

**BEFORE THE
DEPARTMENT OF TRANSPORTATION
OFFICE OF THE SECRETARY**

In the Matter of

**Nondiscrimination on the Basis
of Disability in Air Travel – Medical
Oxygen and Portable Respiration
Assistive Devices**

Docket OST-2005-22298

14 CFR Part 382

IATA, the International Air Transport Association, and its Members¹ are fully committed to the safe air transport of passengers with disabilities on the basis of nondiscrimination, with dignity and with full rights as passengers. IATA is therefore pleased to have an opportunity to respond to the Department's Notice of Proposed Rulemaking (NPRM), 70 Fed Reg. 53108 (Sept. 7, 2005), 70 Fed. Reg. 61241 (Oct. 21, 2005).²

The Department has issued this Medical Oxygen NPRM, while its related and more basic rulemaking on non-discrimination on the basis of disability in air travel remains pending. The Department's underlying rulemaking with respect to Part 382 (Docket OST-2004-19482, 69 Fed. Reg. 64364 (Nov. 4, 2004)) (hereinafter the "Basic Part 382 NPRM") "does not contain any proposed regulatory changes relating to the carriage and use of medical oxygen by

¹ IATA is the association of the world's international airlines. It brings together 261 airlines, including the world's largest. Flights by IATA airlines comprise more than 95 percent of all international scheduled air traffic.

² The layering of this new NPRM on top of the currently pending Part 382 rulemaking in Docket 19482 is unfortunate because it introduces extra complexity and possible confusion to a process that is already quite complicated on its own. (Just the renumbering of the regulations proposed last year required inclusion of a conversion chart to assist those studying and commenting on the proposal. See 69 Fed. Reg. at 64376.) As the Department notes in this NPRM, it has amended its rule on non-discrimination on the basis of disability in air travel ten times since it was first adopted in 1990. See 70 Fed. Reg. at 53109. Because these rulemakings have often proved lengthy and complex, *e.g.*, Docket 45657, logic would dictate that the Department should seek to reduce complexity and streamline the process rather than commencing an overlapping proceeding.

passengers with disabilities aboard commercial flights.” (70 Fed. Reg. at 53109). Voluminous comments, currently numbering almost 1,300, have been submitted in Docket 19482. The Department states that it intends to “ultimately merge” that rulemaking, which has obviously engendered keen interest and extensive comment, with this new rulemaking, which addresses a topic that features highly technical and sensitive safety issues, rapidly evolving technology and end user products and financial obligations that the Department itself acknowledges are “costly” to the industry. 70 Fed. Reg. at 53115.

The Department states that its reasons for opening a separate rulemaking in a separate docket are related to: 1) “complaints from consumers regarding the lack of accommodations in air travel for passengers who use medical oxygen”; 2) technological advances in oxygen-delivery systems; and 3) passenger complaints that use of respirators and ventilators onboard has been limited because “carriers were concerned about possible electromagnetic interference (EMI) with aircraft navigation and communication systems.” 70 Fed. Reg. at 53110.

The Department also notes that “the instant [medical oxygen] NPRM applies to foreign air carriers in nearly the same manner as proposed in the November 4, 2004 Foreign Air Carrier NPRM,” and that “[t]o the extent that individuals have already submitted comments regarding the extension of Part 382 to foreign carriers in response to the November 4, 2004 Foreign Air Carrier NPRM, those comments will be considered with regard to the final rule issued as a result of the instant NPRM.”

Notwithstanding this assurance of the Department, given the subject matter, the scope of the proposal and the extremely detrimental effect this new NPRM would have on the industry – and the travelling public -- if adopted as proposed, IATA must once again express its extraterritoriality-based objections to

the entire scheme the Department is proposing. As it did in its comments on the Basic Part 382 NPRM, IATA again suggests that the Department:

- choose international cooperation rather than unilateralism;
- acknowledge jurisdictional limits, as a matter of both law and comity, and adopt a policy that gives due consideration to the merits of international harmonization;
- take into account the significant differences between domestic and international air transport;
- reconsider its economic analysis, acknowledge the excessive expenses and undue burden this would impose on the industry, withdraw this proposal and begin the process anew;
- consider a reasonable alternative that is not overly burdensome and does not ignore its mandates under AIR-21, the ACAA and the APA³;
- acknowledge the dangerous goods (hazardous materials) implications, and thus the safety aspects of its proposal; and
- acknowledge that this proposal improperly puts airlines in the position of providing medical services, rather than in the business of accommodating disabilities as part of the provision of air transportation services.

IATA submits that such changes will enable DOT to better achieve the goal of transport of disabled individuals on a non-discriminatory basis, with dignity and with full rights as passengers.

As with the Basic Part 382 NPRM, this proposal, as set forth in the NPRM of September 7, 2005, presents a number of serious issues that involve both international and domestic legal standards and important international policies of comity and reciprocity. Of particular concern are the facts that the NPRM prescribes specific arrangements for disabled passengers within foreign countries and sets standards on how non-U.S. carriers have to treat disabled passengers while their aircraft are within the jurisdiction of other sovereigns. It also proposes an unprecedented testing obligation on all carriers and, like the provisions of the Basic

³ Section 707 of AIR-21 (The Wendell H. Form Aviation Investment and Reform Act for the 21st Century (April 5, 2000) amended ACAA, the Air Carrier Access Act. The Administrative Procedure Act (APA), 5 U.S.C. § 553, sets the standards for rulemaking by federal agencies.

