U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration

1200 New Jersey Avenue, SE
Washington, DC 20590

MAR 23 2011

Ms. Kathryn G. Forgione
Vice President of Quality
O2 Concepts, LLC
14001 McAuley Blvd., Suite 170
Oklahoma City, OK 73134

Ref. No.: 11-0044

Dear Ms. Forgione:

This responds to your February 15, 2011 letter regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to a portable oxygen concentrator. Specifically you ask if the OxLife Independence oxygen concentrator is compliant with Special Provision 188. For your information, in December 2008 this office responded to a similar request for interpretation from OxLife, LLC (Ref. No. 08-0237). In your letter you indicated that in 2010 your company purchased the appropriate legal rights to the OxLife Independence oxygen concentrator.

The information you provided in your letter, reiterates that provided by OxLife LLC in 2008 concerning the contents of the OxLife Independence oxygen concentrator. You indicate the following:

1. The pressure of the oxygen in the device does not exceed 40.6 psia at 20 degrees C;
2. The cells contain no more than 1.5 grams of lithium equivalent content;
3. The lithium ion battery contains an aggregate equivalent lithium content of not more than 8 g;
4. The device contains no other materials subject to the HMR; and
5. The batteries are fully contained in equipment and packaged in a manner to preclude sparks or the generation of a dangerous quantity of heat.

Based on the information provided, the OxLife Independence portable oxygen concentrator meets the requirements of Special Provision 188. Provided it continues to meet the requirements established in Special Provision 188, it is not otherwise subject to the HMR.

You should also note that Federal Aviation Administration (FAA) approval is required before these electronic devices may be used by passengers on board aircraft. The FAA published a final rule in the Federal Register regarding these devices on July 12, 2005 (70 FR 40156). A copy of the rulemaking is enclosed.

I hope this answers your inquiry. If you need additional assistance, please contact the Standards and Rulemaking Division at 202-366-8553.

Sincerely,

Ben Supko
Acting Chief, Standards Development Branch
Standards and Rulemaking Division

Enclosure

Winter
§173.168
§173.220
Oxygen Generator/ Applicability
11-0044

February 15, 2011

Office of Hazardous Materials Standards
U.S. DOT/PHMSA (PHH-10)
1200 New Jersey Avenue, SE East Building, 2nd Floor
Washington, DC 20590

Attention: Mr. Edward T. Mazzullo, Director

Dear Mr. Mazzullo,

In 2010, O2 Concepts, LLC purchased all intangible assets to the OxLife Independence, a Portable Oxygen Concentrator, from OxLife, LLC who obtained FDA clearance for this product on April 16, 2008 under K080082.
The device is a portable oxygen concentrator designed to deliver supplemental oxygen to adult patients. This product is manufactured according to FDA's Quality System Regulation part 820 and Quality Management System according to ISO 13485.

O2 Concepts, LLC is preparing to launch the OxLife Independence (Model #800-0001) and is requesting a confirmation that the OxLife Independence is compliant with the HMR, Special Provision 188.

The OxLife Independence meets the following criteria:

1. The pressure of the oxygen in the device does not exceed 40.6 psia at 20 degrees C.
2. The cells contain no more than 1.5 grams of lithium equivalent content.
3. The lithium ion battery contains an aggregate equivalent lithium content of not more than 8g and has been found to be compliant with UN document ST/SG/AC.10/11 Rev: 3: "Amendments to the third Revised Edition of the Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria."
4. The device contains no other materials subject to the HMR.
5. The batteries are fully contained in equipment and packaged in a manner to preclude sparks or the generation of a dangerous quantity of heat.

If any additional information is required, please contact me via e-mail at kforgione@o2-concepts.com.

Respectfully,

Kathryn G. Forgione
Vice President of Quality
O2 Concepts, LLC

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 11 and 121

[Docket No.: FAA–2004–18596; SFAR No. 106]

RIN 2120–AI30

Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This Special Federal Aviation Regulation (SFAR) will permit passengers to use certain portable oxygen concentrator (POC) devices on aircraft, provided certain conditions in this SFAR are satisfied. The SFAR includes a POC preparation requirement for carry-on baggage transport, and a battery-packaging standard necessary for the safe carriage of extra POC batteries in carry-on baggage. This rulemaking action is necessary to address the travelling needs of people on oxygen therapy.

DATES: This SFAR becomes effective August 11, 2005.

FOR FURTHER INFORMATION CONTACT: David L. Catey, Air Transportation Division, AFS–200, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3732.

SUPPLEMENTARY INFORMATION:

Availability of Rulemaking Documents

You can get an electronic copy using the Internet by:

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

(2) Visiting the Office of Rulemaking's web page at *http://www.faa.gov/avr/arm/index.cfm*; or

(3) Accessing the Government Printing Office's web page at *http://www.access.gpo.gov/su_docs/aces/aces140.html*.

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

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov*.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact its local FAA official, or the person listed under **FOR FURTHER INFORMATION CONTACT**. You can find out more about SBREFA on the Internet at *http://www.faa.gov/avr/arm/sbrefa.cfm*.

Authority for This Rulemaking

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

Background

This final rule responds to comments received on notice of proposed rulemaking (NPRM) titled ''Use of Portable Oxygen Concentrator Devices Onboard Aircraft,'' (69 FR 42324; July 14, 2004). The NPRM proposed a Special Federal Aviation Regulation (SFAR) to allow passengers to operate certain portable oxygen concentrator (POC) devices on aircraft if certain conditions detailed in the proposal were met.

