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Part VII

Department of Transportation

Federal Aviation Administration

14 CFR Parts 61, 63, 65, 108, 121, and 135

Advanced Qualification Program; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61, 63, 65, 108, 121, and 135

[Docket No. FAA–2000–7497; Amendment No. 61–107, 63–30, 65–41, 108–18, 121–280 and 135–78]

RIN 2120–AH01

Advanced Qualification Program

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is establishing a new termination date for Special Federal Aviation Regulation (SFAR) No. 58 (55 FR 40275; October 2, 1990), which provides for the approval of an alternate method (known as "Advanced Qualification Program" or "AQP") for qualifying, training and certifying, and otherwise ensuring the competency of crewmembers, aircraft dispatchers, other operations personnel, instructors, and evaluators who are required to be trained or qualified under 14 CFR parts 121 and 135. This action will establish a new termination date, October 2, 2005, for SFAR 58 to allow time for the FAA to complete the rulemaking process that will incorporate SFAR 58 into the Federal Aviation Regulations.

DATES: Effective October 2, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas M. Longridge, Advanced Qualification Program Branch, AFS–230, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, P.O. Box 20027, Dulles International Airport, Washington, DC 20041–2027; telephone (703) 661–0260.

SUPPLEMENTARY INFORMATION:

Availability of Final Rules

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) of the Government Printing Office's (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 web page 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 amendment number or docket number of this final rule.

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.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact their local FAA official. Internet users can find additional information on SBREFA on the FAA's web page at http://www.faa.gov/avr/arm/sbrefa.htm and may send electronic inquiries to the following Internet address: 9–AWA–SBREFA@faa.gov.

Background

On June 8, 2000, the FAA issued a notice of proposed rulemaking (NPRM) proposing to extend the expiration date of SFAR 58 (65 FR 37836; June 16, 2000). The comment period closed on July 17, 2000, and no comments were received. The amendment is adopted as proposed.

Good Cause Justification for Immediate Adoption

The reasons that justified the original issuance of SFAR 58 still exist. Therefore, it is in the public interest to establish a new expiration date for SFAR 58 of October 2, 2005. If the FAA publishes a final rule incorporating SFAR 58 into the regulations before this expiration date, SFAR 58 will be rescinded concurrently. Ordinarily under the Administrative Procedure Act, a substantive rule must be served or published not less than 30 days before its effective date except, among other things, if the agency finds "good cause" for making it effective sooner. See 5 U.S.C. Section 553(d)(3). The FAA finds that the continuation of SFAR 58 is necessary to permit continued training under this program and to avoid the confusion that would result if the program were discontinued or temporarily suspended because of the general legal requirement to publish a rule at least 30 days before it becomes effective.

For these reasons, and because as a voluntary program AQP imposes no additional burden on any person, the FAA finds "good cause" for making this amendment, which extends the termination date for the SFAR by 5 years, effective immediately upon issuance.

Economic Summary

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs each Federal agency to propose or adopt a regulation only if the agency makes a reasoned determination that the benefits of the regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 required agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. section 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards. The Trade Act directs agencies, where appropriate, to use those international standards as the basis of U.S. standards. And fourth, the Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules. This requirement applies only to rules that include a Federal mandate on State, local, or tribal governments or the private sector, likely to result in a total expenditure of $100 million or more in any one year (adjusted for inflation). In conducting these analyses, FAA had determined this rule: (1) Has benefits that justify its costs, is not a "significant regulatory action" as defined in the Executive Order, and is not "significant" as defined in DOT's Regulatory Policies and Procedures; (2) will not have a significant impact on a substantial number of small entities; (3) has no impact on international trade; and (4) does not impose an unfunded mandate on state, local, or tribal governments or on the private sector.

AQP is not mandatory; consequently, those operators who choose to participate in the program would do so only if it was in their best interest. Enough operators have found it in their best interest that AQP has become an important means for meeting the requirements for air carrier training programs. AQP gives air carriers flexibility in meeting the safety goals of the training programs in 14 CFR parts 121 and 135 without sacrificing any of the safety benefits derived from those programs. Thus, extending AQP for another 5 years will not impose any additional costs nor decrease the

present level of safety. Because this final rule extends an existing, voluntary program that has become an important means for some operators to comply with training requirements, the FAA finds that a detailed regulatory evaluation is not necessary.

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 businesses, organizations, and governmental jurisdictions subject to regulation." To achieve that principle, 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 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 agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This rulemaking allows certain air carriers to continue participating in a voluntary, alternative method for qualifying, training and certifying, and otherwise ensuring competency of crewmembers, aircraft dispatchers, and other operational personnel, instructors, and evaluators who are required to be trained or qualified under 14 CFR parts 121 and 135. As such, this rulemaking will not impose any additional cost on those air carriers. Consequently, the FAA certifies that the rule will not have a significant economic impact on a substantial number of small air carriers.

International Trade Impact Analysis

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. In addition, consistent with the Administration's belief in the general superiority and desirability of free trade, it is the policy of the Administration to remove or diminish to the extent feasible, barriers to international trade, including both barriers affecting the export of American goods and services to foreign countries and barriers affecting the import of foreign goods and services into the United States.

In accordance with the above statute and policy, the FAA has assessed the potential effect of this final rule and has determined that it will have only a domestic impact and therefore no affect on any trade-sensitive activity.

Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. The FAA 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 will not have federalism implications.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), enacted as Pub. L. 104–4 on March 22, 1995, 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 "significant intergovernmental mandate." A "significant intergovernmental mandate" under the Act is any provision in a Federal agency regulation that will 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. 1553, 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.

The FAA determines that this final rule does not contain a significant intergovernmental or private sector mandate as defined by the Act.

International Trade

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activity that crate unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. In addition, consistent with the Administration's belief in the general superiority and desirability of free trade, it is the policy of the Administration to remove or diminish, to the extent feasible, barriers to international trade, including both barriers affecting the export of American goods and services to foreign countries and barriers affecting the import of foreign goods and services to into the U.S.

In accordance with the above statute and policy, the FAA has assessed the potential effect of this final rule and has determined that it will have only a domestic impact and therefore no affect on any trade-sensitive activity.

Environmental Analysis

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

Energy Impact

The energy impact of the notice has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) Pub. L. 94–163, as amended (42 U.S.C. 6362) and FAA Order 1053.1. It has been determined that the final rule is not a major regulatory action under the provisions of the EPCA.

List of Subjects

14 CFR Part 61

Air safety, Air transportation, Aviation safety, Safety.

14 CFR Part 63

Air safety, Air transportation, Airmen, Aviation safety, Safety, Transportation.

14 CFR Part 65

Airman, Aviation safety, Air transportation, Aircraft.

14 CFR Part 108

Airplane operation security, Aviation security, Aviation safety, Air transportation, Air carriers, Airlines, Security measures, Transportation, Weapons.

14 CFR Part 121

Aircraft pilots, Airmen, Aviation safety, Pilots, Safety.

14 CFR Part 135

Air carriers, Air transportation, Airmen, Aviation safety, Safety, Pilots.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends SFAR 58 (14 CFR parts 61, 63, 65, 108, 121, and 135) of Title 14, Code of Federal Regulations, as folows:

1. The authority citation for part 61 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45303.

2. The authority citation for part 63 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40108, 40113, 44701–44703, 44710, 44712, 44714, 44716, 44717, 44722, 45303.

3. The authority citation for part 65 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45302.

4. The authority citation for part 108 continues to read as follows:

Authority: 49 U.S.C. 106(g); 5103, 40113, 40119, 44701–44702, 44705, 44901–44905, 44907, 44913–44914, 44932, 44935–44936, 46105.

5. 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, 449112, 46105.

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

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722.

7. In part 121, SFAR 58 is amended by revising paragraph 13 to read as follows:

Special Federal Aviation Regulation No. 58—Advanced Qualification Program

* * * * *

13. Expiration. This Special Federal Aviation Regulation terminates on October 2, 2005, unless sooner terminated.

Issued in Washington, DC, on September 29, 2000.

Jane F. Garvey,

Administrator.

[FR Doc. 00–25632 Filed 10–6–00; 8:45 am]

BILLING CODE 4910–13–M

121-280

Federal Register

Thursday,
April 12, 2001

Part III

Department of Transportation

Federal Aviation Administration

14 CFR Parts 121 and 135
Emergency Medical Equipment; Final Rule

Seth Gill
AAM-98-234-E
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121 and 135

[Docket No. FAA-2000-7119; Amendment No. 121-280 and 135-78]

RIN 2120-AG89

Emergency Medical Equipment

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action responds to the Aviation Medical Assistance Act of 1998 by requiring that air carrier operators carry automated external defibrillators on large, passenger-carrying aircraft and augment currently required emergency medical kits. It affects those air carrier operations for which at least one flight attendant is required and includes provisions designed to provide the option of treatment of serious medical events during flight time.

EFFECTIVE DATES: Effective May 12, 2004.

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:

Availability of Final Rules

You can get an electronic copy using the Internet by taking the following steps:

(1) Go to the search function of the Department of Transportation's electronic Docket Management System (DMS) Web page http://dms.dot.gov/search).

(2) On the search page type in the last four digits of the Docket number shown at the beginning of this notice. Click on "search."

(3) On the next page, which contains the Docket summary information for the Docket you selected, click on the final rule.

You can also get an electronic copy using the Internet through FAA's web page at http://www.faa.gov/avr/armhome.htm. or the **Federal Register's** web page at http://www.access.gpo.gov/su_docs/aces/aces140.html.

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

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Background

On May 24, 2000, the Federal Aviation Administration (FAA) issued a notice (65 FR 33720) proposing that air carrier operators of large, passenger-carrying aircraft carry automated external defibrillators (AED's) and augment currently required emergency medical kits (EMK's). The FAA proposed to make that action applicable to those air carrier operations for which at least one flight attendant is required. The objectives of that action can be summarized as follows:

- To respond to the Aviation Medical Assistance Act (the Act), enacted April 24, 1998 [Pub. L. 105-170, 49 U.S.C. 44701], which 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.
- To modify, as appropriate, the regulatory requirements for EMK's in light of advancements in medical technology and treatments, the increase in passenger enplanements, and the anticipated increase in the occurrence of inflight medical events.
- To require equipment that would provide crewmembers and passengers who might come forward to assist during an inflight medical event, more up-to-date treatment options, specifically AED's.
- To require flight attendant instruction in cardiopulmonary resuscitation (CPR) and AED usage.
- To require needed modifications to current minimum equipment and training standards without raising expectation among passengers or crewmembers about the ability to receive and/or provide in-flight emergency medical assistance.
- To establish a separate subpart under part 121 of Title 14 of the Code of Federal Regulations (14 CFR part 121) that, while not deviating from established requirements for certain equipment and crewmember training, would provide greater regulatory flexibility in making future modifications that may be needed.
- To allow those affected air carriers that have not made emergency medical equipment modifications sufficient time to provide crewmember instruction and procure medical enhancements.

Comments Received

The FAA received 370 comments on the proposal; 321 from the general public in support of the proposal, in particular, that AED's be carried on board passenger-carrying aircraft. Most of these 321 comments are from family, friends, co-workers, and acquaintances of a 28-year-old man who, they indicate, died on board an airliner in July 2000. These comments state that this passenger had been diagnosed with hypertrophic cardiomyopathy [1] a few months prior to the flight and that, if an AED had been on board, it may have saved his life. These commenters express concern about the welfare of other passengers and state that they want to promote awareness about checking with an air carrier before booking a flight to assure the availability of an AED. This incident is of particular concern to the commenters given the young age and apparent sound physical condition of the passenger who died. The commenters state that he had been an accomplished athlete.

For the remaining comments, which are discussed in further detail below, 25 generally support the proposal but make detailed comments and/or request modifications; 22 express neither support nor opposition for the action but provide comments for consideration.

The former (25) comments are from the following:

- Aerospace Medical Association (ASMA)
- Agilent Technologies (an AED manufacturer)
- Air Line Pilots' Association (ALPA)
- Air Transport Association (ATA)

[1] A primary myocardial disease of unknown cause that is characterized by a hypertrophied, nondilated, hypercontractile left ventricle. The annual mortality is 3-5%. The common mode of demise is sudden cardiac death. (Sudden cardiac death is defined as an unexpected, unpredictable cessation of effective contractions of the heart.) Therefore, the primary objectives of treatment are the amelioration of symptoms, the control of arrhythmias, and the prevention of sudden death. American Journal of Medical Science; Sept 1987: pp 191-210]

- American Heart Association (AHA)
- America West
- Association of Professional Flight Attendants (APFA) (representing American Airlines' flight attendants)
- Complient (a national training center for the American Heart Association and the National Safety Council)
- Food Allergy Network
- Florida International University
- International Association of Firefighters
- International Association of Machinists and Aerospace Workers, AFL–CIO
- International Brotherhood of Teamsters Airline Division
- MedAire, an air carrier medical care provider
- Northwest Airlines
- Pakistan International Airways
- Teamsters Local 2000 (representing Northwest Airlines flight attendants)
- 3 private citizens, 4 private physicians, and a volunteer firefighter

The latter (22) comments are from private physicians, nurses, flight attendants, the Association of Flight Attendants (AFA), Atlantic Southeast Airlines, Continental Express (two separate comments), the Regional Airline Association (RAA), and the Small Business Administration.