Part 382 NPRM, imposes that requirement worldwide, with no consideration of the nationality of the carrier.

As IATA noted in its comments of March 4, 2005 in Docket 19482 (hereinafter “IATA March 4 Comments”), the Department has not even confined itself to proposing to regulate flights to and from the United States; it is also proposing to regulate aircraft operations in foreign locations, putting the onus for meeting these impossible standards on the carriers – both U.S. and foreign. As the IATA March 4 Comments predicted, and as the submissions from foreign governments and foreign government organizations in Docket 19482 have demonstrated, proceeding in this unilateral fashion is viewed as an attempt by the United States to set a universal standard that undermines the fundamental international principle that accords each country the right to exercise jurisdiction over its sovereign airspace, and the corollary principle that airlines should be regulated primarily by their home governments.

The Department must correct this fundamental error, and properly apply the provisions of § 707 of AIR-21, in which the Congress directed the Department to act in accordance with its international agreements, and take into account the applicable laws and requirements of foreign countries. As it did in the IATA March 4 Comments, IATA asks that the Department adjust its approach to give due consideration to the very serious issues of international law and comity involved in this rulemaking. See Section I (pages 3-17), and pages 20-21 and 23-26 of the IATA March 4 Comments.

REGULATORY EVALUATION

IATA’s review of this NPRM, like its review of the Basic Part 382 NPRM, has led to the conclusion that the Department has erred by overestimating the benefits and underestimating the costs. Specifically, IATA raises the following objections to the Regulatory Evaluation:

- It contains several discrepancies that lead to a significant overestimation of the benefits associated with the proposal; and
- It takes little or no account of where the burden of costs and benefits actually lie. Airlines face all of the costs, but the real benefits actually lie elsewhere. It also gives no consideration to the impact on individual airlines, which will be excessively burdened by the costs.

With respect to the benefits analysis and IATA's first objection to the Regulatory Evaluation, there is an inconsistency between the treatment of onboard medical oxygen provision on the cost and the benefits side. The cost of providing gaseous medical oxygen equipment is included in full on the cost side, accounting for \$122.1m (46%) of the low-end total cost estimate and \$418.0 (72%) of the high-end total cost estimate. Yet, on the benefits side, despite the costs of provision being included in full, there is a sizeable benefit for passengers also included, in terms of airline rental charges avoided for their current oxygen provision. **This is double-counting and should not be included.** A proper evaluation must follow the same logic used on the cost side, where the loss of current fees for airlines is offset by the cost of no longer providing that type of service. In that case, the benefit of passengers no longer having to pay fees must be totally offset by the loss of fees for airlines. At a stroke, this would remove \$166.5m (27%) of the estimated low-case benefits and \$221.9m (15%) of the high-case benefits.

But IATA also has concerns over the size of the benefits estimated from higher ticket revenues. Given that the requirement for medical oxygen arises from a medical condition rather than a physical disability, IATA questions whether any demand uplift would even come near the low-case estimate. Potential passengers would still face significant medical constraints on their ability to travel, even with appropriate facilities provided by airlines. As such, the high-end benefits estimate is wholly unrealistic, while the low-end scenario is unduly optimistic. Looked at another way, if such untapped market potential exists, it would indeed be reasonable to

expect airlines – which operate an extremely competitive environment – to have already sought a competitive market advantage by providing additional facilities for medical oxygen users.

With respect to IATA's second objection, the evaluation ignores the important issue of where the burden of the costs and the share of the benefits will lie. Airlines are facing all of the costs – including the significant cost of free provision of medical oxygen, which is certainly not expected of Amtrak or the Washington Metro when medical oxygen users travel by train or subway, or even of Wal-Mart when medical oxygen users patronize its stores. Yet, as discussed above, 27% of the low case benefits and 15% of the high-case benefits are not only erroneously included, but also are not received by the airlines.

In addition, there are a number of free-riders who are not considered within the evaluation. For example, medical oxygen equipment manufacturers receive significant benefits from higher demand without facing any costs. Because airlines will absorb all the costs under the proposal, medical insurance providers would benefit every time an insured user of medical oxygen travels by air. *These* are the sectors that gain most of the benefits from the proposal, and the evaluation fails to take them into account. In order to achieve greater efficiency and equity, these should also be the sectors that bear most of the costs of the proposal. Moreover, the evaluation takes no account of how the fixed costs of testing will affect individual airlines. Nor does it take account of how the loss of staff for training purposes can significantly affect airline operations.

The shortcomings of the conclusion of the Regulatory Evaluation are thrown into sharp perspective when compared to the evidence adduced in a recent decision by the Canadian Transportation Agency, in which Air Canada demonstrated that even imposing a fee “set at a level aimed at recovering the carrier's cost of providing the [oxygen] service without making a profit, in fact in 2000 these fees were

insufficient by \$250,000(CDN) to cover the costs of the provision of oxygen service.”
CTA Decision No. 720-AT-A 2005 at 48 (Dec. 13, 2005).

