing the unit's alarms and seeing alarm light indicators. SFAR No. 106 also requires passengers using a POC to have the cognitive ability to take appropriate action in response to the various POC caution alarms, warning alarms, and alarm light indicators, or travel with someone capable of performing those functions.

In the NPRM, the FAA proposed to eliminate the requirement for a passenger using a POC on board an aircraft to be capable of hearing the unit's alarms and seeing alarm light indicators. An anonymous commenter stated that the FAA should retain this requirement because a continuous audio alarm could be very disruptive and compound other abnormal events occurring in the cabin. The commenter added that the absence of alarm events over the last 10 years does not mean that an alarm event will not occur in the future. Additionally, OTG commented that in its experience, an individual may not be able to respond to alarms even if a physician states that the individual can respond to the POC alarms.

Crewmembers receive training on how to respond to unanticipated events that may arise on board the aircraft including disruptions in the cabin and other abnormal events. Further, it is a passenger's responsibility to read the POC operator's manual and direct questions to their physician to ensure understanding of oxygen flow settings and the appropriate responses to alarms.

The SFAR No. 106 requirements pertaining to POC alarms are based on information in the user manual of the first POC approved by the FAA. *See* 69 FR at 42325. Based on a review of 20 user manuals for POCs identified in SFAR No. 106, the agency has determined POC alarms may provide information regarding the general operation of the POC, as well as information regarding the power source and detection of the POC user's breath. Since these alarms help ensure the device functions as intended, the FAA believes that removing this requirement will not affect aviation safety.

The FAA also emphasizes that it has not identified any incidents regarding POC malfunctions on board aircraft during the period of time that POCs have been permitted on aircraft. A 10-year look-back period includes data from almost 78 million domestic flights with no adverse POC incidents. *See http://www.transtats.bts.gov/Data_Elements.aspx?Data=2.* The agency has determined that this is sufficient data to provide an appropriate indicator of future POC safety. Therefore, as proposed, this final rule eliminates the SFAR No. 106 requirement pertaining to alarms (section 3(b)(1)).

c. Ensuring the Portable Oxygen Concentrator is Free of Petroleum Products

SFAR No. 106, section 3(b)(2) requires a passenger using a POC to ensure the POC is free of oil, grease, or other petroleum products and is in good condition free from damage or other signs of excessive wear or abuse. This provision is similar to a warning statement found in the user manual of the first POC approved by the FAA and to a provision in the medical oxygen rules (§§ 121.574, 125.219, and 135.91). See 69 FR at 42325. The agency proposed to eliminate this SFAR No. 106 provision.

OTG commented that for passengers who rent their POCs, the condition of the device and its batteries is dependent on the purveyor of the equipment. The FAA expects POC users to ensure that a POC they intend to use is in good condition so that it may function properly to provide the needed oxygen therapy whether the POC user is on the ground or on an aircraft. Further, while petroleum products may accelerate an existing fire, the volume of petroleum products necessary to accelerate a fire is unlikely to be found on the exterior of a POC, and this concern is not addressed as a specific requirement for other PEDs carried on board aircraft. Therefore, this final rule eliminates the requirements in section 3(b)(2) of SFAR No. 106 because the requirements are unnecessary.

d. Use of Salves and Lotions

SFAR No. 106, section 3(b)(4) states only oxygen approved lotions or salves may be used by persons using a POC on board an aircraft. In the NPRM, the FAA proposed to eliminate this prohibition in its entirety and did not receive any comments on this proposal.

The requirement in SFAR No. 106, section 3(b)(4) came from the user manual of the first POC approved by the FAA. The FAA believes it is the passenger's responsibility to ensure he or she is using products that meet the POC manufacturer's requirements for salve and lotion usage with a POC. The risks and responsibilities associated with lotions or salves that are not oxygen approved or are petroleum-based are addressed in the preceding discussion on the elimination of the requirement for the user to ensure that the POC is free from petroleum products. Therefore, as proposed, this final rule does not retain the prohibition in section 3(b)(4) of SFAR No. 106.

e. Carriage of a Sufficient Number of Batteries

SFAR No. 106, section 3(b)(5) requires passengers intending to use a POC during a flight to obtain from the aircraft operator, or by other means, the duration of the planned flight and carry a sufficient number of batteries to power the device for the duration of the oxygen use specified in the passenger's physician statement, including a conservative estimate of any unanticipated delays. In the NPRM, the agency proposed to eliminate this SFAR No. 106 requirement.

Delta Air Lines commented that this final rule should retain the battery carriage requirements found in SFAR No. 106 and current 14 CFR 382.133(f)(2) because passengers often mistakenly assume that electrical outlets are available to power portable medical devices. The FAA is not aware of any specific incidents of confusion

[17] Voluntary Disclosure Reporting Program (VDRP), Service Difficulty Reporting System (SDRS), National Transportation Safety Board Aviation Accident and Incident Data Systems (NTSB), National Aeronautics and Space Administration Aviation Safety Reporting System (ASRS) and FAA Accident/Incident Data System (AIDS).

regarding availability of electrical outlets to power POCs. FAA guidance (AC 120–95B as well as previous editions of this AC) addresses aircraft operator and passenger issues pertaining to the use of electrical outlets to power POCs. Further, many air carriers, including the commenter, disclose applicable policies on their Web sites regarding the availability and use of on board electrical outlets for electronic devices intended for use during flight. The FAA encourages air carriers to continue this practice.

Additionally, as noted in the Delta Air Lines comment, existing DOT regulations (14 CFR part 382) permit carriers to require an individual traveling with a POC to bring an adequate number of fully charged batteries into the cabin that will power the POC for no less than 150% of the expected maximum flight duration. *See current* 14 CFR 382.133(f)(2), revised by this rule to 14 CFR 382.133(h)(2). Part 382 also requires carriers to inform passengers who advise the carriers of their intent to use a POC on board an aircraft about the maximum duration of the flight segment. *See* 14 CFR 382.133(f)(1), revised by this rule to 14 CFR 382.133(h)(1).

OTG commented that it is almost impossible for the average passenger to assess the amount of battery power that they may need for the duration of a trip due to time zone changes, the effect of flow rate on battery duration and mistaken assumptions about their ability to recharge batteries between flights. OTG also indicated that POC manufacturer manuals are ''overly optimistic'' about battery duration, often basing their assumptions on data from new batteries.

