DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. FAA–2000–7119; Amendment No. 121–309]

RIN 2120–AI55

Emergency Medical Equipment

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: We are amending the regulations for emergency medical equipment to allow approved power sources that do not have TSO markings to be used in automated external defibrillators carried on board aircraft. We have found that in at least one instance, power sources manufactured before the manufacturer received TSO marking approval are identical to those manufactured with a TSO marking. Allowing already-purchased power sources to be used through their effective life will save operators money and will not result in decreased safety when the agency has made a finding of equivalency.

DATES: This rule is effective March 24, 2005.

FOR FURTHER INFORMATION CONTACT: David H. Rich, AIR–120, Aircraft Certification Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–7141.

Availability of Final Rule

You can get an electronic copy using the Internet by:

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

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

(3) Accessing the Government Printing Office's Web page at *http://www.gpoaccess.gov/fr/index.html.*

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

Small Business Regulatory Enforcement Fairness Act

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

SUPPLEMENTARY INFORMATION:

Background

On April 12, 2001 (66 FR 19028), the FAA amended the aircraft operating rules of 14 CFR part 121 to require air carriers to carry automated external defibrillators (AEDs) on their aircraft as of April 12, 2004. When used on board aircraft, all required electronic equipment that uses lithium batteries as a separate power source must meet the power source requirements of Technical Standard Order (TSO) C97 or C142.

Despite several years notice, a primary supplier of AEDs to the airline industry applied for TSO approval of its batteries only shortly before the effective date of the rule. Since the batteries for these AEDs were neither interchangeable nor commercially available, the FAA granted relief from the regulation by extending the date for compliance with the power source TSO until April 30, 2005 (69 FR 19761, April 14, 2004).

In November 2004, the Air Transportation Association (ATA), on behalf of 12 of its member carriers, petitioned the FAA for further relief from the rule in the form of a long-term exemption (docket number FAA–2004–17481). The ATA stated that the batteries used in two AEDs manufactured by Philips Medical Systems (Philips) before it received TSO marking approval were identical in every respect to the ones that were manufactured later with the TSO marking. The ATA noted that its carriers had in use or in inventory more than 6,700 of the non-TSO-marked batteries.

Philips was granted TSO marking approval for its two batteries in July 2004. As part of our consideration of the exemption petition, the FAA recently made an engineering determination that the two Philips batteries manufactured before TSO marking approval was granted were the equivalent in fit, form and function as those carrying the TSO marking.

We decided, however, that while relief from the TSO marking requirement may be appropriate for the previously manufactured Philips batteries, relief in the form of an exemption to a limited number of operators is not. The FAA anticipates that there are other carriers that use the same Philips AEDs and batteries and are not members of the ATA so as to be included in their petition for relief. In fact, we received a comment to the ATA petition from Comair indicating that the relief requested should be expanded to all air carriers using the subject Philips AED and battery combinations.

We also determined that exemption relief was inappropriate because a large portion of the affected air carrier fleet could potentially be included. When that happens, it is the responsibility of the agency to re-examine the rule and determine whether it needs to be changed. In this case, the FAA finds that the public interest is better served by a rule that allows for power sources that are found to be equivalent to continue to be used, regardless of the carrier or the AED manufacturer.

Accordingly, the FAA is changing the rule to state that AED power sources manufactured before July 30, 2004, and not TSO marked, may continue to be used until their expiration date provided that the power source manufacturer has requested and received from the FAA a finding of TSO equivalency for its product. The FAA is not withdrawing the rule that requires the power sources for AEDs to comply with the appropriate TSO requirements. TSOs play an important role in maintaining the fit, form and function of items used aboard aircraft, and ensure their continued quality of manufacture. Only because one manufacturer was able to show the FAA that its previously manufactured batteries were equivalent did we consider modifying this requirement for the life of the already manufactured batteries. Maintaining the TSO requirement for all power sources manufactured after July 30, 2004, ensures that no other replacement power sources, or ones not approved by the FAA, will be allowed on board aircraft.

By changing the rule, rather than granting an exemption, we are allowing for another manufacturer to request and receive the same findings of equivalency and approval, if appropriate. A manufacturer that seeks the same determination should contact the Aircraft Certification Office (ACO) that issued the TSO approval of its AED power source for an equivalency finding.

The April 30, 2005, compliance date for the power source TSO remains in effect for carriers using an AED power source that has not been specifically

found by the FAA to be equivalent to the TSO-marked item.

The FAA is issuing this rule without prior notice or opportunity for public comment. When the ATA filed its petition, eight commenters responded, all of which supported a grant of relief. Five of the comments were from ATA-member air carriers that would have been included in the exemption relief. A comment was received from the Air Carriers Association of America, requesting that three of its member airlines be included in the relief requested by the ATA. One comment was from Comair, requesting that all carriers using the subject Philips AEDs be included for relief, not just ATA members. The eighth commenter, the Allied Pilots Association, supported the requested relief.

In reviewing the comments to the ATA petition, we found that the compliance requirement is well-recognized in the air carrier industry. The exemption petition from the ATA and the comments received have already served to provide the same information that we would expect from a notice of proposed rulemaking, and have given us confidence that this rule change is appropriate. Further, this rule change is relieving in nature and affects compliance that would be required in the near future. Accordingly, we are adopting this final rule without prior notice and opportunity for prior public comment since later relief would negate the benefit of not having to purchase TSO-marked batteries and replace them before the compliance date.

