

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Parts 121 and 135**

[Docket No. FAA-2000-7119; Notice No. 00-03]

RIN 2120-AG89

Emergency Medical Equipment**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Notice of proposed rulemaking (NPRM).

SUMMARY: This action responds to the Aviation Medical Assistance Act of 1998 by proposing that air carrier operators carry automated external defibrillators on large, passenger-carrying aircraft and also augment currently required emergency medical kits. It would affect those operations for which at least one flight attendant is required and, if adopted, would require instruction on the use of this equipment. This proposal would modify the regulations to include provisions designed to provide the option of treatment of serious medical events during flight time.

DATES: Comments must be received on or before September 21, 2000.

ADDRESSES: Comments on this document should be mailed or delivered in duplicate, to: U.S. Department of Transportation Dockets, Docket No. FAA-2000-7119, 400 Seventh Street, SW., Room Plaza 401, Washington, DC 20590. Comments also may be sent electronically to the Dockets Management System (DMS) at the following Internet address: <http://dms.dot.gov/>. Commenters who wish to file comments electronically, should follow the instructions on the DMS web site.

FOR FURTHER INFORMATION CONTACT: Judi Citrenbaum, AAM-210, Aeromedical Standards, Office of Aviation Medicine, Federal Aviation Administration, 800 Independence Avenue, SW, Washington, DC 20591, telephone (202) 267-9689.

SUPPLEMENTARY INFORMATION:**Comments Invited**

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Comments relating to the environmental, energy, federalism, or economic impact that might result from adopting the proposals in this document are also invited. Substantive comments should be accompanied by

cost estimates. Comments must identify the regulatory docket or notice number and be submitted in duplicate to the DOT Rules Docket address specified above.

All comments received, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking, will be filed in the docket. The docket is available for public inspection before and after the comment closing date.

All comments received on or before the closing date will be considered by the Administrator before taking action on this proposed rulemaking. Comments filed late will be considered as far as possible without incurring expense or delay. The proposals in this document may be changed in light of the comments received.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this document must include a pre-addressed, stamped postcard with those comments on which the following statement is made: "Comments to Docket No. FAA-2000-7119." The postcard will be date-stamped and mailed to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded using a modem and suitable communications software from the FAA regulations section of the Fedworld electronic bulletin board service (telephone: 703-321-3339) or the Government Printing Office (GPO) electronic bulletin board service (telephone: 202-512-1661).

Internet users may reach the FAA's web page at <http://www.faa.gov/avr/arm/nprm/nprm.htm> or the GPO's webpage at <http://www.access.gpo.gov/nara> for access to recently published rulemaking documents.

Any person may obtain a copy of this document 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. Communications must identify the notice number or docket number of this NPRM.

Persons interested in being placed on the mailing list for future rulemaking documents should request from the above office a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Issue

The Aviation Medical Assistance Act (the Act) was introduced in the United States Congress on November 6, 1997. Enacted April 24, 1998 [Pub. L. 105-

170, 49 USC 44701], the Act directs the FAA to determine whether current minimum requirements for air carrier crewmember medical emergency training and air carrier emergency medical equipment should be modified.

Typically, when in-flight medical events occur, airline passengers may be assisted by crewmembers, generally flight attendants working in the cabin, and by other passengers. Flight attendants frequently solicit the voluntary advice and assistance of medically qualified passengers, if on board, to assist with serious medical events. A basic emergency medical kit and a basic first-aid kit are required to be carried on board major air carriers and are available for use. Additionally, and if available, ground-based medical advice may be solicited. If it is subsequently recommended to divert the flight, the pilot in command may elect to land the aircraft.

With passenger enplanements numbering over 600 million in 1998, nearly double what they were in the early 1980's, an increase in passengers needing in-flight medical assistance is anticipated for the future. The overall aging of the general population is expected to result in a greater number of air carrier passengers with medical conditions, passengers who are more likely to experience an in-flight medical event.

The most commonly observed serious in-flight medical events appear to be cardiac in nature, due to chronic pre-existing conditions or to the sudden onset of previously unknown conditions. Reporting seen in various medical journals, as well as in the popular press, reveals the following about cardiac events in general:

- Cardiac arrest (the stopping of effective pumping of blood by the heart) reportedly strikes over 350,000 Americans every year, typically those 41 to 65 years old.

- The most common form of treatable cardiac arrest (a substantial portion of all cardiac events) is caused by an abnormal heart rhythm called "ventricular fibrillation," (where the heart is still beating, although ineffectively pumping blood). Ventricular fibrillation is treatable with defibrillation, electric shocks that stimulate the heart to resume beating normally.

- Survival of individuals undergoing ventricular fibrillation can be as high as 90 percent in some circumstances, if defibrillation is provided during the first minute following collapse and subsequent cardiac care is rapidly provided.

- For every minute that defibrillation is delayed, survival is reported to fall about 10 percent, dropping below 50 percent after 6 minutes.

- By providing early electrical correction of ineffective heart pumping, therapeutic defibrillation is more effective than cardiopulmonary resuscitation (CPR) in sustaining life and function in certain situations.

In light of the aforementioned, and for reasons elaborated in the discussion below, the FAA is reviewing emergency medical equipment and crewmember emergency medical training requirements.

Background

Automated External Defibrillators

Cardiac defibrillator technology has progressed to the point that defibrillation similar to that performed in hospitals can, in many cases, be accomplished effectively outside the hospital environment by automated external defibrillators (AED's). When activated, AED's deliver a high energy electrical pulse to attempt to restore the normal electric heart activity required for normal heart function. At a cost of approximately \$3,500 per unit, AED's are lightweight, compact, virtually maintenance-free, and simple to use. Because these battery-powered systems voice-prompt step-by-step guidance, appropriately trained non-medical personnel may use them fairly confidently to assist in certain, especially treatable, cardiac emergencies.

The type of AED most commonly used can monitor a person's heart rhythm and prompt whether a shock should be administered. The machine determines whether, and when, an individual needs to be administered an electric shock. If defibrillation is needed and is successfully performed, further medical intervention is necessary to determine the underlying cause for definitive treatment.

CPR is a necessary adjunct to AED usage as it may be the only effective assistance available. CPR should be initiated immediately upon encountering any apparent cessation of breathing or cardiac arrest (in an attempt to maintain a person's oxygen flow) and must be continued in the event of any of the following: the AED voice-prompt indicates "no shock," and a pulse is absent; three AED shocks are administered to no avail; the AED malfunctions. As some cardiac events will not be treatable by AED, it is vital that CPR be started and performed as long as necessary.

Some non-medical professionals, among them police officers and fire fighters, have the devices available and are trained to use them. The U.S. Food and Drug Administration (FDA) regulates the use of AED's and began approving use of the devices in an aircraft environment in September 1996. Subsequent to this approval, several air carriers voluntarily have begun or have announced plans to carry them on board.