One commenter, identified as a Registered Nurse, is opposed to the proposal. She indicates, among her other comments, that "if it is deemed necessary to be able to administer advanced medical care on any given flight, then turn this over to flight nurses and/or flight paramedics who are trained in all aspects of flight medicine/pathophysiology/flight physiology."

The Civil Aviation Authority of the Hashemite Kingdom of Jordan states that it would like to implement the proposal for Jordan Air Lines.

Discussion of Comments

Because the additional suggestions and requests for further modifications received from the various commenters are elaborate, for clarity of discussion the FAA categorizes them specifically as follows:

Automated External Defibrillators

Battery Requirements

Agilent Technologies, an AED manufacturer, comments that the FAA should state the minimum requirements that AED's and their batteries must meet to be allowed in the aircraft environment and, in addition, reference the Flood and Drug Administration's (FDA) requirements for ensuring the safety and effectiveness of AED's. Agilent states that the reference in proposed part 121, appendix A to "FDA-approved AED" should be changed to "AED legally marketed in the United States in accordance with FDA requirements."

Agilent requests that the FAA add further requirements to the regulation, specifically that paragraph 2. of the AED section of proposed part 121, Appendix A read as follows:

2. Demonstrated through compliance with applicable sections of Technical Standard Order (TSO) requirements or other standards or testing to meet the following requirements:

(a) The AED does not interfere with the safe operation of other aircraft equipment.

(b) The AED and its power supply have safety features that prevent fire and explosion hazards.

(c) The AED is designed such that the AED system does not create a hazard for occupants of the aircraft cabin.

FAA response: The FAA agrees, and has verified with the FDA, that the reference to "FDA-approved AED" in the proposal should be changed to "AED legally marketed in the United States in accordance with FDA requirements" in the final rule.

The FAA disagrees that further regulatory requirements for AED's are needed for this action. As with all equipment carried on board aircraft the certificate holder must ensure that AED's placed on aircraft do not interfere with safe operation of the aircraft.

The FAA issued TSO–C142 on April 4, 2000. This TSO prescribes the minimum FAA performance standard that lithium cells and batteries must meet to be identified with the applicable TSO marking. The standards of this TSO apply to lithium cells and batteries intended to provide power for aircraft equipment including emergency and standby systems. The FAA intends that any AED powered by lithium batteries placed on an aircraft on or after April 4, 2000, would have to comply with this TSO.

This requirement, in addition to being approved for aircraft use by the FDA, is adequate for the purposes of this action.

Servicing/Maintenance

Complient, a national training center for the AHA and the National Safety Council, suggests that each AED should be serviced twice each year by a trained service specialist. Also, on-site service should be provided within 24 hours after each medical event to ensure that proper AED information and service requirements are met.

FAA response: The FAA disagrees with the comment. As proposed and adopted, part 121, appendix A requires that AED's be maintained in accordance with the manufacturer's specifications. The FAA has determined that this is the best method to meet maintenance requirements.

Storage

The ALPA recommends that AED's be stored in the cockpit. In its view, cockpit placement would assure that the flightcrew is well aware of the presence of an AED. Wtih the AED in the passenger cabin they state that flight attendants may become so focused on its use that the cockpit crew will not be notified about in-flight medical events. Further, the AED is a valuable piece of equipment and will be more secure in the cockpit.

The AFA states that if AED's are required on aircraft, the devices should be in locations that are suitable for quick emergency response.

FAA response: The FAA agrees that AED's should be stored in accessible locations as described under proposed part 121, appendix A.

The FAA does not agree that the devices should be stored in cockpits. If stored in cockpits, the devices would be less accessible to flight attendants, crewmembers who will be required to have instruction in AED usage. Also, as cockpit crew always are to be notified about in-flight medical events as required under § 121.417(b)(1), the FAA anticipated that cabin and cockpit crews will communicate during in-flight medical events.

In addition, just prior to issuing the Notice of Proposed Rulemaking (NPRM), the FAA was made aware of four separate AED battery "rupturing" incidents that had occurred on the ground, including one incident that occurred on a hangared jet. These "rupturing" incidents occurred in AED's powered by lithium sulfur dioxide batteries.

The extremely energetic materials used in lithium cells, and in other AED power sources, are not intrinsically safe. Safety concerns include the possibility of fire, explosion, and the venting of toxic or flammable gases from any portable power source such as AED batteries. The FAA determined, therefore, that AED's would have to meet more rigid standards when carried on aircraft and would be more safely stored in the passenger cabin rather than the cockpit, more critical to safe flight operations.

Visual Inspection

The ATA suggests that he FAA clarify that the inspection/marking requirement under proposed § 121.803(b) does not apply to the visual inspection of emergency equipment typically

performed by flight attendants at the start of each new crew shift.

FAA response: The FAA agrees that the inspection/marking requirement under proposed § 121.803(b) does not apply to visual inspection. However, as with all emergency equipment, AED's must be visually inspected by flight attendants as part of routine pre-flight procedures.

Data Collection

In-Flight Medical Events

The ASMA observes that differences of opinion among the medical community exist because no comprehensive database describing in-flight medical events and deaths exists.

The International Association of Machinists and Aerospace Workers, AFL–CIO, state that, to rely heavily on the data collection only, to support a rulemaking to provide AED's and related drugs on aircraft EMK's is "woefully limited." Further, the FAA did not report from the data collection findings who used the AED's on passengers and whether any drugs were administered.

The RAA states that the evaluation that was used to justify the proposal is not representative of the regional fleet since some regionals are only now equipping some or all in their fleets. Further, without a study that specifically addresses the effective use of AED's on regional flights, it questions whether AED's will be used at all.

Contrary to these commenters, the ATA suggests that detailed reports on in-flight medical events is not needed and that the FAA should "discard" the idea of a supplemental information-gathering action. According to the ATA, it would be costly and burdensome, data submitted to the FAA likely will be subject to release under the Freedom of Information Act, and it will discourage emergency assistance from volunteer doctors and other health care providers.

FAA response: The FAA does not believe that further studies are needed for this action at this time. As described in the NPRM, the FAA has conducted separate and specific studies on in-flight medical events. (Copies of these studies are on file in this docket.) Very limited assumptions can be made as a result of most of the studies conducted by the FAA (as well as outside organizations) on in-flight medical events and EMK usage for the following reasons: the long-term outcome of the passenger(s) beyond what occurs on the aircraft frequently cannot be determined; a passenger's past and subsequent medical history is a private matter and therefore generally unavailable. Thus it is typically difficult to assess why or even what medical event occurred.

When it conducts studies, the FAA is obligated, under the Paperwork Reduction Act [5 CFR 1320.13], not to overburden entities from which it is collecting information. Therefore, the FAA typically does not collect data unless it is absolutely warranted, mandated, and/or invited. For this action, the Act directed that "a major air carrier shall make a good faith effort to obtain, and shall submit quarterly reports on" death or threat-of-death incidents occurring on board its flights. In the data collection that was conducted, up to 15 different air carriers, carrying approximately 85 percent of U.S. domestic airline passengers, contributed data throughout the year. As acknowledged in the NPRM, the data received had multiple limitations and appeared highly variable. Not all of the air carriers who supplied data were carrying AED's and/or enhanced EMK's; however, the intent of the study was, in part, to determine whether AED's (as well as other enhancements) would have been used had they been available. In that regard, out of a total of 188 events, an AED was reported as "not available" for 40 events in which they may have been used.

The FAA was able to determine from this data collection that four passengers who were administered at least one AED shock during flight survived and continue to survive. In at least two of these incidents the event occurred right after takeoff. Subsequent to the data collection, further cases of long-term survival as a result of AED usage were revealed to the FAA, including cases involving crewmembers, some on short-haul flights. Because some events occurred right after takeoff and the flights were diverted back to the airport of departure, it is apparent that these events can occur regardless of the size of the aircraft or the length of the flight.

Overall, 156 (of the total 188) events reported some type of medical assistance being provided on board the flight. The actual number might have been 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. Nitroglycerin and epinephrine were the medications most commonly reported as being used. Atropine and intravenous (IV) saline were used on time each.

Because of conclusions that could be made from its most recent data collection and because the FAA anticipates an increase in in-flight medical emergencies for the future, the FAA has determined that this rule is needed now. The FAA will continue to study in-flight medical emergencies, to consider any recommendations, and to monitor the usage of the enhancements being made to the EMK's.

Emergency Medical Kits

EMK Containers; Location on the Aircraft; and Quantity Needed

America West Airlines comments that, if the FAA intends to mandate that the modified EMK be contained in a single container or compartment, such a requirement should be specified in the rule. Similarly, the ATA indicates that, because the NPRM does not address containers for EMK's the final rule should clarify that soft-sided containers are acceptable. America West Airlines also states that the placement of the items should be left to air carrier discretion. Requiring a single container to include the current and new requirement would require air carriers to retrofit with larger-sized kits, triggering both material and labor expenses.

Northwest Airlines suggests that language be included in the rule that would allow airlines to augment their existing EMK's with other additional specially designated medical kits without reference to any specific kit nomenclature. These additional kits would have as a minimum the additional EMK items called out in the NPRM. This modification would preclude the waste associated with making the existing EMK obsolete. It should also be noted that the additional items required under the NPRM will not fit into the existing EMK box found on Northwest Airlines aircraft.

Pakistan International Airways would like to have the EMK divided into two types; one for the use of the cabin crew and a second for physicians travelling abroad.

The RAA comments that regional airplanes do not have the space to accommodate a larger EMK and that it will be more costly to retrofit a regional airplane.

FAA response: The FAA disagrees, in part, with these commenters. The proposal does not specify that the modified EMK be contained in a single container or in a hard, versus a soft, container. Therefore, this action does not require a retrofit and should not severely affect available storage space on an aircraft.

The FAA modifies part 121, appendix A under this action to state "at least one" EMK to accommodate certain air

carriers who may use more than one container or more than one EMK. Some air carriers, for example, carry a so-called "basic box" to meet the minimum requirements and then also carry their own separate, modified EMK; some others may be carrying "grab-and-go kits;" and the like. Beyond what is set out in the regulation, the certificate holder may choose the number and type of kits desired as long as the basic, minimum EMK requirements are met.

The FAA is aware that many air carriers contract with various medical kit providers and that these providers use various types of containerization, (e.g., soft-sided vinyl bags as well as rugged, double-walled, polyethylene cases.) The choice of which type of EMK, and whether more than one container may be used to meet the minimum requirements, is at the air carrier's discretion.

As some air carriers may be using, or need to use, more than one container to meet the requirements the FAA adds the following paragraph under part 121, appendix A:

3. If all of the above-listed items do not fit into one contained, more than one container may be used.

It should be noted that formerly, under existing § 121.309 (b)(4) and to be adopted under § 121.803 (b)(4), an FAA-required EMK container(s) must be marked as to contents and date of last inspection.

Expiration Date of EMK Medications

America West Airlines suggests that procedures be established to preserve the shelf life of temperature-sensitive medications. Those such as lidocaine, if stored in a standard EMK, would require constant replacement thereby creating additional cost and administrative burden.

FAA response: Currently required EMK medications as well as the following medications proposed for the EMK's have an expiration date of approximately 1 year: atropine, bronchodilator inhaler, dextrose, epinephrine, saline solution, and lidocaine; aspirin, non-narcotic analgesic, antihistamine, and nitroglycerin tablets.

Under current experience (since 1986) with injectable antihistamine, dextrose, epinephrine, and nitroglycerin tablets, the FAA has not found expired medications to be a problem. Therefore, the FAA does not anticipate that medications will require constant replacement. If temperature extremes occur on the aircraft or if the medications have surpassed their expiration date; however, then the certificate holder should replace them. As has been the case since first required, EMK's must be inspected periodically according to schedules developed under operations specifications.

Medications

The following is a list of additional equipment and medication that commenters suggest the FAA should include in EMK's:

Items Suggested:

- AED patient care kit containing a razor and towel
- Audio-prompting device
- Auto-injector to administer epinephrine
- Burn gel
- 16 French Coude catheter
- Connecting tubing, IV Start kit, IV catheters 18g, 20g, 22g, Atropine 1mg, Epinephrine 1:10,000 1mg and Lidocaine 100 mg
- CPR masks fitted with an oxygen inlet and with a standard 15–22-mm connector available in one average size for adults with additional sizes for infants and children, equipped with a 1-way valve that diverts the victim's exhaled gas
- Dexamethasone
- EKG machine
- Endotracheal tube/laryngoscope
- Furosemide injection
- Glucometer
- Glucose gel-administered orally for symptoms of hypoglycemia
- Medication for seizure control
- Nasal cannulas in sizes appropriate for adult, child, and infant
- Pocket masks
- Portable oxygen equipment with regulator capable of delivering between 4 L/min and 12 L/min, including a hose capable of connecting to a resuscitation face mask, bag-valve mask, and a connecting system for use with a nasal cannula.
- A standardized portable response kit to include an AED, AED preparation kit, emergency oxygen, first-aid/BBP kits and supplies, and an audio prompt device.
- A manual resuscitation bag-valve that has:
  - A self-refilling bag
  - A nonjam valve system allowing for a maximum oxygen inlet flow of 30 L/min
  - A non-pop-off valve
  - Standard 15–/22-mm fittings
  - A system for delivering high concentrations of oxygen through an ancillary oxygen reservoir
  - A true nonrebreathing valve
  - The capability to perform satisfactorily under all common environmental conditions and extremes of temperature
- Stretcher
- Torch lights w/spare batteries

Eleven commenters stress the importance of air carriers carrying an epinephrine auto-injector. Although the FAA currently requires epinephrine, and proposes to require an additional quantity of it, the commenters indicate that an auto-injector is far easier and quicker to use and would be critical when attending to a passenger suffering from a severe allergic reaction in flight.