A basic tenet of DOT regulations is that they “may not impose ‘undue financial or administrative burdens.’” 55 Fed. Reg. 8008 (Mar. 6, 1990). See also *APTA v. Lewis*, 655 F.2d 272 (D.C. Cir. 1981) and *Southeastern Community College v. Davis*, 442 U.S. 392, 413 (1979). But here the Department’s conclusion that this NPRM provides net benefits to the carriers is fatally flawed, and the Department itself acknowledges that under any circumstances its proposal is “costly.” This NPRM does *not* strike the “reasonable balance” between the disability groups and the carriers. *Id*⁴

IATA submits that there are so many serious questions about the nature and the cost of the services this proposal would mandate that the Department essentially needs to “start over.” IATA suggests that the Department withdraw this NPRM and supports the call of the ATA that the Department, at minimum, issue a Supplemental NPRM in this matter.⁵

SECTION BY SECTION ANALYSIS

IATA includes here comments on particular proposed sections and particular aspects of those proposals as received from its Members.

⁴ In fact, as noted above, there is no balance, much less a reasonable balance – airlines are facing *all* the costs. Moreover, also as noted below, there is a legitimate concern with respect to whether providing “*medical oxygen*” is indeed an accommodation or rather what its name says it is – a *medical service*.

⁵ When the FAA approved the Air Sep and Inogen POCs for use onboard aircraft, it discussed the rapidly developing technological advances with respect to such devices, as well as its own reluctance, due to the unpredictability of the course of those technological advances, to commence further rulemakings and run the risk of “prematurely develop[ing] standards that have the effect of stifling new technology.” 70 Fed. Reg. at 40157. The Department should heed the wisdom of the FAA. Indeed, further consultation and coordination with the FAA, PHMSA (Pipeline and Hazardous Materials Safety Administration, formerly RSPA, the Research and Special Programs Administration) and TSA, should be undertaken.

**SECTION 382.3:
WHAT DO THE TERMS IN THIS PART MEAN?**

As noted in the IATA March 4 Comments in Docket 19482, IATA's Medical Advisory Group (MAG)⁶ believes that the Basic Part 382 NPRM erroneously relies on Part 382's definition of "individual with disability," which regards disabilities and medical conditions as one and the same.⁷ See comments on proposed § 382.4 (IATA March 4 Comments at 21-23), and §§ 382.25-382.29 (*Id.* at 35-41). This fundamental error has significant consequences in the medical oxygen context.

Due to the principles of altitude physiology,⁸ individuals on long-term oxygen therapy can be adversely affected by the flight environment; they are properly regarded as having a medical condition rather than a disability.⁹ Providing medical oxygen is the job of physicians, and medical oxygen, as the NPRM notes (70 Fed. Reg. at 53115) is a *physician prescribed medicine*.¹⁰

⁶ The MAG is a Special IATA Committee of the officials of ten Member airlines and the IATA Medical Advisor, who specialize in aviation medicine and occupational health. The group advises IATA and the air carrier community on health issues related to travel and liaises with other related organizations, such as the World Health Organization (WHO) and the International Civil Aviation Organization (ICAO), on medical and cabin health matters.

⁷ For example, the definition makes no distinction between those suffering from heart disease and those who are visually impaired. From a medical standpoint, these two types of disability are very different. The air transportation issues of those with chronic disabilities are usually related to logistics, such as special communications devices, special announcements, special seats, etc. The air transportation issues of those with acute illnesses are medical in nature, *i.e.* it is the nature of the illness that puts the passenger at risk of not completing the flight without acute care or diversion.

⁸ The IATA Medical Manual states, at 6.1.2, *General Guidelines for Medical Clearance*, that "medical clearance is required by the airline's medical department if the passenger has a medical condition which may be adversely affected by the flight environment." The IATA Medical Manual is produced in consultation with the IATA Medical Advisory Group and provides detailed guidelines relating to medical issues that affect air carrier administration and operations, specifically with regard to public health, aviation medicine, occupational health and travel medicine.

⁹ Those who need medical oxygen need it for a *medical* condition, which may be adversely affected the flight environment. Without oxygen their lives are at risk, with even normal flight operations posing risks. This distinguishes them from passengers with limited mobility due to injury or congenital condition, passengers who require some accommodation when travelling, and whose lives are not at risk during the normal course of flight operations.

¹⁰ The same is true in other countries. For example, in the United Kingdom, medical oxygen provided to long term patients is classified as a medicinal product under the Medicines Act 1968, is

Providing medical oxygen is an activity that is medical in nature.¹¹ As such it should fall outside the ambit of Part 382.¹² It is unreasonable to place this obligation on the carriers, not only for the costs but also because it forces airlines into medical activities whether or not they wish to assume the complexities, risks and liabilities entailed.

SECTION 382.133:

WHAT ARE THE REQUIREMENTS CONCERNING THE EVALUATION AND USE OF PASSENGER-OWNED ELECTRONIC DEVICES THAT ASSIST PASSENGERS WITH RESPIRATION IN THE CABIN DURING FLIGHT AND THAT DO NOT CONTAIN HAZARDOUS MATERIALS?

Types of Portable Respiration-Related Assistive Devices Covered

The levels of quality assurance that must be achieved before a commercial aviation device is certified for use in flight are extremely high.¹³ It is such stringent testing that enables only types of devices to be tested as opposed to testing each individual device.¹⁴ The multiple certification of such devices for

regulated by the Medicines Control Agency and has to be prescribed. In Brazil RBHA 121.574 and pending IAC 158-1001 involve physicians in the medical oxygen onboard process.

¹¹ Carriers may require a medical certificate for a passenger “who needs medical oxygen during a flight.” 14 CFR § 382.53 (retained in proposed § 382.23 of the Basic Part 382 NPRM).

