Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 1, 121, 125, and 135

[Docket No.: FAA–2014–0554; Notice No. 14–08]

RIN 2120–AK32

Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This rulemaking would replace Special Federal Aviation Regulation No. 106 with acceptance criteria for portable oxygen concentrators to be used by passengers in air carrier operations, commercial operations and certain other operations using large aircraft. Currently, the agency assesses each portable oxygen concentrator on a case-by-case basis to determine whether it is safe for use on board aircraft. If the agency determines that a portable oxygen concentrator is safe for use on board aircraft, the specific model is identified in regulations. This rulemaking would replace the burdensome approval process with acceptance criteria and a requirement for manufacturers to demonstrate compliance by affixing a label on the exterior of the portable oxygen concentrator applied in a manner that ensures it will remain affixed for the life of the device. The proposed acceptance criteria and labeling requirement would only affect portable oxygen concentrators intended for use on board aircraft. Portable oxygen concentrators currently approved for use on board aircraft would not be affected by this proposal and will be listed in this rule as approved. This rulemaking would also eliminate redundant requirements and paperwork requirements that are not necessary for aviation safety thereby reducing burdens for portable oxygen concentrator manufacturers, passengers who use portable oxygen concentrators while traveling, and aircraft operators conducting air carrier operations, commercial operations or certain operations using large aircraft.

DATES: Send comments on or before November 18, 2014.

ADDRESSES: Send comments identified by docket number FAA–2014–0554 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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 legal questions concerning this action, contact Sara L. Mikolop, Office of the Chief Counsel, AGC–220, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3073; email *sara.mikolop@faa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Authority for This Rulemaking

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

II. Overview of the Proposed Rule

This proposed rule would affect the use of portable oxygen concentrators (POC) on board aircraft in operations conducted under 14 CFR parts 121, 125, and 135, by replacing the existing FAA case-by-case POC approval process in Special Federal Aviation Regulation (SFAR) No. 106, with FAA acceptance criteria. With this NPRM, the agency proposes to modify the process by which a POC may be deemed acceptable for use on board aircraft. Rather than amend existing SFAR No. 106 each time the FAA accepts a specific model of POC for use on board aircraft, this proposal identifies acceptance criteria for POCs. With the establishment of acceptance criteria for POCs the FAA would discontinue use of SFAR No. 106 and remove it from parts 121, 125, and 135 of title 14 of the Code of Federal Regulations (CFR).

POCs operate by separating oxygen from nitrogen and other gases comprising ambient air and then dispensing the oxygen in concentrated form to the user. POCs are the only oxygen dispensing devices that a passenger requiring oxygen therapy may carry for their personal use during flight. Although aircraft operators are not required to provide medical oxygen, the only other options for passengers requiring oxygen therapy during flight is to procure medical oxygen directly from the aircraft operator. Operators typically charge for this oxygen service and it can be difficult for passengers to coordinate service between the carrier and supplier of oxygen at the terminal, leaving gaps in oxygen service during travel.

The FAA established standards for the use of POCs on board aircraft through SFAR No. 106—Rules for use of portable oxygen concentrator systems on board aircraft. *See* 70 FR 40156 (July 12, 2005). Without SFAR No. 106 an exemption from the regulations applicable to devices that dispense medical oxygen (§ 121.574, § 125.219, or § 135.91) would be necessary for passengers to carry on and operate their own (not furnished by the aircraft operator) POC. *See* 69 FR 42324, 42325 (July 14, 2004). The agency intended SFAR No. 106 to serve as a special, temporary regulation until POC performance standards (acceptance criteria) could be developed. *See* 70 FR at 40158–40159.

In 2005, SFAR No. 106 identified the first specific POC models approved for use on board aircraft. The FAA has continued to allow the carriage and use of specific POC models only after each individual POC manufacturer has demonstrated to the FAA that its model should be approved for use. Each time a new POC is approved by the FAA for use on board aircraft, the FAA amends SFAR No. 106 by adding the name of the POC to the regulation. The FAA has amended SFAR No. 106 seven times since 2005 to add the names of additional POC models as they are approved for use in part 121, 125, and 135 operations—a process as long as up to two years.[1] The agency proposes to replace this cumbersome POC approval process with POC acceptance criteria and specific labeling requirements to identify POCs as satisfying the proposed acceptance criteria.

As with existing requirements applicable to POC approval for use on aircraft, compliance with the proposed acceptance criteria and labeling requirement is only necessary for POCs used on aircraft. A comparison of the proposed acceptance criteria and labeling requirement with related SFAR No. 106 provisions is provided in Table 1.

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

	Related SFAR No. 106 requirements	Proposed acceptance criteria and labeling requirement
Food and Drug Administration (FDA) clearance to market the device.	The POC must be regulated by the FDA (§ 2(2)) ..... *Note:* To satisfy this requirement, manufacturers currently 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 (§ 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 does not contain hazardous materials.	The POC may not contain any hazardous materials subject to the *Hazardous Materials Regulations (49 CFR parts 171–180),* except as provided for 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 Hazardous Materials Regulations.

[1] Currently, 24 POC models have been approved by the FAA and identified in SFAR No. 106 for use on board aircraft.

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

	Related SFAR No. 106 requirements	Proposed acceptance criteria and labeling requirement
Electromagnetic 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 (§ 3(a)(1)). *Note:* To satisfy this requirement, it is the current practice of operators to use testing data provided by POC manufacturers regarding the electromagnetic emissions of a specific POC model. Manufacturers currently complete testing in accordance with RTCA standard 160G, Section 21, Category M.	Manufacturer must complete testing in accordance with RTCA standard 160G, Section 21, Category M. The POC electromagnetic emissions must fall below the threshold permitted in RTCA standard 160G, Section 21, Category M.
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 (§ 2, § 3(a)). *Note:* Specific POCs approved for use on board aircraft are identified in SFAR No. 106 by manufacturer, make, and model. 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.	POC manufacturers must affix a label for the life of the device that certifies compliance with acceptance criteria pertaining to FDA clearance to market the device, hazardous materials, and testing for electromagnetic emissions. 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.

In accordance with this proposal, manufacturers of POC models not identified in SFAR No. 106 would have to ensure the POC satisfies the acceptance criteria before it may be used on board an aircraft. If a manufacturer determines that a new POC model meets these criteria, the manufacturer would not need to seek approval from the FAA prior to indicating that a POC is safe for air travel. Instead, the manufacturer would affix a label to the POC, as specified in the proposal, indicating the POC meets FAA acceptance criteria. The FAA believes this proposed label would facilitate passenger and crew recognition by identifying the POC as safe for use in the cabin during all phases of flight.

The FAA proposes that the requirement for labeling apply only to POCs not currently listed as approved in SFAR No. 106. 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. Any device that previously demonstrated compliance with SFAR No. 106 criteria would satisfy the proposed acceptance criteria.

The FAA believes it is not necessary or practical to require POC manufacturers to retrofit previously approved POCs with a label. The FAA expects POCs listed in SFAR No. 106 will decrease over time as they age and are replaced with newer models. Therefore, the FAA proposes to maintain in the proposed regulatory text, a list of POCs approved in accordance with SFAR No. 106 and proposes excepting them from the proposed labeling requirement so that passengers and crewmembers can continue to identify these POCs as approved for use on board aircraft.

In addition, the agency proposes to eliminate SFAR No. 106 requirements related to POC use on aircraft that are addressed elsewhere in title 14 or title 49 of the Code of Federal Regulations. For example, existing regulations outside of SFAR No. 106 address stowage of carry-on items (§§ 121.285, 121.589, 125.183, and 135.87) and exit row seating (§§ 121.585 and 135.129). This proposal would also eliminate 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 affected passengers and their physicians as well as crewmembers and aircraft operators. Table 2 summarizes the proposed disposition of all SFAR No. 106 provisions.