FAA response: The FAA disagrees with these commenters. No commenters provided data (as requested in the NPRM) to confirm that these suggested additions for the EMK's would be necessary. Also, as noted in the NPRM, the purpose of the EMK's is to add some medical options; it is not comprehensive. The certificate holder may carry additional equipment/medications if deemed appropriate.

Since 1986, all major, passenger-carrying air carriers have been required to carry epinephrine in on-board EMK's. Part 121, appendix A, requires two quantities of epinephrine (1:1000) in "single dose ampule or equivalent." An additional preparation of epinephrine (1:10,000), a dose that may be used for heart stimulation, proposed under this action is intended to complement the dosage currently required, which is intended for use as a treatment for severe, or anaphylactic, allergic reactions.

The FAA did not propose to require epinephrine auto-injectors because recent and former studies (on file in the docket) that the FAA has conducted on in-flight medical events did not reveal a need to make epinephrine auto-injectors available. These studies did suggest the need for an oral treatment for allergic reactions, therefore, an oral antihistamine was included in the NPRM.

The FAA will review this matter in any future considerations of the EMK contents and for any subsequent regulatory action.

The AHA cautions the FAA to be "extremely conservative" when considering EMK expansion. According to the AHA, the FAA should not approach expansion of the EMK's from the perspective of simply making available every drug and medical device ever requested by an in-flight physician. According to AHA, its international guidelines on CPR and emergency cardiovascular care have recommended far fewer resuscitation medications and medical devices than ever before.

Medications

MedAire comments that consideration should be given to increasing the quantities of the proposed medications (in particular atropine, epinephrine, lidocaine) and that supplies needed to administer certain medications are not being required. For example, saline solution is included in the recommended kit contents, but no provisions have been made for an IV catheter, which is essential to administer the fluid. Also, specific syringe and needle sizes should be required.

FAA response: The FAA disagrees with this comment. The FAA took a very conservative approach when assigning quantities to proposed medications given the limited need to use such medications in flight.

In the preamble to the NPRM, it is clear that the FAA intends to require "an IV administration kit" which would include one or more IV catheters. In the regulatory language under proposed part 121, appendix A, that intent may have been misunderstood as the words "1 set" are used rather than "kit." Therefore, for clarity, in the final rule, the FAA moves the word "set" from the "Quantity" column under proposed part 121, appendix A and places it after "IV Admin" so that the intent is clear.

The FAA did include recommended, appropriate needle and syringe sizes in its proposal to part 121, appendix A. Further, the original language from 1986 ("or sizes necessary to administer required medications") was maintained so that the FAA could remain as descriptive as possible.

Another comment on medications, from the ATA, states that convenience medications, such as low-strength analgesics, should not be included in the kit. The kit should be intended for life-threatening emergencies only, and be opened only in the event of a true emergency by a "responding health care provider" or as directed by a "qualified health care provider."

FAA response: The FAA's study entitled "The Evaluation of In-Flight Medical Care Aboard Selected U.S. Air Carriers from 1996 to 1997" (on file in this Docket) reveals that certain convenience medications, such as an oral antihistamine, a non-narcotic analgesic, and a bronchodilator inhaler are appropriate for inclusion in air carrier EMK's. In its study, the FAA found these items to be necessary additions to the EMK because passengers, especially those with chronic allergies or asthma, do not always carry them or may inadvertently leave them in their checked baggage.

Oral antihistamines may prove useful and necessary for attempting to assist a passenger experiencing severe allergy problems; a non-narcotic analgesic, to relieve muscle aches and headaches; and a brochodilator inhaler, to attempt to restore normal breathing in an asthmatic passenger.

Periodic Review of Appropriate Content

MedAire Inc., an air carrier medical care provider, requests that the FAA conduct a review of the EMK content every 2 years to ensure that required drugs continue to meet the AHA Advance Cardiac Life-Saving guidelines. MedAire indicates that the FAA should establish a database in order to monitor kit usage and the appropriateness of its content.

FAA response: The FAA concurs that EMK content must come under periodic review and the FAA will continue working in close collaboration with the public in that regard. However, the FAA did not propose to adopt the AHA Advance Cardiac Life-Saving guidelines and does not adopt that requirement now.

It should be noted that the AHA, in its comment to the docket, cautions the FAA to be "extremely conservative" when considering expansion of in-flight EMK's. This is the approach that the FAA has adopted at this time. This final rule will establish a separate subpart under part 121 with a view to facilitating short-term issuance of any needed amendments in the future.

Protective Barrier Devices

According the MedAire, the requirement for protective barrier devices (e.g., gloves, masks, etc.) can be simplified by allowing airlines the ability to use those that have been designed for universal application rather than having to house three different, specific sizes within the kit.

For items such as airways, resuscitation devices, and CPR masks, the ATA indicates that, rather than specifying quantity and sizes, the final rule should simply require that the EMK contain those items suitable for all air travelers. This change would permit airlines to select, for example, a universal mask that could fit or be adapted to all travelers, including infants, children, and adults.

The AFA believes that a face mask is more appropriate than a face shield. It is concerned that some of the air carriers have chosen to provide only a face shield. Without the FAA mandating the personal protective equipment required, some air carriers may choose to continue to provide this type of barrier device versus a face mask.

The APFA requests that pocket masks be required and made more accessible. Without a mask, it indicates, flight attendants are potentially exposed to hepatitis, AIDS, and other diseases. The APFA recommends that "grab-and-go parts of acronym-syndrome kits" be made "no-go" items or that each flight attendant be issued a mask and be required to carry it. Pocket masks also could be attached or made part of the "defibrillator kit."

FAA response: The FAA is not opposed to affected air carriers carrying airways, CPR masks, and masks for use with self-inflating manual resuscitation devices designed for universal application, provided they are carried in quantities of three and provided they are appropriate for pediatric and small and large adult use. The devices must, however, be equivalent to those required under the regulation.

The FAA did not propose that any equipment be used but rather that it be available for possible use if the certificate holder or its agents (e.g., flight attendants) so choose. Therefore, if different equipment, in addition to that required is desired then the certificate holder may provide it.

With the addition of the words "or equivalent" after the requirements for airways, self-inflating resuscitation devices, and CPR masks under part 121, Appendix A, the final rule is adopted as proposed.

Quality of EMK's

The Teamsters Local 2000, National Safety and Health Department, representing Northwest Airlines flight attendants, states that, in many cases, EMK's include cheap, disassembled parts, with medical equipment manufacturers taking advantage of the air carriers by placing sub-standard equipment in the kits purchased by the air carriers. The applicable regulations specify contents of the EMK but do not make determinations about their quality. As referenced in the FAA report published in 1991, and based on a 2-year study of medical kit use, the poor technical quality of the most frequently used equipment was revealed. The commenter believes that this aspect of EMK's must be addressed.

FAA response: The FAA disagrees that it requires or allows EMK's of poor technical quality. Part 121, appendix A as it currently exists and as it will be adopted requires an "approved" EMK that must contain "appropriately maintained contents." Not maintaining equipment or carrying sub-standard equipment, therefore, constitutes a violation of part 121. While the FAA does not endorse or recommend

equipment suppliers, it is expected that the certificate holders will procure equipment of appropriate quality.

The available data from the 1991 FAA report entitled "Response Capability During Civil Air Carrier In-flight Medical Emergencies" (filed in this Docket) did not reveal overall poor technical quality of the EMK. Rather, it revealed one case in which an "inopertative" blood pressure cuff was criticized and fewer than five cases in which better airway equipment was recommended. The FAA believes that the quality of the equipment required by the regulations is maintained by routine FAA oversight of air carrier operations.

Usage of EMK's on Regional Air Carriers

The RAA indicates that the proposed enhanced EMK's simply will not be used in a typical regional operation given the lack of opportunity and lack of medical guidance needed to use the materials.

FAA response: The FAA disagrees that in-flight medical events will not occur during regional operations. Cardiac events can occur at any time, in any place, and to anyone. While professional medical guidance may not be as readily available or forthcoming on a regional flight, it is anticipated that certificate holders and its agents will act appropriately to provide for the safety of the passengers on the aircraft.

Flight attendants receive instruction in passenger emergency medical care only to a level that would allow them to attempt care if appropriate and safe. Under this action, they will need to become familiar with the modifications being made to the EMK in the event that care is chosen to be provided or if any other passenger attempts to assist.

It should be noted that crewmembers have been required, under existing § 121.417(b)(3)(iv), to be familiar with what is contained in the EMK. This action does not change that requirement, except to move the provision under § 121.805(b)(3) and to require familiarization with the EMK as modified.

If serious medical events do occur in flight, having enhanced emergency medical equipment available may facilitate the ability to attempt to assist a passenger.

Flight Operations

EMK's/AED's as "No-Go" Items

With the proposed additions to the medical equipment onboard aircraft and the increased cabin crewmember training, MedAire's experience indicates that airlines will be using their onboard medical equipment much more often. Therefore, MedAire comments that consideration should be given to the airlines allowing them to fly a passenger flight to a maintenance facility where the equipment/medical kit can be replaced rather than having them maintain expensive inventories at every destination. The high cost of this equipment and stocking requirements would make it difficult for the airlines to manage the program under a strict "no-go" rule. The possibility exists that a diversion into a non-station airport potentially could ground an aircraft and strand passengers.

The ATA comments that the FAA needs to clarify the intent of the words "unless authorized by the Administrator" under § 121.803 (a) that flights are not delayed or canceled unnecessarily. Specifically, air carriers should not be forced to seek authorization on a case-by-case basis as the issue arises. The ATA recommends that an airplane should be permitted to operate in commercial service for a reasonable period of time (up to 5 days) while an AED is not available, such as for battery replacement or maintenance or, in the case of an EMK, required items are replenished. To achieve this, the FAA could allow conditional FAA Principal Operations Inspector (POI) authorization for such operations in advance through operations specifications, a Master Minimum Equipment List provision, or as past of approved AED maintenance plans.

The APFA recommends that "grab-and-go kits" be made "no-go" items such that aircraft cannot depart without them unless each flight attendant is issued a mask and is required to carry it.

FAA response: The FAA agrees, in part, with these comments. In particular, the ATA's comment that air carriers should not be forced to seek authorization on a case-by-case basis for flights without EMK's and/or AED's available.

Under long-standing regulation, existing § 121.309 (a), an airplane may not be operated unless it is equipped with required emergency equipment, including EMK's. Therefore, EMK's have always been considered "no-go" items and must be carried as listed by the Master Minimum Equipment List. "Grab and go kits," as suggested by the APFA, are not an adequate substitute.

Under § 121.803 (a), as proposed, the FAA carried over the provisions of § 121.309 (a) but added the words "unless authorized by the Administrator." The intent of this proposal was to cover situations in which an AED may be inoperable or not available for flight; however, the FAA inadvertently extended that provision to all "emergency medical equipment" which also would include EMK's. Upon further review, the FAA has determined that AED's should be, and EMK's should remain, "no-go" items.

To allow an airplane without an EMK or AED to be operated in commercial service up to 5 days, as ATA suggests is not consistent with this action. Nor is it consistent to provide conditional POI authorization through operations specifications, a Master Minimum Equipment List, or as part of approved AED maintenance plans. Therefore, until the FAA develops more experience with the enhanced EMK's and AED's it will continue the current provision under § 121.309 (a) and will adopt § 121.803(a) without the words "unless authorized by the Administrator."

Single Flight Attendant Requirement

Continental Express suggests limiting the applicability of the proposal to flight operations requiring two, rather than one, flight attendant. Airplanes with as few as 10 passenger seats are required under § 121.391 to have a flight attendant. Continental Express asserts that it is unreasonable to expect a single flight attendant to attend to a stricken passenger while simultaneously performing the duties associated with approach and landing.

The International Brotherhood of Teamsters, Airline Division, wants the rule to explicitly address potential conflicts between existing regulations and the administration of CPR and/or the provision of any other first-air/responder care. It must also explicitly provide for resolution to these conflicts. While common sense may determine that the flight attendants continue with CPR, the regulations should address these circumstances. Air carriers and their employees should not have to be burdened with conflicting rules.

The Teamsters Local 2000 (representing Northwest Airlines flight attendants) comments that, when medical emergencies occur, compliance with certain regulations pertinent to cabin crewmembers may become more challenging.