The Mayo Clinic commented that many passengers only use a POC temporarily, during a flight, and thus are unfamiliar with the device. The Mayo Clinic added that an FAA requirement for passengers using a POC to carry a certain amount of battery power, would serve as a reminder for the passenger and his or her health care provider regarding the necessity of sufficient power for POC use, noting that the consequences of inadequate supplemental oxygen could result in the need to administer medical oxygen during the flight or divert the aircraft.

The FAA maintains that it is the passengers' responsibility to understand the performance of their POC and its battery life under varying conditions and ensure their POC will enable them to adhere to their physician's instructions. All manuals for the POCs identified in SFAR No. 106 have liter flow and battery duration charts to help users make informed decisions regarding the number of spare batteries they need to bring to power the device and it is the responsibility of passengers using a POC during air travel to be familiar with the manual and consult their physician and POC provider as necessary. As highlighted by OTG, passengers may also want to consider the age of the device and the batteries as they assess the batteries required to power the POC for the amount of time required. The intent of the SFAR and this rulemaking is to allow passengers needing oxygen therapy during a flight to have ready access to a device that can supply that therapy, not to oversee passenger medical care.

Thus, as proposed, the FAA has eliminated the SFAR requirement to carry a certain amount of battery power. However, the Department continues to allow airlines to require individuals using POCs inflight to bring an adequate number of fully charged batteries based on the battery manufacturer's estimate of the hours of battery life while the POC is in use and the maximum duration of the flight. Also, to facilitate a passenger's ability to prepare for POC use during a flight, in AC 120–95B, published with this final rule, the FAA has provided references to the DOT requirements regarding the carriage of spare batteries. The FAA also expects to update its Web site with information a passenger may want to consider when traveling with a POC.

I. Miscellaneous

BPR Medical Limited recommended that the six continuous flow POCs approved under SFAR No. 106 should be retrofitted with an accessory to stop the flow of oxygen in the event that the POC tubing ignites. BPR states that during testing for fire propagation in tubing, BPR found that where a pulse dose mechanism provides oxygen, a fire that has developed will automatically be extinguished and will not propagate along the tubing to the oxygen source. The commenter added that while having a means to stop the flow of oxygen may be more of a concern where cigarettes might be a source of ignition, there are other possible sources of ignition on aircraft such as electro-static discharge from blankets.

FDA has recently recognized a POC performance standard (ISO 80601–2–69:2014) that includes a clause stating that the device shall be equipped with a means to stop the flow of gas towards the patient in the case that the accessory (tubing) becomes ignited. This standard will be considered as the FDA approves or clears new POC models.

Additionally, the previous FDA recognized performance standard for POCs (ISO 8359:1996 including Amendment 1 (2012)) stated that POCs shall include a means to prevent the propagation of fire back through the oxygen concentrator outlet in the case that the tubing ignites. Although it is not clear whether all of the continuous flow devices approved under the SFAR include this means to prevent fire propagation, the FDA is allowing continued use of these devices and is not requiring existing POCs to be modified to comply with the performance standard the agency currently recognizes (ISO 80601–2–69:2014).

Nevertheless, the commenter's suggestion to retrofit continuous flow POCs with an accessory to extinguish fire propagation in tubing is outside of the scope of the proposal and a prohibition on the use of continuous flow POCs on aircraft is not supported by aviation safety data. As previously noted, the FAA reviewed data from VDRP, SDRS, NTSB, ASRS and AIDS, and has not found any instances of POC malfunction during flight since the agency first published the SFAR.

The FAA also researched the service difficulty report (SDR) database for the period beginning the time SFAR No. 106 published (July 12, 2005) through December 2014, and ran multiple queries for the terms fires, blankets, POCs, electrostatic discharges, and insulation materials. This research covers a period where almost 78 million U.S. domestic flights occurred, revealing no SDRs related to POCs. *See http://www.transtats.bts.gov/Data_Elements.aspx?Data=2.*

Finally, although the FAA has not identified a single instance of a fire due to passenger's use of a POC on an aircraft, passenger-carrying aircraft are equipped with effective mitigation (*i.e.,* fire resistant cabin materials and fire extinguishers) if a fire should occur. *See* 14 CFR 25.853, 23.853, 121.215, 121.309, 125.113 and 135.155.

Accordingly, the agency has determined that no aviation safety data exists that would support further FAA action to preclude continuous flow POC models from use onboard aircraft.

J. Technical Amendments

This final rule makes two technical amendments. First, it updates a cross reference to the HMR that appears in §§ 121.574(a)(3), 125.219(a)(3), and 135.91(a)(3) and pertains to the definition of a compressed gas. Second, it removes the OMB Control No. 2120–0702 from § 11.201(b) because the information collection burdens

associated with this control number cease to be effective when SFAR No. 106 is removed from title 14.

K. Nondiscrimination on the Basis of Disability in Air Travel

The Air Carrier Access Act (ACAA) prohibits discrimination by U.S. and foreign carriers against passengers with disabilities. *See* 49 U.S.C. 41705. Part 382 of title 14 contains detailed standards and requirements to implement the ACAA and to ensure that carriers provide nondiscriminatory service to passengers with disabilities.

With regard to POCs, part 382 establishes a framework to ensure accessibility for passengers using POCs and other respiratory assistive devices on aircraft, subject to applicable aviation safety, security, and hazardous materials regulations. In this final rule, the FAA revises its acceptance criteria on POCs, based on which air carriers may choose to, but are not required to, accept those POCs meeting FAA's criteria. On the other hand, part 382 mandates that carriers must accept POCs if they meet the FAA's acceptance criteria. Accordingly, this final rule includes amendments to 14 CFR part 382 to remove the references to SFAR No. 106, to ensure that the requirements of part 382 are consistent with the new acceptance criteria and labeling requirements set forth by the FAA in this rule, and to ensure the continued use of the POCs previously approved under SFAR No. 106, as permitted by the FAA.

When amending regulations, the Administrative Procedure Act (APA) generally requires agencies to publish a notice of proposed rulemaking and give interested persons an opportunity to comment. However, the APA authorizes agencies to dispense with notice and comment if the agency finds for good cause that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(3)(B). ''Good cause'' exists in situations in which notice unavoidably prevents the due and required execution of agency functions or when an agency finds that due and timely execution of its functions is impeded by the notice otherwise required by the APA.