TABLE 2—SUMMARY OF SFAR NO. 106 PROVISIONS AND PROPOSED DISPOSITION

Summary of SFAR No. 106 provision	Description of proposed disposition in NPRM
• Requirement that the POC is legally marketed in the United States in accordance with FDA requirements (§ 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 (§ 3(a)(1)). • Prohibition on POCs containing hazardous materials as determined by the Pipeline and Hazardous Materials Safety Administration (§ 2(1)). • POC model must be identified in SFAR No. 106 prior to use in part 121, 125, and 135 operations (§ 2, § 3(a))*.	SFAR No. 106 Provisions Reflected in Proposed Acceptance Criteria and Labeling Requirement.
• Prohibition on smoking or open flame near POC (§ 3.(a)(2)) ..... • POC model must be identified in SFAR No. 106 prior to use in part 121, 125, and 135 operations (§ 2, § 3(a))*.	SFAR No. 106 Provisions Retained.

TABLE 2—SUMMARY OF SFAR NO. 106 PROVISIONS AND PROPOSED DISPOSITION—Continued

Summary of SFAR No. 106 provision	Description of proposed disposition in NPRM
• 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 (§§ 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 (§ 3.(b)(1)). • Requirement for POC user to ensure that the POC is free of petroleum products or signs of excessive wear or abuse (§ 3.(b)(2)). • Prohibition on use of salves and lotions unless ''oxygen approved'' (§ 3.(b)(4)). • Requirement for passenger to carry a sufficient number of batteries for duration of flight (§ 3.(b)(5)).	SFAR No. 106 Provisions Eliminated in Their Entirety.

* The list of POCs currently identified in SFAR No. 106 would be maintained in parts 121, 125 and 135. All other POCs would need to satisfy the proposed acceptance criteria and bear a label for the life of the device indicating compliance with the acceptance criteria. A detailed discussion regarding the identification of POCs that satisfy the acceptance criteria is provided in the preamble.

This proposed rule would relieve regulatory burdens for POC manufacturers as they would no longer be required to submit a petition for rulemaking to amend SFAR No. 106 for each new POC introduced into the marketplace and intended for use on board aircraft. Similarly, this proposed rule would relieve passengers of the current paperwork burden of obtaining a physician's statement and notifying both the pilot in command and the aircraft operator concerning their POC usage while on board aircraft.

III. Summary of Cost Savings

The FAA estimates that manufacturers would save $108,000 over ten years because they would 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 would be reduced slightly because manufacturers would incur an estimated total one-time cost of $22,000 to comply with the proposed labeling requirement. The FAA estimated additional cost savings because of the discontinuation of certain requirements from SFAR No. 106. Total estimated cost savings are presented in the table below.

Total Cost Savings from Proposed Rule

Cost Savings		7% present value savings	3% present value savings
FAA Savings - No SFAR	$ 91,644	$ 68,871	$ 32,573
Manufacturer Savings - No Petition	$108,000	$75,853	$92,126
No Longer Obtaining Physician's statement	$559,660	$391,402	$476,509
No Longer Notifying Pilot in Command	$36,599,268	$25,595,997	$31,161,620
Total Cost Savings	$37,358,571	$26,132,123	$31,762,828

IV. Background

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

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. At the time the agency published SFAR No. 106, the FAA did not require aircraft operators to provide medical oxygen and many regional air carriers and some larger air carriers did not provide this service. Those carriers that did allow passengers to use the medical oxygen provided the compressed oxygen themselves and typically charged a fee for this service. (The agency notes that today, virtually no certificate holders conducting part 121 operations provide in-flight supplemental oxygen for passengers.)

Further, passengers requiring oxygen therapy during travel faced difficulty coordinating service between the carrier and the supplier of medical oxygen to ensure coverage at the terminal, gate to gate, and on board the aircraft. Sometimes, passengers would spend at least part of the time travelling without medical oxygen due to service problems with the oxygen provider. *See* 70 FR 40156, 40156 (July 12, 2005).

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%. 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 (not furnished by the aircraft operator).

In 2004, rather than wait for petitions for exemption from the existing regulations, the FAA published an NPRM proposing SFAR No. 106. *See* 69 FR 42324 (July 14, 2004). In the NPRM,

the agency proposed to permit passengers to carry on and operate their own POC on board an aircraft as long as certain conditions were met.

The SFAR No. 106 final rule, published July 12, 2005, established criteria for FAA approval of POCs for use on board aircraft. This final rule prohibited passengers from using POCs on board aircraft under part 121, 125, and 135 operations, unless those POCs satisfied the approval criteria and were identified by manufacturer and model name in SFAR No. 106. This final rule also established POC operating rules for aircraft operators, crewmembers and passengers.

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 made conforming amendments to 14 CFR parts 125 and 135 to apply the requirements of SFAR No. 106 to part 119 certificate holders conducting operations under parts 125 and 135.

Since the FAA originally published SFAR No. 106, it has been amended seven times to list additional POCs and currently identifies 24 POCs that may be used on board aircraft.[2] This process is time-consuming for POC manufacturers and the FAA. POC manufacturers who want the FAA to approve a POC for use in part 121, 125, and 135 operations must petition the FAA for rulemaking to amend SFAR No. 106, by adding their POC model to the list and provide the FAA with Food and Drug Administration (FDA) and Pipeline and Hazardous Materials Safety Administration (PHMSA) documentation required for the FAA to make a determination whether the POC may be safely used on board aircraft. This process is also time-consuming for the FAA because rulemaking must be accomplished each time a new POC model is added to SFAR No. 106. As a result of the rulemaking required to add a POC model to the list of POCs in SFAR No. 106, passengers may not use a POC on board an aircraft in part 121, 125, or 135 operations until the FAA identifies the device they wish to use in SFAR No. 106.

V. Discussion of the Proposed Rule

When SFAR No. 106 was originally published, the FAA committed to establishing a single standard for all POC devices. Whenever possible, the FAA tries to regulate by creating performance-based standards rather than approving specific devices on a case-by-case basis. However, the FAA determined that the quickest way to serve both the passenger and the aircraft operator and to avoid creating circumstances that would stifle new technology, was to allow the use of specific POCs approved by the FAA for use on aircraft and identified in SFAR No. 106, a special, temporary regulation. *See* 70 FR at 40157–40159.

After evaluating the provisions contained in SFAR No. 106, the relevant provisions of existing Hazardous Materials Regulations (HMR) (49 CFR parts 171–180), and a decade of accumulated knowledge and experience the FAA has gained with POCs, the FAA proposes to replace the POC case-by-case approval process with performance-based standards (acceptance criteria) as envisioned by the FAA at the time SFAR No. 106 was developed. The proposed rule would specify POC acceptance criteria for POC use in part 121, 125, and 135 operations. A manufacturer would then certify the device meets the FAA acceptance criteria by affixing a label for the life of the device that certifies the POC conforms to FAA acceptance criteria. Additionally, this proposed rule would prescribe limited operational requirements governing the use of POCs on board aircraft. The proposed requirements are discussed below.

A. Definition of Portable Oxygen Concentrator

Currently, SFAR No. 106 explains POCs perform by separating oxygen from nitrogen, and other gasses contained in ambient air, and dispensing the oxygen in a concentrated form to the user.

The FAA proposes to define a POC 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 explanation used in existing SFAR No. 106 and Advisory Circular 120–95, Portable Oxygen Concentrators[3] as well as the device description used by POC manufacturers and the FDA,[4] the federal agency with primary regulatory authority over POCs for medical use.

By including this definition in 14 CFR 1.1, the FAA intends to distinguish POCs from portable oxygen generators and other medical devices that use compressed or liquid oxygen for medical oxygen therapy, because devices that use compressed or liquid oxygen must satisfy separate and more rigorous requirements to mitigate the risks they present.

B. Applicability and Effective Date

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. Further, SFAR No. 106 does not require aircraft operators to allow passengers to operate POCs on board aircraft. Rather, it authorizes the use of specific POCs on board aircraft in operations conducted under parts 121, 125, or 135 if the conditions in SFAR No. 106 are satisfied.

With this NPRM, the agency proposes to modify the process by which a POC may be deemed acceptable for use on board aircraft. Rather than amend existing SFAR No. 106 each time the FAA accepts a specific model of POC for use on board aircraft, this proposal identifies acceptance criteria for POCs. With the establishment of acceptance criteria for POCs the FAA would discontinue use of SFAR No. 106 and remove it from parts 121, 125, and 135 of title 14 of the CFR.