The RAA indicates that the proposed rule fails to address the potential safety concerns in having one flight attendant devote time to attending to a medical event when this flight attendant has regulatory responsibilities and other passengers. On a regional airline there is the possibility that a flight attendant could accidentally shock him or herself. The suggested airborne medical emergency procedures will subject the flight attendant and other passengers to a greater risk of injury from airplane

movement particularly if a flight diversion occurs. In contrast to these commenters, MedAire believes that the recommendation to include aircraft with a single cabin crewmember as a part of the ruling is a sound one.

According to MedAire, since a person must be defibrillated within 10 minutes following cardiac arrest, it becomes impossible for any aircraft to reach life-saving medical attention in time. Today's single cabin crewmembers routinely are taught CPR during emergency training. Defibrillation has become a portion of the basic life support capability that is embodied within the CPR skill. Just as on any other aircraft, a flight attendant who is handling a medical emergency must redirect priorities if another emergency occurs that stands to impact the lives of others onboard.

FAA response: The FAA disagrees that this action conflicts with existing regulations as there is no regulation that the certificate holder or its agents *provide care.*

As noted previously, the FAA amended § 121.309(d)(1)(ii) under the "Commuter Rule" to require an EMK in airplanes for which a flight attendant is required. This action transfers that provision to § 121.803 and expands it to include an AED as well as an EMK. The FAA bases the determination to continue this requirement on the 5 years of experience it has had under the regulation and did not find a need to modify it.

While not a routine occurrence, in-flight medical events, like other on-board events such as smoke or fire, do affect the ability of flight attendants to perform their duties. For this reason, unexpected scenarios, and how to respond to them while maintaining a safe, calm, and orderly passenger cabin environment, must be trained. But exactly how to deal with these events is at the discretion of the certificate holder and its agents.

Size/Seating Capacity of Aircraft Affected

Continental Express indicates that the FAA has not factored airplane size or route length into its justification and that it appears that the size of aircraft affected was an arbitrary decision. The added weight, unit expense, and scarce cabin space may render the smaller (50 passengers and less) aircraft unlikely candidates for this rule. It suggests that the applicability of this rule, and others like it, be driven by passenger seat capacity (a fixed value) versus a variable weight. Further, Continental Express asserts that the probability a passenger suffering a medical event while on board a small airplane operating a short flight segment is much lower than the probability of a passenger suffering a medical event on a large airplane, operating a long flight segment.

FAA response: The size of the aircraft affected under this action was constrained in part by the direction set forth in the Act as follows:

> "(d) Limitation.—The Administrator may not require automatic external defibrillators on helicopters and on aircraft with a maximum payload capacity (as defined in section 119.3 of title 14, Code of Federal Regulations) of 7,500 pounds or less."

Although there are variables in payload capacity and size of aircraft, the more than 7,500 pound payload capacity roughly translates to aircraft with a capacity for 30 passengers.

In 1995, the FAA required one flight attendant as part of the "Commuter Rule" [60 FR 65832; December 20, 1995] for this size aircraft. This rule also required an EMK. Based on its experience, the FAA has determined that this size aircraft is the size necessary for EMK's and AED's.

The FAA has no data to indicate that the probability of a passenger experiencing an in-flight medical event is lower on a small airplane operating a short-flight segment. The FAA has determined that all passengers should be treated equally by having, to the extent possible, the same options for in-flight medical treatment.

Good Samaritan Protection

Seven commenters raise the issue of the applicability of the "Good Samaritan" provision.

A flight attendant indicates that flight attendants need legal protection under a "Good Samaritan law" that would provide them tort immunity (except in the case of gross negligence). If this is not the case, this flight attendant points out that he may not respond as quickly or aggressively as he might otherwise out of fear of being sued.

The AFA and the Trinity Medical Network, a global emergency medical evacuation company based in Singapore, propose that letters of indemnification be given to flight attendants to protect them from liability.

The International Association of Machinists and Aerospace Workers, AFL–CIO, appreciates the fact that the Act includes a "Good Samaritan" provision that limits air carriers' liability when obtaining medically qualified non-employee passengers to assist persons but questions whether this same protection applies to flight attendants.

The ALPA recommends that the "Good Samaritan" provisions be clearly stated in the rule itself and should be a specific required training subject. Knowledge of the "Good Samaritan" protection could positively influence the willingness of a medical professional to step forward to assist in an in-flight medical emergency.

The International Brotherhood of Teamsters, Airline Division, observes that the NPRM only briefly touches on legal liability issues in its background discussion section. Legal liability issues may arise out of these new requirements and expectations. This liability must not be placed on the shoulders of the flight attendant or flight deck crewmember. Crewmembers must be indemnified. At the very least, air carriers must be required to provide indemnification for their employees who respond in accordance with air carrier policies and *procedures.*

Teamsters Local 2000 (representing Northwest Airlines flight attendants), reveals that the legal immunity afforded flight attendants in the use of emergency medical equipment presents a concern. The legal protection afforded flight attendants must be clearly defined and made a part of the proposed regulations applicable to crewmember actions in support of a medical emergency, whether on or off the aircraft (as in the jetway for example).

FAA response: The FAA disagrees with these commenters. As stated before, there is no requirement that certificate holders or their agents provide medical assistance to passengers. If the certificate holder or its agents voluntarily choose to provide care, the provisions of the Act will apply. The "Good Samaritan" provisions of the Act do not require further implementation by the FAA. The issues raised by the commenters are between employees and employers and as such are not subject to this rulemaking.

Quality Control

Complient suggests that reference to data management criteria should be provided in the final regulation. It suggests a program to track and report the details of every in-flight medical event via the Internet. This process would ensure compliance and allow immediate access to all quality assurance information.

The AHA concludes that the FAA should implement strong quality improvement components by establishing close medical review of all uses of an AED during commercial air travel. This review should include both appropriate, and perhaps not so appropriate, use of the AED.

The ASMA and America West Airlines suggest a standardized review program that would provide an efficient and expeditious process for monitoring the use and effectiveness of the equipment and medicines and aid in determining the need for possible future modifications to the kits.

Complient recommends that the FAA review new technologies that support the mission and implementation of the "AED program."

A private citizen, who does not identify affiliation, observes that the distribution of technology does not ensure its proper use. A significant portion of the plan for this distribution should be focused on proper training for flight attendants and education for the airborne public.

FAA response: The FAA disagrees with these comments. As discussed in the NPRM preamble, while the FAA believes that this action is needed, it is also aware that adding enhancements could be misinterpreted. The FAA is not establishing a proposal for in-flight medical care. Passenger expectations regarding the level of medical care should not unrealistically raised by this action. In-flight medical assistance will continue to be discretionary to the certificate holder and its agents. In-flight medical care voluntarily provided must be regarded as limited emergency treatment with no unrealistic expectations of favorable outcomes for passengers having medical events in flight.

While it is not within the purview of the FAA to mandate or regulate health care, the FAA can require that certain equipment be available. When equipment is carried on the aircraft, the FAA requires that airline personnel must be familiar with where it is located and how it is used. Making the equipment available and having airline personnel recognize where it is located and how it is used, if so desired, is the basic intent of this action.

The FAA has long-standing procedures and personnel in place to assure that all equipment carried on board an aircraft are maintained and stored properly. The FAA continues this by including AED safety standards, initial training requirements for crewmembers, and recurrent training provisions for flight attendants.

Training

Annual vs. Biennial Recurrent Training Hours Needed

MedAire recommends that the FAA adopt, at the very least, an annual recurrent training requirement, which would tie into the flight attendants' annual training program.

The AFA states that, until an air carrier adopts the concept of performance-based standards, the training schedule for AED and CPR should be conducted every 12 months. It is imperative that the FAA follow the guidelines set by the American Red Cross and the AHA. These guidelines best represent the knowledge of training in these areas and set the minimum recurrent standards that these two organizations have set. According to the AFA, the last training outline that it received from these organizations revealed that a training certificate was valid for 1-year intervals. Therefore, the FAA should follow that guidance.

The International Brotherhood of Teamsters, Airline Division, concurs that the regulation should require recurrent training annually rather than every 24 months.

According to the International Association of Machinists and Aerospace Workers, AFL–CIO, non-medical professionals, such as police officers and fire fighters most likely are faced with having to use an AED than are flight attendants and have assistance more readily available. The huge majority of flight attendants probably will never face such situations or maybe once in their careers. Receiving appropriate training every 2 years when they may never have encountered a real-life situation does not ensure the confidence level that the rule is assuming.

FAA response: While the FAA recognizes that annual performance drills would be preferable and applauds those air carriers that conduct the drills at 1-year intervals, under existing § 121.417 similar recurrent training is conducted on a 24-month basis. The FAA did not want to deviate from existing practice by establishing a separate training schedule.

Blood-Borne Pathogens/Occupational Safety and Health Administration (OSHA)

The International Association of Machinists and Aerospace Workers, AFL–CIO, comments that blood-borne pathogens have not been addressed in the NPRM and that it must be addressed in conjunction with the IV kits. At the least, the training aspect of dealing with blood-borne pathogens must be included in this rule.

The International Brotherhood of Teamsters, Airline Division, remarks that the proposed rule does not address occupational safety and health risks for flight attendants who potentially may be exposed to blood-borne pathogens in the performance of their duties. Further, it does not require enforcement of the OSHA Bloodborne Pathogen Standard to safeguard against those risks. This standard, and a requirement for compliance by air carriers, must be incorporated by reference into the final rule. Such action would demonstrate the FAA's intent to act on the Memorandum of Understanding recently signed with OSHA.

Teamsters Local 2000 (representing Northwest Airlines flight attendants), comments that flight attendants must have both the training and personal protection to take on "first responder" responsibilities. Such training must include blood-borne pathogens, with the current OSHA Bloodborne Pathogen Standard applied to Flight Attendants to safeguard against the known risks involved. It would be irresponsible to require AED training and not include CPR and blood-borne pathogen training as well.

According to the AFA, it is anticipated that the OSHA standard on blood-borne pathogens will be one of several OSHA standards that will be proposed as OSHA rules covering flight attendants after an initial OSHA/FAA team report is completed by December 6, 2000. If the air carriers are going to be doing training on CPR and in AED usage, OSHA promulgation of its blood-borne pathogen standard covering flight attendants should be coordinated to take effect on the same date as this FAA final rule. This will ascertain that the air carriers have an obligation to provide training on occupational exposure to blood-borne pathogens and other potentially infectious materials, in addition to other protections provided by the standard.

Complient comments that, if employees are trained and designated as responsible for rendering first-aid or medical assistance as part of their job duties, they are covered by the protections of the OSHA standard. It is an OSHA violation if employees who administer first-aid as a collateral duty are not offered a hepatitis B vaccine. It also comments that a program of blood-borne pathogen training mandated annually would provide impetus to conduct at least an annual review of AED–CPR procedures.

FAA response: Because of the FAA's ongoing review [2] of blood-borne pathogens, among other issues, with OSHA, this action does not include a regulatory reference to blood-borne

[2] See the First Report of the FAA/OSHA Aviation Safety and Health Team, dated December 2000, entitled, "Application of OSHA's Requirements to Employees on Aircraft in Operation" on file in this docket.

pathogens. The FAA continues to promote awareness of blood-borne pathogen exposure through guidance material found under Advisory Circular 120–44; March 9, 1995.

Guidance Material for FAA Inspectors

The AFA is in favor of FAA inspectors being provided with criteria to use when approving the training associated with this rule. If the FAA intends to provide criteria or guidance through another means such as an Advisory Circular or Handbook Bulletin, this should be stated in the preamble. These criteria should be made available for public comment before they are published, within 6 months following the issuance of the final rule.

FAA response: The FAA developed a Flight Standards Information Bulletin for Airworthiness, FSAW 98–05, that provides POI's with information regarding installation and use of medical portable electronic devices abroad aircraft. Specifically, it familiarizes and standardizes the carriage, testing, and operational use of AED's aboard aircraft, and provides policy and guidance concerning this issue.

Typically, the FAA does not issue Advisory Circulars until adoption of a final rule. Whatever guidance the FAA issues as a result of this action will be published *in the* **Federal Register** *for* public comment.

On-Line Training Programs

Complient mentions an on-line training program as a means of ensuring that all flight attendants are properly trained and of containing initial and recurrent training costs.

FAA response: Flight Standards Handbook Bulletin for Air Transportation, HBAT 98–09, clarifies and presents guidance for POI's in responding to operators' requests to substitute home study training modules for approved traditional classroom training modules. The FAA POI must ensure that the course of study will effectively duplicate the classroom training to be replaced. No substitutions are considered for any flight training, Basic Indoctrination, Initial, Transition, or Upgrade training. Requests for substitutions to Recurrent, Requalification, or Refresher training are considered. Only cognitive or knowledge-based training is eligible for consideration for home study. Hands-on AED or CPR training would not be possible.

Standardization

The AHA recommends standardizing the "in-flight" defibrillation course" to a nationally recognized CPR–AED curriculum, such as the Heartsaver AED course of the AHA, the National Safety Council, or the American Red Cross. A training curriculum is needed that integrates both CPR and the use of the AED into a single integrated course. Further, customize the course for the specialized clinical environment of in-flight commercial aircraft. It indicates that it has assisted organizations, such as the recreational ski industry and the cruise-ship industry, with industry-specific protocols.