¹² It is thus, as a medical service, distinguishable from disability-related services, *not* distinguishable from “other disability-related” services.” The unreasonable novelty of the Department’s analysis is evident upon an examination of 49 CFR § 175.10, which allows airlines, despite the general Part 175 prohibition of transportation of “hazmats” by air, to choose to carry passengers who, as patients, require special devices such as battery powered wheelchairs, compressed gas cylinders for the operation of mechanical limbs, etc. Airlines are not required to provide these “hazmat” items, just as they are not required to provide the medical devices, such as pacemakers, that are exempted from the prohibitions of 14 CFR § 91.21.

¹³ The paramount importance of safety to aviation and to aviation regulators and its relationship to materials used in or on aircraft and to items carried onboard (in either the cabin or the hold) is evidenced by the significance the FAA has placed on detecting and eliminating counterfeit aircraft parts. See, e.g., 14 CFR §§ 21.125, 21.145, 21.303, 21.305, 21.500, 21.502 and 21.605, FAA Advisory Circulars 21-29B and 20-62D and the FAA’s description of its Safety Hotline facility for Detecting and Reporting Unsuspected Unapproved Parts: http://www.asy.faa.gov/safety_products/unapprovedparts.htm.

This concern for the safety of items carried onboard is also evidenced by the RSPA/PHMSA’s ongoing rulemaking in Docket RSPA-04-17664 with respect to the transportation of compressed oxygen, other oxidizing gases and chemical oxygen generators.

¹⁴ Devices that are not developed specifically for commercial aviation use are simply not subject to such testing and are not conformity controlled. Under the proposal of the NPRM there could be no guarantee (and no obligation on the part of the manufacturers) that two individual respiration assistive

use in flight proposed in this NPRM is therefore unworkable. Novel approaches of the kind proposed here are simply not appropriate when safety is the primary concern.

In addition, commercial aviation equipment and devices used on aircraft are subject, by law, to regular and stringent maintenance requirements. The same cannot be said of personally-owned respiration assistive devices, which as discussed more fully below, are by their very nature hazardous materials that are allowed onboard aircraft only subject to special exceptions from the rules that govern the transport of dangerous goods. Under the scheme proposed in this NPRM, carriers would not be able to ensure that an individual device is in good working order. The potential consequences of the failure or the malfunction of such a device during the course of a flight that could be as long as 18 hours in duration are obvious.¹⁵

It is because of the issues outlined above that the carriers that have chosen to allow the use of passenger-owned devices onboard have done so only in very specific situations and only under carefully prescribed conditions.

Typically, airlines require that such devices be certified as safe to use onboard, be clearly labelled by the manufacturer as being for medical purposes and be battery-operated. Carriers should be allowed to retain the freedom to make this

devices are of equal quality simply because they consist of the same parts bearing the same part numbers.

¹⁵ In a practical sense, in the event of the malfunction of an oxygen device, the aircraft would most likely be forced to make an emergency diversion, which would entail serious financial and operational consequences to the airline and the passengers. Indeed, as a worst-case scenario, a medical diversion on an ultra long-haul journey could escalate the potential costs to the air carrier to over \$100,000US, just in operational terms, and cause untold disruptions to the passengers, who under various legal regimes, might seek compensation for damages caused by such disruptions. As the FAA has acknowledged, the alternative of providing the medical oxygen-using passenger with the aircraft's first aid oxygen may not always be sufficient, 70 Fed. Reg. at 40160. In terms of more serious consequences as evidenced by the ValuJet crash, see 69 Fed. Reg. 25470, and the tragic series of events outlined in the RSPA sponsored December 1999 report *Threat Assessment of Hazardous Materials Transportation in Aircraft Cargo Compartments* (see pages 105-06), the liability issues are virtually beyond comprehension.

choice, deciding on an individual basis if they can achieve a competitive advantage by accepting passenger-owned devices on board. Such a triumph of market forces over unnecessary regulation is surely the hallmark – and the aim -- of deregulation. This was certainly the view taken by the FAA, which noted that its approval of the Air Sep and Inogen products for use on board in SFAR No. 106 “will open the door for air carriers to take advantage of the new market available through passenger use of these devices.” 70 Fed. Reg. at 40159.

Proposed Testing Requirements

Placing the obligation of testing portable respiration assistive devices on air carriers is impractical and overly burdensome in any circumstances but is most particularly so, and is indeed financially irresponsible, given the current state of the airline industry. Unfortunately, this NPRM fails to propose any involvement for those likely to gain the most from portable respiratory assistive devices being permitted in flight, namely the manufacturers of such devices. The manufacturers clearly stand to enjoy the largest financial benefit in this whole equation and adding an extra feature (approval for use onboard) to their specifications could also give them a competitive edge. Placing the testing obligations on the manufacturer would also share the responsibility more equitably because each manufacturer would only be responsible for its own models, whereas the NPRM proposes to make the air carriers responsible for all models, which obviously multiplies the cost. In short, the Department should place such burden where it would have the least negative impact and where in fact it could have a positive impact.¹⁶

¹⁶ Moreover, the international implications of proposed § 382.133(b) are staggering – in terms of the broad sweep of its extraterritorial implications. IATA has already reiterated the objections it made on these grounds in the IATA March 4 Comments on the Basic Part 382 NPRM.