Consistent with SFAR No. 106, this proposal applies only to those POC models intended for use on board aircraft in part 121, 125, and 135 operations and does not create a requirement for operators to allow POC use. Requirements for air carriers to allow the use of a POC on an aircraft continue to be found in 14 CFR part 382, Nondiscrimination on the Basis of Disability in Air Travel.

The agency seeks to make this proposal effective as soon as practicable. The agency recognizes, however, that part 119 certificate holders may need to revise operating manuals and training programs. The agency expects these revisions to occur within the normal course of business and is therefore considering an effective date of 90 days after the publication of the final rule in the **Federal Register**.

C. Portable Oxygen Concentrator Acceptance Criteria

The agency proposes to require POCs used on board aircraft to satisfy specific acceptance criteria. The acceptance criteria are discussed in more detail in this section of the preamble and are summarized as follows:

[2] 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).

[3] AC 120–95 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 . . .''

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

• The POC manufacturer complies with all FDA requirements to legally market the device in the United States.

• The POC may not contain any hazardous materials subject to the *Hazardous Materials Regulations (49 CFR parts 171 through 180)* except as provided for 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 per the HMR.

• The POC electromagnetic emissions must fall below the threshold permitted in RTCA standard 160G, Section 21, Category M.

The agency further proposes that any POC (except those previously approved for use on aircraft under SFAR No. 106) carried or used by a passenger on an aircraft in part 121, 125, or 135 operations must bear a manufacturer's label using a means to ensure it will remain affixed for the life of the device indicating compliance with these FAA acceptance criteria.

1. Food and Drug Administration Premarket Determination

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 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).

Currently, SFAR No. 106 requires all POCs used on board aircraft in operations conducted under 14 CFR parts 121, 125, and 135 must be legally marketed 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 portable oxygen concentrator (POC). To demonstrate compliance with this requirement, POC manufacturers must submit evidence 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.[5]

The FAA proposes to maintain the requirement that any POC used on board an aircraft must be cleared or approved by the FDA for marketing in the United States. However, manufacturers would no longer submit evidence of this clearance or approval to the FAA. Rather, POC manufacturers would certify that the FDA has approved the device for marketing in the United States by affixing a label to the POC, in which the manufacturer confirms compliance with all FAA requirements for the use of the POC on board aircraft. The proposed labeling requirement is discussed in more detail later in this preamble.

As an alternative to identifying the requirement for FDA approval to legally market the device as one of the POC acceptance criteria, the agency is considering incorporating this one acceptance criterion into the POC definition because this criterion already applies to all POCs marketed in the United States per FDA requirements and not just those POCs intended for use on aircraft. The agency seeks comment on this alternative.

2. Electromagnetic Interference Emissions Threshold (RTCA DO–160G, Section 21, Category M)

The agency recognizes POCs as a type of portable electronic device (PED) and permits the use of PEDs during flight, only if the aircraft operator has determined the device does not cause interference with the navigation or communication system of the aircraft in which the device will be used. Further, in accordance with §§ 121.306, 125.204, and 135.144, the aircraft operator is responsible for determining which PEDs may be safely used on its aircraft.

Each operator may establish a method to make a determination regarding the effects of PEDs on its aircraft's avionics. Historically, a common method for making this determination has been to complete evaluations of electromagnetic interference (EMI) on a device-by-device basis which involves comparing the device's emissions against the current RTCA DO–160 standards for airborne equipment.

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., meet the requirements of RTCA DO–307 or another PED tolerance demonstration). *See* InFO 13010 and InFO 13010SUP.[6] The agency does not, however, require aircraft assessment of PED tolerance in accordance with InFO 13010 and InFO 13010SUP. These PED 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 if it wants to expand the use of passenger supplied and operated PEDs via a determination of PED tolerance for certain aircraft types. Some aircraft operators may choose to continue to rely on the individual PED evaluations that occur today.

SFAR No. 106, section 3(a)(1) contains a requirement pertaining to POC interference with aircraft equipment that has the same effect as the requirements in §§ 121.306, 125.204, and 135.144 pertaining to all PEDs. SFAR No. 106 permits operators engaged in part 121, 125, and 135 operations to allow passengers the use of specific POC models that have been tested to ensure that they will not interfere with the aircraft electrical, navigation or communication equipment.

For POC EMI evaluation, the FAA currently accepts as proof of non-interference, emissions test results provided by manufacturers showing a specific POC does not exceed certain maximum emissions thresholds established by RTCA in DO–160, Environmental Conditions and Test Procedures for Airborne Equipment.[7] The agency has determined that Section 21 Category M of RTCA DO–160 establishes safe and conservative

[5] 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.*

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

[7] RTCA and components of RTCA function as advisory committees in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, Public Law 92–463, 5 U.S.C. App. 2. RTCA membership is drawn from across the aviation industry. RTCA employs the expertise of the aviation community to generate recommendations in response to requests from the FAA to address a wide range of technical aviation issues or questions. RTCA generally provides recommendations (1) broad-gauged policy and investment priority recommendations used by FAA when considering policy and program decisions; and (2) minimum performance standards, reports, and guidance documents used by FAA in regulatory decisions and rulemaking. *See* FAA Order 1110.77U, Charter for RTCA, Inc., April 1, 2013. *http://www.faa.gov/documentlibrary/media/order/1110.77u.pdf.*

emissions limits for electronic devices on board aircraft.[8]

The agency allows aircraft operators to use emissions test results provided by POC manufacturers to demonstrate compliance with section 3(a)(1) of SFAR No. 106.[9] It is current practice for manufacturers to provide the RTCA test compliance statements to the FAA; the FAA then makes the RTCA test compliance statements available on its Web site for aircraft operator reference. The RTCA compliance statements may be viewed at *http://www.faa.gov/about/initiatives/cabin_safety/portable_oxygen/.*

The agency recognizes the current SFAR No. 106 requirement for an operator to evaluate POC interference with aircraft equipment is redundant with the requirements in §§ 121.306, 125.204, and 135.144. Further, many part 121 operators have already conducted aircraft assessment of PED tolerance in accordance with InFO 13010 and InFO 13010SUP, which would make an independent assessment of POC electromagnetic emissions unnecessary.

Nevertheless, because of the need to ensure service for passengers who require oxygen during air travel, the FAA believes it is necessary to create a regulatory structure to ensure that passengers may continue to use POCs on board aircraft even when an operator does not choose to assess a POCs electromagnetic emissions, or assess the aircraft they operate for PED tolerance. Although aircraft operators conducting part 121, 125, and 135 operations are the only entities authorized to provide medical oxygen for use on their aircraft during these operations, they are not required to do so. Those carriers that do provide medical oxygen typically charge for the service although many carriers simply do not offer medical oxygen at all; and, it can be difficult for the passenger to coordinate oxygen service between the carrier and a supplier of medical oxygen at the terminal, leaving gaps in oxygen service during travel. POCs, however, provide an effective alternative for passengers requiring uninterrupted oxygen therapy during travel. The current practice used by POC manufacturers to demonstrate that POC electromagnetic emissions do not cause interference with aircraft equipment is an effective way to ensure that POCs will be available for continuous use for the duration of a passenger's travel, including all phases of flight and movement on the surface.

Thus, consistent with the current practice, the agency proposes to require POC manufacturers to conduct a POC EMI assessment in accordance with RTCA DO–160G, Section 21, Category M[10] for each POC the manufacturer intends to market for use on aircraft and label as compliant with FAA POC acceptance criteria. As currently permitted, a POC that tests below the maximum emission threshold contained in RTCA DO–160G, Section 21, Category M, in all modes of operation, may be used on board the aircraft during all phases of flight without any additional testing by the aircraft operator. In addition, POCs currently approved by the FAA that have demonstrated emissions below the maximum emissions threshold in DO–160G, Section 21, Category M will not need to be retested prior to use on board aircraft. The agency also proposes to add POCs to the list of devices excepted from the general PED testing requirements in §§ 121.306, 125.204, and 135.144 because the testing requirements in §§ 121.306, 125.204, and 135.144 are redundant and unnecessary for POCs that have completed POC EMI assessments in accordance with RTCA DO–160, Section 21, Category M.