Part 121, Appendix A is being amended to allow the use of AED power sources that were manufactured before July 30, 2004, and do not have the TSO marking required, provided that the manufacturer of the power source has received a finding of equivalency from the appropriate ACO. The FAA chose the July 30, 2004, date based on the information presented by the ATA in its petition for exemption. The ATA stated that Philips received its TSO marking authorization for one battery on June 9, 2004, and the other on June 17, 2004, and that the batteries became available for shipment approximately July 17, 2004. The manufacturing date of July 30, 2004 we have chosen allows time for orders in process at the time of approval to have been fulfilled. Once the TSO batteries became available, non-TSO'd batteries should no longer have been purchased, since the requirements of the rule and the shelf life of the batteries were well known.

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, section 44701 regarding safety regulations. Under that section, the FAA is charged with prescribing regulations for equipment and procedures that the Administrator finds necessary for safety in air commerce. The regulations requiring AEDs were promulgated in 2001 in response to the Aviation Medical Assistance Act of April 24, 1998 [Pub. L. 105–170]. This regulation is within the scope of that authority since it affects the use of emergency medical equipment, which has been found as necessary for safety in air commerce.

Paperwork Reduction Act

There are no new requirements for information collection associated with this amendment. It is voluntary for a manufacturer to seek an equivalency finding for its products manufactured prior to receiving approval to mark its product as compliant with the applicable TSO.

International Compatibility

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

Good Cause for Immediate Adoption

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. Sections 553(b)(3)(B)) authorizes agencies to dispense with certain notice procedures for rules when they find ''good cause'' to do so. Under section 553(b)(3)(B), the requirements of notice and opportunity for comment do not apply when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.''

As noted, the rule being amended takes effect April 30, 2005. Prior notice and public comment is not feasible before that date. Allowing the rule to take effect while the change is under consideration would result in significant expenditures to purchase TSO-marked batteries and replace those in service that have already been found to be equivalent, making the delay contrary to the public interest. Also as noted, the petition from the ATA and the comments filed in response serve the same purpose and have most likely resulted in the same comments that would have been generated by an NPRM. Accordingly, the FAA finds that notice and public comment to this final rule are unnecessary, and contrary to the public interest.

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 proposed rule indicates that it will have a positive economic impact by saving numerous carriers the cost of replacing serviceable batteries.

In its petition requesting an exemption, the ATA estimated that an exemption would save its 12 member operators $829,661 over the next ten years. This figure represents the value of batteries already purchased, plus the additional cost of TSO-marked batteries that would have to be purchased and installed by April 30, 2005. Comments submitted in response to the ATA petition indicate that several other air carriers not represented by the ATA that use Philips AEDs are in the same situation of currently using non-TSO marked batteries and having others in replacement inventory. The FAA considers the cost savings of this rule to be at least the amount stated by the ATA.

Since the costs and benefits of this change do not make it a ''significant regulatory action'' as defined in the Order, we have not prepared a ''regulatory impact analysis.'' Similarly, we have not prepared a ''regulatory evaluation,'' which is the written cost/benefit analysis ordinarily required for all rulemaking proposals under the DOT Regulatory and Policies and Procedures. We do not need to do the latter analysis where the economic impact of a proposal is minimal. This rule does not impose any new costs. The costs of compliance with this rule were already accounted for when the AED requirement was adopted in 2001.

Proposed changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs each Federal agency

to 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 also requires agencies to consider international standards and, where appropriate, use them as 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, of $100 million or more annually (adjusted for inflation).

In conducting these analyses, FAA has determined this rule (1) has benefits which do justify its costs, is not a ''significant regulatory action'' as defined in the Executive Order nor ''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) presents no barriers to international trade; and (4) does not impose an unfunded mandate on state, local, or tribal governments, or on the private sector.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) of 1980, 5 U.S.C. 601–612, directs the FAA to fit regulatory requirements to the scale of the business, organizations, and governmental jurisdictions subject to the regulation. We are required to determine whether a proposed or final action will have a ''significant economic impact on a substantial number of small entities'' as defined in the Act. If we find that the action will have a significant impact, we must prepare a ''regulatory flexibility analysis.''

This final rule has no associated costs but provides benefits to all air carriers using AEDs for which a power source equivalent to the TSO-marked source exists. Any economic impact is minimal. Therefore, we certify that this action will not have a significant economic impact on a substantial number of small entities.

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. The FAA has assessed the potential effect of this rulemaking and has determined that it will impose the same costs on domestic and international entities and thus has a neutral trade impact.

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 State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a $100 million or more expenditure (adjusted periodically 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 1050.1E identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this final rule qualifies for the categorical exclusion identified in paragraph 312f of the Order and involves no extraordinary circumstances.

Energy Impact

The energy impact of the final rule 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 in 14 CFR Part 121

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

The Amendment

In consideration of the foregoing the Federal Aviation Administration amends Chapter I of Title 14 Code of Federal Regulations 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. In Appendix A to part 121, revise paragraph 2 of ''Automated External Defibrillators,'' to read as follows:

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

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Automated External Defibrillators

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2. After April 30, 2005:

(a) Have a power source that meets FAA Technical Standard Order requirements for power sources for electronic devices used in aviation as approved by the Administrator; or

(b) Have a power source that was manufactured before July 30, 2004, and been found by the FAA to be equivalent to a power source that meets the Technical Standard Order requirements of paragraph (a) of this section.

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Issued in Washington, DC, on March 17, 2005.

Marion C. Blakey,

Administrator.

[FR Doc. 05–5764 Filed 3–18–05; 2:16 pm]

BILLING CODE 4910–13–P