The Department should take note of how long the FAA took to certify the Air Sep Lifestyle and Inogen One POCs. The aviation safety agency of the world's greatest aviation power, an agency with specialized expertise, took more than a year to complete tests on just two devices.¹⁷ If air carriers were required to conduct testing as proposed by the NPRM, the simple formula of number of device types multiplied by number of affected air carriers multiplied by number of aircraft types operated by those air carriers provides a clear and simple indication of the logistical and financial impossibility of this proposal.¹⁸ This is all the much more so given the speed with which technology advances. The Department appears to have failed to consider the fact that a continuous stream of new products can be expected notwithstanding its citation of technological advances in oxygen delivery systems as its second reason for initiating this special rulemaking and notwithstanding the circumstances of the FAA's clearance of the Air Sep Lifestyle and Inogen One POCs. See 70 Fed. Reg. at 53109; see also 70 Fed. Reg. at 40157.

If air carriers were forced to conduct all of the testing proposed by the Department, there is no guarantee that all air carriers would implement testing procedures that would employ the same methods and standards. For all of the safety and standardization reasons discussed above, testing conformity, which should be the goal, could only be guaranteed if the responsibility for conducting the testing were placed with a more limited number of entities, and, in the international area, it could only be guaranteed pursuant to an international

¹⁷ The FAA process to approve use of the Air Sep and Inogen products onboard aircraft, which was subsequent to approval of the POC medical oxygen technology by the FDA, took at least one full year. The FAA issued the NPRM on July 14, 2004 (69 Fed. Reg. 42324) and issued the Final Rule on July 12, 2005 (70 Fed. Reg. 40156) for effect August 11, 2005. The government should not impose on carriers a timeframe that it cannot match itself. A one year timeframe would be appropriate.

¹⁸ The industry believes that each test of each device for each aircraft type could easily reach five figures, with estimates ranging between \$10,000 and \$20,000US.

agreement by sovereigns. IATA therefore suggests that the Department pursue its interest in streamlining the testing requirement by involving aircraft manufacturers, 70 Fed. Reg. at 53111, presumably working with the manufacturers of the devices themselves, or rely on the FAA, following the process that resulted in SFAR No. 106. IATA also suggests that the Department consider carefully the proposal made by the Air Transport Association that the FAA (using an RTCA standard) define the testing standards and require the manufacturers of the devices to conduct tests, and the ATA suggestion that the Department's Office of the Secretary and Federal Aviation Administration adopt a labelling requirement for the oxygen delivery systems. This would offer a neutral and workable solution and has the advantage of possible utility in seeking agreement on an international standard. Using the FAA would have the advantage of a government-authorized approval process, which the U.S. could seek to have adopted, endorsed or recognized as valid by other sovereigns. There is also the possibility of an international organization becoming involved in a harmonized, internationalized approval process. Moreover, the FAA itself has indicated that it believes that further individual endorsements should be deferred, in light of the technological changes and advances in this technology. This highlights the fundamental flaw in the Department's scheme – and, as noted above -- IATA agrees with the suggestion of ATA that the Department avoid a rush to a Final Rule during what is obviously a period of change and rapid advances in the field of personal oxygen delivery systems. Withdrawal of this NPRM, or, at a minimum, issuance of an SNPRM, would be the better course.

Time Limits for Testing and Acceptance of a Device

IATA has a grave concern regarding the Department's proposal that air carriers have only 30 days from the date of a positive determination to implement

procedures to permit a device's use. In addition, the problems with "one time" testing – lack of regular checking and no assurance of ongoing compliance or safety – have been noted above. If substantial modifications to particular aircraft were required, 30 days would not even come close to allowing enough time.¹⁹

The Department should also be mindful of the financial and logistical implications of testing under "applicable foreign safety rules." Language barriers and differing medical practices could result in further delays in completing the testing of devices -- and the longer the delays, the greater the financial disadvantages to air carriers, and the longer the wait for passengers wishing to use oxygen onboard. The reasonable remedy is the standardization and international harmonization urged by IATA and numerous other commenters in this Docket and in the Docket for the Basic Part 382 NPRM.

Requirements regarding use of Respiratory Assistive Devices

The basic regulatory standards that are the essential background for this discussion are those related to the prohibition on the use of portable electronic devices during takeoff and landing and the requirements for secure cabin stowage. Other than the products specially authorized by the FAA in SFAR No. 106 (70 Fed. Reg. 40156 (July 12, 2005)), and the inaccessible devices such as hearing aids and pacemakers excepted by 14 CFR § 91.21(b), it is universally accepted that portable electronic devices must be turned off during take-off and landing in order that they do not interfere with an aircraft's navigation or communications systems. See, e.g., 14 CFR § 91.21 and FAA Advisory Circular No. 91.21-1A. The secure stowage of all baggage and cargo carried onboard is another universal requirement. See, e.g., 14 CFR 121.589.

¹⁹ The costs, too, are burdensome. Estimates for adding an electrical outlet to a typical midrange aircraft range from \$400,000-\$600,000US.

The relevant international standards in the ICAO TIs (Part 1, Chapter 1.1.3), and in turn the IATA DGR (Section 1.2.3)²⁰ will be amended effective 1 January 2007, to revise their coverage of goods carried on an aircraft for the purpose of providing medical aid to a patient during flight. The amended TIs will incorporate a number of additional provisions to assure air safety and to require the approval of the air operators.