The agency seeks comment on an alternate approach to the acceptance criterion pertaining to POC-specific EMI assessments that would eliminate redundancy in those instances when operators test aircraft for PED tolerance without affecting the opportunity for POC use on aircraft. Specifically, the agency seeks comment on an alternative to the proposed acceptance criterion pertaining to POC-specific EMI assessments that would allow POC electromagnetic emissions to be assessed under the general PED regulatory structure in existing §§ 121.306, 125.204, and 135.144. Under this alternate approach, the agency assumes that manufacturers would continue to voluntarily complete the RTCA testing they complete today if they want a POC to be available for use on aircraft because not all operators have conducted aircraft assessments of PED tolerance. The agency seeks comment on how this alternative approach to POC EMI assessments would affect passenger use of POCs on aircraft and whether this alternative would result in possible burdens on passengers and aircraft operators.

Further, the agency recognizes that other Federal agencies may require electromagnetic compatibility assessments that may test to standards that could be used to demonstrate compliance with the generally applicable PED requirements. Accordingly, the agency seeks comment on (1) whether there are other electromagnetic compatibility assessments that POC manufacturers complete, that test to a standard that is technically equivalent to the standard in RTCA DO–160G, Section 21, Category M, and (2) whether there are any differences in the standards of any alternate emissions assessments.

3. Hazardous Materials

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 regulations (the Hazardous Materials Regulations (HMR) (49 CFR parts 171 through 180)) and standards for classifying, handling and packaging shipments of hazardous materials within the United States.

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 or lithium ion batteries often used to power these units are hazardous materials subject to PHMSA regulations for the transportation of batteries and the carriage of batteries by aircraft passengers.[11]

[8] 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.

[9] *See* Advisory Circular 120–95, Portable Oxygen Concentrators, Advisory Circular 91–21.B, Use of Portable Electronic Devices Aboard Aircraft.

[10] The FAA intends to incorporate RTCA DO–160G, Section 21, Category M by reference in §§ 121.574, 125.219 and 135.91.

[11] On July 29, 2014, PHMSA issued a final rule, ''Hazardous Materials: Transportation of Lithium Batteries'' (RIN 2137–AE44). *See* 79 FR 46012 (August 6, 2014). Compliance with this final rule is required six months after the date of publication in the **Federal Register**, February 6, 2015. For purposes of this NPRM, the relevant changes that will be put in place by the PHMSA final rule are those that (1) remove *Special Provision* 188 and relocate it, in part, to a revised 49 CFR 173.185; (2) replace equivalent lithium content with Watt-hours for lithium ion cells and batteries; and (3) revise the HMR exceptions for hazardous materials carried by aircraft passengers and crewmembers. The revisions to the HMR exceptions for hazardous materials carried by aircraft passengers and crewmembers will take a more conservative approach than existing regulations (i.e., requiring approval by the air operator for the carriage of spare lithium ion batteries larger than 8 grams (approximately 100 Wh) and reducing the maximum Watt-hours for spare lithium ion batteries from 300 Wh to 160 Wh)). However, given that compliance with the PHMSA final rule will not be required until after the close of the comment period for this NPRM, for purposes of the passenger and crewmember

In general, a lithium ion battery that is more than 8 grams aggregate lithium content (approximately 100 Wh) must satisfy the shipping and packaging requirements of the HMR. *See* 49 CFR 173.185. Lithium ion batteries of 8 grams or less aggregate lithium content (approximately 100 Wh) are exempt from most requirements of the HMR. *See* 49 CFR 173.185.

The agency notes however, that PHMSA allows exceptions for the carriage of specified hazardous materials on board aircraft when carried by aircraft passengers or crewmembers, provided certain requirements are met. For example, aircraft passengers may carry an unlimited number of lithium ion batteries of 8 grams (100 Wh) or less and up to two lithium ion batteries of 8 grams up to 25 grams (100–300 Wh) if each spare battery is protected to prevent short circuits. Beginning on February 6, 2015, compliance with a more conservative upper limit of 160 Wh will be required. *See* 79 FR 46012 (August 6, 2014); 49 CFR 175.10(a)(18).[12]

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 the PHMSA Administrator. *See* SFAR No. 106, section 2(1). Under the authority of SFAR No. 106, the agency requires POC manufacturers to obtain a determination letter from PHMSA stating the POC does not contain hazardous materials as one of the prerequisites for the FAA to identify the POC in the SFAR. (PHMSA reviews information provided by the POC manufacturer for each POC model as the basis for this determination letter.) Although the agency proposes to maintain the broad prohibition on hazardous materials in POCs used by passengers on board aircraft, the agency proposes to remove the current requirement for a PHMSA determination letter confirming the POC does not contain hazardous materials. The PHMSA determination letter is unnecessary given the prohibition on hazardous materials in POCs.

Further, this proposal provides direct references to PHMSA regulations (the HMR) including the exceptions for passengers identified in 49 CFR 175.10. As a result, up to two batteries larger than those currently permitted by SFAR No. 106 may be carried to power POCs that are used on board aircraft. SFAR No. 106 does not contain any specific language regarding the aggregate lithium content of any battery used to power a POC (installed or spare). However, given the SFAR No. 106 prohibition of hazardous materials in a POC, SFAR No. 106 does effectively limit lithium ion batteries to 8 grams or less aggregate lithium content. A lithium ion battery with more than 8 grams aggregate lithium content is subject to the requirements of the HMR. *See* 49 CFR 173.185. Consequently, in accordance with the limits of SFAR No. 106, aircraft passengers are not permitted to use or carry a POC with a lithium battery or a spare lithium battery that is larger than 8 grams. However, the FAA notes this battery limitation does not apply to other portable electronic devices powered by lithium ion batteries being used or carried in accordance with aircraft passenger and crew exceptions in 49 CFR 175.10(a)(18).

Currently, neither the HMR nor SFAR No. 106 limits the number of lithium ion batteries that passengers may carry. Passengers using or carrying POCs on board aircraft may carry as many lithium ion batteries as they wish as long as each battery has an aggregate lithium content of 8 grams or less and the batteries are carried in carry-on baggage only. By allowing the exceptions in 49 CFR 175.10 to apply to POCs, passengers would also be able to carry and use up to two batteries larger than 8 grams, but not more than 25 grams aggregate lithium content (approximately 300 Wh) to power their POCs subject to the limitations of 49 CFR 175.10(a)(18).[13] *See* 79 FR 46012 (August 6, 2014).

While this proposed rule would expand battery options for passengers who use POCs, it would remain consistent with the level of lithium ion battery safety established by PHMSA. In 2007, after an evaluation of the transportation mode, battery size, quantity of batteries, product design, and emergency response, PHMSA (in consultation with the FAA), issued a final rule on the transportation of lithium batteries. In this 2007 final rule, PHMSA imposed stricter and more effective safeguards for the transportation of certain types and sizes of lithium batteries in certain transportation contexts, while at the same time providing an exception from these requirements for the carriage of lithium ion batteries by passengers in passenger carrying aircraft operations. While PHMSA acknowledged that lithium batteries are considered a hazardous material for purposes of transportation regulation because they can overheat and ignite in certain conditions, like certain other products that contain hazardous materials PHMSA determined that lithium batteries can be safely transported provided appropriate precautions are taken in design, packaging, handling, and emergency response as prescribed by the HMR. *See* 72 FR 44930, 44930 (August 9, 2007).

After consideration of the current PHMSA requirements applicable to lithium batteries carried in accordance with § 175.10(a)(18) and the pending PHMSA amendments pertaining to the carriage of lithium ion batteries on aircraft, the FAA has determined that SFAR No. 106 is unnecessarily restrictive with regard to battery size. Accordingly, this proposal allows batteries of expanded size to be installed in POCs or carried as spares to be used with POCs.

4. Maximum Oxygen Pressure

As previously discussed, the SFAR No. 106 acceptance 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.

The FAA believes this operating pressure restriction should continue to be applied so as to ensure that POCs used on board aircraft will not present the hazards associated with compressed oxygen. Accordingly, the agency

exceptions, the FAA continues to refer to the lithium ion battery requirements that will remain in effect until compliance with the new regulations pertaining to these exceptions is required. In light of this circumstance, the FAA requests that any comments pertaining to lithium ion batteries used in POCs or carried as spares for POCs, consider the impact of the PHMSA final rule.