As stated in the NPRM, the FAA recognizes that there is a critical need to improve service for passengers who have a medical need to travel with medical oxygen. Passengers requiring medical oxygen during air travel have faced significant difficulties obtaining adequate air service. Many carriers do not provide medical oxygen during air travel. Those carriers that provide the service often charge for the service—sometimes at a cost that equals the price of a ticket. Additionally, it can be difficult to coordinate service between the carrier and a supplier of medical oxygen to ensure passenger coverage both at the terminal and on the aircraft. Sometimes, the passenger must spend at least part of the time travelling without medical oxygen due to service problems with the oxygen provider.

Compressed oxygen is regulated as a Hazardous Material by the Pipeline and Hazardous Materials Safety Administration (PHMSA), formerly the Research and Special Programs Administration (RSPA), under title 49 CFR 172.101. The FAA also regulates oxygen furnished by aircraft operators to passengers who have a medical need for oxygen on board the aircraft. Oxygen is highly regulated because, as an oxidizer, it can enhance an existing fire, and it can support combustion of certain flammable materials, whether or not an ignition source is present. The FAA's medical oxygen regulations, 14 CFR 121.574, 125.219, and 135.91, currently allow aircraft operators to furnish equipment for the storage, generation, or dispensing of oxygen to passengers provided all of the following conditions are met:

The equipment is:

1. Furnished by the certificate holder;
2. Of an approved type or is in conformity with the manufacturing, packaging, marking, labelling and maintenance requirements of 49 CFR parts 171, 172 and 173 except 173.24(a)(1);
3. Maintained by the aircraft operator in accordance with an approved maintenance program;
4. Free of flammable contaminants on all exterior surfaces;
5. Capable of providing a minimum mass flow of oxygen to the user of four liters per minute (this provision is not contained in either part 125 or 135 regulations);
6. Constructed so that all valves, fittings and gauges are protected from damage; and
7. Appropriately secured.

Recently new medical oxygen technologies have been approved by the Food and Drug Administration that reduce the risks typically associated with compressed oxygen. Two companies—AirSep Corporation and Inogen, Inc.—have developed small POCs that work by filtering out nitrogen from the air and providing the user with oxygen at a concentration of about 90%. The POCs operate using either rechargeable batteries or, if approved by the FAA, aircraft electrical power.

In addition, PHMSA, formerly RSPA, has determined that the POCs are not hazardous materials. Thus they do not require the same level of special handling as compressed oxygen, and are safe for use onboard aircraft provided certain conditions for their use are met.

Summary

This SFAR establishes requirements applicable to passenger-supplied POCs used on aircraft. With the adoption of this rule, passengers will be able to choose between two different kinds of

portable oxygen concentrator (POC) devices to operate onboard an aircraft during travel. The NPRM published in July 2004 explained the proposal and this final rule adopts much of that original proposal, with some modifications, including:

1. Some proposed requirements that would have been placed on air carriers are now the responsibility of the POC user;

2. The Inogen One POC, mentioned only as being studied in the NPRM, is included as an eligible portable electronic device in the SFAR in response to comments;

3. We will allow passengers using a POC to walk around the cabin while carrying the device. However, when a passenger has a medical need to use a POC during movement on the surface, takeoff, and landing, the person using the POC must be seated in seat location so as not to restrict other passenger's access to, or use of, any required emergency, or regular exit. Additionally, the POC user must be seated in a location so as not to restrict access to the aisle(s) of the passenger compartment. Passengers who do not have a medical need to use a POC during movement on the surface, takeoff and landing, and are not seated in accordance with the preceding requirements, must properly stow the POC so it does not block access to the aisleway (*e.g.*, under the passenger seat in front of the user). In either case, POCs and the extra batteries needed to power them must be properly stowed in accordance with the applicable carry-on baggage requirements of 14 CFR 91.523, 91.525, 121.285, 121.589, 125.183, and 135.87.

4. Several extra batteries may be required to power the POCs for some flights and we are including a battery-packaging standard for POC batteries included in carry-on baggage. (Section 3(b)(6) of the SFAR)

We don't feel that any of these modifications go outside the scope of the original NPRM since we specifically cited the Inogen One POC and sought comment on who should be responsible for certain aspects of the rule. All comments are addressed below.

The SFAR is an enabling rule, which means that no aircraft operator is required to allow passengers to operate these devices onboard, but they may allow them to be operated onboard. If an aircraft operator chooses to allow a passenger to operate these devices onboard the aircraft operator's aircraft the conditions in the SFAR must be met.

Presently, there are only two acceptable POCs on the market (Inogen and Airsep) and we cannot predict how future products may be developed and work. Accordingly, while we are committed to developing a performance-based standard for all future POC devices, we do not want to prematurely develop standards that have the effect of stifling new technology of which we are unaware. It is only under exceptionally rare circumstances that the FAA would permit a specific product to be used in a regulation. However, we believe such an approach is appropriate in this case until such time that a performance-based standard can be developed because the rule accommodates individuals who would otherwise be unable to fly. This approach is consistent with the Department of Transportation's desire to reduce travel barriers to persons with disabilities.