- Hazardous materials for the purpose of providing medical aid may only be taken on-board with the approval of the aircraft operator
- The hazardous materials in question must be under the control of trained personnel when they are in use on the aircraft.

Provision must be made to stow and secure hazardous materials during take-off and landing and at all other times when deemed necessary by the pilot-in-command.

Thus, only if the testing of an onboard device confirms that it is safe for all phases of flight and can be properly stowed, can the questions of this section even come into play.

Passenger Information

While the principle of maintaining centralized lists of acceptable devices is sound, there are practical, legal and operational issues with the scheme the

²⁰ Standards related to the carriage of hazardous materials are set out in an ICAO document entitled "The Technical Instructions for the Safe Transport of Dangerous Goods by Air" (the "TIs"). The ICAO Technical Instructions came into effect in 1983 as advisory material and into legal force in 1984. The TIs have legal effect by virtue of Annex 18 to the Chicago Convention. Annex 18 and its associated TIs apply as mandatory requirements for international operations of civil aircraft. In addition, the Annex recommends that States comply with the Annex and the TIs for domestic civil aircraft operations. The ICAO TIs, as the legal requirements applicable to the international transport of dangerous goods by air, are reflected in the IATA Dangerous Goods Regulations (DGR). The U.K. Air Navigation (Dangerous Goods) Regulations 2002 reference the ICAO Technical Instructions. In India, it is the Aircraft Rules (Carriage of Dangerous Goods 2003), in Australia, Civil Aviation Safety Regulations Part 92 - Consignment and carriage of dangerous goods by air, and in New Zealand, Civil Aviation Rules Part 92 - Carriage of Dangerous Goods, etc., etc.

In contrast, Title 49 of the Code of Federal Regulations contains dangerous goods regulations for all modes of transport, road rail, sea and air. Amendments to the U.N. Model Regulations, the International Maritime Organization IMDG Code and ICAO Technical Instructions are generally added directly to the content of 49 CFR, by means of the U.S. rulemaking process. Thus the U.S. "hazmat" regulations generally track the ICAO TIs but are not necessarily an exact mirror of or reference to them, as is the case in numerous other jurisdictions.

Department has proposed. Providing such information through web sites and ensuring that the information is always up to date would be a daunting task, and is too important to be left to such an impersonal and imperfect method of disseminating complex information with serious medical implications.²¹ In addition, public display of lists of accepted devices (and thus public indication or implication that other devices are unacceptable) would create its own new array of issues.²²

Generally, IATA's Members believe that the needs of both passengers and air carriers are best satisfied when information is provided directly to the passenger by the air carrier on a one-by-one basis when a passenger inquires as to the acceptance of a particular device. Such human-to-human contact leaves the least room for misunderstanding or miscommunication and leaves both parties in possession of as much current information as possible.²³

²¹ A passenger who sees his or her device listed as accepted on an air carrier's web site might conclude that there is no need to contact the air carrier to provide advance notice of his or her intention to bring a personally-owned device on board even if the carrier's policy is to require such advance notice.

²² A far better alternative would be for the manufacturers of the devices to be responsible, as suggested above, for testing them, and to also be *the* source of information on which devices are acceptable for air travel.

²³ This importance of personal contact and the points made above about how the competitive choices of the carriers should be allowed to come into play, are also relevant to the Department's statement:

"We would also expect that a carrier would inform the passenger, upon request, about the availability or lack thereof of electrical outlets onboard aircraft that might be available to power the device."

70 Fed. Reg. at 53112. This statement again highlights the need for interagency coordination urged above in footnote 5. With respect to the use of aircraft electrical outlets for passenger personal devices, the FAA has stated that it "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." 70 Fed. Reg. at 40158. This makes it clear that the FAA, the aviation *safety* regulator, takes the view that such use of electrical outlets is not automatically allowed and certainly not guaranteed, but is permissible only when "aircraft operators obtain FAA authorization." Moreover, once such an authorization is in place, the FAA, on the question of providing information on the availability of electrical outlets, has stated that it "does not have the authority under the Air Carrier Access Act to require such an action," *id.*, such determinations being reserved, by law, to the Office of the Secretary. However, OST, in its statement in this NPRM, chooses not to make a clear statement based on legal authority, but rather *implies* that the carriers have such an obligation: "We would also expect that a carrier would inform the passenger, upon request, about the

Advance Notice

Generally, IATA's Members favor advance notice by passengers who wish to use their own respiration assistive devices in flight:

- If advance notice were not provided, verification of the acceptability of a particular device would need to take place at check-in. As check-in staff would not have the expertise to make such a determination, qualified staff would then need to be called upon, which would take time and, as a worst-case scenario, potentially delay the take-off of the flight.
- Advance notice would enable the air carrier to ensure that the passenger wishing to use the device is fully aware of the implications of reduced cabin pressure for persons suffering from respiratory disease.
- Without advance consultation and confirmation, there is a greater chance that a device might be found to be unacceptable just before a flight and ruin travel plans – a result that neither the passengers nor the airlines want.
- With advance notice, the air carrier would be able to inform the passenger if there were no electrical outlets on the operating aircraft.
- With the personal contact of advance notice, airline personnel could be sure that the passenger understands the possibility of last minute operational changes that could affect their travel, such as equipment changes that would result in the unavailability of electrical outlets.

Advance Check-in Time

Advance check-in should not be required if advance notice has been provided by the passenger and if no other special assistance is required.