[12] The lithium ion battery exception was drafted to be consistent with the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions) at the time of the rulemaking. *See* 72 FR 44930, 44937 (August 9, 2007). The ICAO Technical Instructions have since been updated. PHMSA evaluated the updated ICAO Technical Instructions in a separate rulemaking initiative that has recently resulted in a final rule amending the lithium ion battery exception. *See* 79 FR 46012 (August 6, 2014).

[13] As previously noted, beginning on February 6, 2015, the upper limit for the maximum Watt-hours will be reduced from 300 Wh to 160 Wh and approval of the air operator will be required to carry these larger batteries. *See* 79 FR 46012 (August 6, 2014).

proposes to include a design standard establishing a maximum oxygen pressure allowed for POCs intended for use on board aircraft of less than 200 kPa gauge (29.0 psig/43.8 psia) at 20 °C (68 °F). Under the proposed rule, a POC that exceeds this threshold could not be labeled as meeting the standards for use on board aircraft.

The agency believes that inclusion of the requirement regarding oxygen pressurization does not overlap with 49 CFR 173.115, 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 Certification and Labeling

Currently, the agency does not require manufacturers to label a POC approved for use in accordance with SFAR No. 106 to certify or indicate compliance with the standards in SFAR No. 106. Instead, the agency conducts a review of each individual POC when a manufacturer seeks to market its POC for use on board aircraft. If the agency determines the POC meets the criteria for FAA approval for use on board aircraft, it amends SFAR No. 106 to add the specific POC model.

As previously discussed, the FAA proposes to replace its current case-by-case POC approval process with acceptance criteria. To certify POC compliance with the acceptance criteria, the FAA proposes to require manufacturers to affix a label to the POC certifying it meets the FAA acceptance criteria. The FAA's proposed labeling requirement is the only element of the proposal that is not based on SFAR No. 106.

The FAA proposes to require the label to contain the following statement: ''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.'' The agency proposes to require manufacturers to use red lettering for this statement to facilitate recognition of the POC by passengers and crewmembers. The label would also serve to inform the user that the POC is safe for use in the cabin during all phases of flight because one of the proposed acceptance criteria is the completion of EMI testing in accordance with RTCA DO–160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21, Category M.

The agency also proposes to require POC manufacturers to use a labeling method that would ensure that the label remains affixed for the life of the device. The purpose of this requirement is to ensure the label cannot be transferred to another type of oxygen dispensing device presenting a higher safety risk without corresponding mitigation measures (e.g. a device that uses compressed oxygen).

Further the proposed labeling requirement is consistent with recommended labeling practices described in InFO 09006, Department of Transportation (DOT) Final Rule, ''Nondiscrimination on the basis of Disability in Air Travel'' and the Use of Respiratory Assistive Devices on Aircraft, and anticipated in the DOT final rule ''Nondiscrimination on the basis of Disability in Air Travel.'' *See* 73 FR 27614, 27630 (May 13, 2008). The agency reiterates only those manufacturers intending to market their devices for use on board aircraft must comply with the acceptance criteria in this proposal. This proposal does not affect other Federal agencies' regulatory requirements applicable to POCs. Accordingly, POC manufacturers that choose not to comply with the acceptance criteria required for POC use on board aircraft would not be subject to the FAA's proposed POC labeling requirement, and in that case, a passenger would not be permitted to use the non-labeled POC on board an aircraft in part 121, 125, or 135 operations.

The FAA believes POC manufacturers wishing to market their POCs for use on board aircraft will be able to readily comply with this proposed labeling requirement. As discussed in the Regulatory Notices and Analysis section of this preamble, the FAA assumes most POC manufacturers currently affix labels to POCs and thus this proposed labeling requirement should result in minimal costs.

This proposed labeling requirement would not apply to POCs currently approved under SFAR No. 106, as the FAA believes it is not necessary or practical to require POC manufacturers to label POCs identified in SFAR No. 106 as approved for use on board aircraft. POC models previously listed in SFAR No. 106 as approved for use on board aircraft have satisfied SFAR No. 106 criteria and would also satisfy the proposed acceptance criteria. In addition, the FAA expects use of POCs already listed in SFAR No. 106 will lessen over time as the POCs age and their users replace older models with newer ones obviating the need to retrofit existing POC models with a label.

Thus, the FAA proposes including in the regulatory text of §§ 121.574, 125.219, and 135.91, the list of POC models currently identified in SFAR No. 106 to assist with their identification by crewmembers. The FAA notes that a POC manufacturer could elect to place a label on a POC previously approved under SFAR No. 106 indicating the POC complies with the FAA's requirements for POCs used on board aircraft. Although, the agency is not proposing to require a label for POCs identified in SFAR No. 106, the FAA seeks 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.

Finally, the agency is aware that some manufacturers of POCs identified in SFAR No. 106 currently apply a label to those POCs indicating FAA approval for use on board aircraft. The agency clarifies however, this label does not provide a means by which a certificate holder, crewmember or passenger may determine compliance with SFAR No. 106 or with this proposal. The only label that may be used to determine compliance with this proposal 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 the proposal.

To mitigate any potential confusion that may arise from a POC label indicating FAA approval that pre-dates the labeling proposal in this NPRM, certificate holders, crewmembers and passengers must determine whether a particular POC may be used on a part 121, 125, or 135 operation by either (1) identifying the specific POC on the list of POC models approved for use on board aircraft under SFAR No. 106 and incorporated into the proposed regulatory text; or (2) by reviewing the manufacturer's certification statement on the label prescribed by this proposal.

E. Prohibition on Smoking or Open Flame

Consistent with SFAR No. 106, the FAA proposes to retain the existing prohibition on smoking or open flame within 10 feet of any person using a POC. 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 proposes to 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 specifically prohibiting an open flame.

The prohibition on smoking 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, the agency proposes to explicitly prohibit an open flame in addition to smoking as in SFAR No. 106. The agency also proposes to amend the regulatory text in § 125.219(b) to clarify that smoking is not only prohibited within 10 feet of where medical oxygen is being used but that it is also prohibited within 10 feet of where it is stored. This clarification 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).

F. Discussion of Special Federal Aviation Regulation No. 106 Requirements Excluded From Proposal

As previously noted, this rule proposes that several requirements currently contained in SFAR No. 106 be included in the new regulations establishing acceptance criteria for POCs. The FAA has determined, however, that many of the requirements currently included in SFAR No. 106 are overly prescriptive or redundant with existing rules and are therefore not necessary. Accordingly, the FAA is not proposing to include them in this rule. A discussion of the SFAR No. 106 requirements excluded from this proposal and the rationale therefore follows.

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

a. Stowage of Portable Oxygen Concentrators on Board Aircraft

SFAR No. 106, section 3(a)(3) states that during movement on the surface, takeoff, and landing, the POC must (1) 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; or (2) if it is to be operated by the user, be used 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.

Existing FAA regulations in parts 121, 125, and 135, address the stowage of carry-on items and carriage of cargo in the passenger cabin to ensure an appropriate stowage location and 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 stowage requirement in SFAR No. 106 is unnecessary and the FAA is proposing to eliminate it.

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 continue to use the unit while stowed under a seat.

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

SFAR No. 106, section 3(a)(6) states, ''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.''

The agency included this provision in SFAR No. 106 in response to commenters' concerns that limitations on the ability of medical oxygen users to move around the cabin during flight, would apply to POC users. In the final rule implementing SFAR No. 106, the agency specifically 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.

The proposed revisions to §§ 121.574, 125.219, and 135.9, distinguish requirements applicable to passengers carrying and using POCs from requirements applicable to passenger use of other equipment for the storage, generation or dispensing of oxygen. Therefore, if this proposed rule is finalized, a provision similar to section 3(a)(6) of the SFAR would be unnecessary.

c. Exit Row Seating

SFAR No. 106, section 3(a)(4) states that no person using a POC is permitted to sit in an exit row. The FAA believes this requirement is unnecessary because current regulations in parts 121 and 135 require the certificate holder to determine the suitability of passengers it permits to occupy exit row seats. *See* 14 CFR 121.585 and 135.129. For example, a person using a POC may not be qualified to sit in an exit row if the POC would inhibit the passenger's ability to handle the emergency exit and assist other passengers exiting the aircraft. Therefore, the FAA proposes to eliminate this SFAR No. 106 requirement.