Reference Material

After reviewing the, ''United Kingdom Civil Aviation Authority study titled ''Dealing With In-Flight Lithium Battery Fires in Portable Electronic Devices'', and recent incident data detailing battery abuse and short circuit problems associated with the carriage of batteries, it became clear that we must provide a means for reducing the hazard of personal injury and fire from loose POC batteries included as carry on items in passengers' carry-on baggage. Although most battery pack manufacturers employ various protective devices to prevent abuse such as thermal or pressure disconnects and shutdown separators to prevent battery overheating and fires, abuse conditions such as physical damage to the cell(s) or external short circuits do occur. Abuse of the battery can cause those safeguards to become ineffective unless other protective measures, such as battery outer protective packaging, are used. (See the discussion under the subtopic heading ''Safety of Carrying Multiple Batteries'' under the main topic heading ''Discussion of Comments'' below).

Related Activity

The FAA's Office of Security and Hazardous Materials is coordinating with the Office of Hazardous Materials Safety in the DOT's Pipeline and Hazardous Materials Safety Administration (PHMSA) to examine battery safety. More specifically, PHMSA is considering a rulemaking that is aimed at preventing short circuit, sparking, and heat from all batteries and battery-powered devices in transportation. No formal or official rulemaking has begun at the time this SFAR is being published.

Discussion of Comments

The NPRM leading to this final rule was published in the **Federal Register** on July 14, 2004. We set a 30-day comment period ending on August 13, 2004. The Air Transport Association (ATA) requested that we extend the comment period for an additional 60 days to allow more time to examine the proposal and submit appropriate comment. After reviewing the ATA's request, we determined that they misunderstood the proposal and that such a significant extension would unnecessarily delay the final decision on this rule. We extended the comment period an additional 15 days to allow additional time to review and analyse the proposal.

The new comment period closed on August 30, 2004. As of September 8, 2004, we had received about 2,270 comments. All comments submitted after the comment period closing date were considered in this final rule.

Support for this proposed SFAR was overwhelming. Of the 2,270 comments, 2,267 favored at least the spirit of our proposal. Commenters had many substantive and helpful comments that suggested changes to our original proposal. Many of the comments were used to draft our Final Rule, a product that benefits greatly from the thought and detail put into the comments.

A large majority of the comments in favor of our proposal were form letters organized by a number of interest groups supporting the SFAR. We also received approximately 40 letters with extensive substantive comments, including questions, comments, suggestions, and ideas. We are responding to both the suggestions found in the form letters, as well as the ideas and suggestions found in the 40 letters with extensive substantive comments.

We asked for comments on the following questions in the NPRM:

1. Should the aircraft operator be required to inform the user about the availability of electrical outlets suitable for the Airsep portable oxygen concentrator?

2. Should the user be required to carry batteries for the duration of the flight including reasonable delays if there are electrical outlets available on the flight?

3. Are the meanings of the terms ''anticipated delay'' and ''reasonable delay'' sufficiently clear?

Question 1. Use of Electrical Power

Potential travellers commented in support of the aircraft operator informing the travelling public of the availability of electrical outlets on board

aircraft. Potential travellers requiring oxygen therapy stated that other passengers routinely plug a laptop computer or other entertainment device into the aircraft's power supply, so a POC user should be given the same opportunity. Some commenters feel that a POC user should be given priority over all users of other types of portable electronic equipment.

In contrast, industry and air carrier comments (including American Trans Air and the Air Transport Association) strongly objected to informing passengers of the availability of electrical outlets to power a POC. These commenters stated that electrical outlets are not widely available on the aircraft and that a carrier cannot guarantee access to an outlet because outlets may not be available for a particular seat assignment or, aircraft without outlets may be substituted unexpectedly for aircraft with outlets. Additionally, these commenters noted that some electrical outlets are designed to shut off automatically if the aircraft experiences electrical overload conditions. Any of these scenarios would create a problem for a POC user that had planned on using the aircraft's electrical supply and had not brought an appropriate number of batteries. American Trans Air was concerned with passengers being allowed to plug anything into the ship's power because it could open a ''Pandora's Box.''

FAA Response: The FAA agrees that if aircraft operators obtain FAA authorization, access to the electrical power supply of the aircraft can be made available for a POC user, but it is not requiring the operator to inform the passenger about the availability of electrical outlets. There are too many variables that may change before the flight that could affect the availability of electrical outlets. If carriers wish to provide such information to potential POC users it is their choice to do so. The FAA does not have the authority under the Air Carrier Access Act to require such an action.

If, for example, an operator of a transport category airplane provides a passenger access to aircraft electrical power for use with a POC, the operator must ensure that the installation and cabling, up to the point where the passenger plugs in the POC, meets the airworthiness standards of 14 CFR 25.1301, 25.1309, 25.1353, and 25.1357. These sections ensure that the wiring and circuit protection are sufficient for the intended use. The sections also ensure that the POC will not negatively affect aircraft power.

In regard to the issue about giving POC users priority to use any available electrical outlets over people who are not using POCs, the Department of Transportation (DOT), under the Air Carrier Access Act, would have to assess whether the law requires a POC user to have such priority access.

Question 2 and 3. Number of Batteries in Carry-on To Address Anticipated or Reasonable Delay

In the NPRM we asked whether the user should be required to carry batteries for the duration of the flight, including enough to cover reasonable delays if there are electrical outlets available on the flight. We also asked whether the terms ''anticipated delay'' and ''reasonable delay'' were sufficiently clear to a user to enable them to make the decision as to how many batteries would be needed.