In this case, the agency finds that there is good cause to conclude that providing notice and public comment for the Department's conforming amendments is unnecessary, impracticable and contrary to the public interest. Notice and public comment are impracticable because they would cause undue delay. Providing additional notice and comment would be impracticable and contrary to the public interest because during the delay caused by providing notice and public comment, the Department's disability regulations would be inconsistent with FAA regulations. This could potentially cause confusion and affect disabled individuals' ability to bring necessary medical devices on flights.

Notice and comment on these conforming amendments is also unnecessary because the public has already had an opportunity to comment on the substantive issues addressed by this rulemaking. The Department is making minor amendments to part 382 that simply conform the Department's disability regulations to the FAA's safety regulations. The Department does not believe that it would receive new substantive comments, in addition to those already received and addressed in this document, if it sought comment on the conforming amendments. For these reasons the Department has determined that the notice and comment rulemaking process is unnecessary, impracticable, and contrary to the public interest for these conforming amendments.

1. Mandatory Acceptance of POCs That Meet FAA Acceptance Criteria

In 2008, DOT amended part 382 to include a provision requiring covered carriers to permit a passenger with a disability to use an SFAR-approved POC on all covered flights. More specifically, part 382 requires U.S. carriers to permit an individual with a disability to use an SFAR-approved POC, a ventilator, a respirator, or a continuous positive airway pressure machine (CPAP machine) on all flights unless the device does not meet applicable FAA requirements for medical portable electronic devices and does not display a manufacturer's label that indicates the device meets those FAA requirements. *See* 14 CFR 382.133(a). Foreign carriers must permit individuals with a disability to use a POC of a kind equivalent to a SFAR- approved POC, a ventilator, a respirator, or a CPAP machine for use on U.S. carriers in the passenger cabin on all covered flights unless the device does not meet the requirements for medical portable electronic devices set by the foreign carrier's government if such requirements exist and/or the POC does not display a manufacturer's label that indicates the device meets those requirements. *See* 14 CFR 382.133(b).

In 2009, because the SFAR-approved POCs were not required to have labels under the FAA's regulations, DOT issued guidance encouraging carriers to allow passengers to use these approved POCs even if the device had not been labeled, although carriers were not legally obligated to do so.[18] Since then, airlines have largely implemented a policy to allow passengers to use SFAR-approved POCs even if they do not have labels.

In this final rule, the Department is amending its disability regulation to ensure that, consistent with the FAA's actions in this rule, passengers with SFAR-approved POCs continue to be permitted to use these devices on aircraft, regardless of whether they are labeled, and that passengers with other POCs that satisfy the FAA acceptance criteria and labeling requirements will be able to use those POCs on their flights. As the FAA's regulations are enabling rules, these changes in the Department's disability regulation require carriers covered by part 382 to accept these POCs for air travel.

2. Other Amendments to 14 CFR Part 382

The Department is revising § 382.133(c)(3) (redesignated as § 382.133(e)(3)) by eliminating the reference to SFAR No. 106 with respect to the packaging and protection of spare batteries carried in an aircraft cabin, as this final rule removes the SFAR from the CFR. Instead, the Department is referring directly to the applicable PHMSA requirements.

The Department is also revising § 382.133(c)(6) (redesignated as § 382.133(e)(6) in this final rule) by eliminating the reference to federal aviation regulations with respect to the physicians statement, as in this final rule the FAA eliminates the SFAR No. 106 requirement for a physician's statement. The Department, however, is retaining the reference to § 382.23(b)(1)(ii) that permits carriers to require a medical certificate from passengers who need medical oxygen during a flight. In that regard, there is also no change to our rules that permit a U.S. carrier or a foreign carrier to ensure that the passengers traveling with POCs have sufficient numbers of spare batteries to power the POC for up to 150% of the maximum flight duration.

V. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a

[18] *See, Notice—The Use of Passenger-supplied Electronic Respiratory Assistive Devices on Aircraft, October* 28, 2009, *https://www.transportation.gov/sites/dot.gov/files/docs/Notice_10_28_09.pdf.*

regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) 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. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 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. We suggest readers seeking greater detail read the full regulatory evaluation, a copy of which we have placed in the docket for this rulemaking.

In conducting these analyses, FAA has determined that this final rule: (1) Has benefits that justify its costs, (2) is not an economically ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, (3) is not ''significant'' as defined in DOT's Regulatory Policies and Procedures; (4) will not have a significant economic impact on a substantial number of small entities; (5) will not create unnecessary obstacles to the foreign commerce of the United States; and (6) will not impose an unfunded mandate on state, local, or tribal governments, or on the private sector by exceeding the threshold identified above. These analyses are summarized below.

Total Benefits and Costs of This Rule

The total cost savings from this final rule is $39.5 million ($27.6 million at 7% present value and $33.6 million at 3% present value). The largest cost savings of $39 million occurs from the reduction of crew time to review the physician's statement.

The FAA estimated that POC manufacturers that are expected to market POCs for use on aircraft will save a total of $108,000 over the ten year analysis period because the FAA will no longer require POC models to be identified in SFAR No. 106 prior to their use on aircraft. As a result of this action, POC manufacturers will no longer incur the administrative costs of petitioning the FAA which the FAA estimated would be $108,000. Further, because the manufacturer will no longer have to await resolution of that petition in order for a POC to be permitted for use on aircraft they will be able to introduce these devices sooner to the market.

The FAA estimates that the cost of this final rule will be a one-time total cost of $22,000 incurred by all those POC manufacturers who comply with this final rule to modify a label and the associated costs that manufacturers will incur to change their current labeling process to affix a label with the language on the devices.

Assumptions:

- Present Value Discount rates—7% and 3%
- Period of Analysis—ten years
- 24 new POCs over ten years

Entities Potentially Affected by This Rule:

- POC manufacturers
- Passengers carrying POCs on board aircraft
- Physicians providing written statements to POC users
- Aircraft operators (including crewmembers)

Benefits of this Rule

The replacement of the SFAR No. 106 device approval process with a process by which POC manufacturers label those devices that satisfy FAA acceptance criteria, will shorten the time for manufacturers to begin selling new POC models that can be used on aircraft. Therefore, one benefit of this rule will be to eliminate delays and enable manufacturers to bring their devices to market sooner. Further the FAA estimates total industry cost savings of $108,000 because manufacturers will no longer incur the administrative costs of petitioning the FAA for each new device. These cost savings easily exceed the labeling costs.

Furthermore, this final rule will result in cost savings because POC-using passengers will no longer have to obtain a physician's written statement as a prerequisite to bringing POCs on board aircraft in parts 121, 125, and 135 operations.

