

U.S. Code. Subtitle 1, Section 106 discusses 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, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes controlled airspace at the Akutan Airport, Akutan, AK.

#### **Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures," paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

#### **List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

#### **Adoption of the Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

#### **PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS**

- 1. The authority citation for 14 CFR Part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

#### **§ 71.1 [Amended]**

- 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9X, Airspace Designations and Reporting Points, dated August 7, 2013, and effective September 15, 2013 is amended as follows:

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

\* \* \* \* \*

#### **AAL AK E5 Akutan, AK [New]**

Akutan Airport, AK  
(Lat. 54°08'41" N., long. 165°36'15" W.)

That airspace extending upward from 700 feet above the surface within a 3.5-mile

radius of the Akutan Airport and within 1-mile each side of the 311° bearing extending from the 3.5-mile radius to 5.5-miles northwest of the airport.

Issued in Seattle, Washington, on September 16, 2013.

**Clark Desing,**

*Manager, Operations Support Group, Western Service Center.*

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§ 121.279(a), with adoption of § 121.803(a) without the words "unless authorized by the Administrator" would remain until the FAA developed more experience with the enhanced EMKs and AEDs. *Id.*

As described in the background section, the FAA has data obtained from the airline industry to demonstrate that use of the emergency medical equipment required by § 121.803(a) would rarely be used on back-to-back flights and therefore has allowed relief for one flight with an incomplete, missing, or inoperative Emergency Medical Kit (EMK) or automated external defibrillator (AED). A copy of Master Minimum Equipment List (MMEL) Policy Letter (PL) 73, Revision 5, Relief for Emergency Medical Equipment, is available for review on the Flight Standards Information Management System found on the FAA's Web site at: <http://fsims.faa.gov/>. A copy will also be posted to the docket for this action.

#### **Background**

FAA PL-73, MMEL Relief for Emergency Medical Equipment, was originally issued on March 4, 1994. The PL was created to provide standardized MMEL requirements for the deferral of approved emergency medical equipment, including EMK, First Aid Kits (FAK), and AEDs required by 14 CFR § 121.803. The purpose of the PL has remained consistent throughout its five revisions, although the relief specifics have been further defined. Revision 1 reformatting the PL to conform to PL standardization requirements. Revision 2 expanded the relief for FAKs to include relief for all emergency medical equipment. Revision 3 clarified that emergency medical equipment in excess of the regulatory requirements can be inoperative. Revision 4 provided three-flight limited dispatch authority for all incomplete, missing, or inoperative EMKs, FAKs, and AEDs that do not meet the minimum regulatory requirements. Revision 5 reduced the limited dispatch authority available from three flights to one flight in all situations.

On April 6, 2001, the FAA issued the final rule requiring certain aircraft operating under part 121 to carry EMKs, FAKs, and AEDs. See 66 FR 19028. The final rule's preamble reflected the FAA's long-standing position that emergency medical equipment items are "no-go" items and AEDs should also be considered "no-go" items meaning that if they are not operating pursuant to the regulatory standard then the flight should not be permitted to takeoff. In that final rule, the FAA also indicated

## **DEPARTMENT OF TRANSPORTATION**

### **Federal Aviation Administration**

#### **14 CFR Parts 121 and 135**

**[Docket No. FAA-2000-7119]**

**RIN 2120-AG89**

#### **Emergency Medical Equipment**

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

**ACTION:** Final rule; notice of policy change and availability.

**SUMMARY:** This action supplements the preamble published in the **Federal Register** on April 12, 2001 (66 FR 19028). The FAA has reviewed data for automated external defibrillators and enhanced emergency medical kits to amend the "no go" provision. Data show that allowing these items to be incomplete, missing, or inoperative for one flight in accordance with the FAA master minimum equipment list does not adversely affect aviation safety. This action provides notice of the data finding and makes available the corresponding policy change for the one-flight relief for use of emergency medical equipment.

**DATES:** This action becomes effective September 27, 2013.

#### **FOR FURTHER INFORMATION CONTACT:**

Gregory J. Janosik, New Program Implementation and International Support Branch, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202-267-8166; facsimile: 202-267-5229; email: [Gregory.Janosik@faa.gov](mailto:Gregory.Janosik@faa.gov).

**SUPPLEMENTARY INFORMATION:** In the final rule entitled, "Emergency Medical Equipment," published on April 12, 2001 (66 FR 19028), the preamble states that automated external defibrillators (AED) should be, and enhanced emergency medical kits (EMK) should remain, "no-go" items. See 66 FR 19033. That final rule's preamble also states that the current provision under

that the “no go” policy would remain in effect until the agency develops more experience with the equipment. Consistent with the regulation, the FAA issued Advisory Circular (AC) 121-33B which restated the policy that “EMKs and AEDs are ‘no-go’ items and must be carried as indicated on the” MEL on January 12, 2006. The AC indicated that the air carrier may elect to carry redundant equipment to ensure that after use of the equipment in flight, the minimum required equipment is still on board the aircraft.