Most commenters felt that those terms were not sufficient to determine the number of batteries that would be necessary in the event of any type of delay. Some suggested we simply require enough batteries to cover 150% of the flight time. Airbus commented that the user should be responsible for carrying the appropriate number of batteries to cover for delays, even if there are electrical outlets available on the aircraft. Airbus specifically notes that the outlets can only serve as backup for the devices under certain conditions because they will not always be available, and can be limited in power rating (typically around 75 Watts).

FAA Response: The FAA does not believe that simply adding 150% to the scheduled flight time is adequate to cover the number of batteries that may be needed by an oxygen dependent passenger. Flight time in the Official Airline Guides, for example, only accounts for the usual time between aircraft pushback at the departure airport gate and the aircraft's arrival at the gate at the destination airport. It does not account for delays that occur after passengers are boarded at the departure gate; after pushback from the departure gate but before takeoff; during in-flight holding at the arrival airport awaiting landing clearance; as a result of flight to a diversion airport due to either adverse weather conditions at the planned destination airport or an aircraft emergency; and after landing at the planned destination airport. Scheduled travel time then would not appear, in our eyes, to account for all contingencies during travel. For example, time spent on the ground prior to departure and while awaiting arrival at a gate can easily exceed an hour. Weather delays commonly exceed an hour if the weather conditions at the departure or planned destination airports cause air traffic instrument flight rules aircraft separation criteria to be increased at peak airport departure and arrival times. Under the 150% flight time increase comment, a 2 hour flight would only require enough batteries to power the POC for 3 hours. Under that scenario, a weather delay of an hour coupled with normal ground time, could easily drain the battery power before the trip was completed.

The passenger's physician can help the passenger determine how much oxygen the patient may need on a flight. The physician, in the physician statement, can note whether the passenger needs oxygen for the entire air travel time, including ground and in-flight delays, or only portions of those times. It is then up to the user to carry the number of extra batteries necessary to cover the possible contingencies.

Generic Standard or Manufacturer Specific

Many commenters, including Inogen, Inc., the Paralyzed Veterans of America, National Home Oxygen Patients Association, and the American Thoracic Society, requested that we not limit POCs by specific brand or manufacturer. These commenters wanted a generic standard that would apply to different types of devices. Over 150 commenters, however, asked that if we did limit the POC by manufacturer we include the Inogen One POC in the SFAR. Overall, there was broad support for writing a rule that would provide standards for a manufacturer to meet in order to have an acceptable model of POC.

FAA Response: As noted in the NPRM, the FAA was reviewing the Inogen One POC and accompanying material at the time of the NPRM's publication. The FAA's review and evaluation had to be completed prior to determining whether the Inogen One POC would be eligible to be operated as a POC, as well as a portable electronic device for use onboard aircraft. Since the issuance of the NPRM, we have completed our review of the Inogen POC and we agree with commenters that the Inogen One device is functionally similar to the AirSep POC and should be included in the Final Rule. The FAA has determined that this device may be operated onboard aircraft, subject to certain conditions in the regulation, and the SFAR will include this device along with the Airsep Lifestyle POC.

We agree that future rulemaking should include generic standards that future POC's would be required to meet. Since this future rulemaking will require time to develop the standards, the FAA will proceed, in the interim, with this SFAR. This SFAR is the

quickest way to enable the use of these two devices by passengers who have a medical need to continue to receive oxygen therapy during their air travel. The FAA will create a generic standard for all POCs that will be the basis for a follow-on rulemaking that will amend 14 CFR permanently. This SFAR is intended to be the first step in allowing passenger-furnished POC devices to be used on aircraft.

Role of FAA and RSPA (Now PHMSA) in Determining a Material ''Hazardous''

Several commenters asked specifically about a statement we included in the NPRM that pertained to the review and approval process for devices that may be considered non-hazardous by RSPA (now PHMSA) and whether or not the FAA can overrule PHMSA on such a determination.

FAA Response: The two steps in the process, while related, are not exclusively connected to one another. A PHMSA determination that a medical oxygen device is not regulated as a hazardous material does not automatically qualify such a device as safe for use in air commerce. The FAA also must review and evaluate the device to determine if there are any additional safety concerns pertaining to the use of the product on board an aircraft. A ruling by the FAA that such a device cannot be carried on board an aircraft, however, does not mean that the device is a hazardous material under PHMSA's regulations in Title 49.

Requiring Airlines To Permit the Use of POCs

Another commenter requested that we ''require'' aircraft operators to allow passengers needing oxygen therapy to carry on and operate the POCs onboard aircraft. The NPRM only stated that operators may choose to allow passengers on oxygen therapy to carry on and operate the devices onboard their aircraft.

FAA Response: The FAA does not have the statutory authority under the Air Carrier Access Act to require air carriers to allow these devices to be carried or operated onboard their aircraft. That authority is granted only to the Department of Transportation (DOT). It is DOT's decision whether or not to designate these devices as assistive devices, and to require air carriers to allow the transport of these devices and, in conjunction with the FAA, require air carriers to allow passenger operation of these devices onboard aircraft. This SFAR will open the door for air carriers to take advantage of the new market available through passenger use of these devices.