Emergency Medical Kits

In 1986, the FAA promulgated a final rule, "the Emergency Medical Equipment Requirements Rule," requiring large, passenger-carrying aircraft to carry emergency medical kits [51 FR 1218; January 9, 1986, effective August 1, 1986]. The FAA set a minimum standard for kit contents requiring the following: a sphygmomanometer, which is an instrument for measuring blood pressure; a stethoscope; three different sizes of oral airways (breathing tubes); syringes; needles; 50 percent dextrose injection, for hypoglycemia or insulin shock; epinephrine, for asthma or acute allergic reactions; diphenhydramine, for allergic reactions; nitroglycerin tablets, for cardiac-related chest pain; and basic instructions on the use of the drugs.

The rule has been amended once, in October 1994, [59 FR 52640; October 18, 1994], to require protective gloves. Also, in January 1996, under the "Commuter Rule," commuter air carriers operating 20-to-30-seat airplanes, that previously were required to carry only first-aid kits, have been required to carry the emergency medical kit described above [60 FR 65831, December 20, 1995].

At the time the emergency medical kit rule was promulgated, there was controversy over what types of instruments and medications the FAA should require since some commenters to the proposed rule expressed concerns about controlled substances (originally proposed for the action) being stowed on board any passenger aircraft. It was argued that an aircraft should not be a flying hospital, but that the proper course of action in the event of an on-board medical emergency is for the pilot in command to decide if the aircraft can be landed safely to allow the ailing passenger to receive appropriate medical care. As a result of these concerns, the FAA scaled down its original proposal in terms of the contents that would be required of emergency medical kits. The rule promulgated was designed to ensure that, at the very least, U.S.-registered aircraft would have the basic, minimum equipment on board if the crew chose to

attempt treatment and/or to aid in decisions regarding diversion. The rule also required airlines to report to the FAA principal operations inspector, for a period of 24 months after the effective date of the rule, information on each medical emergency occurring during flight time and resulting in the use of the emergency medical kit or the diversion of aircraft.

Related Studies

The FAA's Civil Aeromedical Institute (CAMI), located in Oklahoma City, has conducted four specific studies on in-flight medical emergencies and the use of the emergency medical kit. These technical reports, issued by CAMI in 1991, 1997, and 2000, are described briefly below. Copies of the CAMI reports are available for review in the public docket established for this rulemaking action.

CAMI Technical Reports

- "Response Capability During Civil Air Carrier In-flight Medical Emergencies" [March 1991; DOT/FAA/AM-91/3] and "Utilization of Emergency Kits by Air Carriers." [March 1991; DOT/FAA/AM-91/2].

The former report reveals the preliminary findings and the latter report reveals the comprehensive findings of data collected from part 121 air carriers on medical emergencies. As described above, "The Emergency Medical Equipment Requirements Rule" issued in 1986 required that, for a 2-year period, all part 121 air carriers maintain records on each medical event occurring during flight time which resulted in the use of the emergency medical kit, diversion of the aircraft, or death of a passenger or crewmember.

During the 2-year monitoring period, a total of 2,322 medical events were documented (equating to approximately three per day) with 33 deaths reported. In the 2,293 actual uses of the medical kit, a physician was the provider in over 85% of the cases. The most common presenting symptom was pain, followed by unconsciousness, impaired breathing, nausea and/or vomiting; the most common presenting "sign" was described as a "myocardial problem."

Although only 2 years of data were available for review, the pattern of medical kit item usage was very similar in the first and second years. An increase in the number of cases also was noted in the second year. The FAA did not find justification to make any modifications to the emergency medical kits following the 2-year regulatory reporting period.

- “In-flight Medical Care, An Update” [February 1997; DOT/FAA/AM-97/2].

From 1990 to 1993, CAMI obtained information from two airlines and two in-flight medical care delivery companies to determine which category of in-flight medical event occurred most frequently and which category accounted for the greatest number of diversions. The trend in the frequency of diversions for medical reasons also was assessed. The effect of in-flight medical advice was then evaluated by comparing the number of diversions that resulted in hospitalizations to the number that did not. The findings showed that neurological, syncopal, and cardiac episodes respectively, were the most frequent categories of medical emergencies encountered in flight, while cardiac, neurological, and respiratory events, in that order, accounted for the most diversions.

- “The Evaluation of In-flight Medical Care Aboard Selected U.S. Air Carriers from 1996 to 1997” [April 2000; DOT/FAA/AM-00/13].

- CAMI analyzed 1,132 in-flight medical incidents that occurred between October 1, 1996, and September 30, 1997. The data included information from six airlines that accounted for approximately 20 percent of all U.S. domestic enplanements for the period. This study was not designed to provide an in-depth review of in-flight medical care delivery; however, the data did reveal that in-flight diagnoses by ground-based physicians frequently can be in close agreement with hospital discharge diagnoses, indirectly implying that the proper diagnosis was made in flight. In particular, in the case of cardiac patients, the agreement rate was 94.1 percent, and passengers appeared to be conservatively diagnosed and treated in flight. Many of these in-flight diagnoses were made with the assistance of a ground-based physician.

Additionally, this study suggested that the items that should be considered for possible addition to a future medical kit include a bronchodilator inhaler, an oral antihistamine, and some form of oral non-narcotic analgesic medication. These items are not commonly available because they are not routinely carried by other passengers or the airline. No data were collected in this study concerning AED's as they were not being carried on board at the time of the study. As a result, no consideration was given to adding cardiac drugs to the emergency medical kit for use after an AED intervention.

Related Activity

In 1995, in light of changing demographics of air carrier passengers and advances in clinical medicine, some FAA physicians began an informal analysis of in-flight medical events. These physicians explored the issue with individual air carriers, the Aerospace Medical Association (AsMA), the Air Transport Association (ATA), and MedAire, Inc. (a for-profit firm that provides medical advice to flight crews through air-to-ground communication links). The physicians did not produce any written technical reports or recommend any regulatory changes; they merely gathered information on the issue.

In May 1997, the U.S. House of Representatives Committee on Transportation and Infrastructure, Subcommittee on Aviation, held hearings on in-flight medical events. Witnesses who testified at these hearings strongly supported additional crew training and the inclusion of AED's in the onboard medical equipment.

In August 1997, AsMA convened a task force of physicians across the major medical specialties to review the contents of emergency medical kits. This task force recommended certain minimum medications and medical supplies for air carriers. The group further recommended that air carriers consider AED's on wide body aircraft for use on specific routes, particularly lengthy or over-water flights. It was recommended that AED's be tested for their possible effects on installed avionics and that airlines use an appropriate training program with particular attention given to safety considerations of in-flight use. These recommendations were based on a survey of 2,300 AsMA physicians who had treated at least one passenger on a commercial flight.

In December 1997, an ATA Medical Panel recommended that ATA member airlines place AED's on at least 20 percent of the aircraft in their fleets (initially), upgrade emergency medical kits, and modify flight attendant training on the use of this equipment. (In forming this recommendation, this ATA group collected information from nine member airlines on in-flight medical emergencies and medical kit usage.)

In January 1998, the FAA received a petition for rulemaking from a physician who had assisted a passenger on board a December 1997 flight who apparently suffered a fatal heart attack. The petitioner requested that the FAA take action to upgrade emergency medical

equipment being carried on board major air carriers.