The FAA notes that part 125 does not specifically address the suitability of passengers for exit row seating. However, this proposed rule does not affect the ability of part 125 operators to apply their current seating policies.

d. 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 are 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). When a battery-powered POC is carried on board aircraft as carry-on baggage, and is not intended to be used during the flight, the battery must be removed and packaged 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 portion of SFAR No. 106, section 3(b)(6) addressing spare batteries is redundant with PHMSA regulations applicable to spare batteries carried by passengers on board aircraft. PHMSA regulations require spare batteries carried on board aircraft to be individually protected from short circuit to mitigate the risk of a fire during flight. *See* 49 CFR 175.10(a)(18). Thus, SFAR No. 106 provisions applicable to spare batteries carried by passengers on board aircraft for use in POCs are unnecessary and excluded from this proposal.

However, 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. Existing PHMSA regulations 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 agency's review of the 24 POC models currently accepted for use on board aircraft, the FAA has determined those POCs all have at least two design features preventing inadvertent or accidental operation. Thus, for those POCs that are currently accepted for use on board aircraft, batteries may remain in the devices while 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. Specifically, PHMSA requires all lithium ion batteries to include overcharge protection and testing that prevents a battery from overheating and preventing a fire. 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 current approved POCs and 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 batteries available for new devices must be equipped with overcharge protection, therefore, the risk of a fire originating from the battery is minimal. Accordingly, the FAA did not propose to retain this provision in the NPRM.

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

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

SFAR No. 106, section 3(b)(3) requires passengers intending to use a POC to have a written statement, to be kept in that person's possession, signed by a licensed physician 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 must allow the crew of the aircraft to review the contents of the physician's statement. Similarly, SFAR No. 106, section 3(a)(5) requires pilot in command notification whenever a passenger brings and intends to use a POC on board the aircraft. The pilot in command must also be informed about the contents of the physician's written statement including the nature of the passenger's oxygen needs and the passenger's ability to understand operational and warning information presented by the POC.

The FAA has reconsidered the requirements for a physician's statement, as well as pilot notification of the contents of the physician's statement, and operator notification of intended POC use, and believes that these requirements are not necessary to maintain the safety of a passenger using a POC or the safe operation of the aircraft. The requirements for a physician's statement and pilot in command and operator notification impose a significant paperwork burden on affected passengers and their physicians as well as crewmembers and aircraft operators that are both unnecessary and unreasonable. Accordingly, the agency proposes to remove these requirements.

Physician statement: When the agency issued the final rule on SFAR No. 106, the agency anticipated the passenger's physician would help the passenger determine their need to use the POC during flight (e.g., during the whole flight, during portions of the flight, or as needed). At the time of the SFAR No. 106 final rule, the agency also expected a passenger's physician to verify, in a written statement, the passenger's ability to operate the device and respond to any alarms. After reviewing this requirement the agency determined, since a passenger may only obtain a POC by medical prescription, a secondary statement regarding the need and the passenger's ability to use the device, results in an unnecessary burden.

Additionally, POC usage is the same on board the aircraft as any other location. The pressure in the aircraft cabin allows a POC to be used without changes in settings or liter flow, or other adjustments. Requiring passengers to obtain a physician's statement specifying oxygen flow rate unnecessarily duplicates information provided to the passenger by the prescribing physician. Therefore, this proposal would eliminate the current FAA requirement for passengers to obtain a physician's statement prior to using a POC on board an aircraft in part 121, 125, and 135 operations.[14]

Pilot and aircraft operator notification: In the SFAR No. 106 final rule preamble, the FAA reasoned that the pilot in command should be aware of POC use on a flight because POC failure could possibly create a medical event requiring emergency action. Additionally, because some POCs may use electrical outlets in the cabin, the FAA wanted the pilot in command to be aware that a power restriction could affect POC use so that the pilot could make an appropriate announcement if the use of that power needed to be restricted. The SFAR No. 106 preamble was unclear regarding reasons for operator notification of intended POC use.

The agency has reevaluated the requirement for the pilot in command to be informed about the contents of the physician's written statement and determined that a requirement for any crewmember to review an affected passenger's medical information has no nexus to the safety of aircraft operations. Further, unlike other medical oxygen devices for passenger use that must be maintained and supplied by aircraft operators, neither an aircraft operator nor its crew has any responsibility for the operation of the POC or the concentration of oxygen dispensed. The responsibility for the use of a passenger's POC rests with the passenger.

Finally, based on a review of air carrier safety data[15] since publication of SFAR No. 106, the agency has not identified any instances of POC malfunction during flight. Nevertheless, the agency notes that while advanced notice that a passenger may need assistance in the event of POC failure could be helpful to crewmembers, crewmembers currently receive training on how to respond to unanticipated events that may arise on board an aircraft, including medical events. Based on the foregoing discussion, the agency's proposal would eliminate the requirement for passengers to notify the pilot in command of intended POC use

[14] Pursuant to Department of Transportation regulations, U.S. and foreign air carriers may require passengers who expect to use a POC during flight to obtain a physician's statement (i.e., medical certificate) as a condition of transportation. *See* 14 CFR 382.23(b)(1)(ii).

[15] The agency reviewed data from the following accident, incident and voluntary reporting databases: 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).

and the contents of the physician's statement. The same rationale applies to the agency's proposal to eliminate the requirement for passengers to notify the aircraft operator of intended POC use during a flight.

b. Portable Oxygen Concentrator Alarms

SFAR No. 106, section 3.(b)(1) requires a passenger using a POC on 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. These requirements 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.

The FAA believes it is the responsibility of the passenger or the passenger's caregiver to ensure the POC is operating properly and to know how to respond when it is not operating properly. The agency further believes removing this requirement will not affect aviation safety because these alarms are primarily intended to ensure the device continues to function as intended. The FAA also emphasizes that it has not identified any incidents regarding POC malfunctions on board aircraft.[16] Therefore, the FAA is proposing to eliminate this SFAR No. 106 requirement (section 3(b)(1)).

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

SFAR No. 106, section 3(b)(2) requires the user 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. The NPRM proposing SFAR No. 106 stated 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).

The FAA does not believe this requirement is necessary to ensure safe POC use in the aircraft environment. While the agency acknowledges petroleum products may accelerate an existing fire, neither a POC nor concentrated oxygen produced by the POC would increase this risk. Further, 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. The agency notes it is the passenger's responsibility to maintain their POC in good condition so that it may function properly. Therefore, the agency proposes eliminating the SFAR No. 106 requirement for a passenger to ensure their POC is in good condition (free of damage, excessive wear, abuse, etc.) and free of oil, grease, or other petroleum products.

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 an airplane. This requirement came from the user manual of the first POC approved by the FAA. The FAA believes it is the passenger's responsibility to ensure they are using products meeting the manufacturer's requirements for salve and lotion usage with a POC. To the extent SFAR No. 106 contemplated a petroleum-based lotion or a salve, the risk and responsibilities are addressed in the discussion pertaining to the elimination of the requirement for the user to ensure that the POC is free from petroleum products and associated risks. Therefore, the FAA is proposing to eliminate 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. The passenger must carry on the flight 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.

The FAA believes it is the passenger's responsibility to understand the performance of their POC and their POCs battery life under varying conditions, and further to ensure their POC will enable them to adhere to their physician's instructions. Passengers who use a POC during air travel should carefully read the owner's manual to ensure the selected model meets their needs. All POC user manuals have liter flow and battery duration charts to help users make informed decisions regarding the number of spare batteries to bring. Therefore, the FAA proposes to eliminate this SFAR No. 106 requirement.

The FAA notes, however, that in accordance with DOT regulations regarding assistive devices, U.S. and foreign carriers may still require passengers to carry an adequate number of batteries required to power the POC for not less than 150% of the expected maximum flight duration. *See* 14 CFR 382.133(f)(2).

G. Miscellaneous

The agency proposes to update 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.

VI. Advisory Circulars

The FAA expects to revise the existing Advisory Circular pertaining to POC use on aircraft in part 121, 125 and 135 operations. A draft revised Advisory Circular will be provided in the docket of this rulemaking for comment.