The largest cost-savings will accrue to airline crews as there will no longer be a requirement for the crew to review the contents of the physician's statement and to notify the pilot in command about the contents of the physician's statement and the intention of the passenger to use the POC on board.

The quantified cost savings of this final rule are summarized in table 4.

TABLE 4—TOTAL ESTIMATED COST SAVINGS FROM FINAL RULE

	Cost savings	7% present value savings	3% present value savings
FAA Savings—No SFAR	$91,644	$68,871	$80,519
Manufacturer Savings—No petition for rulemaking	108,000	75,853	92,126
Removal of FAA requirement for user to obtain a physician's statement for POC use on aircraft	569,961	401,645	486,914
Removal of FAA requirement for crew review of physician's statement and PIC notification	38,726,085	27,083,677	32,972,652
Total Cost Savings	$39,495,690	$27,630,045	$33,632,212

The FAA also identified another benefit that it did not quantify. This benefit comes from the use of a performance-based RF emissions acceptance criterion. Currently the manufacturers provide radiated RF emissions tests results showing that the device does not exceed thresholds established in Section 21 Category M of RTCA DO–160 to the FAA which posts these results on its Web site for aircraft operators to access. This final rule will include a performance-based RF emissions acceptance criterion that allows POC manufacturers to determine how to assess whether their POC meets the RF emissions limits for use on aircraft before they affix a label to the device confirming that this criterion has been satisfied. This might save manufacturers some cost if they can demonstrate in a less expensive way that their device meets the RF emissions criteria and will not degrade safety as

the alternative method is an equivalent level of safety to the RTCA standard.

Costs of This Rule

As estimated in the NPRM, the FAA expects that POC manufacturers will incur costs of $22,000 to modify labels that they already affix to the POC, to contain the language required by this rule.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 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 is expected to reduce SFAR No. 106 requirements that currently result in a burden on POC manufacturers who produce POC devices for use on aircraft. This final rule will also result in small costs to manufacturers by requiring POCs intended for use on aircraft to bear a label indicating the device meets FAA requirements for use on board aircraft. The FAA learned from five of the small POC manufacturers that they might incur a one-time cost ranging from $200 to $1,500 which averages $0.20 to $1 per label.[19] These costs will be offset by cost savings because manufacturers will no longer have to petition for rulemaking and lose marketing time awaiting a final regulatory action. One manufacturer stated these cost savings are worth $4,500 for each petition.

The FAA identified nine companies that produce POCs intended for use on board aircraft. The FAA determined that the appropriate North American Industry Classification System (NAICS) codes of these manufacturers are 339112 and 339113 and the threshold for determining whether a company is a small business is 500 employees for those industries. Through online research, the FAA found data [20] indicating that six of the nine manufacturers are small entities and concluded that a substantial number of manufacturers are small entities. However, the FAA does not expect the rule to impose a significant economic impact on any of these small entities because the estimated cost savings of no longer having to petition the FAA (estimated at $4,500 per manufacturer) exceed the estimated costs of modifying the label (estimated at $2,400 per manufacturer) to comply with this final rule. Also, there is a benefit to POC manufacturers, in that the manufacturers will receive revenue sooner because they will be able to market new portable oxygen concentrators sooner.

Although a substantial number of operators conducting parts 121, 125 and 135 operations are small entities, all parts 121, 125 and 135 operators are expected to experience cost savings because the proposal will no longer require the PIC to be apprised when a passenger brings and intends to use a POC on board the aircraft and be informed on the contents of the physician's statement as does SFAR No. 106. The FAA did not receive comments on the initial regulatory flexibility analysis where we first discussed these cost savings. Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing 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 is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does 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 has assessed the potential effect of this final rule and determined that it will have only a domestic impact and therefore no effect on international trade.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) 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 (in 1995 dollars) 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 $155.0 million in lieu of $100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information collection associated with this final rule.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to ICAO Standards and Recommended Practices to the maximum extent practicable. Annex 18 to the Convention on International Civil Aviation requires that dangerous goods are carried in accordance with the ICAO Technical Instructions on the Transport of Dangerous Goods by Air. The ICAO Technical Instructions do not contain specific provisions for POCs but Part 8 of the ICAO Technical Instructions (passenger and crew exceptions) allows for their carriage on board aircraft as portable medical electronic devices subject to certain conditions. Although the format is different, the conditions in

[19] A sixth manufacturer that was contacted estimated costs of $10,200, but this manufacturer is not a small business.

[20] *http://www.manta.com/.*

Part 8 pertaining to batteries used to power POCs are the same as the allowances given in 49 CFR 175.10(a)(18).

G. Environmental Analysis

FAA Order 1050.1F 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 5–6.6 and involves no extraordinary circumstances.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

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

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

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

VII. How To Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet —

1. Search the Federal eRulemaking Portal (*http://www.regulations.gov*);

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

3. Access the Government Publishing Office's Web page at *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9677.

B. Comments Submitted to the Docket

Comments received may be viewed by going to *http://www.regulations.gov* and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

C. 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. A small entity with questions regarding this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects

14 CFR Part 1

Air transportation.

14 CFR Part 11

Reporting and recordkeeping requirements.

14 CFR Part 121

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

14 CFR Part 125

Aircraft, Aviation safety.

14 CFR Part 135

Air taxis, Aircraft, Aviation safety.

14 CFR Part 382

Air Carriers, Consumer protection, Individuals with disabilities.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration and the Office of the Secretary amend chapters I and II of title 14, Code of Federal Regulations as follows:

PART 1—DEFINITIONS AND ABBREVIATIONS

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701.

■ 2. Amend § 1.1 by adding a definition for ''portable oxygen concentrator'' in alphabetical order to read as follows:

§ 1.1 General definitions.

* * * * *

Portable oxygen concentrator means a medical device that separates oxygen from other gasses in ambient air and dispenses this concentrated oxygen to the user.

* * * * *

■ 3. Amend § 1.2 by adding the abbreviation ''POC'' in alphabetical order to read as follows:

§ 1.2 Abbreviations

* * * * *

POC means portable oxygen concentrator.

* * * * *

PART 11—GENERAL RULEMAKING PROCEDURES

■ 4. The authority citation for part 11 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40109, 40113, 44110, 44502, 44701–44702, 44711, and 46102.

■ 5. In § 11.201, amend the table in paragraph (b) by revising the entry for part 121 to read as follows:

§ 11.201 Office of Management and Budget (OMB) control numbers assigned under the Paperwork Reduction Act.