On April 24, 1998, the Aviation Medical Assistance Act of 1998 (the Act), Pub. L. 105-170, 49 U.S.C 44701, was enacted. The Act directs that the FAA take the following action:

- Evaluate the equipment required to be carried in air carrier emergency medical kits and the training of flight attendants on the use of such equipment; issue a Notice of Proposed Rulemaking (NPRM) if regulations need to be modified.

- Collect data for 1 year from a major air carrier on medical emergencies that result in death and any information necessary to determine whether AED's should be required on board air carriers (with a maximum payload capacity of more than 7,500 pounds) and/or at airports.

- Following an analysis of the results of the data collection, determine whether to issue one of the following: an NPRM to require AED's on air carriers (with a maximum payload capacity of more than 7,500 pounds) and/or at airports;¹ a recommendation to Congress for legislation; or a notice in the **Federal Register** that would indicate why this action is not required.

- Issue a final rule within 120 days following the date on which comments are due on an NPRM. The Act includes a “Good Samaritan” provision that limits air carriers’ liability in obtaining medically qualified non-employee passengers to assist persons. The “Good Samaritan” provision limits non-employee passenger liability for providing assistance during an in-flight medical event unless the assistance is grossly negligent, or is willful misconduct.

In September 1998, in a letter sent to the Federal Air Surgeon, the Association of Flight Attendants (AFA) discussed the potential implications of the Act on its members.

On December 10, 1999, the FAA held a public meeting on airline workplace safety. Some flight attendants who spoke at the meeting stated that, based on their personal experiences in handling in-flight medical events, currently required emergency medical equipment needs to be enhanced.

¹ The Act requires the Administrator to make a decision on requiring AD's at airports, as well as on air carrier aircraft. The Act recognized that the decision on requiring the devices for airports may be in a form different than the decision for air carriers. As a result, the FAA decided to undertake separate efforts in gathering and analyzing information for airports and air carrier aircraft. A cardiac event on an aircraft occurs in a totally different environment from a cardiac event that occurs on an airport. This NPRM applies only to air carriers. A decision on whether or not to require AED's at airports will be issued separately.

A copy of the information provided to the FAA on the recommendations from the AsMA and the ATA Medical Panels, as well as a copy of the petition, the Act, and the AFA letter have been placed in the public docket established for this proposal. Information provided to the FAA at the December 10, 1999, public meeting is available under Docket number FAA-1999-6342.

July 1, 1998, to June 30, 1999, Data Collection

On July 1, 1998, the FAA initiated a data collection, as directed in the Act, to gather information on in-flight medical events that result in death or threat of death. The FAA developed a 1-page checklist, the "In-Flight Medical Event Report," (the event report) designed for the use of nonmedical professionals such as crewmembers. (A copy is on file in the docket.) The FAA asked the ATA and several flight attendant unions to review the event report. The ATA agreed to distribute the event reports among its members, to collect any input received, and to forward it to the FAA on a quarterly basis. Up to 15 different ATA-member airlines, carrying approximately 85% of U.S. domestic airline passengers, contributed some data throughout the year.

The event report was intended to record incidents that were likely to be of cardiac origin and, thus, possibly require use of an AED. As other medical conditions may have similar symptoms, additional checklist choices were provided in an attempt to distinguish non-cardiac problems.

Based on the symptoms, treatment, and follow-up information on the event report, a general medical category was assigned to each event. In an effort to indicate more specifically when an AED may have been useful, a category also was assigned based only on symptom and in-flight treatment information. In some cases, this assignment was not possible because of the limited or incomplete information provided. A few reports included a specific follow-up diagnosis based on a hospital evaluation.

Data collected for the Act resulted in the submission of 188 in-flight medical event forms, not including 15 that were provided in an unusable format. Of the 188 events, 177 events occurred on the aircraft (either in flight, at the gate, or while taxiing), 10 events occurred on the ground (either in the jetway or the terminal) and one event occurred in a taxi enroute to the airport. A total of 108 deaths were reported (out of the 188 total events) either by the end of the flight or after the passenger was

transferred to a hospital. Of the 80 remaining events, 14 passengers were reported as being alive, 56 were reported on the event report as "Unknown," and 10 were submitted with no outcome reported.

Of the 177 events that occurred on the aircraft, 119 were thought to be of cardiac origin based on a review of all the information provided on the event reports. (The average age of those passengers on the aircraft with reported cardiac problems was 62 years.) Sixty-four of these 119 passengers were reported as having died. For the remainder, 42 passengers had unknown dispositions and 10 passengers were reported as having survived. Three events had unreported results.

The AED was used to deliver at least one shock in 17 separate events, 14 on the aircraft and three on the ground. From these events, four passengers were reported as having survived, 11 as having died, and two as having unknown outcomes. It is believed the AED use was the event that changed the outcome for those who were reported as having survived. For cardiac-related events on the aircraft, an AED was reported as "Not available" for 40 events, "Not needed" for 12 events, and "Not reported" for 40 events.

CPR was reportedly performed 82 times on the aircraft.

A total of 74 diversions for passenger medical emergencies were reported; 52 for cardiac events.

While not a primary focus of this data collection, aircraft emergency medical kit item usage also was reported: six uses of epinephrine and six uses of nitroglycerin. (Both epinephrine and nitroglycerin currently are required to be carried in the emergency medical kits.) Intravenous (IV) saline and atropine (neither currently required by the FAA but carried by some airlines) were reported used once each. All events reporting these medications were apparent cardiac problems.

Overall, 156 (of the total 188) events reported some type of medical assistance being provided on board the flight, although the actual number may be somewhat lower as it was impossible sometimes to determine whether a reported paramedic or emergency medical technician was a passenger or part of the ground response team. Physicians were reported available on the aircraft for 92 events, nurses for 49 events.

As is common when collecting this type of information, the data have multiple limitations. The accuracy of the data provided appeared highly variable, and analysis to assign a specific medical category often was

difficult or impossible. Early in the data collection, various draft iterations of the event report were submitted that were slightly different from the final event report adopted for use. Because a limited data form was used (so that the data collection would not be overly burdensome), ambiguity with respect to precise symptom reporting was allowed. Reports often were incomplete, resulting in additional uncertainty about the type of event. Finally, no method exists for confirming whether participating air carriers reported every death or near-death event or whether privacy constraints may have limited the information in the event reports submitted to the FAA.

The availability of AED's changed through the year as more airlines began carrying them on their aircraft. For this reason, it was not possible to determine the number of aircraft carrying AED's at any point during the data collection. Additionally, the number of airlines submitting data varied for each quarter of data collection with some airlines reporting no events in later quarters. The survival rate may have been greater than the four possible lives saved if AED's had been aboard each aircraft of each participating air carrier throughout the data collection. If the survival rate during the test period had been higher, then the projected number of lives that potentially could be saved over time would be higher; however, this cannot be established from the data received during the July 1998-June 1999 timeframe.

In spite of these limitations, however, the FAA can conclude from the data collection that deaths occur on air carriers and that certain medical interventions can be useful and may change the outcome for some.