Seating Accommodations

Since Part 382 does not permit air carriers to limit the number of disabled passengers on flights, IATA submits that the Department has failed to address one of the consequences of this policy decision – the problem of what air carriers should do in the event that there are fewer electrical outlets than the number of

availability or lack thereof of electrical outlets onboard aircraft that might be available to power the device.” (70 Fed. Reg. at 53112.)

passengers wishing to use them for medical purposes. The logical response of airlines facing such a situation would be to adopt a “first come, first served” policy. Anything else would put carriers in the impossible position of having to make judgments about the relative medical needs of the passengers.

Batteries

Different aircraft have different electrical outlets with different voltage levels, many of which are disabled below a certain altitude and which have limitations based on the number of users. Many aircraft do not have electrical outlets whatsoever. It is therefore imperative that passengers carry the requisite number of batteries to power devices for the duration of any journey *and* enough extra batteries to accommodate any unforeseen delays. This should also be required even if the operating aircraft has available electrical supplies in case of electrical failure or in case the operating aircraft has to be replaced by another aircraft (which could potentially not have electrical outlets) shortly before departure.²⁴ Given the severity of the potential consequences, the air carrier must be able to deny boarding to a passenger who does not have a sufficient number of batteries.²⁵

The Department should need no reminding that some types of battery are regarded as hazardous materials. The FAA has stated that it shares “concerns

²⁴ Airbus has expressed the view “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.” According to the FAA, “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).” 70 Fed. Reg. at 40158.

²⁵ The FAA has commented in detail on the difficulties of the extra battery issue, and has clearly stated that it does not believe that batteries sufficient for a period equal to 150% of the flight time should be viewed as enough. The FAA considered all the various possible delays relating to air traffic control, weather and emergencies and concluded that there are many circumstances where delays can exceed a 150% standard. 70 Fed. Reg. at 41058. For that reason, the FAA has concluded that it must be the oxygen user, ideally in consultation with his or her physician, who should determine the “number of extra batteries necessary to cover the possible exigencies.” *Id.*

about the safety of carrying multiple extra batteries in carry on baggage to be used to power” POCs. 70 Fed. Reg. at 40159.²⁶.

SECTION 382.135:

WHAT ARE THE REQUIREMENTS CONCERNING PROVISION OF MEDICAL OXYGEN FOR PASSENGERS WITH DISABILITIES?

First and foremost IATA believes that providing in-flight medical oxygen should not be mandated, but should be left to the individual air carrier. One of the assumptions made by the Department is that more persons dependent on medical oxygen would elect to buy air transport services if they were provided access to medical oxygen on board. If the provision of medical oxygen (including possible carrier provision of oxygen concentrators) were not mandated, individual air carriers would have the opportunity to provide it in order to gain a competitive advantage over other air carriers that had elected not to provide medical oxygen. In this regard, market forces would determine which air carriers benefited from the extended customer base.

Applicable Safety Regulations

In its notations in this section, the Department refers to 49 CFR §175.10(a)(7) and outlines the procedural mechanism by which the Department applies its standards for safe use medical oxygen onboard to foreign carriers that *choose* to provide it during their operations that are subject to U.S. jurisdiction. The procedural details and the jurisdictional niceties that are embedded in the regulations described here are important – because the regulations deal with matters at the heart of aviation safety, and because those who drafted them took careful consideration of sovereign rights and obligations and reflected them

²⁶ The FAA has noted that for those reasons, “PHMSA is considering a rulemaking that is aimed at preventing short circuit, sparking, and heat from all batteries and battery-powered devices in transportation.” 70 Fed. Reg. at 40157.

properly in their final product. IATA urges the Department to apply the same care and respect for sovereign rights to the medical oxygen regulations at issue in this rulemaking.

Types of Carrier-supplied Devices

IATA's Medical Advisory Group was asked to provide feedback on the specific questions posed by the Department in this section of the NPRM. Its answers are quoted below:

Question: Do oxygen concentrators provide medical oxygen at a purity level and flow rate required by most individuals dependent on medical oxygen?

Answer: Oxygen cylinders normally provide 100% oxygen. Assuming that DOT defines purity by percentage of oxygen, manufacturers of concentrators generally claim that the concentrators will provide a minimum oxygen concentration of 90%. This is medically acceptable. Most individuals dependent on medical oxygen required a flow rate of 2 to 4 litres per minute. The concentrators provide up to 5 litres per minute.

Question: What other devices dispense medical oxygen with the same or comparable purity and flow rate as compressed oxygen delivered from a canister?

Answer: Liquid oxygen devices provide gaseous oxygen from a cylinder but the gas is under lower pressure. However, liquid oxygen is absolutely forbidden for transport aboard aircraft, either as cargo (on a passenger aircraft or a cargo aircraft) or in the passenger cabin. See 70 Fed. Reg. at 40160 and 49 CFR § 175.85(a), which prohibits passengers from carrying hazardous materials, like liquid oxygen, in aircraft cabins. Consequently, liquid oxygen systems do not represent a possible alternative.²⁷

²⁷ The ICAO Technical Instructions (Table 3-1 – Dangerous Goods List) further state that liquid oxygen is forbidden on both passenger and cargo aircraft with a Special Provision (SP A 2, which states that the substance may only be transported on a passenger or cargo aircraft with the prior approval of the appropriate authority of the State of origin.

Question: What medical reasons would prevent a person who requires medical oxygen from using a large (e.g. the Air Life concentrator) or portable oxygen concentrator?