According to the AFA, using organizations such as the American Red Cross and the AHA will give the flying public assurance that training is being performed to a well-recognized worldwide standard. According to the AFA, the FAA has a responsibility to set minimum standards and can do so by looking to the guidelines provided by the national organizations. The minimum guidelines that these national organizations set should be the same minimum that the FAA requires.

The AFA supports the concept of "performance-based training" rather than specified minimum training hours. The AFA believes that this approach would mirror the concepts listed in AC 120–54, Advanced Qualification Program. Each flight attendant should receive a Certificate of Proficiency upon successfully completing the training, prior to undertaking in-flight medical event duties. This certification will enhance the confidence of the flight attendant to perform life-saving tasks.

The International Brotherhood of Teamsters, Airline Division, states that the level of flight attendant training varies greatly from carrier to carrier. In many instances, flight attendants are not sufficiently trained for the first-aid/first response duties already assigned to them. Upgrading the equipment on aircraft without simultaneously upgrading the training requirements for flight attendants will only exacerbate this problem. At the very least, air carriers should be required to train flight attendants to a standard equivalent to that received by other "flight responders." The standard must be specified in the regulation, not left to the discretion of the air carriers.

Teamsters Local 2000 (representing Northwest Airlines flight attendants), would like to see comprehensive first-aid training requirements, increased programmed hours of instruction/frequency for CPR, and proficiency requirements.

The ATA concurs with the FAA proposal not to require a specific number of hours of training.

According to the ATA, the final rule should clarify, however, that the result of the training is not to "certify" the trainee. It should be explained that the purpose of the training is to ensure that the trainee has satisfactorily completed the training course. Using terms such as "certify" creates an expectation, if not a legal standard.

According to the ATA, it is extremely important for the text of the final rule, not just the preamble, to state expressly that it is not the intention of the FAA to convert flight attendants or flightcrew into emergency medical personnel. Therefore proposed § 121.801 should have a new paragraph added to read as follows:

> Nothing in this subpart is intended to require crewmembers to provide emergency medical care or to establish a standard of care for the provision of emergency medical care by crewmembers or air carriers covered by this subpart.

Further a new § 121.805 (c) should be added to clarify that the required training is not intended to achieve a level of proficiency required of emergency medical personnel as follows:

> (c) The training required by this section is not intended to achieve the level of proficiency required to be attained by trained emergency medical personnel.

Other comments received from individual commenters on the issue of standardization included the following: Medical training for flight attendants should be standardized and regulated; the minimal training that needs to be done is a certified paramedic training program; involve the Association of Air Medical Services, the Emergency Nurses Association, and the National Association of Paramedics; staff the cabin crew with several members certified in basic life support; and include at least two passenger cabin personnel who are certified in first-aid and CPR.

FAA response: Given that almost every major air carrier voluntarily has implemented some form of acceptable and approved training program for flight attendants on the proposed modified EMK's, including AED's, the FAA did not propose to standardize "one-size-fits-all" requirements. The FAA believes that a specific, recommended course of standardized training would be overly burdensome. It does recommend, however, that instruction conform to national programs including those offered by the AHA or the American Red Cross. But as the provision of care is up to the certificate holder, it is up to the certificate holder to decide what program best fits its needs.

Requiring flight attendants to be certified as first responders would put more responsibility on them, which is not the intent of this action. While in some cases, flight attendants may be the first and only responders to an in-flight medical event, it is up to the certificate holder to decide what, if any, care will be provided. Requiring first responder certification would be inconsistent with this action.

Hands-on drills for medical emergencies are useful to have as an option for care. But, like other events for which training and drilling occur (e.g., fire) no certificate is provided.

The FAA concurs that the ATA's recommended amendments to §§ 121.801 and 121.805 would serve to clarify the intent of this action and adopts them, with minor modifications, under the final rule.

Suggested Training for Pilots

Pakistan International Airways believes that cockpit and cabin crew should be able to institute IV fluids. All cockpit/cabin crew should acquire basic training in CPR and basic life support.

The ALPA supports having flightcrew members being given initial training in the AED to include instruction in its proper use. While the flight attendants generally are the crewmembers who will use the AED, it also would be beneficial for pilots to be given such training.

FAA response: Although the FAA does not require it, air carriers are not precluded from providing more extensive training to any crewmembers, including pilots. The FAA did not require pilot training on the AED's because it could not foresee, except under rare circumstance,s that the equipment would be used by pilots during flight.

Other Comments Received

The following are additional comments received that, because they did not apply within the categories discussed above, are rendered here below categorized as "OTHER COMMENTS RECEIVED."

Airports

The AHA, the ATA, and a private citizen request that this proposal be extended to include airport action.

The AHA indicates that the airport programs already implemented have reported a remarkable level of early success. It urges the FAA to consider the successes of these current airport public access to defibrillation programs and reconsider its decision not to act to advance these successes in other airports.

The ATA states that the NPRM "does not deal" with the issue of whether airports should "install" AED's and EMK's. Experience demonstrates that passengers do have medical emergencies in airports for which the availability of AED's and EMK's could be beneficial. The ATA urges the FAA to initiate rulemaking to address this need.

FAA response: The FAA addressed airport medical events under separate action pursuant to the Act. As indicated in its June 6, 2000, Notice of Decision [65 FR 35971], the FAA determined that it would not require the same kind of enhancements at airports.

The FAA conducted a survey and found that most airports are already well-equipped and have well-trained personnel available to respond to airport medical events. Data on 130 airports indicate that 108, or 83 percent, have defibrillators, and that 11 airports, or 8.5 percent, have an off-airport response rate of less than 6 minutes. Thus, 119 airports, or 91.5 percent, have the medical capability to address medical events including those in which AED's may be of assistance.

In light of the determinations, of the widespread availability of emergency medical care, including AED's, at or near airports, the FAA decided not to propose action at airports.

First-Aid Kits

The ATA requests that ammonia inhalants be deleted form the first-aid kit content as they are an "archaic modality." Attempting to administer ammonia inhalants to a passenger in Sudden Cardiac Arrest would waste valuable time. ATA also comments that the requirement to carry up to four first-aid kits is excessive because multiple uses of first-aid kits on a single flight are rare. Therefore, only one first-aid kit per airplane should be required.

FAA response: The focus of this action is on EMK's and not first-aid kits. The FAA does not address first-aid kits in this action except to delete an outdated, obsolete (and therefore meaningless) reference to a Defense Department specification. The commenter's suggestions regarding first-aid kits cannot be considered because the FAA does not have data that would warrant removing the requirement to carry ammonia inhalants and/or reducing the number of first-aid kits required to be carried.

Ground-Based Medical Advisory Providers

The RAA and MedAire mention the need to have a ground-based medical advisory provider. MedAire indicates that this service can be a valuable resource in helping to reduce medical-related diversions. The RAA indicates that several regional air carriers use these services but, in every instance, the flightcrew makes the call and not the flight attendants since air-to-ground phones are not available in the passenger cabin on regional airplanes.

FAA response: As noted before, certificate holders can add equipment, including communication links, if they deem the equipment necessary. The FAA did not propose nor will it require this equipment as it is up to the certificate holder to provide whatever care the certificate holder deems appropriate.

New Subpart X Unnecessary

Continental Express comments that, by removing the existing requirement in part 121, subpart K for EMK's (effective now) and putting it into new subpart X (effective in 3 years), the EMK requirement is inadvertently deleted in the interim. Continental Express finds that creation of a new Subpart X is unnecessary and cumbersome and that if the FAA intends to establish a separate subpart for emergency medical equipment only, it also should establish separate subparts for fire extinguishers, flotation equipment, crash axes, and megaphones. It suggests incorporating changes to emergency medical equipment requirements into existing subpart K and changes to crewmember training into existing subpart N. Otherwise, it can be construed that the air carriers will be required to provide identical training to crewmembers under two separate training programs. Also, removing the requirement in existing subpart K for training in "other abnormal situations" removes training requirements for addressing situations such as abusive passengers, intoxicated passengers, passengers who might jeopardize safety, turbulence encounters, and crew coordination.

FAA response: The requirement to carry an EMK is not deleted in this action. Section 121.803 (c)(2) as added under new subpart X, will continue to require an approved EMK; however, air carriers will have 36 months to modify their existing EMK's to meet the new standard. But, as the rule language could be misread, the FAA adds new paragraph (b)(4) under § 121.805 and a new paragraph 2. under part 121, appendix A "Emergency Medical Kits" to be more explicit.

The requirement for training to accommodate "other abnormal situations" is not deleted; it continues to be found under existing § 121.421(a)(1)(ii).

It is not the intent of the FAA to create a need for two separate training programs to comply with the crewmember training requirements outlines in § 121.805. It is the intent of the FAA that these training requirements will be incorporated into each air carriers' approved training program.

The FAA developed a new subpart X for several reasons. Currently provisions for emergency medical equipment are dispersed throughout subparts N and O and, in the course of developing this action, the FAA determined that it would be more appropriate to incorporate emergency medical equipment requirements into one subpart. Because existing part 121 sets forth specifications for emergency medical equipment under one separate appendix (part 121, appendix A), the FAA determined that regulatory provisions corresponding to these specifications would be more easily understood set forth under one separate subpart.

Noticing Intent of the Regulation in Airports and in Ticket Jackets

The International Brotherhood of Teamsters, Airline Division, states that, to provide clear notice to the public of the intent of the regulation, notice should be posted in airports and in ticket jackets much the same as is required of security and hazardous materials information.

FAA response: The FAA disagrees that signage requirements at airports and notification in passenger ticket jackets is necessary. As the intent of this action is to provide the certificate holder and its agents the option of providing in-flight medical assistance, there is no reason to alert the public by sinage that limited in-flight medical assistance may be available from the certificate holder.

The FAA has always encouraged the public to seek qualified medical advice before travelling regarding any medical concerns.

Other Suggested Proposals for This Action

Certain commenters request that the FAA do the following:

- Staff flights with medical personnel ready to respond to medical events.
- Limit alcoholic beverages consumed on flights.
- Establish a coordinated training program for crewmembers that would link them to ground EMS.
- Establish one centralized school for training flight attendants.
- Have passengers inform air carriers about particular physical status and/or special dietary needs.
- Deny air passage to pregnant women.
- Maintain oxygen with a flow regulator in a container adequate for at least 4 hours on overwater flights.
- Require two separate blood-borne pathogen kits (a response kit and a cleanup kit) containing several items.

FAA response: These suggestions are inconsistent with and beyond the scope of the FAA's proposal. Commenters desiring these changes can submit separate petitions to the FAA for consideration of such actions.

Other Suggested Rule Language Changes for This Action

The ATA comments that proposed § 121.805(b)(3) should be deleted in its entirety. This proposed paragraph merely says, in a different way, what will be required by proposed § 121.805(b) (1) and (2). If this provision is not deleted, it should be clarified that the "handling" of medical events means only "responding" in a general sense. Also, although the term "familiarization" is a carryover from existing regulations, it is somewhat vague and imprecise when contrasted with the specific requirements set forth in § 121.805 (b)(1) and (2). If retained, this term should be explained.

The final rule should set forth the compliance date for training in more direct terms than proposed, ATA states. For example, the final rule could state:

> The training required in this section shall be completed on [36 months after the effective date of the final rule.

The AFA would like the words "programmed hours of instruction" added to proposed § 121.805 (b)(4)(iii). Further, proposed § 121.805 only mentions the word "instruction" therefore leaving the reader with the implication that "hand-on" training would not be required. Not requiring "hands-on" training with respect to CPR and AED usage is not acceptable. Proposed § 121.805 does not mention the word "perform" anywhere in the text of the new sub-paragraph.

FAA Response: The FAA agrees that paragraphs (b)(1), (2), and (3) of § 121.805 may contain redundancies as proposed and has revised these paragraphs based on the ATA's comment. These changes are made to clarify that crewmembers are not expected to know how to use but rather to be able to recognize, and therefore be familiar with, the content of the EMK's.

The FAA agrees that it should specify, under § 121.805, the 3-year timeframe allowed before being required to carry enhanced EMK's and has added a new paragraph accordingly. The FAA does not a add a specific compliance date for completing any of the required instruction. As noted in the NPRM, however, the required instruction must be completed within 36 months after the effective date and before compliance is required.

The FAA concurs with the AFA's comment and has revised § 121.805 (b)(4) accordingly. To further clarify the intent of this action, the FAA deletes references, that may have appeared erroneous, to § 121.421 (under proposed paragraphs (b)(4)(i) and (ii)) and to § 121.427 (under proposed paragraphs (b)(4) (iii)).

Reducing the Proposed 3-Year Compliance Date

Teamsters Local 2000 (representing Northwest Airlines flight attendants) believes that the time has come to directly address the increase in passengers needing in-flight medical assistance and the continuing growth of passengers flying with medical conditions who are more likely to experience an in-flight medical event. From a realistic viewpoint, the proposed rule changes are long overdue. In fact, the 36-month compliance date noted for the affected rule is in question, in that many U.S. air carriers have addressed many of the provisions of the proposal.