Given the normal circumstances of flight (e.g., reduced air pressure, reduced humidity, high ambient noise levels, reduced space, possible air turbulence, delayed access to the most effective hospital care, etc.) the aircraft is a difficult environment in which to treat a serious medical event, cardiac or otherwise. When serious medical incidents do occur in flight, however, having enhanced emergency medical equipment available may facilitate the response of flight attendants, and others who may volunteer to assist them.

General Discussion of the Proposal

The data collection revealed that four passengers who were administered at least one AED shock during flight survived and the FAA has confirmed that these passengers continue to survive. Subsequent to the data collection, further FAA investigation

has revealed that more passengers, and a flightcrew member, have had similar experiences. Therefore, the option of not requiring action appears inappropriate.

The FAA reviewed various ways of proposing this action before deciding on what it determined would be an appropriate course of action. In particular, the FAA considered an action that would amend 14 CFR part 91 to allow specifically the use of AED's on board aircraft. It was determined that this action would not be adequate, however, because it would not address issues such as maintenance and safe and appropriate usage of the device. The FAA determined that, to provide for the safe carriage and appropriate usage of AED's, it was necessary to amend part 121 to modify current emergency medical equipment and emergency medical training requirements to appropriately address AED usage.

Therefore, the FAA is proposing that all air carriers operating passenger-carrying airplanes under part 121 with a maximum payload capacity of more than 7,500 pounds, and required to have at least one flight attendant on board, take the following actions:

- Have at least one AED on board each flight.
- Require initial and recurrent training for all flight attendants on AED usage and in CPR.
- Require initial training for all pilots on the location of the AED and its instruction set.
- Enhance emergency medical kits to include the following additional medications: non-narcotic analgesic (such as acetaminophen, 325 mg, or ibuprofen, 200 mg, or equivalent); oral antihistamine (such as diphenhydramine, 25 mg or equivalent); aspirin (325 mg); atropine (0.5 mg, 5cc single dose ampule or equivalent); a bronchodilator inhaler (such as albuterol, metered dose inhaler or equivalent); lidocaine (5 cc, 20 mg/ml, injectable, single dose ampule or equivalent) and saline solution (500 cc) for intravenous infusion.
- Enhance emergency medical kits to include the following additional equipment: an IV administration kit with connectors (and, for placing the IV, alcohol sponges, tape, bandage scissors, and a tourniquet); a self-inflating manual resuscitation device with three sizes of masks (one pediatric, one small adult, one large adult), such as an AMBU bag; and three sizes of CPR masks (one pediatric, one small adult, one large adult).
- Require initial, familiarization training on enhanced emergency medical kit content for all crewmembers.

It should be noted that the decision to offer treatment or take other action (including safe diversion of the aircraft) is discretionary with the air carrier and its agents. While the FAA believes that this action is justified, it is also aware that adding enhancements to the medical kit could result in their unintentional misuse. Passenger expectations regarding the level of medical care should not be unrealistically raised by this action. Onboard medical assistance will continue to be discretionary as well as limited and must be regarded as emergency treatment with no unrealistic expectations of favorable outcomes for passengers having medical events in flight. The FAA believes that it is unrealistic to expect crewmembers to achieve the same level of proficiency as emergency medical personnel who perform medical procedures routinely on a daily basis.

It is recognized that the availability of these enhancements (equipment and medication) will not eliminate the logistical and medical difficulties experienced in attempting to treat a stricken passenger effectively while in flight. The intent of the regulation is to provide options for treatment, not to raise expectation in the passenger or physician community regarding the level of medical care available in flight.

Section-by-Section Discussion of the Proposal

The FAA proposes to amend 14 CFR part 121 by adding subpart X and by amending appendix A and the following sections: §§ 121.303, 121.309, 121.323, 121.325, 121.415, 121.417, 121.427. A minor editorial amendment is proposed for part 135 under § 135.177. These modifications are described below.

Section 121.303 Airplane Instruments and Equipment

Paragraphs (b) and (d) of § 121.303 currently address airworthiness requirements and operable conditions for airplane instruments and equipment. Under this proposal, paragraphs (b) and (d)(2), which reference other sections including § 121.309, would be modified to include a reference to proposed § 121.803.

Section 121.309 Emergency Equipment

Paragraph (d) of § 121.309 currently addresses first aid and emergency medical equipment and protective gloves. Under this proposal, the provisions would be moved to proposed subpart X, and paragraph (d) of § 121.309 would be removed and reserved.

Section 121.323 Instruments and Equipment for Operation at Night

Section 121.323 currently addresses instruments and equipment for operations at night. The introductory paragraph references other sections including § 121.309. Under this proposal, the introductory paragraph would be modified to include a reference to the proposed § 121.803.

Section 121.325 Instruments and Equipment for Operations Under IFR or Over-The-Top

Section 121.325 currently addresses instruments and equipment for operations under IFR or over-the-top. The introductory paragraph references other sections including § 121.309. Under this proposal, the introductory paragraph would be modified to include a reference to proposed § 121.803.

Section 121.415 Crewmember and Dispatcher Training Requirements

Paragraph (a)(3) currently requires each training program to provide ground training, including emergency training for crewmembers as specified in § 121.417. Under this proposal, paragraph (a)(3) would be modified to reference emergency training specified in both § 121.417 and proposed § 121.805.

Section 121.417 Crewmember Emergency Training

Paragraph (b)(2)(ii) currently requires, in part, that crewmembers receive individual instruction in the location, function, operation, and proper use of first aid equipment. Paragraph (b)(3)(iv) currently requires, in part, that crewmembers receive instruction in handling "illness, injury, or other abnormal situations" involving passengers or crewmembers and that this training include familiarization with the emergency medical kit. Under this proposal, the provisions would be modified and moved to proposed subpart X. Paragraphs (b)(2)(ii) and (b)(3)(iv) of § 121.417 therefore would be removed and reserved.

Section 121.427 Recurrent Training

Paragraph (b)(2) of § 121.427 currently requires recurrent training instruction, as necessary, in the subjects required for initial ground training by § 121.415(a), as appropriate, including emergency training (not required for aircraft dispatchers). Under this proposal, paragraph (b)(2) would be modified to reference emergency training specified in proposed § 121.805.

Subpart X Emergency Medical Equipment and Training

Under this proposal, subpart X would be added to part 121 to describe emergency medical equipment and requirements for instruction applicable to all certificate holders operating certain passenger-carrying airplanes. These requirements would include existing requirements for emergency medical equipment and training that would be modified and moved to this new subpart.

Section 121.803 paragraph (a) would adopt existing § 121.309(a) requirements and add the words "unless authorized by the Administrator." These words would be added to cover situations in which an AED may be inoperable or not available for flight. In such cases, the certificate holder would have to obtain approval from the FAA principal operations inspector before operating a flight.

Section 121.803 paragraph (b) would adopt provisions of existing § 121.309 (b) regarding inspection, accessibility, and marking requirements for emergency equipment.

Section 121.803 paragraphs (c)(1) and (2) would require each passenger-carrying airplane to have approved first-aid kits and a modified emergency medical kit (in airplanes for which a flight attendant is required). The required minimum number of first-aid kits is specified under part 121, appendix A, as are the specifications and requirements for the emergency medical kit. This requirement is currently specified in paragraph (d) of § 121.309.