* * * * *

(b) * * *

14 CFR part or section identified and described	Current OMB control No.
* * * *	* * *
Part 121	2120–0008, 2120–0028, 2120–0535, 2120–0571, 2120–0600, 2120–0606, 2120–0614, 2120–0616, 2120–0631, 2120–0651, 2120–0653, 2120–0691, 2120–0739, 2120–0760, 2120–0766.
* * * *	* * *

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

■ 6. The authority citation for part 121 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40119, 41706, 42301 preceding note added by Public Law 112–95, sec. 412, 126 Stat. 89, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44729, 44732, 46105; Public Law 111–216, 124 Stat. 2348 (49 U.S.C. 44701 note); Public Law 112–95, 126 Stat. 62 (49 U.S.C. 44732 note).

Special Federal Aviation Regulation No. 106 [Removed]

■ 7. Remove Special Federal Aviation Regulation No. 106.

■ 8. Amend § 121.306 as follows:
■ a. In paragraph (b)(4), remove ''or'' following the semicolon;
■ b. Redesignate paragraph (b)(5) as paragraph (b)(6);
■ c. Add new paragraph (b)(5); and
■ d. In paragraph (c), remove the reference ''(b)(5)'' and add in its place ''(b)(6)''.

The addition reads as follows:

§ 121.306 Portable electronic devices.

* * * * *

(b)* * *

(5) Portable oxygen concentrators that comply with the requirements in § 121.574; or

* * * * *

■ 9. Amend § 121.574 as follows:
■ a. Revise the section heading;
■ b. Revise paragraph (a) introductory text;
■ c. In paragraph (a)(3), remove the reference ''49 CFR 173.300(a)'' and add in its place ''49 CFR 173.115(b)'';
■ d. Revise paragraph (b); and
■ e. Add paragraph (e).

The revisions and addition read as follows:

§ 121.574 Oxygen and portable oxygen concentrators for medical use by passengers.

(a) A certificate holder may allow a passenger to carry and operate equipment for the storage, generation, or dispensing of oxygen when all of the conditions in paragraphs (a) through (d) of this section are satisfied. Beginning August 22, 2016, a certificate holder may allow a passenger to carry and operate a portable oxygen concentrator when the conditions in paragraphs (b) and (e) of this section are satisfied.

* * * * *

(b) No person may smoke or create an open flame and no certificate holder may allow any person to smoke or create an open flame within 10 feet of oxygen storage and dispensing equipment carried in accordance with paragraph (a) of this section or a portable oxygen concentrator carried and operated in accordance with paragraph (e) of this section.

* * * * *

(e) *Portable oxygen concentrators*—(1) *Acceptance criteria.* A passenger may carry or operate a portable oxygen concentrator for personal use on board an aircraft and a certificate holder may allow a passenger to carry or operate a portable oxygen concentrator on board an aircraft operated under this part during all phases of flight if the portable oxygen concentrator satisfies all of the requirements in this paragraph (e):

(i) Is legally marketed in the United States in accordance with Food and Drug Administration requirements in title 21 of the CFR;

(ii) Does not radiate radio frequency emissions that interfere with aircraft systems;

(iii) Generates a maximum oxygen pressure of less than 200 kPa gauge (29.0 psig/43.8 psia) at 20 °C (68 °F);

(iv) Does not contain any hazardous materials subject to the Hazardous Materials Regulations (49 CFR parts 171 through 180) except as provided in 49 CFR 175.10 for batteries used to power portable electronic devices and that do not require aircraft operator approval; and

(v) Bears a label on the exterior of the device applied in a manner that ensures the label will remain affixed for the life of the device and containing the following certification statement in red lettering: ''The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft.'' The label requirements in this paragraph (e)(1)(v) do not apply to the following portable oxygen concentrators approved by the FAA for use on board aircraft prior to May 24, 2016:

(A) AirSep Focus;
(B) AirSep FreeStyle;
(C) AirSep FreeStyle 5;
(D) AirSep LifeStyle;
(E) Delphi RS–00400;
(F) DeVilbiss Healthcare iGo;
(G) Inogen One;
(H) Inogen One G2;
(I) Inogen One G3;
(J) Inova Labs LifeChoice;
(K) Inova Labs LifeChoice Activox;
(L) International Biophysics LifeChoice;
(M) Invacare Solo2;
(N) Invacare XPO2;
(O) Oxlife Independence Oxygen Concentrator;
(P) Oxus RS–00400;
(Q) Precision Medical EasyPulse;
(R) Respironics EverGo;
(S) Respironics SimplyGo;
(T) SeQual Eclipse;
(U) SeQual eQuinox Oxygen System (model 4000);
(V) SeQual Oxywell Oxygen System (model 4000);
(W) SeQual SAROS; and
(X) VBox Trooper Oxygen Concentrator.

(2) *Operating requirements.* Portable oxygen concentrators that satisfy the acceptance criteria identified in paragraph (e)(1) of this section may be carried or operated by a passenger on an aircraft provided the aircraft operator ensures that all of the conditions in this paragraph (e)(2) are satisfied:

(i) *Exit seats.* No person operating a portable oxygen concentrator is permitted to occupy an exit seat.

(ii) *Stowage of device.* During movement on the surface, takeoff and landing, the device must 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 to the row. If the device is to be operated by the user, it must be operated only at a seat location that does not restrict any passenger's access to, or use of, any required emergency or regular exit, or the aisle(s) in the passenger compartment.

PART 125—CERTIFICATION AND OPERATIONS: AIRPLANES HAVING A SEATING CAPACITY OF 20 OR MORE PASSENGERS OR A MAXIMUM PAYLOAD CAPACITY OF 6,000 POUNDS OR MORE; AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 10. The authority citation for part 125 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701–44702, 44705, 44710–44711, 44713, 44716–44717, 44722.

Special Federal Aviation Regulation No. 106 [Removed]

■ 11. Remove Special Federal Aviation Regulation No. 106.

■ 12. Amend § 125.204 as follows:
■ a. In paragraph (b)(4), remove ''or'' following the semicolon;
■ b. Redesignate paragraph (b)(5) as paragraph (b)(6);
■ c. Add new paragraph (b)(5); and
■ d. In paragraph (c), remove the reference ''(b)(5)'' and add in its place ''(b)(6)''.

The addition reads as follows:

§ 125.204 Portable electronic devices.