Use of POCs During Takeoff and Landing and Passenger Movement in Flight

Commenters wanted to make sure that our rule allowed passengers using a POC to operate the device for the entirety of the flight if necessary. Many oxygen users' physicians may stipulate that there is a medical need for their patients to use a POC during the entire flight, including movement on the surface, takeoff, and landing. Movement on the surface, takeoff, and landing are times when the current regulations require that, among other things, medical oxygen equipment be properly stowed, and each person using the equipment to be seated at a seat location that does not restrict passenger access to, or use of, any required exit (emergency or regular), or the aisle(s) in the passenger compartment.

FAA Response: This final rule will allow passengers to use a POC during the flight, including movement on the surface, takeoff, and landing. Additionally, once passengers are allowed to move about the cabin of the aircraft, they will be allowed to carry a POC along with them. This allowance is specifically cited in the new Section 3(a)(6) in the regulatory text of this final rule.

A new section was also included in the regulatory text that requires the physician statement to include information on the extent to which the user must use the portable oxygen concentrator (*e.g.*, During takeoff and landing only, during the whole flight, only when needed, etc.)

Safety of Carrying Multiple Batteries

One commenter raised concerns about the safety of carrying multiple extra batteries in carry-on baggage to be used to power the POC.

FAA response: This commenter's concerns are shared by the FAA. We are adopting the requirement that passengers whose physician statement stipulates a medical need for extensive oxygen use must carry enough extra batteries to power the POC for the duration of time the passenger may be on board the aircraft.

Comments received in response to the NPRM stated that the battery life for the AirSep Lifestyle POC is approximately 50 minutes, while the Inogen One has a battery life of approximately 2 to 3 hours. Since the battery life for these devices is so short, it is likely that passengers using these devices may have to carry many extra batteries onboard the aircraft in order to comply with their physician's oxygen prescription. The number of extra batteries must be able to power the POC in the event the aircraft operator does not permit these devices to be powered by the aircraft electrical system, or the aircraft electrical system is inoperative or otherwise unusable.

Therefore, the FAA is including a new section in the SFAR. Section 3(b)(6) requires the user to ensure that all POC batteries carried onboard aircraft as carry-on baggage are protected from short-circuit problems, and are packaged in a manner that protects them from physical damage. Protection from short-circuit problems may be provided by batteries designed with recessed battery terminals or by packaging that keeps the battery terminals from contacting metal objects (including the battery terminals of other batteries). When a battery-powered oxygen concentrator is carried onboard aircraft as carry-on baggage and is not intended to be used during flight, the battery must be removed and packaged separately, unless the concentrator contains at least two effective protective features to prevent accidental operation and battery overheating during transport.

The passenger will be responsible for ensuring that all extra batteries carried in carry-on baggage are properly packaged, but we do not envision passengers packaging the batteries themselves.

A POC manufacturer may not be able to develop a product to meet the packaging standard in this SFAR by the time the rule becomes effective (30 days after publication). However, the battery packaging standard contained in the regulatory language of this SFAR must be met before the extra batteries will be allowed as carry-on baggage onboard the aircraft. Companies with experience meeting shipping standards will likely be able to assist a passenger to meet this standard.

We believe passengers can also arrange for the following entities to package extra POC batteries to meet the standard:

—Homecare providers;
—Airlines;
—Other entities specializing in small package shipments.

As for the POC itself, we anticipate the homecare provider would be able to prepare the device for transport.

There is a history of battery problems with other portable electronic devices when a battery is being charged during flight. We currently do not have data to establish a limit on the recharging of POC batteries during flight. Therefore, if the aircraft electrical system is available to recharge a POC battery, it is currently permissible to do so under this SFAR.

In the future, the FAA may consider developing a technical standard order (TSO) to reduce the risk of overcharging for certain types of rechargeable batteries in portable electronic devices that are carried in the aircraft passenger compartment.

Battery Backup for the POC in the Event of Failure

Some comments we received asked what sort of contingency or emergency precautions would be taken if a POC were to fail during the flight, or if battery power ran out during the flight. The American Association for Respiratory Care suggested that, if a POC malfunctions, the flight crew should provide the user access to supplemental oxygen from the emergency oxygen source. The National Home Oxygen Patients Association also supports the idea of consulting with the patient if a POC fails, and relying on the emergency medical oxygen that would be available if an airline-provided oxygen system were to fail. Access to the aircraft's emergency oxygen would eliminate the need to divert the flight in many instances.

FAA Response: We agree that the appropriate action, in case of aircraft electrical power or battery failure, would be to refer to the passenger's physician statement and consult with the passenger using the POC. The crewmember should determine, through the statement and discussion, the person's medical need for oxygen use and provide access to the aircraft's first aid oxygen equipment if necessary. However, it should be noted that only aircraft required to be operated under 14 CFR part 121 are required to be equipped with first aid oxygen equipment. We do not feel it is necessary to include this particular detail in this SFAR, but strongly encourage the aircraft operator to make the availability of first aid oxygen equipment clear to the passengers who may have a medical need for it. We also encourage passengers who have a medical need for lengthy periods of oxygen use to ensure that this equipment is available before arranging for a flight.

Application of RTCA/DO–160D, Section 21, Category M (Classified as a Medical-Portable Electronic Device)

We received comments with concern to section 3(a)(1) of the proposed rule that required the aircraft operator to ensure that a POC does not interfere with electrical, navigation, or communication equipment on which the device is being used. Several commenters felt that this requirement may mean that each aircraft operator had to test each device for every model of aircraft they are flying to see if it is safe. For instance, as the joint comment headed by the American Thoracic Society noted, the requirement would seem to mean that if U.S. Airways tested the POC device on a Boeing 747 and found that there was no interference, Delta Airlines would still have to test the same device on the same model of aircraft for themselves. The Air Transport Association echoed the question, and sought some answers about whether or not the FAA's Advisory Circular (AC) 91.21–1A would be applicable to a POC. If the POC were tested to the standard established for a medical-portable oxygen device (M–PED) contained in RTCA Document DO–160D, would that be acceptable to meet the requirement of section 3(a)(1) of the SFAR?