Paragraph (c)(3) of § 121.803 is a new provision that would require, in airplanes for which a flight attendant is required, an approved AED.

Paragraph (b)(2) of § 121.805 would include a provision that all crewmembers be instructed in the location, function, and operation of emergency medical equipment which, under the proposal, would include modified emergency medical kits and AED's. This requirement is currently specified in paragraph (b)(2)(ii) of § 121.417.

Paragraph (b)(3) of § 121.805 would include a provision that all crewmembers be instructed in the handling of emergency medical events involving passengers or crewmembers to include familiarization with the emergency medical kit, as modified under the proposal. This requirement is currently specified in paragraph (b)(3)(iv) of § 121.417.

Paragraph (b)(4) of § 121.805 would include additional provisions for flight attendants that would require

appropriate instruction in the proper use of AED's; appropriate instruction in CPR; and appropriate recurrent training in the use of AED's and in CPR. All emergency medical training would have to be completed before 36 months after the effective date of the rule. The instruction required under proposed § 121.805(b)(4) would be in addition to the programmed hours of training required for flight attendants under §§ 121.421 and 121.427.

Specific training-hour requirements are not proposed under this regulatory action. Since some air carriers have already voluntarily enhanced emergency medical response capabilities and have initiated and implemented specific training programs, it would be overly burdensome to try to standardize training. The FAA anticipates, however, that the initial and recurrent instruction that would be needed in CPR and in AED usage would conform to national programs conducted for ground-based trainees who initially certify and recertify in CPR procedures and AED usage. These national programs would include those offered, for example, by the American Heart Association or the American Red Cross. The FAA proposes that recurrent instruction in the proper use of AED's and in CPR procedures be conducted at least once every 24 months.

It is expected that some time will be required for air carriers to modify training programs, to enhance emergency medical kits and associated protocols, and to procure AED's. Therefore, the agency is proposing that a final rule take effect 36 months after publication. This would mean that the required training must be completed within 36 months after the effective date and before compliance is required.

Appendix A to Part 121-First-Aid Kits and Emergency Medical Kits

Appendix A sets forth the specifications and requirements for first-aid kits and emergency medical kits. Under this proposal, appendix A would be amended to include an AED and proposed enhancements to the emergency medical kit. The appendix also would be revised for overall clarity; specific amendments are described below.

"First-Aid Kits"

The reference to "Federal Specification GG-K-391a" would be deleted. This reference is obsolete as the specification was cancelled as of July 6, 1986. No changes are proposed for either the quantity of kits required or the content.

"Emergency Medical Kit"

This section would be amended to propose that the following be included in an approved emergency medical kit:

Medications: oral antihistamine, non-narcotic analgesic, aspirin, atropine, a bronchodilator, additional epinephrine, lidocaine, and saline for intravenous infusion.

Equipment: an IV administration kit with connectors (and, for placing the IV, alcohol sponges, tape, bandage scissors, and a tourniquet); a self-inflating manual resuscitation device with three sizes of masks (1 pediatric, 1 small adult, and 1 large adult), such as an AMBU bag; and three sizes of CPR masks (1 pediatric, 1 small adult, and 1 large adult).

Paragraph (4) under "Emergency Medical Kits" would be removed. This paragraph was added under 1994 action to require protective gloves. Because all affected air carriers have now complied with the requirement, the compliance date is no longer needed and may be removed. It should be noted, however, that the FAA proposes to change the reference to protective gloves from "protective latex gloves or equivalent" to "protective nonpermeable gloves or equivalent." When the emergency medical kit action was first adopted, potential for allergic reaction to latex was not clear. Because there may be a potential for allergic reaction to latex, however, the FAA has determined that it would be best to remove the reference to latex under this action.

Rationale for Amending the Emergency Medical Kits

The FAA's study entitled "The Evaluation of In-Flight Medical Care Aboard Selected U.S. Air Carriers from 1996 to 1997," reveals that an oral antihistamine (used mainly to relieve symptoms associated with allergies and hay fever), a non-narcotic analgesic (used mainly to relieve muscle aches and headaches), and a bronchodilator inhaler (used to help restore normal breathing in asthmatics) are appropriate for inclusion in air carrier emergency medical kits.

The FAA consulted with the University of Oklahoma, Department of Biostatistics and Epidemiology in analyzing the data received for this study. Frequency response and contingency analyses were performed, giving special attention to items that are not part of the currently mandated emergency medical kit that were used during in-flight medical events. If such items appeared to have been obtained and used frequently, it suggested that they should be considered for inclusion.

Upon review of the data, researchers determined that additional items should be considered for inclusion in the medical kit if the item was used in more than 1 or 2 percent of all cases. After identifying items that might be considered for inclusion in the medical kit, their effect on in-flight medical care was investigated. Of those items that potentially could be added to the kit, a bronchodilator inhaler and an oral antihistamine appeared to have the greatest effect on passengers; analgesic therapy also showed effective results.

The recent data collection mandated by the Act did not reveal a need for any further modification of the emergency medical kits. Nitroglycerin and epinephrine, already required items, were the medications most commonly reported as being used. Atropine and IV saline were used one time each.

Because the FAA proposes to require AED carriage, however, it is appropriate to require the following items in the emergency medical kits that might be useful to medical personnel who may treat a stricken passenger(s):

Aspirin: a general oral medication that may be needed to alleviate head and muscle aches and, possibly, a cardiac event.

Atropine: a drug, most effectively administered intravenously and used to increase heart rate, that may be needed to assist a passenger with an unstable cardiac rhythm.

Lidocaine: a drug, most effectively administered intravenously, that may be needed in cases of unresponsiveness to defibrillation and possibly for maintenance of normal heart rhythm after successful defibrillation.

An IV administration kit with connectors (and, for placing the IV, alcohol sponges, tape, bandage scissors, and a tourniquet): for administering IV drugs (e.g., atropine or lidocaine) that may be needed to sustain heart function.

A self-inflating manual resuscitation bag (with 3 masks: 1 pediatric, 1 small adult, and 1 large adult): that may be needed for continuation of respiratory support.

CPR masks (1 pediatric, 1 small adult, 1 large adult): that may be needed if CPR is required.

The FAA has determined that these additions are justified based on the proposed addition of the AED and on best medical practice. It should be noted that an additional preparation of epinephrine, a drug that may be used for heart stimulation, also is being proposed. This additional preparation is intended to complement the dosage of epinephrine currently required which is intended for use as a muscle relaxant.

Comments on these proposed additions to the emergency medical kits are specifically invited.

“Approved” first-aid kit and “approved” emergency medical kit would continue to mean that the FAA principal operations inspector assigned to the holder of an operating certificate exercises approval for the Administrator, as appropriate, of equipment to be carried aboard a certificate holder’s aircraft.