However, on April 12, 2006, the FAA issued Notice 8000.320, which allowed MMEL relief for EMKs and AEDs, despite the contrary statements in the rule and AC discussed earlier. The FAA allowed the MMEL relief based on data collected from major air carriers, beginning in 1998 that showed using an EMK on back-to-back flights was rare. The notice also determined that “a large number of passengers may be at more risk at a diversion airport than they would be if MMEL relief” was available allowing the aircraft to be dispatched to its intended destination. This notice, which reversed previous FAA policy as stated in the preamble to the 2001 final rule, was not published for public comment before its issuance. It was eventually cancelled after 12 months on April 12, 2007.

On April 18, 2006, soon after the release of Notice 8000.320, the FAA released PL-73, Revision 4, MMEL Relief for Emergency Medical Equipment. Consistent with Notice 8000.320, this revision granted limited dispatch authority for aircraft with EMKs, FAKs, and AEDs that did not meet the minimum requirements of 14 CFR § 121.803. PL-73, Revision 4 authorized an air carrier to complete up to three flight cycles (3 flights) without the required equipment allowing time for the air carrier to repair or replace emergency medical equipment. PL-73, Revision 4 remained in effect until June 15, 2011.

PL-73, Revision 5 was released on June 15, 2011. Revision 5 resulted from a review conducted by FAA Flight Standards Service, which concluded that the MMEL relief offered by revision 4 was not consistent with regulation and was counter to the FAA’s established position that EMKs and AEDs are “no-go” items. Revision 5 allows only one flight cycle (1 flight), in any situation, for an air carrier to obtain the minimum required emergency medical equipment on board the aircraft. However, upon review of the policy, the FAA concluded that revision 5, though more restrictive than revision 4, is still not consistent with the regulation nor does

it comply with the intent of the regulation as expressed in the preamble. Because revision 5 was a shift in the FAA’s stated policy, the public should have been notified and provided opportunity for comment before adopting the new policy.

The FAA’s position is that although the preamble to the rule is clear that EMKs and AEDs are “no go” items, as contemplated by that final rule. Our experience has led us to conclude that relief should be allowed in limited circumstances. However, it is foreseeable that required medical equipment may be used during a flight, and the pilot will divert the aircraft to a location where the utilized medical equipment cannot be replenished or replaced. Therefore, the FAA has determined that allowing the air carrier to conduct one flight so that the aircraft can fly to a location where supplies are available would allow passengers on such a flight to reach their destinations without adversely affecting safety. As discussed earlier, air carriers have presented statistical information about EMK usage on aircraft to the FAA, which indicates that once an EMK or AED is used during a flight, there is only a remote possibility that it would need to be used on the next flight.

Airlines for America (A4A) recently resubmitted that data along with an analysis of EMK use to support its position that three-flight relief would be acceptable. A4A’s analysis was based on the likelihood of using an EMK on the first successive flight and extrapolated that data to conclude the likelihood of using an EMK on three consecutive flights would be  $1: 3.8 \times 10^{-13}$ . The FAA evaluated A4A’s analysis and determined that the conclusion regarding use on three consecutive flights was not statistically valid. The FAA notes that A4A’s analysis failed to consider that the likelihood of needing to use an EMK on any of the three successive flights would be the same as needing it on the first flight. A4A’s letter has been placed in the docket associated with this notice.

The probability of needing an EMK does not decrease because an EMK was opened on the first flight. We believe, therefore, that the probability of needing the EMK on subsequent flights would be  $5.5 \times 10^{-5}$  to  $7.8 \times 10^{-5}$  (3 times as high as the one-flight case). Therefore, because there is a relatively low probability of needing the EMK on any particular flight, we are allowing one-flight relief to air carriers with an inoperative EMK or AED so that if the flight lands at a location where the equipment cannot be repaired or replenished, the airplane can move to a

location where such services are available. However, because the probability of needing to use an EMK on subsequent flights does not diminish, we do not believe that three-flight relief would be acceptable.

Issued in Washington, DC, on September 18, 2013.

**John S. Duncan,**  
*Director, FAA Flight Standards Service.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 501

[Docket No. FDA-2013-D-1088]

### Guidance for Industry #223: Small Entity Compliance Guide—Declaring Color Additives in Animal Foods; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #223 entitled “Small Entity Compliance Guide—Declaring Color Additives in Animal Foods.” This small entity compliance guide (SECG) aids industry in complying with the requirements of the final rule that published in the **Federal Register** of November 17, 2011. FDA issued the regulation in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, FDA amended its regulations regarding the declaration of certified color additives on the labels of animal food including animal feeds and pet foods.

**DATES:** The guidance is effective September 27, 2013. Submit either electronic or written comments on the SECG at any time.

**ADDRESSES:** Submit requests for single copies of the SECG to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

Submit electronic comments on the SECG to <http://www.regulations.gov>. Submit written comments to the