FAA response: Because many of the major air carriers already comply or will comply with the proposal, the compliance date is an issue mainly for the regional air carriers. The FAA set a 3-year compliance date to allow those air carriers that have not made modifications sufficient time to provide crewmember instruction and procure medical enhancements.

Use of Equipment by Medical Professionals Only/International Civil Aviation Organization (ICAO) Standards

The International Association of Machinists and Aerospace Workers, AFL–CIO, suggests permitting the use of the enhanced equipment only when qualified medical personnel are on board, or when a ground-to-air link with qualified medical personnel can be made. This would eliminate a flight attendant being put in the position of physician.

It also comments that it agrees with ICAO Standards on crew training and equipment requirements and that the approach of the proposed rule is "way beyond the scope" of the ICAO Standard.

FAA response: As explained in the NPRM, the FAA acknowledges that it is unrealistic to expect crewmebers to achieve the same level of proficiency as emergency medical personnel who perform medical procedures routinely on a daily basis and that this action only adds the option of limited in-flight medical assistance. Even in the case of a threat-of-death, in-flight medical event when on-board medical assistance is available, the certificate holder and its agents have to choose what assistance, if any, to provide a stricken passenger. The FAA does not have the authority, nor is this action intended, to mandate or regulate health care on board commercial air carriers; it can only require that the equipment be available.

Because the FAA will be requiring AED's, while ICAO Standards and Recommended Practices (SARP's) do not, the FAA will exceed ICAO SARP's for equipment in one area. This action, therefore, does not constitute a serious difference. The FAA concurs with the ICAO Recommended Practice that it is preferable that EMK's be used by qualified and trained personnel but, under U.S. law, it is the certificate holder who makes that decision. With the advent of medical assistance via radio, certificate holders may choose to have less qualified personnel use the EMK to assist stricken passengers under the guidance of ground-based medical providers.

Alternative Considered

The following are alternatives the FAA could have considered for this action:

- Continue case-by-case approval, without codified regulations, of voluntary AED carriage for those air carriers who seek it.
- Amend 14 CFR part 91 only and limit the action to providing authority for air carriers to carry AED's on board aircraft.
- Apply the proposal only to those air carriers having a passenger seating capacity of 51 seats or more and serviced by at least two flight attendants.

The FAA determined that, absent regulations codified under part 121, none of these options would be fully responsive to the Act and the majority of the commenters for the following reasons:

- Nothing would preclude air carriers from taking AED's off of aircraft.
- Regular maintenance and safe and appropriate usage of AED's could not be enforced.
- Enhanced emergency medical equipment would not be available on smaller air carriers.
- EMK's have been required on aircraft under 51 seats serviced by just one flight attendant for many years. The FAA could not justify allowing such aircraft to be exempt from modifications to be required under part 121.
- CPR instruction for flight attendants would not be required on all passenger-carrying aircraft. CPR, not currently required, is a necessary adjunct to AED usage as it must be initiated and 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; or the AED malfunctions.

Adopting the final rule as proposed appears to be the most appropriate FAA option. The data collection conducted as directed under the Act revealed at least 40 events in which AED's may have been used had they been available. It also revealed four events in which AED's were available and used to shock stricken passengers; these passengers continue to survive today. Subsequent to the data collection, further FAA investigation reveals that more passengers, and a crewmember, have had similar experiences.

Many public commenters request that the FAA require more emergency medical equipment and training than proposed. Because the FAA determined that these additional modifications would be burden some and would require supplemental notice for public comment, these requests could not be considered.

Comments from the Small Business Administration (SBA), the RAA, and Continental Express address the economic impact of this action on small entities. These comments are described and analyzed in further detail directly below.

Summary of Economic Comments

Small Business Administration

The SBA's comment disagrees with the FAA's statement in its NPRM (preliminary) evaluation that the proposed rule would not have "a significant economic impact on a substantial number of small entities." The SBA notes that the FAA's NPRM evaluation estimates that the rule would impact 60 small air carriers, and cites to the contrary data from the Bureau of Census to the effect that "scheduled air transportation firms totaled 715 employee firms. Of these, 452 firms have less than 20 employees; 192 firms have between 20 and 499 employees. Taken together, small firms constitute 90 percent of the industry, not 75 percent. Only 71 firms have 500 or more employee."

The SBA also finds fault with the FAA's preliminary analysis as it concerns (a) the threshold of "significant impact;" (b) the cost estimates of AED's, EMK's, and training in terms of their being disadvantageous to small business in particular.

FAA response: The FAA reviewed its preliminary analysis and now agrees with the SBA that this rule will have "a significant economic impact on a substantial number of small entities," according to the SBA formula. However, the FAA finds that the burden is neither as significant nor is the number of small entities as substantial as the SBA presents. As shown in Table A of the Regulatory Flexibility Analysis (see page 22 of the Final Rule Regulatory Evaluation on file in the Docket), this rule will impact 28 small businesses. Of these, 17 will be significantly impacted. A full discussion of the impact of this rule on these small businesses is provided in the Regulatory Flexibility Analysis. This section of the final rule Regulatory Evaluation also details the procedure by which the 28 small air carriers were identified. As noted in the Regulatory Flexibility Analysis section of the Regulatory Evaluation on file in the Docket, the FAA used the Fleet PC™ database product maintained by Back Associates, Inc., first to identify all the rule-designated airplanes (those with maximum payloads greater than 7,500 pounds) that are active or inactive (for example, undergoing maintenance checks) used in civil aviation by U.S. operators, and then to match the airplanes with their operators. The resulting data were further pared down to eliminate cargo operations, non-part 121 operations, businesses that have 1,500 or more employees, businesses that are owned as subsidiaries by other businesses, and businesses that are decertified or are otherwise operationally dormant. This approach ensured that the FAA would not omit any affected, certificated air carrier.

The group of small air carriers that resulted from this process is volatile. Within this group, between September, 1998 and September, 2000:

- DOT certificated six airlines to start operations;
- DOT recertificated a previously dormant airline;
- DOT decertificated four airlines, three for dormancy and one for cause; and three airlines were in Chapter 11 (reorganization) bankruptcy.

For this analysis, all the newly certificated airlines and the re-certificated airline were assumed to be subject to this rule. In August 1999, one

of thre three bankrupt airline emerged from the Chapter 11 bankruptcy of its parent company. Because it had not suspended its operations during bankruptcy, because it is a non-subsidiary, and because it reported financial data to the FAA, it is included in this analysis as subject to this rule.

As shown in Table A of the section on Regulatory Felxibility (see page 22 of the final rule Regulatory Evaluation, on file in the Docket) the FAA determined that only 28 carriers [3] with no more than 1,500 employees are certificated by the FAA to conduct operations subject to this rule.

The FAA's estimate of this rule's average initial burden on these small business carriers is $43,301. In no case is this amount more than one percent of any carrier's annual operating revenue, even though for this analysis, the FAA assumes that these carriers will bear all the initial cost of compliance in the first year of effectiveness, rather than spread the costs over the first 36 months of effectiveness, as the rule permits. The follow-on burdens of operation and upkeep were ignored in this analysis because (a) they are much smaller than the initial costs, (b) the financial data are limited, and (c) this carrier size category displays short business life spans. However, because 17 of these carriers reported negative *net* operating revenue for the immediately preceding reporting period (generally, which ended June 30, 2000), the FAA reasoned that these 17 could not pay the costs of compliance from current net revenue. The FAA concludes this rule will have "a significant impact" on these 17 carriers. The FAA's final estimate of AED costs is $3,140, ready for use in flight. This estimate was produced by combining the list price of the device with prices known to have been paid by air carriers already in voluntary compliance. The FAA's attenpts to learn vendor discount policy resulted in the information that such policy was confidential, that a discount could be given on as small an order as one AED, and that other factors, such as early or prominent adoption, also account for discounts. Thus, the FAA can make no conclusive statement on the availability of discounts on AED's.

For this final rule Regulatory Evaluation, based on comments, updates, and clarifications, the FAA also revised its estimates of costs of AED's, EMK's and training from the values noted by SBA. The FAA agrees with the SBA that the costs of complying with the rule will fall disproportionately on small carriers, because 90 percent of the affected air carrier industry (based on revenue passenger miles) is known to already have initiated voluntary compliance. This 90 percent includes all but one of the major air carriers and many of them small airlines, will bear the burden of compliance with this rule when it becomes effective.

In clarifying earlier comments to the FAA, one of the two major vendors of AED's noted that discounts had been given on orders as small as a single unit. This vendor noted that early or prominent adopters were as likely as volume buyers to be given discounts.

Regional Airline Association

The RAA's comments include suggestions that the applicability of the rule be limited to operations that require at least two flight attendants, and that further study be devoted to the feasibility of use of AED's and enhanced EMK's on airplanes typically operated by RAA members.

FAA response: This FAA response replies only to the economic and not to the physical or operational feasibility implications of this rule, which the FAA already has discussed above. Table B of the Regulatory Flexibility Analysis (see page 28 of the Regulatory Evaluation, on file in the Docket), shows that of 185 RAA members, only 28 will be impacted by this rule. Fifteen of the 28 are subsidiaries of larger businesses. Nine more non-subsidiary air carriers have code-sharing or other affiliation arrangements with other, larger businesses.

One thousand two hundred and fifty-nine airplanes of the total fleet of airplanes operated by these 28 air carriers will be subject to this rule. Only 132 of these airplanes offer 51 or more seats and thus require two or more attendants. The FAA has no reason to believe that the population of passengers on the 30–50 seat airplanes operated by RAA members is different in terms of its medical needs than the passengers on the 627,956 American Airlines departures equipped with AED's on which AED use was studied in 1997–1999. Thus the FAA believes that similar benefits would be generated on flights by RAA members and by American Airlines, when those flights are operated subject to this rule. Because the FAA in its regulatory evaluation determined this rule to be cost-beneficial, the FAA believes that applying this rule only to 132 of the 1,259 affected airplanes operated by RAA members would be likely to be less cost-beneficial than applying it to all.

Continental Express

As above, this response addresses only specific economic comments. Continental Express provides very detailed cost estimates of its burden of complying with the rule. The Continental Express comment extends item cost estimates for AED's, EMK's, and training, to its fleet and to its staff of attendants.

FAA response: Generally, the FAA accepted Continental Express's cost breakdown structure categories and incorporated them into its final rule evaluation. The FAA did not accept all of its estimates of item cost.

The FAA believes that its estimate more closely resembles actual industry practice than Continental Express' estimate. The FAA's procedure (shown in Tables 2, 3, and 4 of the Regulatory Evaluation, on file in the Docket) tracked the provisions of the rule that allow each carrier 36 months to bring its existing fleet and staff into compliance. Thus, the FAA estimated costs separately for each of the 10 years of the period of analysis including 2001 through 2011 and discounted each annual total to its present value. In contrast, Continental Express provides 10-year lump sum totals.

The FAA's estimate also differed from Continental Express' in distinguishing between the existing fleet of airplanes that require only to have their EMK's brought up to enhanced status (1,194 airplanes at $155 each) and those newly added airplanes added annually at 4.1 percent growth rate to the fleet from 2001 (49) through 2011 (70 at $514 each).

The FAA accepted Continental Express' assertion of the need to annually train the attendants who must be hired to replace those lost through attrition at the annual rate of 20 percent. The FAA used the same elements and rates of cost that Continental Express provided for its training cost estimate, but the FAA believes this training is better characterized as taking one day instead of two. Thus, the FAA maintains Continental Express' training cost of 4 hours of flight pay credit per day of training cost of 4 hours of flight pay credit per day of training at $28 per hour, but applies it to one day. The FAA retains the Continental Express estimate of $94 per night for lodging for one night, but applies the estimate of $32.40 per diem allowance to only one day.

The FAA reduced Continental Express' estimate of $3,500 per AED to $3,000 to reflect prices known to have been paid by air carriers. The FAA

[3] In December, 2000, one of the small carriers included in this group suspended operations and sought Chapter 11 bankruptcy protection. This analysis does not reflect that event.

retained Continental Express' estimate of $140 for installation. The FAA departed from Continental Express' estimate of $30 to enhance existing EMK's, and continued to rely on its NPRM cost of $155 for enhancement only for the fleet in existence at the base year, 2000. For the new airplanes to be added annually afterward, the FAA used the list price of $514 for the bottom-of-the-line enhanced EMK. In summary, to a great extent, the FAA incorporated Continental Express' economic comments into its estimate.

However, as the FAA shows in Table B of the Regulatory Flexibility Analysis (on file in the Docket), and also as reported on the Form 10K report filed for the year 1999 by Continental Airlines, Inc., with the Securities and Exchange Commission of the United States, Continental Express is a wholly-owned subsidiary of Continental Airlines, Inc., which already has initiated voluntary compliance with this rule. This relationship implies that the cost burden presented by Continental Express would be borne by its parent, Continental Airlines, Inc., in a manner similar to that in which other parent corporations, such as AM Corp., Inc., already bear the cost of voluntarily equipping their wholly-owned subsidiaries, such as American Airlines, Inc., and American Eagle Holding Company (American Eagle) Inc., to comply with this rule.