“Automated External Defibrillator”

This section would be added to set forth AED specifications. Currently, AED’s are powered by primary (not rechargeable) lithium batteries. Safety of these batteries is stressed because extremely energetic materials are used in lithium cells and they are not intrinsically safe. Safety concerns include the possibility of fire, explosion, and the venting of toxic or flammable gases. In this regard, and given the limitations of the aircraft environment, AED carriage on aircraft presents special circumstances in terms of the storage of the device and proper maintenance. Therefore, certificate holders must be vigilant about inspecting and visually checking the device and its battery on a regular basis. The FAA proposes to enhance the level of safety by requiring that certificate holders comply with all requirements in applicable Flight Standards Information Bulletins for Airworthiness, such as the one for medical portable electronic devices (FSAW 98-05), and in applicable Technical Standard Orders, such as the one for lithium batteries (FAA TSO-C142).

“U.S. Food and Drug Administration-approved AED” would mean that the U.S. Food and Drug Administration has approved the device for medical use and that the device conforms to its standards. “Otherwise approved by the Administrator” would mean that certificate holders would have to seek individual approval from FAA principal operations inspectors for power sources for which an FAA TSO does not exist.

Section 135.177 Emergency Equipment Requirements for Aircraft Having a Passenger Seating Configuration of More Than 19 Passengers

This section would be amended to remove the obsolete reference to “Federal Specification GG-K-391a” and to generally conform to clarifying language proposed for part 121, appendix A. No content changes are proposed under this action.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507 (d)), the FAA has determined that there are no requirements for information collection associated with this proposed rule.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to review International Civil Aviation Organization (ICAO) Standards and Recommended Practices (SARP’s) and to comply to the maximum extent possible.

ICAO Standard (Annex 6, Part 1, Chapter 6, Section 6.2.2) states that airplanes shall be equipped with “accessible and adequate medical supplies appropriate to the number of passengers the aeroplane is authorized to carry.” ICAO Recommended Practice (Annex 6, Part 1, Chapter 6, Section 6.2.2) states that medical supplies should comprise “one or more first-aid kits” and “a medical kit for the use of medical doctors or other qualified persons in treating in-flight medical emergencies for aeroplanes authorized to carry more than 250 passengers.” Attachment B to this Recommended Practice lists, in part, the “typical contents” of first-aid kits and emergency medical kits.

Part 121, Appendix A, as currently drafted, complies with these ICAO SARP’s insofar as first-aid kits and emergency medical kits are required to be carried. Part 121, Appendix A does not include all ICAO-recommended emergency medical kit items under ICAO Attachment B, however, and does not specify who is authorized to use the emergency medical kit.

The FAA proposes to add to the emergency medical kits those items warranted for inclusion as a result of its study entitled “The Evaluation of In-Flight Medical Care Aboard Selected U.S. Air Carriers from 1996 to 1997” and those items necessary to support AED protocol. The FAA concurs with the recommendation that emergency medical kits be used by qualified and trained personnel only. Adding such a requirement to part 121, however, would involve defining the various medical specialties and, perhaps, limiting access to the extent that the only person available to assist on a flight might not be included.

ICAO Standard (under Annex 6, Part 1, Chapter 12, Section 12.4) states, in part, that cabin attendants shall complete training programs that ensure that each person is “drilled and capable

in the use of emergency and life-saving equipment required to be carried, such as . . . , first-aid kits." Existing § 121.417 and proposed 121.805 comply with these ICAO guidelines.

ICAO SARPS do not address AED usage on aircraft.

Regulatory Evaluation Summary

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 effect of regulatory changes on small entities. Third, OMB directs agencies to assess the effect of regulatory changes on international trade. In conducting these analyses, the FAA has determined this proposed rule is a "significant regulatory action" under section 3 (f) of Executive Order 12866 and, therefore, is subject to review by the Office of Management and Budget. This proposed rule is considered significant under the regulatory policies and procedures of the Department of Transportation (44 FR 11034, February 26, 1979). This proposed rule would not have a significant impact on a substantial number of small entities. Furthermore, this proposal would not constitute a barrier to international trade. The FAA invites the public to provide comments and supporting data on the assumptions made in this evaluation. All comments received will be considered in the final regulatory evaluation.

Benefits

The proposed rule is intended to require equipment that might preserve the lives of passengers who have serious cardiac medical events on board commercial airplanes operating under part 121 for which a flight attendant is required and with a maximum payload of more than 7,500 pounds. This proposal would require certain passenger-carrying air carrier operators to carry AED's on board their aircraft and to augment currently required emergency medical kits with additional medications and medical equipment. Another requirement of this proposal is to augment the emergency medical training of crewmembers, in particular flight attendants and those who may assist them, for responding to in-flight medical events.

Medical reporting shows that the chances of surviving ventricular fibrillation, a critical cardiac event, are enhanced by the application of AED

technology. Aero-medical groups have recommended placing AED's on board airplanes and the experiences of airlines that already carry AED's have been positive. Up to 15 different Air Transport Association members participated in a 1-year in-flight medical event data collection effort in cooperation with the FAA. This effort was in response to one of the provisions of the Aviation Medical Assistance Act of 1998. The data were collected for the period July 1, 1998, through June 30, 1999. There were 188 death or threat-of-death incidents resulting in a total of 108 deaths. (It should be noted that 11 of these incidents occurred on the ground.) AED's were used a total of 17 times, 14 times to deliver at least one shock on board an aircraft. From these events, four passengers were reported as having survived. Assuming the four passengers survived due to the use of AED's, the AED survival rate per hundred million passenger enplanements is 0.7193. The survival rate may have been different if AED's had been aboard all participating carriers' aircraft for the entire data collection period. If the survival rate during the test period had been higher, then the projected number of lives saved over the next 10 years would be higher. However, since this number cannot be established from the available data, the FAA will use the conservative projection.

Applying the survival rate to the estimated 7.5819 billion enplaned passengers over the next 10 years may result in 55 passenger medical event outcomes being changed by AED's during that period.

The FAA acknowledges the difficulty of quantifying benefits with any precision at this stage of the rulemaking. The FAA also believes that there is merit in continuing to collect data on in-flight medical incidents. Therefore, the FAA may propose in the future that data be collected on all uses of the emergency medical kits and AED's by the certificate holder or its agents. This data would be used to further refine the contents of and training for the use of the medical kits and the AED's. Data would be collected directly from the certificate holders in a manner prescribed by the Administrator. The FAA seeks comment on the need for further data collection. The FAA may also issue a supplementary notice to elicit comments on a specific proposed data collection.

Costs

The FAA has analyzed the expected costs of this regulatory proposal for a 10-year period, 2000 through 2009. All

costs in this analysis are expressed in 1998 dollars.

The estimated industry costs over 10 years total \$138.1 million, or \$95.6 million discounted. These costs consist of the initial cost to equip the aircraft, for carriers who have not voluntarily placed AED's and emergency medical kits aboard their aircraft; the cost of equipping new aircraft that the industry will add to the fleet over the next 10 years; the cost of maintaining the equipment and replacing medications, and the weight penalty cost of carrying the additional equipment. In addition, the carriers will incur the cost of initially training flight attendants in the proper usage of the AED's and for recurrent training. The cost of AED's is estimated at \$26.7 million, (\$20.2 million discounted); the cost of upgrading the emergency medical kits at \$4.0 million, (\$2.8 million discounted); and additional fuel is estimated to cost \$4.4 million, (\$3.0 million discounted). The training of flight attendants is estimated to cost \$103.0 million, (\$69.7 million discounted).