Answer: Most chronic medical conditions require between 2 and 4 litres per minute. As such, oxygen concentrators should suffice for most medical conditions unless oxygen is needed to drive a piece of equipment, in which case a much higher flow rate is required.

Extent of the Medical Oxygen Service

IATA fully supports the proposal's position that air carriers not be responsible for the provision of medical oxygen at airports. Both the legal and practical reasons outlined in the NPRM are valid.

Advance Notice Requirements

The proposal that advance notice by passengers requesting medical oxygen cannot exceed 48 hours is neither practical nor realistic. Certain airports may not have medical oxygen readily available; provision of oxygen may require up to 5 days. For airlines with limited operations to the U.S., as well as for U.S. carriers with operations from foreign airports so limited, this provision, with its implicit requirement that carriers be required to be prepared for the arrival of such passengers at all times, would impose an undue and unnecessary burden. In addition, for carriers with a policy that services such as stretchers and onboard oxygen, etc must be cleared with headquarters, 48 hours notice may not be sufficient, given flight schedules and international time differences. Advance notice of more than 48 hours better assures proper planning for allocation of such services to outlying and overseas stations.

Timeframe for implementing Carrier-supplied Medical Oxygen

For air carriers that do not currently provide medical oxygen in-flight, substantial physical and procedural modifications would need to be made in order

to comply with the provisions of the NPRM. A one-year timeframe is both more reasonable and more realistic.

Other Issues

IATA also suggests that the Department consult with and seek the guidance of the Department of Homeland Security's Transportation Security Administration (TSA) to ensure that the use of such kits would entail no additional security threats to aircraft. Even if TSA were to certify that such kits pose no such security threats, IATA believes that it would be overly burdensome to expect air carriers to train their check-in staff to ensure that an oxygen kit has not been tampered with and that it is an approved system at the time of check-in. Even if check-in staff had such expertise, such a process would entail substantial check-in delays. IATA suggests that it should properly be the role of TSA to confirm that kits are authorized for use onboard at the time of check-in.

Again, for this and the reasons set forth above, IATA encourages the Department to issue a Supplemental NPRM so as to be able to fully and properly consider these aspects of this proposal, and to fully and properly consult and coordinate with other agencies.

SECTION 382.137:

MAY A CARRIER CHARGE A PASSENGER FOR COSTS RELATED TO THE USE OF PASSENGER-OWNED RESPIRATION ASSISTIVE DEVICES OR THE PROVISION OF CARRIER-SUPPLIED MEDICAL OXYGEN DEVICES?

Having noted the Department's comment that it "is well aware that because of the unique characteristics of medical oxygen, the provision of medical oxygen can be costly, " IATA is at a loss to understand why air carriers should be required to provide medical oxygen for free. Neither medical professionals, pharmacists, oxygen delivery system manufacturers, employers nor any other

parties are required to provide medical oxygen for free in order to enable an individual to pursue his or her daily life. There is no reason to single out air carriers.²⁸

While carriers that currently provide medical oxygen do levy a charge, but the charge is usually not enough to cover the actual cost.²⁹ Charging passengers a fee for the cost of providing medical oxygen is not discriminatory. Airlines do not impose a fee when passengers use their own POCs because the airlines incur no costs. Providing medical oxygen, however, is a different matter, and charging a fee is the only way an airline can recover at least some of the costs of the service itself and the costs of the safety risks created by medical oxygen onboard. But the key is that the carriers *themselves* elect whether to provide the oxygen and they alone elect whether to make a loss by doing so. In this regard, IATA would again like to stress that market forces should prevail; if air carriers believe that they could gain a competitive advantage by providing free medical oxygen, they should be free to do so, but the air carriers should be the ones to decide, not a regulator.

²⁸ Furthermore, IATA has been informed that in numerous instances passengers request medical oxygen “just in case” of emergency rather than because it is absolutely necessary. IATA has also consulted with doctors who have reported that sometimes during the clearance of sick passengers who wish to travel, oxygen is requested “just in case” the patient may need it. Doctors often accommodate patients making such requests. However, airlines and airline doctors also report that in virtually all of the cases where they believe the “just in case” factor is at work, passengers have withdrawn their requests for medical oxygen when they learn that a charge is involved. Allowing carriers to continue to levy a charge for medical oxygen would prevent the provision of unnecessary oxygen supplies, which could obviously involve substantial costs for the industry, and increased operational risks.

²⁹ As noted above, Air Canada’s records reveal that despite its charge for medical oxygen, it still recovered \$250,000(CDN) less in fees in the year 2000 than it spent in providing medical oxygen to passengers.

CONCLUSION

IATA once again urges the Department to reconsider its approach to its entire Part 382 revision process, including this rulemaking. IATA asks the Department to act in accordance with its Congressional mandate, to take into consideration the demands of international law and comity and to retreat from the ill-advised extraterritorial approach that has put it at odds with other sovereigns. IATA also urges the Department to consider carefully the financial burdens it is proposing to impose on an already beleaguered industry. The record on which the Department relies in this NPRM is faulty, and has led to a proposal that does not achieve the reasonable balance required and that indeed would impose an undue financial burden on the industry. For these reasons, IATA submits that rather than the path it has chosen, the Department, the industry and users of medical oxygen would be better served if the Department makes the choices and adopts the approaches suggested herein.

Respectfully submitted,

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