FAA Response: A POC, whether it is the Inogen One or the AirSep Lifestyle, is considered a medical-portable electronic device (M–PED), and thus is eligible to meet the standards contained in RTCA DO–160D. Both devices fall under the scope of AC 91.21–1A, and each manufacturer can test their device to the standard called for in the AC. It must be clear though that the requirement found in section 3(a)(1) remains applicable to the aircraft operator. If a POC manufacturer tests the device to meet the RTCA standard and shows that it meets the standard, the manufacturer may provide the positive testing results to the aircraft operator on the POC itself. The aircraft operator will have to be able to show that the device has been tested and meets the applicable standard regardless of the test method used.

If either the Inogen or AirSep POC have been tested to meet the RTCA standard found in AC 91.21–1A, and the test results are provided to, and verified by, the aircraft operator, no further testing by the aircraft operator would be required.

POC as Carry on Baggage

We received comments from several interested parties, including the American Association for Respiratory Care, the American Thoracic Society, the Pulmonary Hypertension Association, and others that requested we allow passengers to bring two carry-on bags if they are using a POC on the flight. Their recommendation would not include the POC itself as one of those carry-on items, only the regular carry-on baggage common for most travellers, and the extra batteries that will be necessary for each flight.

FAA Response: The FAA does not agree with the recommendations of the commenters. Because aircraft operators' aircraft passenger compartment configurations have differing capability to accommodate the safe stowage of different sizes and amounts of carry-on baggage, the FAA cannot simply establish a requirement in its regulations that, henceforth, aircraft operators subject, for example to the requirements of 14 CFR 121.589, must allow POC users to bring into the passenger compartment, two carry-on bags and the extra POC batteries in addition to their POC. The FAA's regulations pertaining to the carriage of carry-on baggage in passenger compartments of aircraft, 14 CFR 91.523, 91.525, 121.285, 121.589, 125.183, and 135.87, provide that no aircraft operator may allow the carriage of carry-on baggage on its aircraft unless the applicable requirements prescribed by those regulations are met.

The FAA plans to provide information about the size and weight of the POCs covered by this SFAR to aircraft operators. This information may cause certain operators to review their carry-on baggage programs to determine whether they may be able to accommodate the carriage of the POCs.

Liquid Oxygen Devices Onboard Aircraft

We received several comments, mostly from individual commenters—not from industry or interest groups, asking why we couldn't also allow passengers to use the Helios liquid oxygen device, or other devices using a liquid oxygen supply.

FAA Response: Liquid oxygen is classified as a hazardous material by the Department of Transportation's hazardous materials regulations (49 CFR, parts 100–185). Paragraph 175.85(a) of 49 CFR prohibits passengers from carrying hazardous materials in the cabin of the aircraft. The Office of Hazardous Materials Safety of the U.S. DOT Pipeline and Hazardous Materials Safety Administration (PHMSA) is the responsible office for this regulation. Those seeking change to or relief from this regulation should address their concerns to PHMSA. At this writing, we are aware that the manufacturer of the Helios portable liquid oxygen device is seeking an exemption from PHMSA to allow passengers to carry on the Helios device on passenger-carrying aircraft. If PHMSA issues an exemption to its regulations, the manufacturer of the Helios device still would need to petition the FAA for an exemption to the SFAR, or for an amendment to the SFAR to permit the use of this liquid

oxygen device on board aircraft. Existing FAA regulations (e.g., Sections 121.574(a)(2); 125.219; 135.91) restrict the use of liquid oxygen to those devices furnished by the aircraft operator itself.

Pilot in Command Notification

We received a comment from the National Home Oxygen Patients Association that asked us to clarify the section in the NPRM that required the aircraft operator to ensure that the pilot in command be apprised of a passenger using a POC. This section, section 3(a)(10) in the NPRM, read, ''The pilot in command must be apprised when a passenger is using a portable oxygen concentrator.'' The comment asked if this meant that the pilot was to be informed when a passenger brought a POC onboard the aircraft and intended to use it during the flight, or if the pilot was to be informed specifically when a POC is turned on and off. The comment goes on further to question why it is necessary to inform the pilot that the device is onboard at all, and whether or not the physician letter required by the NPRM is an appropriate notification to the aircraft operator.

FAA Response: The intent of this section, now section 3(a)(5) in this final rule, is to make sure that the pilot in command is informed that a POC has been brought on the aircraft and the passenger's physician statement states that the passenger has a medical need for oxygen for a substantial portion of the duration of the flight. It is necessary for the pilot in command to know this information because of the possibility the device will fail and the user may have a medical emergency requiring emergency action on the part of the flight crew. Also, if a POC is using the electrical power of the aircraft as its main power source, the pilot will benefit from the knowledge and be able to announce and inform users if the use of that power needs to be restricted during the flight.

The physician's statement is appropriate to inform the aircraft operator that a passenger is carrying a POC onboard the aircraft with the intent to use it. The requirement found in section 3(a)(5) of this SFAR addresses only what the aircraft operator must do when allowing the POCs onboard for a flight.