* * * * *

(b) * * *

(5) Portable oxygen concentrators that comply with the requirements in § 125.219; or

* * * * *

■ 13. Amend § 125.219 as follows:
■ a. Revise the section heading;
■ b. Revise paragraph (a) introductory text;
■ c. In paragraph (a)(1)(iii), after the semicolon, remove ''and'';
■ d. Redesignate paragraph (a)(1)(iv) as paragraph (a)(1)(v);
■ e. Add new paragraph (a)(1)(iv);
■ f. In paragraph (a)(3), remove the reference ''title 49 CFR 173.300(a)'' and add in its place ''49 CFR 173.115(b)'';
■ g. Revise paragraph (b); and
■ h. Add paragraph (f).

The revisions and additions read as follows:

§ 125.219 Oxygen and portable oxygen concentrators for medical use by passengers.

(a) Except as provided in paragraphs (d) and (f) of this section, no certificate holder may allow the carriage or operation of equipment for the storage, generation or dispensing of medical oxygen unless the conditions in paragraphs (a) through (c) of this section are satisfied. Beginning August 22, 2016, a certificate holder may allow a passenger to carry and operate a portable oxygen concentrator when the conditions in paragraphs (b) and (f) of this section are satisfied.

(1) * * *

(iv) Constructed so that all valves, fittings, and gauges are protected from damage during that carriage or operation; and

* * * * *

(b) No person may smoke or create an open flame and no certificate holder may allow any person to smoke or create an open flame within 10 feet of oxygen storage and dispensing equipment carried under paragraph (a) of this section or a portable oxygen concentrator carried and operated under paragraph (f) of this section.

* * * * *

(f) *Portable oxygen concentrators*—(1) *Acceptance criteria.* A passenger may carry or operate a portable oxygen concentrator for personal use on board an aircraft and a certificate holder may allow a passenger to carry or operate a portable oxygen concentrator on board an aircraft operated under this part during all phases of flight if the portable oxygen concentrator satisfies all of the requirements in this paragraph (f):

(i) Is legally marketed in the United States in accordance with Food and Drug Administration requirements in title 21 of the CFR;

(ii) Does not radiate radio frequency emissions that interfere with aircraft systems;

(iii) Generates a maximum oxygen pressure of less than 200 kPa gauge (29.0 psig/43.8 psia) at 20 °C (68 °F);

(iv) Does not contain any hazardous materials subject to the Hazardous Materials Regulations (49 CFR parts 171 through 180) except as provided in 49 CFR 175.10 for batteries used to power portable electronic devices and that do not require aircraft operator approval; and

(v) Bears a label on the exterior of the device applied in a manner that ensures the label will remain affixed for the life of the device and containing the following certification statement in red lettering: ''The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft.'' The label requirements in this paragraph (f)(1)(v) do not apply to the following portable oxygen concentrators approved by the FAA for use on board aircraft prior to May 24, 2016:

(A) AirSep Focus;
(B) AirSep FreeStyle;
(C) AirSep FreeStyle 5;
(D) AirSep LifeStyle;
(E) Delphi RS–00400;
(F) DeVilbiss Healthcare iGo;
(G) Inogen One;
(H) Inogen One G2;
(I) Inogen One G3;
(J) Inova Labs LifeChoice;
(K) Inova Labs LifeChoice Activox;
(L) International Biophysics LifeChoice;
(M) Invacare Solo2;
(N) Invacare XPO2;
(O) Oxlife Independence Oxygen Concentrator;
(P) Oxus RS–00400;
(Q) Precision Medical EasyPulse;
(R) Respironics EverGo;
(S) Respironics SimplyGo;
(T) SeQual Eclipse;
(U) SeQual eQuinox Oxygen System (model 4000);
(V) SeQual Oxywell Oxygen System (model 4000);
(W) SeQual SAROS; and
(X) VBox Trooper Oxygen Concentrator.

(2) *Operating requirements.* Portable oxygen concentrators that satisfy the acceptance criteria identified in paragraph (f)(1) of this section may be carried or used by a passenger on an aircraft provided the aircraft operator ensures that all of the conditions in this paragraph (f)(2) are satisfied:

(i) *Exit seats.* No person operating a portable oxygen concentrator is permitted to occupy an exit seat.

(ii) *Stowage of device.* During movement on the surface, takeoff and landing, the device must 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 to the row. If the device is to be operated by the user, it must be operated only at a seat location that does not restrict any passenger's access to, or use of, any required emergency or regular exit, or the aisle(s) in the passenger compartment.

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 14. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 41706, 40113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722, 44730, 45101–45105; Public Law 112–95, 126 Stat. 58 (49 U.S.C. 44730).

Special Federal Aviation Regulation No. 106 [Removed]

■ 15. Remove Special Federal Aviation Regulation No. 106.

■ 16. Amend § 135.91 as follows:
■ a. Revise the section heading and paragraph (a) introductory text;
■ b. In paragraph (a)(1)(iii), after the semicolon, remove ''and'';
■ c. Redesignate paragraph (a)(1)(iv) as paragraph (a)(1)(v);
■ d. Add new paragraph (a)(1)(iv);
■ e. In paragraph (a)(3), remove the reference ''title 49 CFR 173.300(a)'' and add in its place ''49 CFR 173.115(b)'';
■ f. Revise paragraph (b); and
■ g. Add paragraph (f).

The revisions and additions read as follows:

§ 135.91 Oxygen and portable oxygen concentrators for medical use by passengers.

(a) Except as provided in paragraphs (d) and (e) of this section, no certificate holder may allow the carriage or operation of equipment for the storage, generation or dispensing of medical oxygen unless the conditions in paragraphs (a) through (c) of this section are satisfied. Beginning August 22, 2016, a certificate holder may allow a passenger to carry and operate a portable oxygen concentrator when the conditions in paragraphs (b) and (f) of this section are satisfied.

(1) * * *

(iv) Constructed so that all valves, fittings, and gauges are protected from damage during carriage or operation; and

* * * * *

(b) No person may smoke or create an open flame and no certificate holder

may allow any person to smoke or create an open flame within 10 feet of oxygen storage and dispensing equipment carried under paragraph (a) of this section or a portable oxygen concentrator carried and operated under paragraph (f) of this section.