The flight attendants receiving the training as a result of this proposal would probably view this as enhancing their job skills and could lead to efforts to raise their wages based on this perception. The FAA has no basis for estimating this possible impact on industry costs. Public comments are invited; the FAA requests that all comments be accompanied by clear and detailed economic documentation.

Cost-Benefit Analysis

If the proposed rule becomes effective, the FAA estimates that as many as 55 passenger medical outcomes could possibly be changed over the next 10 years. Based on the estimated cost of \$138.1 million and an estimated 55 lives possibly saved, the rule is estimated to cost \$2.5 million per life saved.

Approximately \$88 million of the total cost will be borne by the air carriers that have voluntarily placed the AED's and expanded emergency medical kits aboard their aircraft principally due to the cost of recurrent training of flight attendants. The cost to major carriers that currently do not carry this equipment is estimated at \$39 million and small carriers would incur a cost of \$11 million as a result of this proposal.

The FAA invites public comments and requests that all comments be accompanied with clear and detailed economic documentation.

Initial 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, organization, and government jurisdictions subject to regulation." To achieve that principal, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act 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 (RFA) as described in the Act.

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 1980 act provides that the head of the agency may so certify and a RFA is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The Small Business Administration suggests that "small" represent the impacted entities with 1,500 or fewer employees. For this proposed rule, the small entity group is considered to be part 121 operators (Standard Industrial Classification Code 4512) with 1,500 or fewer employees. The FAA has identified a total of 60 operators that meet this definition.

To determine the impact of the proposed rule on small part 121 operators, the FAA has estimated the annualized cost impact on each of those small entities potentially impacted by the proposed rule. The proposed rule is expected to impose an estimated cost of \$10.9 million on the 60 small entities over the next 10 years. The annualized cost per small operator is estimated at \$18,300. This amount represents less than one-tenth of the annual cost (\$265,300, in 1998 dollars) to small operators that the FAA considers economically significant in that it may entail either an increase in airline ticket fares or a requirement to create operating cost efficiencies to preserve the economic stability of impacted airlines. None of the 60 part 121 small entities would incur a substantial

economic impact in the form of higher annual costs in excess of \$265,300, as the result of the proposed rule.

Therefore, the FAA has determined that this proposed rule would not have a significant impact on a substantial number of small entities. Accordingly, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605 (b), the Federal Aviation Administration certifies that this rule would not have a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The provisions of this proposed rule would have little or no impact on trade for U.S. firms doing business in foreign countries and foreign firms doing business in the United States.

A number of foreign carriers carry AED's and enhanced emergency medical kits on flights to and from the United States. U.S. carriers that have voluntarily upgraded their emergency medical equipment account for a majority of the U.S.-flag international service.

Federalism Implications

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

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 2 U.S.C. (the Act), codified in 2 U. S. C. 1501-1571, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. Section 204(a) of the Act, 2 U.S.C. 1534(a) requires the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local and tribal governments on a proposed "significant intergovernmental mandate." A "significant intergovernmental mandate" under the Act is any provision in a Federal agency regulation that would impose an enforceable duty upon State, local, and tribal governments, in the aggregate of \$100 million (adjusted annually for

inflation) in any one year. Section 203 of the Act, 2 U.S.C. 1533, which supplements section 204(a), provides that before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency shall have developed a plan that, among other things, provides for notice to potentially affected small governments, if any, and for a meaningful and timely opportunity to provide input in the development of regulatory proposals.

This proposed rule does not contain a Federal intergovernmental or private sector mandate that exceeds \$100 million a year.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental assessment or environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), this rulemaking action qualifies for a categorical exclusion.

Energy Impact

The energy impact of the notice has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) P.L. 94-163, as amended (43 U.S.C 6362) and FAA Order 1053.1. It has been determined that the notice is not a major regulatory action under the provisions of the EPCA.

List of Subjects

14 CFR Part 121

Air carriers, Aircraft, Airmen, Alcohol abuse, Aviation safety, Charter flights, Drug abuse, Drug testing, Reporting and recordkeeping requirements, Safety, Transportation.

14 CFR Part 135

Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend parts 121 and 135 of Title 14, Code of Federal Regulations (14 CFR parts 121 and 135) as follows:

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

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

Authority: 49 U.S.C. 106(g), 40113, 40119, 44101, 44701-44702, 44705, 44709-44711,

44713, 44716-44717, 44722, 44901, 44903-44904, 44912, 46105.

2. Amend § 121.303 by revising paragraphs (b) and (d)(2) to read as follows:

§ 121.303 Airplane instruments and equipment.

* * * * *

(b) Instruments and equipment required by §§ 121.305 through 121.359 and 121.803 must be approved and installed in accordance with the airworthiness requirements applicable to them.

* * * * *

(d) * * *

(2) Instruments and equipment specified in §§ 121.305 through 121.321, 121.359, 121.360, and 121.803 for all operations, and the instruments and equipment specified in §§ 121.323 through 121.351 for the kind of operation indicated, wherever these items are not already required by paragraph (d)(1) of this section.

* * * * *

§ 121.309 [Amended]

3. Amend § 121.309 by removing and reserving paragraph (d).

4. Amend § 121.323 by revising the introductory text to read as follows:

§ 121.323 Instruments and equipment for operations at night.

No person may operate an airplane at night under this part unless it is equipped with the following instruments and equipment in addition to those required by §§ 121.305 through 121.321 and 121.803:

* * * * *

5. Amend § 121.325 by revising the introductory text to read as follows:

§ 121.325 Instruments and equipment for operations under IFR or over-the-top.

No person may operate an airplane under IFR or over-the-top conditions under this part unless it is equipped with the following instruments and equipment, in addition to those required by §§ 121.305 through 121.321 and 121.803:

* * * * *

6. Amend § 121.415 by revising paragraph (a)(3) to read as follows:

§ 121.415 Crewmember and dispatcher training requirements.

(a) * * *

(3) For crewmembers, emergency training as specified in §§ 121.417 and 121.805.

* * * * *

§ 121.417 [Amended]

7. Amend § 121.417 by removing and reserving paragraphs (b)(2)(ii) and (b)(3)(iv).

8. Amend § 121.427 by revising paragraph (b)(2) to read as follows:

§ 121.427 Recurrent training.

* * * * *

(b) * * *

(2) Instruction as necessary in the subjects required for initial ground training by §§ 121.415(a) and 121.805, as appropriate, including emergency training (not required for aircraft dispatchers).

* * * * *

9. Amend part 121 by adding subpart X to read as follows:

Sec.

Subpart X—Emergency Medical Equipment and Training 121.801 Applicability.

121.803 Emergency medical equipment.

121.805 Crewmember training for in-flight medical events.

Subpart X—Emergency Medical Equipment and Training

§ 121.801 Applicability.

This subpart prescribes the emergency medical equipment and training requirements applicable to all certificate holders operating passenger-carrying airplanes under this part.

§ 121.803 Emergency medical equipment.