VII. 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 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 proposed rule.

[16] The agency reviewed data from the following accident, incident and voluntary reporting databases: VDRP, SDRS, NTSB, ASRS and AIDS.

The agency suggests readers seeking greater detail read the full regulatory evaluation, a copy of which has been placed in the docket for this rulemaking.

In conducting these analyses, FAA has determined that this proposed 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) would not have a significant economic impact on a substantial number of small entities; (5) would not create unnecessary obstacles to the foreign commerce of the United States; and (6) would 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 FAA estimates that the cost of the proposed rule would be a one-time cost of $22,000 incurred by manufacturers to modify a label and would be associated with costs that manufacturers would incur to change their current labeling process to affix a label with the proposed language on the devices. The FAA also estimated that manufacturers would save $108,000 over ten years by no longer having to petition the FAA for rulemaking to include a new Portable Oxygen Concentrator (POC) in the SFAR No. 106. The total cost savings from the proposed rule is $37.4 million ($26.1 million at 7% present value and $31.8 million at 3% present value).

Who is potentially affected by this rule?

- POC manufacturers
- Passengers carrying POCs on board aircraft
- Physicians providing written statements to POC users
- Aircraft operators and crews

Assumptions:

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

Benefits of This Rule

With the elimination of the SFAR and the replacement with a process where the manufacturers self-certify based on meeting the acceptance criteria described in the rule and label the devices, manufacturers would be able to introduce new POCs sooner to the market. Therefore, one benefit of this rule would be to eliminate delays and enable manufacturers to bring their devices to market sooner.

Furthermore, the proposed rule would result in cost savings because the pilot in command would no longer have to be notified when an affected passenger intends to use a POC on the aircraft and be informed about the contents of the physician's written statement. The proposed rule would also result in additional cost savings because affected passengers would no longer have to obtain a physician's written statement, as a prerequisite to bringing POCs on board aircraft in part 121, 125, and 135 operations.

The cost savings of this proposal are summarized in the table below.

Total Cost Savings from Proposed Rule

Cost Savings		7% present value savings	3% present value savings
FAA Savings - No SFAR	$ 91,644	$ 68,871	$ 32,573
Manufacturer Savings - No Petition	$108,000	$75,853	$92,126
No Longer Obtaining Physician's statement	$559,660	$391,402	$476,509
No Longer Notifying Pilot in Command	$36,599,268	$25,595,997	$31,161,620
Total Cost Savings	$37,358,571	$26,132,123	$31,762,828

Costs of This Rule

The industry would incur costs of $22,000 to modify labels that they already affix to the POC, to contain the language proposed by this rule. The industry cost savings of $108,000 by no longer having to petition the FAA for each new device easily exceed the labeling costs.

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.

The FAA identified nine companies that produce portable oxygen concentrators for use on 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 on-line research, the FAA found data [17] indicating that six of the nine manufacturers are small entities and concludes 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 they will be able to market new portable oxygen concentrators sooner.

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

Although a substantial number of operators conducting part 121, 125 and 135 operations are small entities, all part 121, 125 and 135 operators are expected to experience cost savings because the proposal would no longer require the pilot in command 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 proposed rule is expected to reduce burdens that SFAR No. 106 currently imposes on the Portable Oxygen Concentrator (POC) manufacturers. This NPRM would impose small costs on manufacturers by requiring a label indicating the device meets FAA requirements for use on board aircraft. The FAA learned from five of the small manufacturers that they might incur a one-time cost ranging from $200 to $1,500 or $0.20 to $1 per label.[18] These costs would be offset by cost savings from the elimination of having to petition for rulemaking and await a final regulatory action. One manufacturer stated these cost savings are worth $4,500 for each petition.

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.

The FAA solicits comments regarding this determination.

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 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 proposed rule and determined that it would have only a domestic impact and therefore no effect on international trade.

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

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 $151.0 million in lieu of $100 million. This proposed 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 would be no new requirements for information collection associated with this proposed rule.

This rule proposes to discontinue the requirements quantified in FAA information collection 2120–0702, Use of Certain Personal Oxygen Concentrator (POC) Devices on Board Aircraft. The agency addressed the reasons for the discontinuance of this collection in the preamble discussion regarding the substantive provisions of the proposal.

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 International Civil Aviation Organization (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 (ICAO TI). ICAO TI does not contain specific provisions for POCs but Part 8 (passenger and crew exceptions) allows for their carriage on board aircraft as portable medical electronic devices subject to certain conditions. The conditions in Part 8 pertaining to batteries used to power POCs are similar to the allowances given in 49 CFR 175.10(a)(18).

G. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, (77 FR 26413 (May 4, 2012)) promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

H. Environmental Analysis

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

VIII. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this proposed rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would 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, would not have Federalism implications.

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

The FAA analyzed this proposed 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 would not be a ''significant energy action'' under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

IX. Additional Information

A. Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The agency also invites

comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The agency may change this proposal in light of the comments it receives.

Proprietary or Confidential Business Information: Commenters should not file proprietary or confidential business information in the docket. Such information must be sent or delivered directly to the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document, and marked as proprietary or confidential. If submitting information on a disk or CD ROM, mark the outside of the disk or CD ROM, and identify electronically within the disk or CD ROM the specific information that is proprietary or confidential.

Under 14 CFR 11.35(b), if the FAA is aware of proprietary information filed with a comment, the agency does not place it in the docket. It is held in a separate file to which the public does not have access, and the FAA places a note in the docket that it has received it. If the FAA receives a request to examine or copy this information, it treats it as any other request under the Freedom of Information Act (5 U.S.C. 552). The FAA processes such a request under Department of Transportation procedures found in 49 CFR part 7.

B. Availability of Rulemaking Documents

An electronic copy of rulemaking documents may be obtained from the Internet by—

- Searching the Federal eRulemaking Portal at *http://www.regulations.gov;*
- Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies* or
- Accessing the Government Printing Office's Federal Digital System at *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced above.

List of Subjects

14 CFR Part 1

Air transportation.

14 CFR Part 121

Air carriers, Aircraft, Aviation safety, Charter flights, Incorporation by reference, Safety, Transportation.

14 CFR Part 125

Aircraft, Aviation safety, Incorporation by reference.

14 CFR Part 135

Air taxis, Aircraft, Aviation safety, Incorporation by reference.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend chapter I of title 14, Code of Federal Regulations as follows:

PART 1—DEFINITIONS AND ABBREVIATIONS

■ 1. The authority citation for part 1 is revised 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.

* * * * *

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

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

Authority: 49 U.S.C. 106(f), 106(g), 40113, 40119, 41706, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 44732, 46105; Pub. L. 111–216, 124 Stat. 2348 (49 U.S.C. 44701 note); Pub. L. 112–95, 126 Stat. 62 (49 U.S.C. 44732 note).

Special Federal Aviation Regulation No. 106 [Removed]

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

■ 5. Amend § 121.306 as follows:

■ A. In paragraph (b)(4), remove ''or'' following the semi-colon;

■ 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 of this part; or

* * * * *

■ 6. Amend § 121.574 as follows:

■ A. Revise 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 paragraphs (e) and (f).

The revisions and additions read as follows:

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

(a) Except as provided in paragraph (e) of this section, a certificate holder may allow a passenger to carry and operate equipment for the storage, generation, or dispensing of oxygen when the following conditions are met:

* * * * *

(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) A passenger may carry and operate a portable oxygen concentrator for personal use and a certificate holder may allow a passenger to carry and 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 following requirements:

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

(2) Meets the standards of RTCA DO–160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21, Category M issued December 8, 2010;

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

(4) Does not contain any hazardous materials subject to the Hazardous Materials Regulations (49 CFR parts 171–180) except as provided in 49 CFR 175.10; and

(5) 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 portable oxygen concentrator has determined this device conforms to all applicable FAA requirements for portable oxygen concentrator carriage and use on board aircraft.'' The label requirements in this paragraph do not apply to the following portable oxygen concentrators approved by the FAA for use on board aircraft prior to [DATE 90 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]:

(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.