Ability To See and Hear a POC Alarm and React

Some commenters, including the National Home Oxygen Patients Association, recommended that we require the physician to determine whether a user is able to see and/or hear the alarm on a POC and respond appropriately. Others asked, with reference to this requirement in the NPRM, how the aircraft operator could appropriately ensure that a passenger would be able to meet the requirement to see and hear the alarms. Aircraft operators opposed the requirement that they be responsible for assessing the ability of a passenger to see and hear an alarm and react appropriately because they felt their employees are not qualified to make such an assessment.

FAA Response: In the NPRM, we proposed that the aircraft operator be responsible for ensuring that the passenger using a POC onboard the aircraft could see or hear the alarm if it activated on the device, and be able to respond to the alarm appropriately. We agree with the industry comments that said this requirement was too difficult for the aircraft operator to implement. We also agree with the commenters that such an assessment is more appropriately completed by the prescribing physician. We also agree with the National Home Oxygen Patients Association, and others, that this statement must be part of the required information in the physician statement in section 3(b)(3) of this SFAR. In addition to the information added to the physician statement in section 3(b)(3), the proposed requirement in section 3(a)(3) is adopted with modification in section 3(b)(1) of this SFAR.

Amend Proposal To Make Passenger Responsible for Complying With Certain Conditions

In the NPRM, we outlined specific conditions that the aircraft operator would be responsible for in order to allow a passenger to carry on and operate a POC onboard the aircraft. We received several comments from air carriers and groups representing air carriers that objected to many of the responsibilities placed on them under section 3(a) in the NPRM. Specifically, there was objection to each of the following conditions under section 3(a) beginning with (a) 2: Section 3. Operating requirements—

(a) The AirSep Lifestyle Portable Oxygen Concentrator unit may be used by a passenger on board an aircraft provided the operator ensures that the following conditions are satisfied:

* * * * *

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

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

* * * * *

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

* * * * *

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

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

FAA Response: In response to comments, we are amending the requirements placed on the operator and, instead, placing these requirements on the passenger. As a result, we are removing the requirements on aircraft operators proposed in section 3(a)(2), (3), (5), (8), and (9), and transferring some of those conditions to the passenger outlined in section (3)(b). See the FAA's response under the topic heading ''Ability to see and hear a POC alarm and react'' as discussed above.

We have expanded the section that requires the passenger to carry a physician statement to clarify what needs to be included in the statement. We would also like to make it clear that a new physician statement will not be necessary for each flight a passenger takes. A single physician statement that includes all of the information required in section 3(b)(3) can be used for all future flights.

Paperwork Reduction Act

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

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

in the rule were received and addressed in the Discussion of Comments above.

We estimate that an average of 44,500 physician statements would be filed annually. It is estimated to take 5 minutes, or 0.083 hours, to complete each written statement. Hence, the estimated annual hour burden for the first year, and over the next ten years, are estimated to be:

First Year: 0.083 hours × 400,000 = 33,200 hours.

Years 2–10: 0.083 hours × 5,000 = 415 hours.

Annual Hour Burden: .083 × 44,500 = 3,693.5 hours.

The average loaded hourly wage for a physician is $65.32. Thus, the estimated average annual cost of obtaining a physician's statement is estimated to be:

First Year: $65.32 × 33,200 = $2,168,624.

Years 2–10: $65.32 × 415 = $27,108.

Annual Cost Burden: $65.32 × 3,693.5 = $241,259.

We estimate that in a typical year, passengers affected by this final rule would make about 1,690,000 flights per year. On each flight either a flight attendant or a gate agent would notify the pilot in command that a POC would be in use during flight. We estimate that it will take five minutes for the flight attendant or gate agent, to notify the pilot in command, and one minute for the pilot to record it.

Annual Time for Flight Attendant/Gate Agent: .083 × 1,690,000 = 140,270 hours.

Annual Time for Pilot in Command: .017 × 1,690,000 = 28,730 hours.

The average loaded hourly wage rate for a Flight Attendant/Gate Agent is estimated to be $23.97, and the average loaded hourly wage rate for a pilot in command is estimated to be $121.56.

Annual Cost for Flight Attendant/Gate Agent: $23.97 × 140,270 = $3,362,272.

Annual Cost for Pilot in Command: $121.56 × 28,730 = $3,492,419.

Cost Summary

In summary, this final rule is estimated to have a total hour burden of 2,135,000 hours, and estimated total costs of $70,959,901, which correlates to an estimated annual burden of 213,500 hours, and an estimated annual cost of $7,095,950.

SUMMARY OF PAPERWORK COSTS

Action	Total hours	Total costs	Annual hours	Annual cost
Obtaining Physician's Statement	36,935	$2,412,594	3,693.5	$241,259
Notifying PIC	1,690,000	68,546,907	169,000	6,854,691
Totals	1,726,935	70,959,501	172,693.5	7,095,950

Please note that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB Control Number associated with this collection is 2120–0702.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

Economic Assessment, Regulatory Flexibility Determination, Trade Impact Assessment, and Unfunded Mandates Assessment

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, to 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).

In conducting these analyses, FAA has determined this rule: (1) Has benefits that justify its costs, is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is not ''significant'' as defined in DOT's Regulatory Policies and Procedures; (2) will not have a significant economic impact on a substantial number of small entities; (3) will not affect international trade; and does not impose an unfunded mandate on state, local, or tribal governments, or on the private sector. These analyses, available in the docket, are summarized below.