(a) No person may operate a passenger-carrying airplane under this part unless it is equipped with the emergency medical equipment listed in this section or unless authorized by the Administrator.

(b) Each equipment item listed in this section—

(1) Must be inspected regularly in accordance with inspection periods established in the operations specifications to ensure its condition for continued serviceability and immediate readiness to perform its intended emergency purposes;

(2) Must be readily accessible to the crew and, with regard to equipment located in the passenger compartment, to passengers;

(3) Must be clearly identified and clearly marked to indicate its method of operation; and

(4) When carried in a compartment or container, must be carried in a compartment or container marked as to contents and the compartment or container, or the item itself, must be marked as to date of last inspection.

(c) For treatment of injuries, medical events, or minor accidents that might occur during flight time each airplane must have the following equipment that

meets the specifications and requirements of appendix A of this part:

(1) Approved first-aid kits.

(2) In airplanes for which a flight attendant is required, an approved emergency medical kit, as modified effective [36 months after the effective date of the final rule.]

(3) In airplanes for which a flight attendant is required and with a maximum payload capacity of more than 7,500 pounds, an approved automated external defibrillator as of [36 months after the effective date of the final rule].

§ 121.805 Crewmember training for in-flight medical events.

(a) Each training program must provide the instruction set forth in this section with respect to each airplane type, model, and configuration, each required crewmember, and each kind of operation conducted, insofar as appropriate for each crewmember and the certificate holder.

(b) Training must provide the following:

(1) Instruction in procedures for responding to medical events including coordination among crewmembers.

(2) Instruction in the location, function, and operation of emergency medical equipment.

(3) Instruction in the handling of medical events involving passengers or crewmembers to include familiarization with the emergency medical kit, as modified on [36 months after the effective date of the final rule].

(4) For each flight attendant—

(i) Instruction in the proper use of automated external defibrillators, in addition to the programmed hours of instruction required by § 121.421(c).

(ii) Instruction in cardiopulmonary resuscitation, in addition to the programmed hours of instruction required by § 121.421(c).

(iii) Recurrent training in the proper use of automated external defibrillators and in cardiopulmonary resuscitation, at least once every 24 months, in addition to the instruction required by § 121.427(c).

10. Revise Appendix A to part 121 as follows:

Appendix A to Part 121—First-aid Kits and Emergency Medical Kits

Approved first-aid kits, at least one approved emergency medical kit, and at least one approved automated external defibrillator required under § 121.803 of this part must be readily accessible to the crew, stored securely, and kept free from dust, moisture, and damaging temperatures.

First-Aid Kits

1. The minimum number of first-aid kits required is set forth in the following table:

Number of passenger seats	Number of first-aid kits	Contents	Quality	Contents	Quality
0-50	1	Adhesive bandage compresses, 1-inch	16	Bandage scissors	1
51-150	2	Antiseptic swabs	20	3. Arm and leg splints which do not fit within a first-aid kit may be stowed in a readily accessible location that is as near as practicable to the kit. <i>Emergency Medical Kits</i>	
151-250	3	Ammonia inhalants	10		
More than 250	4	Bandage compresses, 4-inch	8		
		Triangular bandage compresses, 40-inch	5		
		Arm splint, noninflatable	1		
2. Except as provided in paragraph (3), each approved first-aid kit must contain at least the following appropriately maintained contents in the specified quantities:		Leg splint, noninflatable	1	1. At least one approved emergency medical kit that must contain at least the following appropriately maintained contents in the specified quantities:	
		Roller bandage, 4-inch	4		
		Adhesive tape, 1-inch standard roll	2		

Contents	Quantity
Sphygmomanometer	1
Stethoscope	1
Airways, oropharyngeal (3 sizes): 1 pediatric, 1 small adult, 1 large adult	3
Self-inflating manual resuscitation device with 3 masks (1 pediatric, 1 small adult, 1 large adult)	1:3 masks
CPR mask (3 sizes), 1 pediatric, 1 small adult, 1 large adult ¹	3
IV Admin Tubing w/2 Y connectors: 1	1 set
Alcohol sponges ¹	2
Adhesive tape, 1-inch standard roll adhesive ¹	1
Tape scissors ¹	1 pair
Tourniquet ¹	1
Saline solution, 500 cc ¹	1
Protective nonpermeable gloves or equivalent	1 pair
Needles (2-18 ga., 2-20 ga., 2-22 ga., or sizes necessary to administer required medications)	6
Syringes (1-5 cc, 2-10 cc, or sizes necessary to administer required medications)	4
Analgesic, non-narcotic, tablets, ¹ 325 mg	4
Antihistamine tablets, ¹ 25 mg	4
Antihistamine injectable, 50 mg, (single dose ampule or equivalent)	2
Atropine, 0.5 mg, 5 cc (single dose ampule or equivalent) ¹	2
Aspirin tablets, 325 mg ¹	4
Bronchodilator, inhaled ¹ (metered dose inhaler or equivalent)	1
Dextrose, 50%/50 cc injectable, (single dose ampule or equivalent)	1
Epinephrine 1:1000, 1 cc, injectable, (single dose ampule or equivalent)	2
Epinephrine 1:10,000, 2 cc, injectable, (single dose ampule or equivalent)	2
Lidocaine, 5 cc, 20 mg/ml, injectable (single dose ampule or equivalent) ¹	2
Nitroglycerin tablets, 0.4 mg	10
Basic instructions for use of the drugs in the kit	1

¹ Required on and after [36 months after the effective date of the final rule.]

Automated External Defibrillators

At least one U.S. Food and Drug Administration-approved automated external defibrillator that must:

1. Be stored in the passenger cabin.
2. Meet FAA Technical Standard Order requirements for power sources for electronic devices used in aviation or be otherwise approved by the Administrator.
3. Be maintained in accordance with the manufacturer's specifications.

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON-DEMAND OPERATIONS

11-12. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(g), 44113, 44701-44702, 44705, 44709, 44711-44713, 44715-44717, 44722.

13. Amend § 135.177 by revising paragraph (a)(1) to read as follows:

§ 135.177 Emergency equipment requirements for aircraft having a passenger seating configuration of more than 19 passengers.

- (a) * * *
- (1) At least one approved first-aid kit for treatment of injuries likely to occur in flight or in a minor accident that must:
- (i) Be readily accessible to crewmembers.
 - (ii) Be stored securely and kept free from dust, moisture, and damaging temperatures.
 - (iii) Contain at least the following appropriately maintained contents in the specified quantities:

Contents	Quantity
Adhesive bandage compresses, 1-inch	16
Antiseptic swabs	20
Ammonia inhalants	10

Contents	Quantity
Bandage compresses, 4-inch	8
Triangular bandage compresses, 40-inch	5
Arm splint, noninflatable	1
Leg splint, noninflatable	1
Roller bandage, 4-inch	4
Adhesive tape, 1-inch standard roll	2
Bandage scissors	1
Protective nonpermeable gloves or equivalent	11

¹ Pair.

* * * * *

Issued in Washington, D.C., on May 18, 2000.

L. Nicholas Lacey,

Director, Flight Standards Service.

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