* * * * *

(f) *Portable oxygen concentrators*—(1) *Acceptance criteria.* A passenger may carry or operate a portable oxygen concentrator for personal use on board an aircraft and a certificate holder may allow a passenger to carry or operate a portable oxygen concentrator on board an aircraft operated under this part during all phases of flight if the portable oxygen concentrator satisfies all of the requirements of this paragraph (f):

(i) Is legally marketed in the United States in accordance with Food and Drug Administration requirements in title 21 of the CFR;

(ii) Does not radiate radio frequency emissions that interfere with aircraft systems;

(iii) Generates a maximum oxygen pressure of less than 200 kPa gauge (29.0 psig/43.8 psia) at 20 °C (68 °F);

(iv) Does not contain any hazardous materials subject to the Hazardous Materials Regulations (49 CFR parts 171 through 180) except as provided in 49 CFR 175.10 for batteries used to power portable electronic devices and that do not require aircraft operator approval; and

(v) Bears a label on the exterior of the device applied in a manner that ensures the label will remain affixed for the life of the device and containing the following certification statement in red lettering: ''The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft.'' The label requirements in this paragraph (f)(1)(v) do not apply to the following portable oxygen concentrators approved by the FAA for use on board aircraft prior to May 24, 2016:

(A) AirSep Focus;

(B) AirSep FreeStyle;

(C) AirSep FreeStyle 5;

(D) AirSep LifeStyle;

(E) Delphi RS–00400;

(F) DeVilbiss Healthcare iGo;

(G) Inogen One;

(H) Inogen One G2;

(I) Inogen One G3;

(J) Inova Labs LifeChoice;

(K) Inova Labs LifeChoice Activox;

(L) International Biophysics LifeChoice;

(M) Invacare Solo2;

(N) Invacare XPO2;

(O) Oxlife Independence Oxygen Concentrator;

(P) Oxus RS–00400;

(Q) Precision Medical EasyPulse;

(R) Respironics EverGo;

(S) Respironics SimplyGo;

(T) SeQual Eclipse;

(U) SeQual eQuinox Oxygen System (model 4000);

(V) SeQual Oxywell Oxygen System (model 4000);

(W) SeQual SAROS; and

(X) VBox Trooper Oxygen Concentrator.

(2) *Operating requirements.* Portable oxygen concentrators that satisfy the acceptance criteria identified in paragraph (f)(1) of this section may be carried on or operated by a passenger on board an aircraft provided the aircraft operator ensures that all of the conditions in this paragraph (f)(2) are satisfied:

(i) *Exit seats.* No person operating a portable oxygen concentrator is permitted to occupy an exit seat.

(ii) *Stowage of device.* During movement on the surface, takeoff and landing, the device must 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 to the row. If the device is to be operated by the user, it must be operated only at a seat location that does not restrict any passenger's access to, or use of, any required emergency or regular exit, or the aisle(s) in the passenger compartment.

■ 17. Amend § 135.144 as follows:

■ a. In paragraph (a) introductory text, remove ''of the following'';

■ b. In paragraph (b)(4), remove ''or'' following the semicolon;

■ c. Redesignate paragraph (b)(5) as paragraph (b)(6);

■ d. Add new paragraph (b)(5); and

■ e. In paragraph (c), remove the reference ''(b)(5)'' and add in its place ''(b)(6)''.

The addition reads as follows:

§ 135.144 Portable electronic devices.

* * * * *

(b) * * *

(5) Portable oxygen concentrators that comply with the requirements in § 135.91; or

* * * * *

PART 382—NONDISCRIMINATION ON THE BASIS OF DISABILITY IN AIR TRAVEL

■ 18. The authority citation for part 382 continues to read as follows:

Authority: 49 U.S.C. 41705.

■ 19. In § 382.27, revise paragraph (a) to read as follows:

§ 382.27 May a carrier require a passenger with a disability to provide advance notice in order to obtain certain specific services in connection with a flight?

(a) Except as provided in paragraph (b) of this section and § 382.133(e)(4) and (5) and (f)(5) and (6), as a carrier you must not require a passenger with a disability to provide advance notice in order to obtain services or accommodations required by this part.

* * * * *

■ 20. Revise § 382.133 to read as follows:

§ 382.133 What are the requirements concerning the evaluation and use of passenger-supplied electronic devices that assist passengers with respiration in the cabin during flight?

(a) Except for on-demand air taxi operators, as a U.S. carrier conducting passenger service you must permit any individual with a disability to use in the passenger cabin during air transportation an electronic assistive device specified in paragraph (c) of this section on all aircraft originally designed to have a maximum passenger capacity of more than 19 seats unless:

(1) The device does not meet applicable FAA requirements for medical portable electronic device; or

(2) The device cannot be stowed and used in the passenger cabin consistent with applicable TSA, FAA, and PHMSA regulations.

(b) Except for foreign carriers conducting operations of a nature equivalent to on-demand air taxi operations by a U.S. carrier, as a foreign carrier conducting passenger service you must permit any individual with a disability to use in the passenger cabin during air transportation to, from or within the United States, an electronic assistive device specified in paragraph (d) of this section on all aircraft originally designed to have a maximum passenger capacity of more than 19 seats unless:

(1) The device does not meet requirements for medical portable electronic devices set by the foreign carrier's government if such requirements exist;

(2) The device does not meet requirements for medical portable electronic devices set by the FAA for U.S. carriers in circumstances where requirements for medical portable electronic devices have not been set by the foreign carrier's government and the foreign carrier elects to apply FAA requirements for medical portable electronic devices; or

(3) The device cannot be stowed and used in the passenger cabin consistent with applicable TSA, FAA and PHMSA

regulations, and the safety or security regulations of the foreign carrier's government.

(c) Except as provided in paragraph (a) of this section, as a covered U.S. air carrier, you must accept the passenger supplied electronic assistive device in this paragraph (c):

(1) A portable oxygen concentrator (POC), a ventilator, a respirator or a continuous positive airway pressure machine that displays a manufacturer's label that indicates the device meets FAA requirements; and

(2) The following POC models whether or not they are labeled:

(i) AirSep Focus;
(ii) AirSep FreeStyle;
(iii) AirSep FreeStyle 5;
(iv) AirSep LifeStyle;
(v) Delphi RS–00400;
(vi) DeVilbiss Healthcare iGo;
(vii) Inogen One;
(viii) Inogen One G2;
(ix) Inogen One G3;
(x) Inova Labs LifeChoice;
(xi) Inova Labs LifeChoice Activox;
(xii) International Biophysics LifeChoice;
(xiii) Invacare Solo2;
(xiv) Invacare XPO2;
(xv) Oxlife Independence Oxygen Concentrator;
(xvi) Oxus RS–00400;
(xvii) Precision Medical EasyPulse;
(xviii) Respironics EverGo;
(xix) Respironics SimplyGo;
(xx) SeQual Eclipse;
(xxi) SeQual eQuinox Oxygen System (model 4000);
(xxii) SeQual Oxywell Oxygen System (model 4000);
(xxiii) SeQual SAROS; and
(xxiv) VBox Trooper Oxygen Concentrator.