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 kids" 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 those ICAO SARO'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 has added 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 121.805 comply with these ICAO guidelines.

ICAO SARPS do not address AED usage on aircraft.

Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866, Regulatory Planning and Review, directs the FAA to assess both the costs and benefits of a regulatory change. We are not allowed to propose or adopt a regulation unless we make a reasoned determination that the benefits of the intended regulation justify its costs. Our assessment of this proposal indicates that its economic impact is minimal.

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

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (19 U.S.C. section 2531–2533) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, or $100 million or more, in any one year (adjusted for inflation).

In conducting these analyses, the FAA has determined that this rule: (1) Has benefits which do justify its costs, is not a "significant regulatory action" as defined in the Executive Order but is "significant" as defined in DOT's Regulatory Policies and Procedures; (2) will have a significant impact on a substantial number of small entities; (3) has a minimal impact on international trade; and (4) does not impose an unfunded mandate on state, local, or tribal governments, or on the private sector. These analyses, available in the Docket, are summarized below.

The Evolution of the Estimates of Benefits and Costs

While this final rule evaluation derives directly from the NPRM evaluation, the cost estimates are lower and the benefits estimates are higher for the final rule than for the NPRM. The reasons for these differences are as follows:

- The extent of voluntary compliance by affected carriers has increased since the NPRM was issued. The carriers known to have initiated voluntary compliance account for about 90 percent of revenue passenger miles flown by carriers subject to this final rule. Thus, this analysis applies only to those carriers not now in voluntary compliance;
- The increased extent of voluntary compliance reduced the base year fleet and staff estimates for non-complying carriers from 2,600 to 1,194 airplanes, and from 54,400 to 25,500 attendants;
- The final rule evaluation assumed currently non-complying carriers would take the full 36 months allowed by the rule to equip their existing airplanes and to train their existing attendants;
- Reviewing, updating, and clarifying the comments to the NPRM resulted in

the upward revision of the costs of some items, including training and the fully enhanced EMKs, and in its downward revision of the costs of the AEDs; and

• Review of a study published in the October 26, 2000 New England Journal of Medicine resulted in revising the estimated ten-year forecasts of averted (statistical) fatalities upward from 55 to 94.8.

The Estimate of Benefits

Quantifiable Benefits

The FAA estimate of the total benefits is based principally on the findings of *a study based on American Airlines* operations and published in the New England Journal of Medicine October 26, 2000. Considering only those passengers flying on carriers not already in voluntary compliance, the FAA expects the number of fatalities averted because of this rule becoming effective will total to 95 over the 10-year period of analysis that includes 2001 through 2010. This total compares to the 55 of the NPRM evaluation.

Based on the $2,700,000 value of an averted fatality, the total quantifiable safety benefit over the ten year period of analysis is about $176.8 million dollars, when discounted at seven percent annually to its present (year 2000) value as prescribed by OMB. Viewed over 10 years, this discounted value converts to uniform annual benefits of about $25.2 million dollars.

Unquantifiable Benefits

The FAA has identified but has not attempted to quantify benefits from the availability of enhanced EMK's, and also from the use of AED's apart from the benefits of defibrillation. Incidental to their use in defibrillation, AED's detect and provide electrocardiographic (EKG's) parameters of passenger/patients. Properly interpreted by a passenger/physician, these EKG's possibly can rule out the necessity for diverting a flight, as otherwise might be determined prudent absent a properly interpreted EKG readout. Further, the availability of on-board enhanced EMK's for use by a passenger/physician could rule out the necessity of diverting a flight. Because flight diversions are costly, their reduction is a benefit, but the FAA has not attempted to quantify it.

The Estimate of Costs

The comments to the NPRM resulted in the FAA's upward revision of the costs of some items, including AED's, enhanced EMK's and training. For example, the vendor's list price of $514 for the entry-level EMK was determined to be a more accurate reflection of carriers' costs than was the NPRM estimate. The FAA estimate of initial training costs was raised from its NPRM value of $151 to $238.40. The new estimate reflects partial acceptance of the costs provided by a commenter who postulated 2 days of initial training at $384. The FAA estimate applies that commenter's cost elements over 1 day of training. For this final rule evaluation, a 20 percent annual attrition rate among attendants was included in the computation of training costs. The cost of a defibrillator was decreased from its NPRM $3,500 list price to $3,000, reflecting reports of actual pricing. Installation costs of $140 were added to this acquisition cost. The annual operational cost of the current generation of AED batteries and pads was increased to $157.50 from $100 as clarified and updated by a vendor/*commenter.*

For AED's EMK's and training, this final rule evaluation assumes each affected carrier not already in voluntary compliance will spread fleet complianace over the full 36 months allowed by the rule. This means that for AED's and enhanced EMK's the base year 2000 fleet of 1,194 airplanes will be brought to compliance at the rate of one third of this fleet or 398 airplanes per year. In like manner, the base year complement of about 25,500 attendants to be trained will be trained at 8,481 per year until all are trained.

These estimates also incorporated new airplanes and new attendants assumed to be added annually in step with FAA estimates of industry growth. Finally, this estimate included one-half day of recurrent training at 2–year intervals.

The FAA totaled all the expected costs over the 10-year period including 2001 through 2010 (the period of analysis) of this regulatory proposal. The present value of this cost stream was calculated using a discount factor of seven percent annually.

The FAA's estimates of the costs of this final rule are as follows:

AEDs	$5,759,129
Enhanced EMKs	1,692,184
Training	8,848,821
Fuel weight penalty	319,860
Total	16,619,994
Uniform Annual Cost over ten years	2,366,687

Benefits/Costs Comparison

Discounted to their present (year 2000) value, the benefits of this rule are about $176.8 million. The present value of the total costs of this rule is about $16.6 million dollars. Viewed over the 10-year period of analysis, the comparison of uniform costs and benefits is about $25.2 million dollars annually for benefits and about $2.4 million dollars annually for costs. This final rule is cost beneficial.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities (small business and small not-for-profit government jurisdictions) are not unnecessarily and disproportionately burdened by Federal regulations. The RFA, which was amended March 1996, requires regulatory agencies to review rules to determine if they have "a significant economic impact on a substantial number of small entities." The Small Business Administration defines small entities to be those airlines with 1,500 or fewer employees for the air transportation industry.

For this final rule, the small entity group of interest is drawn from among those air carriers that are certificated by the FAA to operate under 14 CFR part 121, and which have 1,500 or fewer employees. The final rule specifically applies to the use by such carriers of airplanes that have maximum payloads of more than 7,500 pounds and more. Although this rule also encompasses air carriers certificated to operate under 14 CFR part 135, the rule as it regards them includes only a non-substantive editorial change, with no economic impact. Thus for operators certificated under 14 CFR part 135, the economic impact of this final rule on such carriers is negligible.

The FAA determined this final rule will have a significant economic impact on a substantial number of small entities. Twenty-eight small business air carriers will feel the impact of this rule. To ensure that the estimated burden of these small carriers would not be understated, the FAA assumed they would undertake to comply with the rule within 1 year, instead of the 3 allowed. In no case was the actual burden estimated to be greater than one percent of annual operating income. However, because 17 of these carriers had negative net operating income for the year that ended June 30, 2000, the FAA stipulates that these carriers cannot meet the costs of this rule out of their operating income.

International Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic

objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. In addition, consistent with the Administration's belief in the general superiority and desirability of free trade, it is the policy of the Administration to remove or diminish to the extent feasible, barriers to international trade, including both barriers affecting the export of American goods and services to foreign countries and barriers affecting the import of foreign goods and services into the United States.

In accordance with the above statute and policy, the FAA has assessed the potential effect of this final rule and has determined that it will have little or no effect on trade-sensitive activities. U.S. carriers that have voluntarily upgraded their emergency medical equipment account for a majority of the U.S.-flag international service. The FAA believes that the popularity among U.S. carriers of the provisions of this rule extends to foreign carriers in international flights to and from the United States. The FAA is aware that many foreign carriers carry AEDs on flights to and from the United States. Among those of which the FAA is aware are the following: Aegean Airlines; Air Canada; Air Zimbabwe; British Airways; Cathay Pacific; Emirates Airlines; Finnair; Iberia; Malev; Quantas; Swiss Air; Varig; And Virgin Atlantic.

Final Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (the Act.), enacted as Pub. L. 104–4 on March 22, 1995, is intended, among other things, to curb the practice of imposing unfunded Federal mandates on States, local, and tribal governments.

Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action."

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Executive Order 13132, Federalism

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

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) 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) Pub. L. 94–163. as amended (42 U.S.C. 6362) and FAA Order 1053.1. It has been determined that the final rule 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 Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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

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. Nothing in this subpart is intended to require certificate holders or its agents to provide emergency medical care or to establish a standard of care for the provision of emergency medical care.

§ 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.

(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.

(3) In airplanes for which a flight attendant is required, an approved emergency medical kit as modified effective April 12, 2004.

(4) 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 April 12, 2004.

§ 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 emergency medical event procedures, including coordination among crewmembers.

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

(3) Instruction to familiarize crewmembers with the content of the emergency medical kit.

(4) Instruction to familiarize crewmembers with the content of the emergency medical kit as modified on April 12, 2004.

(5) For each flight attendant—

(i) Instruction, to include performance drills, in the proper use of automated external defibrillators.

(ii) Instruction, to include performance drills, in cardiopulmonary resuscitation.

(iii) Recurrent training, to include performance drills, in the proper use of an automated external defibrillators and in cardiopulmonary resuscitation at least once every 24 months.

(c) The crewmember instruction, performance drills, and recurrent training required under this section are not required to be equivalent to the expert level of proficiency attained by professional emergency medical personnel.

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:

No. of passenger seats	No. of first-aid kits
0–50	1
51–150	2
151–250	3
More than 250	4

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:

Contents	Quantity
Adhesive bandage compresses, 1-inch	16
Antiseptic swabs	20
Ammonia inhalants	10
Bandage compresses, 4-inch	8
Triangular bandage compresses, 40-inch	5
Arm splint, noninflatable	1
Leg splint, noninflatable	1
Roller bandage, 4-inch	4

Contents	Quantity
Adhesive tape, 1-inch standard roll	2
Bandage scissors	1

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.

Emergency Medical Kits

1. Until April 12, 2004, at least one approved emergency medical kit that must contain at least the following appropriately maintained contents in the specified quantities:

Contents	Quantity
Sphygmomanometer	1
Stethoscope	1
Airways, cropharyngeal (3 sizes)	3
Syringes (sizes necessary to administer required drugs)	4
Needles (sizes necessary to administer required drugs)	6
50% Dextrose injection, 50cc	1
Epinephrine 1:1000, single dose ampule or equivalent)	2
Diphenhydramine HC1 injection, single dose ampule or equivalent	2
Nitroglycerin tablets	10
Basic instructions for use of the drugs in the kit	1
protective nonpermeable gloves or equivalent	1 pair

2. As of April 12, 2004, at least one approved emergency medical kit that must contain at least the following appropriately maintained contents in the specified quantities:

Contents	Quantity
Sphygmonanometer	1
Stethoscope	1
Airways, oropharyngeal (3 sizes): 1 pediatric, 1 small adult, 1 large adult or equivalent	3
Self-inflating manual resuscitation device with 3 masks (1 pediatric, 1 small adult, 1 large adult or equivalent)	1:3 masks
CPR mask (3 sizes), 1 pediatric, 1 small adult, 1 large adult, or equivalent	3
IV Admin Set: Tubing w/ 2 Y connectors	1
Alcohol sponges	2
Adhesive tape, 1-inch standard roll adhesive	1
Tape scissors	1 pair
Tourniquet	1
Saline solution, 500 cc	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, 325 mg	4
Antihistamine tablets, 25 mg	4
Antihistamine injectable, 50 mg, (single dose ampule or equivalent)	2
Atropine, 0.5 mg, 5 cc (single dose ampule or equivalent)	2
Aspirin tablets, 325 mg	4
Bronchodilator, inhaled (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)	2
Nitroglycerin tablets, 0.4 mg	10
Basic instructions for use of the drugs in the kit	1

3. If all of the above-listed items do not fit into one container, more than one container may be used.

Automated External Defibrillators

At least one approved automated external defibrillator, legally marketed in the United States in accordance with Food and Drug Administration requirements, 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 as approved by the Administrator.

3. Be maintained in accordance with the manufacturer's specifications.

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

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
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 nonperméable gloves or equivalent	1 pair

* * * * *

Issued in Washington, DC, on April 6, 2001.

Jane F. Garvey,

Administrator.