Costs and Benefits of the Rule

The rule is estimated to cost about $79.9 million (or $58.1 million discounted) over the next ten years. The rule will also result in potential cost savings because passengers will have an option of using a POC onboard an airplane other than renting oxygen from the carrier.

Who Will Be Potentially Affected by the Rule

The rule will affect people who use POCs on airplanes.

Our Cost Assumptions

Covers the years 2006–2015.

All monetary values are expressed in 2004 dollars.

Discount rate—7%.

The packaging for batteries costs an average of $10, and holds up to 3 batteries.

Users of the AirSep POC will purchase three packages, and users of the Inogen POC will purchase one package.

Each effected passenger makes at least one round trip flight, per year, with at least one stop in each direction for a total of four separate flights.

Final Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle,

the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. 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 proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This rule does not affect small businesses, since it does not require small entities to allow passengers to use POCs, rather it has a direct effect on individuals. Accordingly, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Federal Aviation Administration certifies that this final rule will not have a significant impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreements Act of 1979 prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards.

In accordance with the statute, the FAA has assessed the potential affect of this final rule and has determined that it will have only a domestic impact and therefore it will not affect on any trade-sensitive activity.

Unfunded Mandates Reform Act Assessment

The Unfunded Mandates Reform Act of 1995 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $120.7 million in lieu of $100 million.

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

Executive Order 13132, Federalism

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

Environmental Analysis

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

Regulations That Significantly Affect Energy Supply, Distribution, or Use

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

List of Subjects

14 CFR Part 11

Administrative practice and procedure, Reporting and recordkeeping requirements.

14 CFR Part 121

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

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends part 11 of Title 14, Code of Federal Regulations, of Title 14, Code of Federal Regulations, and adds SFAR No. 106 to Chapter II of Title 14, Code of Federal Regulations, as follows:

PART 11—GENERAL RULEMAKING PROCEDURES

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

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

Subpart B—Paperwork Reduction Act Control Numbers

■ 2. Amend the table in § 11.201(b) by revising the entry for part 121 to read as follows:

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

* * * * *

(b) * * *

14 CFR part or section identified and described	Current OMB Control No.
* * * * * * *	
Part 121	2120–0008, 2120–0028, 2120–0535, 2120–0571, 2120–0600, 2120–0606, 2120–0614, 2120–0616, 2120–0631, 2120–0651, 2120–0653, 2120–0691, 2120–0702
* * * * * * *	

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

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

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

■ 4. Special Federal Aviation Regulation No. 106 is added to read as follows:

SPECIAL FEDERAL AVIATION REGULATON NO. 106. RULES FOR USE OF PORTABLE OXYGEN CONCENTRATOR SYSTEMS ON BOARD AIRCRAFT.

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

Section 2. *Definitions*—For the purposes of this SFAR the following definitions apply: Portable Oxygen Concentrator: means the AirSep Lifestyle or *Inogen One* Portable Oxygen Concentrator medical device units as long as those medical devices units: (1) Do not contain hazardous materials as determined by the Pipeline and Hazardous Materials Safety Administration; (2) are also regulated by the Food and Drug Administration; (3) provide oxygen therapy through pulse technology; and (4) assist a user of medical oxygen under a doctor's care. These units perform by separating oxygen from nitrogen and other gases contained in ambient air and dispensing it in concentrated form to the user.

Section 3. *Operating requirements*—

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

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

(2) No smoking or open flame is permitted within 10 feet of any seat row where a person is using a portable oxygen concentrator.

(3) During movement on the surface, takeoff, and landing, the unit must:

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

(ii) 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;

(4) No person using a portable oxygen concentrator is permitted to sit in an exit row;

(5) The pilot in command must be apprised whenever a passenger brings and intends to use a portable oxygen concentrator on board the aircraft and the pilot in command must be informed about the contents of the physician's written statement (as required in Section 3(b)(3) of this SFAR), including the magnitude and nature of the passenger's oxygen needs.

(6) 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.

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

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

(2) The user must ensure that the portable oxygen concentrator 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;

(3) The user must inform the aircraft operator that he or she intends to use a portable oxygen concentrator on board the aircraft and must allow the crew of the aircraft to review the contents of the physician's statement. The user must have a written statement, to be kept in that person's possession, signed by a licensed physician that:

(i) 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;

(ii) States whether or not oxygen use is medically necessary for all or a portion of the duration of the trip; and

(iii) Specifies the maximum oxygen flow rate corresponding to the pressure in the cabin of the aircraft under normal operating conditions.

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

(5) The user, whose physician statement specifies the duration of oxygen use, must obtain from the aircraft operator, or by other means, the duration of the planned flight. The user must carry on the flight a sufficient number of batteries to power the device for the duration of the oxygen use specified in the user's physician statement, including a conservative estimate of any unanticipated delays; and

(6) The user must ensure that all portable oxygen concentrator batteries carried onboard 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 oxygen concentrator is carried onboard 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 concentrator contains at least two effective protective features to prevent accidental operation during transport.

Section 4. *Expiration Date*—This SFAR No. 106 will remain in effect until further notice.

* * * * *

Issued in Washington, DC, on July 1, 2005.

Marion C. Blakey,

Administrator.

[FR Doc. 05–13664 Filed 7–11–05; 8:45 am]

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