(f) *Incorporation by reference.* RTCA DO–160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21, Category M issued December 8, 2010 is incorporated by reference into this section with the approval of the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Federal Aviation Administration must publish notice of change in the **Federal Register** and the material must be available to the public. Copies of this standard may be obtained from RTCA, Inc. 1150 18th Street NW., Suite 910, Washington, DC 20036; telephone (202) 833–9339; *www.rtca.org/store_list.asp.* This standard is available for inspection at the Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–9677. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

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

■ 7. 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]

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

■ 9. Amend § 125.204 as follows:

■ A. In paragraph (b)(4) remove ''or'' following the semi-colon;

■ 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 of this part; or

* * * * *

■ 10. Amend § 125.219 as follows:

■ A. Revise section heading;

■ B. Revise paragraph (a) introductory text;

■ C. In paragraph (a)(3) remove the reference ''title 49 CFR 173.300(a)'' and add in its place ''49 CFR 173.115(b)'';

■ D. Revise paragraph (b); and

■ E. Add paragraphs (f) and (g).

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), (e) 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 unit to be carried is constructed so that all valves, fittings, and gauges are protected from damage during that carriage or operation and unless the following conditions are met:

* * * * *

(b) No person may smoke or crate 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) A passenger may carry and operate a portable oxygen concentrator for personal use and a certificate holder may allow a passenger to carry and 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 following requirements:

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

(2) Meets the standards of RTCA DO–160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21, Category M issued December 8, 2010;

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

(4) Does not contain any hazardous materials subject to the Hazardous Materials Regulations (49 CFR parts 171–180) except as provided in 49 CFR 175.10; and

(5) 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 portable oxygen concentrator has determined this device conforms to all applicable FAA requirements for portable oxygen concentrator carriage

and use on board aircraft.'' The label requirements in this paragraph do not apply to the following portable oxygen concentrators approved by the FAA for use on board aircraft prior to [DATE 90 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**]:

(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
(xiv) VBox Trooper Oxygen Concentrator.

(g) *Incorporation by reference.* RTCA DO–160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21, Category M issued December 8, 2010 is incorporated by reference into this section with the approval of the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Federal Aviation Administration must publish notice of change in the **Federal Register** and the material must be available to the public. Copies of this standard may be obtained from RTCA, Inc. 1150 18th Street NW., Suite 910, Washington, DC 20036; telephone (202) 833–9339; *www.rtca.org/store_list.asp.* This standard is available for inspection at the Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–9677. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

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

■ 11. 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, 45101–45105.

Special Federal Aviation Regulation No. 106 [Removed]

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

■ 13. Amend § 135.91 as follows:

■ A. Revise paragraph (a) introductory text;

■ B. In paragraph (a)(3) remove the reference ''title 49 CFR 173.300(a)'' and add in its place ''49 CFR 173.115(b)'';

■ C. Revise paragraph (b); and

■ D. Add paragraphs (f) and (g).

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), (e) 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 unit to be carried is constructed so that all valves, fittings, and gauges are protected from damage during that carriage or operation and unless the following conditions are met—

* * * * *

(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) A passenger may carry and operate a portable oxygen concentrator for personal use and a certificate holder may allow a passenger to carry and 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 following requirements:

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

(2) Meets the standards of RTCA DO–160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21, Category M issued December 8, 2010;

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

(4) Does not contain any hazardous materials subject to the Hazardous Materials Regulations (49 CFR parts 171–180) except as provided in 49 CFR 175.10; and

(5) 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 portable oxygen concentrator has determined this device conforms to all applicable FAA requirements for portable oxygen concentrator carriage and use on board aircraft.'' The label requirements in this paragraph do not apply to the following portable oxygen concentrators approved by the FAA for use on board aircraft prior to [DATE 90 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **Federal Register**]:

(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.

(g) *Incorporation by reference.* RTCA DO–160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21, Category M issued December 8, 2010 is incorporated by reference into this section with the approval of the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Federal Aviation Administration must publish notice of change in the **Federal Register** and the material must be available to the

public. Copies of this standard may be obtained from RTCA, Inc. 1150 18th Street NW., Suite 910, Washington, DC 20036; telephone (202) 833–9339; *www.rtca.org/store_list.asp.* This standard is available for inspection at the Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–9677. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

■ 14. Amend § 135.144 as follows:

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

■ B. In paragraph (b)(4) remove ''or'' following the semi-colon;

■ 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 of this part; or

* * * * *

Issued under the authority provided by 49 U.S.C. 106(f) and 44701(a) in Washington, DC, on September 9, 2014.

John S. Duncan,

Director, Flight Standards Service.

[FR Doc. 2014–21964 Filed 9–18–14; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–111839–13]

RIN 1545–BL62

Transitional Amendments To Satisfy the Market Rate of Return Rules for Hybrid Retirement Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations that would provide guidance regarding certain amendments to applicable defined benefit plans. Applicable defined benefit plans are defined benefit plans that use a lump sum-based benefit formula, including cash balance plans and pension equity plans, as well as other hybrid retirement plans that have a similar effect. These proposed regulations would permit an applicable defined benefit plan that does not comply with the requirement that the plan not provide for interest credits (or equivalent amounts) at an effective rate that is greater than a market rate of return to comply with that requirement by changing to an interest crediting rate that is permitted under the final hybrid plan regulations, without violating the anti-cutback rules of section 411(d)(6). These regulations would affect sponsors, administrators, participants, and beneficiaries of these plans. This document also provides a notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by December 18, 2014. Outlines of topics to be discussed at the public hearing scheduled for January 9, 2015, at 10 a.m. must be received by December 18, 2014.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–111839–13), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–111839–13), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically, via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–111839–13). The public hearing will be held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Neil S. Sandhu or Linda S. F. Marshall at (202) 317–6700; concerning submissions of comments, the hearing, and/or being placed on the building access list to attend the hearing, Oluwafunmilayo (Funmi) Taylor at (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

I. In General

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 411(b)(5) of the Internal Revenue Code (Code).

Generally, a defined benefit pension plan must satisfy the requirements of section 411 in order to be qualified under section 401(a) of the Code. Section 411(b)(5), which modifies the accrual requirements of section 411(b), was added to the Code by section 701(b) of the Pension Protection Act of 2006, Public Law 109–280 (120 Stat. 780 (2006)) (PPA '06). Section 411(b)(5) and certain related effective date provisions were subsequently amended by the Worker, Retiree, and Employer Recovery Act of 2008, Public Law 110–458 (122 Stat. 5092 (2008)) (WRERA '08).

Under section 411(b)(5)(B)(i), a statutory hybrid plan is treated as failing to satisfy the requirements of section 411(b)(1)(H) (which provides that the rate of an employee's benefit accrual must not be reduced because of the attainment of any age) if the terms of the plan provide any interest credit (or an equivalent amount) for any plan year at a rate that is in excess of a market rate of return. Section 411(b)(5)(B)(i) is generally effective for plan years beginning after December 31, 2007.

Section 411(d)(6) provides generally that a plan does not satisfy section 411 if an amendment to the plan decreases a participant's accrued benefit. For this purpose, a plan amendment that has the effect of eliminating or reducing an early retirement benefit or a retirement-type subsidy or eliminating an optional form of benefit with respect to benefits attributable to service before the amendment is treated as reducing accrued benefits.

Sections 204(b)(5)(B)(i) and 204(g) of the Employee Retirement Income Security Act of 1974, Public Law 93–406 (88 Stat. 829 (1974)), as amended (ERISA), contain rules that are parallel to sections 411(b)(5)(B)(i) and 411(d)(6), respectively. Under section 101 of Reorganization Plan No. 4 of 1978 (43 FR 47713), the Secretary of the Treasury has interpretive jurisdiction over the subject matter addressed in these proposed regulations for purposes of ERISA, as well as the Code. Thus, these proposed regulations would apply for purposes of sections 411(b)(5)(B)(i) and 411(d)(6) of the Code, as well as for purposes of sections 204(b)(5)(B)(i) and 204(g) of ERISA.

Section 1.411(d)–4, A–2(b)(1), of the Income Tax Regulations provides, in part, that the Commissioner may, consistent with the provisions of § 1.411(d)–4, provide for the elimination or reduction of section 411(d)(6) protected benefits that have already accrued to the extent that such elimination or reduction is necessary to permit compliance with other requirements of section 401(a). The Commissioner may exercise this authority only through the publication