[FR Doc. 01–8932 Filed 4–11–01; 8:45 am]

BILLING CODE 4910–13–M

121-280

[Federal Register: June 11, 2001 (Volume 66, Number 112)]
[Rules and Regulations]
[Page 31145-31146]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr11jn01-11]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 61, 63, 65, 108, 121 and 135

[Docket No. **FAA**-2000-7497; Amendment No. 61-107, 63-30, 65-41, 108-18, 121-280 and 135-79]
RIN 2120-AH01

Advanced Qualification Program; Correction

AGENCY: Federal Aviation Administration (**FAA**), DOT.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the final rule, published in the Federal Register on October 10, 2000 (65 FR 60334). That final rule established a new termination date for Special Federal Aviation Regulation (SFAR) No. 58 (55 FR 40275; October 2, 1990), which provided the approval of an alternate method (known as ``Advanced Qualification Program'' or ``AQP'') for qualifying, training and certifying, and otherwise ensuring the competeny of crewmembers, aircraft dispatchers, other operations personnel, instructors, and evaluators who are required to be trained or qualified under 14 CFR parts 121 and 135.

FOR FURTHER INFORMATION CONTACT: Thomas M. Longridge, (703) 661-0260.

Correction of Publication

In the final rule FR Doc. 00-25951, beginning on page 60334 in the Federal Register issue of October 10, 2000, make the following corrections:

1. On page 60334, in column 1, in the heading section, beginning on line 7,

[[Page 31146]]

correct ``Amendment No. 61-107, 63-30, 65-41, 108-18, 121-280 and 135-78'' to read ``Amendment Nos. 61-107, 63-30, 65-41, 108-18, 121-280 and 135-79''.

Issued in Washington, DC on June 6, 2001.
Donald Byrne,
Assistant Chief Counsel, Regulations Division.
[FR Doc. 01-14656 Filed 6-8-01; 8:45 am]
BILLING CODE 4910-13-M

Corrections

Federal Register

Vol. 66, No. 98

Monday, May 21, 2001

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121 and 135

[Docket No. FAA–2000–7119; Amendment No. 121–280 and 135–78]

RIN 2120–AG89

Emergency Medical Equipment

Correction

In rule document 01–8932 beginning on page 19028 in the issue of Thursday, April 12, 2001, make the following corrections:

1. On page 19029, in the third column, under the "Storage" heading, fifth line, "Wtih" should read "With".

2. On the same page, in the same column, under the "Visual Inspection" heading, first line, "he" should read "the".

3. On page 19030, in the second column, in the third paragraph, 16th line "on" should read "one".

4. On page 19031, in the first column, item number 3., the second line, "contained" should read "container".

5. On the same page, in the second column, ninth line from the bottom of the page, "A non-pop off valve" should read "A no-pop off valve".

6. On page 19033, in the second column, in first complete paragraph, 22nd line, "past" should read "part".

7. On the same page, in the third column, under the heading "Single Flight Attendant Requirement", second paragraph, sixth line, "first-air" should read "first-aid ".

8. On page 19037, in the first column, under the heading "Suggested Training for Pilots", in the "FAA response", eighth line, "circumstance,s" should read "circumstances, ".

9. On page 19038, in the first column, first paragraph, fifth line, "outlines" should read "outlined".

10. On the same page, in the second column, under the heading "Other Suggested Rule Language Changes for This Action", fourth paragraph, seventh line, "hand-on" should read "hands-on".

11. On page 19039, in the first column, the heading **Alternative Considered;** should read **Alternatives Considered.**

12. On the same page, in the second column, fourth paragraph, sixth line, "burden some" should read "burdensome".

13. On page 19040, in the first column,in the first line, "thre" should read "the" and "airline" should read "airlines ".

14. On the same page, first full paragraph, second line, "Felxibility " should read "Flexibility".

15. On page 19041, in the second column, first paragraph, "SARO" should read "SARP".

16. On page 19042, in the second column, first full paragraph, first line, "AED's EMK's and training" should read "AED's, EMK's, and training".

[FR Doc. C1-8932 Filed 5-18-01; 8:45 am]
BILLING CODE 1505-01-D

Issued in Kansas City, Missouri, on May 30, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–14143 Filed 6–5–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91, 121, 125 and 135

Exemptions and Exceptions for Flight Data Recorder Requirements

AGENCY: Federal Aviation Administration, DOT.

ACTION: Statement of policy.

SUMMARY: This document identifies the current FAA policies regarding requests for exemption or exception from the operating rules governing the use of flight data recorders in either fixed-wing aircraft or rotorcraft. The final compliance date for the 1997 rule changes and policy changes adopted in 1997 is August 20, 2001. The Federal Aviation Administration (FAA) is publishing this document to provide guidance to operators that have applied or expect to apply for an exemption or exception from the flight data recorder requirements of any operating part.

FOR FURTHER INFORMATION CONTACT: Mr. Howard Swancy, Special Assistant to the Director (AFS–3), Flight Standards Service, FAA, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–8237.

SUPPLEMENTARY INFORMATION:

Background

In 1997, the Federal Aviation Administration promulgated new operational regulations for flight data recorders (FDRs) (62 FR 38362, July 17, 1997). At that time, the agency also withdrew a previous information bulletin that stated policy regarding earlier FDR regulations.

Following the publication of the rule and policy statement, the FAA began to receive requests for exemption from the regulations. The FAA uses the term *exemption* to refer to temporary relief from a regulation as granted to a specific petitioner. The FAA is currently reviewing all requests and exemptions in effect regarding FDRs to determine whether they will be made permanent, rescinded, or allowed to expire in the final compliance date, August 20 of this year.

When the 1997 rule was promulgated, the FAA included in § 121.344(l)(2), § 121.344a(f), § 125.226(l)(2), and § 135.152(k) those aircraft models that the FAA found were too old, too few, and too expensive to upgrade and still be economically viable to operate. These aircraft were excepted from the FDR requirements and have permanent relief from compliance with the FDR regulations of the applicable section. The FAA indicated that if operators found that additional aircraft models should be considered for permanent exception, a petition for rulemaking that included full support for the exception request should be submitted. Since that time, there have been a considerable number of requests filed.

Following this paragraph is a list of the minimum information necessary to be submitted for *each aircraft model requesting an exception*. Petitioners that already have submitted petitions should review this list and consider supplementing their petitions if they have not previously provided the necessary information. The FAA will consider any information submitted and determine whether more information is necessary for the agency to make a decision whether it is appropriate to propose exception status for a particular aircraft model. Petitioners are cautioned that exception status should *not* be considered automatic when information is submitted, nor should any grant of a temporary exemption from the FDR requirements while an exception request is pending be used to presume that permanent exception status will be granted. This applies to exemptions already issued that expire after August 20, 2001, as well. The FAA anticipates that some aircraft models that have been granted exemptions may not qualify for exception status, and will have to be modified to fully comply with the applicable regulations.

- Is this model currently in production?
- What other models are currently in production (or not in production) that are similar to this model?
- If this model is not currently in production, is there another model that is similar in a way that would facilitate this model's adaptability for FDR retrofit?
- How many aircraft of this model were produced by the manufacturer? How many of similar models?
- How many are still in operation in the United States? How many worldwide?
- Does a supplemental type certificate (STC) exist to retrofit this model (or a similar model) with the required flight data recorder equipment?
- If no STC exists, what is the expected detailed cost to develop a digital flight data recorder (DFDR) STC for this model? Provide the source of your estimates, including a person who the FAA may contact for verification. Estimates that do not include support from a person or organization qualified to make the estimate will not be accepted.
- What is the expected cost of STC installation per aircraft? Provide a source of information as discussed above.
- What is the estimated downtime per aircraft to install the required equipment? Provide a source for your information as discussed above.
- Operator estimate of cost of aircraft downtime per week for retrofit.
- Costs may be estimated as a range but must be noted as to how the range was established.
- Other information specific to an individual petition for rulemaking may be requested by the agency based on the circumstances presented.

Although only one complete petition for exception need be submitted for each model aircraft, operators are advised not to rely on the submissions of other operators that are seeking relief for the same or similar model aircraft. The FAA will accept materials from petitioners jointly, but will not assemble material from separate petitions to make a complete case for a particular aircraft model.

Petitioners should also be precise as to what requirements they are seeking relief from. No petitioner may expect that exemption or exception status will allow them to remove operational FDR equipment. For example, if an airplane meets the current FDR regulations but petitions for relief from the upgrades required by the 1997 rules, only upgrade relief will be considered. The current regulations must continue to be met, and all installed equipment must continue to be used and maintained according to the regulations. Further, these aircraft should not be presumed to be expected from future changes to the regulations.

Those submitting petitions for rulemaking to seek exception to the FDR requirements should submit the required information to the following: (1) For paper submissions, send the original signed copy of your petition for rulemaking to U.S. Department of Transportation, Docket Management System, 400 7th Street, SW., Room PL 401, Washington, DC 20591–0001; or (2) For electronic submissions, submit your petition to FAA through the Internet using the Docket Management System web site at this Internet address: http://dms.dot.gov/.

Recent Concerns

Since the time petitioners first requested that other aircraft be excepted from the applicable FDR regulations, the FAA has learned of at least two circumstances that will affect the way exception requests are analyzed. First, after the initial exemptions were granted, the FAA was informed that operators of exempted aircraft actively sought out more aircraft of these models from overseas and brought them into the United States. Those operators already held exemptions from the FDR regulations for those models, and therefore, believed that those models should be included in their original exemptions. This situation weakens the argument for exception status in at least two ways. First, the greater number of aircraft allows the cost of retrofit to be spread across additional aircraft, reducing the per-aircraft retrofit cost. Second, it lessens any public interest argument an operator may have by increasing the number of aircraft allowed to operate without FDRs. The presence of FDRs has been well established as being in the public interest and an important source of information on accidents and incidents.

The FAA always intended exception status to be very limited. The agency was and remains concerned that older aircraft of which few are left operating under limited circumstances not be denied what use might be left in them. Large numbers of aircraft with considerable economic viability were never meant to be the subject of exception status. For this reason, the FAA will take into account all aircraft worldwide for any model submitted for exception status.

The second circumstance concerns the practice of routinely adding and removing the same aircraft from the registries of the United States and other countries for benefit. The language added to § 135.152 in 1988 was specific in its intent of capturing all aircraft that were brought onto the U.S. register after October 11, 1991, primarily to stop the continued importation of older aircraft that would not need FDRs if the rule had instead used a date of manufacture. In 1997, that provision was expanded to include aircraft that were added to U.S. operations specifications (under foreign registry) after that date. Some of these aircraft were affected by the information bulletin that the agency withdrew in 1997; it was only after withdrawal that the FAA learned that several operators were using the information bulletin, combined with the practice of swapping airplanes between registries, to gain a benefit. The information bulletin presumed to grandfather any aircraft that had once been registered in the United States from the "brought on the U.S. register" language of § 135.152. Once that information bulletin was withdrawn as being in distinct conflict with the clear language and intent of the rule, the FAA indicated that all persons operating under it had 4 years to bring their aircraft into compliance. It was then that the FAA began to receive numerous requests for exception status. Operators are cautioned that all circumstances will be examined closely. Exception status will most likely *not* be proposed by the FAA when a significant number of any model is still operating. Nor does the fact that an aircraft model is no longer being manufactured automatically mean that exception status will be proposed.

The FAA has been sensitized to the situation that has resulted in distinct benefits being gained by some operators in manipulating the status of their aircraft while the FDR regulations were in flux. The loss of this benefit will not be considered in deciding whether an aircraft model is appropriate for relief from the FDR requirements. This is especially true for aircraft models that have never been brought into compliance with the regulations promulgated in 1988.

Conclusion

All operators are reminded that the compliance date for the 1997 regulations to upgrade FDRs is August 20, 2001. Similarly, aircraft that were affected by the withdrawal of the Flight Standards Information Bulletin in 1997 had the same 4 years to upgrade their aircraft to meet § 135.152. Given the considerable notice of these requirements provided by the final rule, the FAA does not intend to issue exemptions from that date except in the most limited, temporary circumstances, where fully justified. Request for exemption based on lack of installation data (i.e., no STC for their aircraft), parts availability, or generalized plans to retire aircraft will not be granted.

Issued in Washington, DC on May 31, 2001.

Nicholas Sabatini,

Director, Flight Standards Service.

[FR Doc. 01–14176 Filed 6–1–01; 3:30 pm]

BILLING CODE 4910–13–M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 270 and 275

[Release Nos. IC–24991 and IA–1945; File No. S7–06–01]

RIN 3235–AI05

Electronic Recordkeeping by Investment Companies and Investment Advisers; Correction

AGENCY: Securities and Exchange Commission.

ACTION: Correction to final rule.

SUMMARY: This document contains a correction to the final rule, which was published on Wednesday, May 30, 2001 (66 FR 29224). This rule relates to electronic recordkeeping by investment companies and investment advisers. In FR Document No. 01–13526 beginning on page 29224 for Wednesday, May 30, 2001, the docket line contains an error. The docket line is correct as set forth above.

EFFECTIVE DATE: May 31, 2001.

FOR FURTHER INFORMATION CONTACT: Frances Sienkiewicz at (202) 942–7072.

Dated: May 31, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–14218 Filed 6–5–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 00P–1275 and 00P–1276]

Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; notice of extension of period for issuance of final rule.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 25, 2001, the period for issuance of a final rule in response to its interim final rule of September 8, 2000, entitled "Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease." FDA's regulations require the agency to issue a notice of such extension if it finds, for cause, that it is unable to issue a final rule within 270 days from the date of publication of the