(d) Except as provided in paragraph (b) of this section, as a covered foreign air carrier, you must accept the supplied electronic assistive devices in this paragraph (d):

(1) A POC, a ventilator, a respirator or a continuous positive airway pressure machine that displays a manufacturer's label according to FAA requirements in circumstances where requirements for labeling these devices have not been set by the foreign carrier's government; and

(2) The following POC models whether or not they are labeled:

(i) AirSep Focus;
(ii) AirSep FreeStyle;
(iii) AirSep FreeStyle 5;
(iv) AirSep LifeStyle;
(v) Delphi RS–00400;
(vi) DeVilbiss Healthcare iGo;
(vii) Inogen One;
(viii) Inogen One G2;
(ix) Inogen One G3;
(x) Inova Labs LifeChoice;
(xi) Inova Labs LifeChoice Activox;
(xii) International Biophysics LifeChoice;
(xiii) Invacare Solo2;
(xiv) Invacare XPO2;
(xv) Oxlife Independence Oxygen Concentrator;
(xvi) Oxus RS–00400;
(xvii) Precision Medical EasyPulse;
(xviii) Respironics EverGo;
(xix) Respironics SimplyGo;
(xx) SeQual Eclipse;
(xxi) SeQual eQuinox Oxygen System (model 4000);
(xxii) SeQual Oxywell Oxygen System (model 4000);
(xxiii) SeQual SAROS; and
(xxiv) VBox Trooper Oxygen Concentrator.

(e) As a U.S. carrier, you must provide information during the reservation process as indicated in paragraphs (e)(1) through (6) of this section upon inquiry from an individual concerning the use in the cabin during air transportation of a ventilator, respirator, continuous positive airway machine, or a POC. The information in this paragraph (e) must be provided:

(1) Any applicable requirement for a manufacturer-affixed label to reflect that the device has been tested to meet applicable FAA requirements for medical portable electronic devices;

(2) The maximum weight and dimensions (length, width, height) of the device to be used by an individual that can be accommodated in the aircraft cabin consistent with FAA safety requirements;

(3) The requirement to bring an adequate number of batteries as outlined in paragraph (h)(2) of this section and to ensure that extra batteries carried onboard to power the device are packaged and protected from short circuit and physical damage in accordance with applicable PHMSA regulations regarding spare batteries carried by passengers in an aircraft cabin;

(4) Any requirement, if applicable, that an individual contact the carrier operating the flight 48 hours before scheduled departure to learn the expected maximum duration of his/her flight in order to determine the required number of batteries for his/her particular ventilator, respirator, continuous positive airway pressure machine, or POC;

(5) Any requirement, if applicable, of the carrier operating the flight for an individual planning to use such a device to check-in up to one hour before that carrier's general check-in deadline; and

(6) For POCs, the requirement of § 382.23(b)(1)(ii) to present to the operating carrier at the airport a physician's statement (medical certificate).

(f) As a foreign carrier operating flights to, from or within the United States, you must provide the information during the reservation process as indicated in paragraphs (f)(1) through (7) of this section upon inquiry from an individual concerning the use in the cabin during air transportation on such a flight of a ventilator, respirator, continuous positive airway machine, or POC. The information in this paragraph (f) must be provided:

(1) Any applicable requirement for a manufacturer-affixed label to reflect that the device has been tested to meet requirements for medical portable electronic devices set by the foreign carrier's government if such requirements exist;

(2) Any applicable requirement for a manufacturer-affixed label to reflect that the device has been tested to meet requirements for medical portable electronic devices set by the FAA for U.S. carriers if requirements for medical portable electronic devices have not been set by the foreign carrier's government and the foreign carrier elects to apply FAA requirements for medical portable electronic devices;

(3) The maximum weight and dimensions (length, width, height) of the device to be used by an individual that can be accommodated in the aircraft cabin consistent with the safety regulations of the foreign carrier's government;

(4) The requirement to bring an adequate number of batteries as outlined in paragraph (h)(2) of this section and to ensure that extra batteries carried onboard to power the device are packaged in accordance with applicable government safety regulations;

(5) Any requirement, if applicable, that an individual contact the carrier operating the flight 48 hours before scheduled departure to learn the expected maximum duration of his/her flight in order to determine the required number of batteries for his/her particular ventilator, respirator, continuous positive airway pressure machine, or POC;

(6) Any requirement, if applicable, of the carrier operating the flight for an individual planning to use such a device to check-in up to one hour before that carrier's general check-in deadline; and

(7) Any requirement, if applicable, that an individual who wishes to use a POC onboard an aircraft present to the operating carrier at the airport a physician's statement (medical certificate).

(g) In the case of a codeshare itinerary, the carrier whose code is used on the flight must either inform the individual inquiring about using a ventilator, respirator, CPAP machine or POC onboard an aircraft to contact the carrier operating the flight for information about its requirements for use of such devices in the cabin, or provide such information on behalf of the codeshare carrier operating the flight.

(h)(1) As a U.S. or foreign carrier subject to paragraph (a) or (b) of this section, you must inform any individual who has advised you that he or she plans to operate his/her device in the aircraft cabin, within 48 hours of his/her making a reservation or 24 hours before the scheduled departure date of his/her flight, whichever date is earlier, of the expected maximum flight duration of each segment of his/her flight itinerary.

(2) You may require an individual to bring an adequate number of fully charged batteries onboard, based on the battery manufacturer's estimate of the hours of battery life while the device is in use and the information provided in the physician's statement, to power the device for not less than 150% of the expected maximum flight duration.

(3) If an individual does not comply with the conditions for acceptance of a medical portable electronic device as outlined in this section, you may deny boarding to the individual in accordance with § 382.19(c) and in that event you must provide a written explanation to the individual in accordance with § 382.19(d).

Issued under authority provided by 49 U.S.C. 106(f) and 44701(a), and authority provided by 49 U.S.C. 41705, delegated at 49 CFR 1.27, in Washington, DC, on May 11, 2016.

Kathryn B. Thomson,

General Counsel, Department of Transportation.

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[FR Doc. 2016–11918 Filed 5–23–16; 8:45 am]

BILLING CODE 4910–13–P