

received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of Notice of Proposed Rulemakings (NPRMs)

An electronic copy of this document may be downloaded through the Internet at <http://dms.dot.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at <http://www.faa.gov> or the Superintendent of Document's Web page at <http://www.access.gpo.gov/nara>.

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA-400, 800 Independence Avenue, SW., Washington, DC 20591 or by calling (202) 267-8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267-9677, to request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to the Code of Federal Regulations (14 CFR Part 71), which would revise the Class E airspace at Middleton Island, AK. The intended effect of this proposal is to revise Class E airspace upward from 700 ft. and 1,200 ft. above the surface to contain Instrument Flight Rules (IFR) operations at Middleton Island, AK.

The FAA Instrument Flight Procedures Production and Maintenance Branch has amended two SIAPs and created two new SIAPs for the Middleton Island Airport. The amended approaches are (1) Very High Frequency Omni-directional Range (VOR) Runway (RWY) 01, Amendment (Amdt) 2; and (2) VOR/Distance Measuring Equipment (DME) RWY 19, Amdt 5. The new approaches are (1) Area Navigation (Global Positioning System) (RNAV (GPS)) RWY 01, Original; and (2) RNAV (GPS) RWY 19, Original. This action would modify the Class E controlled airspace extending upward from 700 ft. and 1,200 ft. above the surface near the Middleton Island Airport. The proposed airspace is sufficient in size to contain aircraft

executing instrument procedures at the Middleton Island Airport.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9N, *Airspace Designations and Reporting Points*, dated September 1, 2005, and effective September 15, 2005, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, 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, Subpart 1, Section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it proposes to create Class E airspace sufficient in size to contain aircraft executing instrument procedures at Middleton Island Airport and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; 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 Federal Aviation Administration Order 7400.9N, *Airspace Designations and Reporting Points*, dated September 1, 2005, and effective September 15, 2005, is to be amended as follows:

* * * * *

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

* * * * *

AAL AK E5 Middleton Island, AK [Revised]

Middleton Island Airport, AK
(Lat. 59°27'00" N., long. 146°18'26" W.)
Middleton Island VOR/DME
(Lat. 59°25'19" N., long. 146°21'00" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Middleton Island Airport, and within 4 miles either side of the 038° radial of the Middleton Island VOR/DME extending from the 6.5-mile radius to 12 miles northeast of the VOR/DME, and that airspace extending upward from 1,200 feet above the surface within a 42-mile radius of the Middleton Island VOR/DME.

* * * * *

Issued in Anchorage, AK, on February 7, 2006.

Anthony M. Wylie,

Manager, Safety, Area Flight Service Operations.

[FR Doc. E6-2190 Filed 2-14-06; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121 and 135

[Docket No. FAA-2005-22593]

Mode S Transponder Requirements in the National Airspace System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Policy notice and disposition of comments.

SUMMARY: On October 7, 2005, the Federal Aviation Administration (FAA) published a document in the **Federal Register** announcing its long-term policy for Mode S transponder equipment requirements. The policy also sought comment on the proposed termination date of March 1, 2007, for operators currently exempted from the Mode S transponder requirement of 14 CFR parts 121 and 135. This action responds to the comments and adopts the proposed date for which all applicable exemptions will terminate.

ADDRESSES: The complete docket for the proposed exemption policy may be examined at the DOT Docket Web site: <http://dms.dot.gov>. Interested persons may perform a Simple Search at that Web site, entering the docket number 22593. Comments may also be examined in Room PL-401, on the Plaza Level of the Department of Transportation Building, 400 Seventh Street, SW., Washington, DC between 9 a.m. and 5 p.m., except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ida Klepper, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267-9677.

SUPPLEMENTARY INFORMATION

Background

On October 7, 2005, the FAA published two notices in the **Federal Register** concerning the Mode S transponder equipment requirements in 14 CFR parts 121 and 135. The first notice withdrew Notice No. 96-5, which proposed to withdraw the Mode S transponder requirements for part 135 and certain 121 operations. The first October 7 notice summarized our reassessment of the requirements and articulated the basis for our conclusion to retain the Mode S transponder equipment requirements. (See 70 FR 58966.) Accordingly, the FAA withdrew Notice No. 96-5.

The second notice published on October 7 announced our policy with respect to the exemptions granted from the Mode S transponder equipment requirements. (See 70 FR 58976.) We explained that since Notice 96-5 was published in May 1996, the agency granted several exemptions to the Mode S transponder requirements because we were progressing toward the removal of this equipment requirement from all aircraft, except those aircraft operated under part 121 and that have TCAS II. As we subsequently revised our long-

term plan for Mode S transponders, we sought comment on the appropriate date for which all current exemptions should terminate. The notice proposed March 1, 2007, as the appropriate termination date.

Discussion of Comments

We received comments from AirTran Airways, Inc., Federal Express (FedEx), the Regional Airlines Association (RAA), and one individual. However, while the notice specifically sought comment on whether March 1, 2007 was the appropriate date to terminate current exemptions, no comment responded to that request. Although all comments were beyond the scope of the request, we respond to those comments below.

AirTran Airways fully supported that all applicable aircraft comply with the Mode S transponder equipment requirements.

FedEx commented on two aspects of the notice. First, it questioned whether it must request an extension of its current exemption to continue to use the Mode C and Mode A transponders installed on its Caravan airplanes until March 1, 2007. (FedEx's exemption expires on March 1, 2006.) Second, FedEx stated that it has both Mode A and Mode C transponders installed on its Caravan airplanes. FedEx questioned whether it must replace each transponder with a separate Mode S transponder.

The FAA does not intend to grant new exemptions or subsequent extensions of current exemptions during this interim period unless circumstances warrant. FedEx may continue to operate its Caravan airplanes with Mode A and Mode C installed, even after expiration of its exemption, until the transponders are no longer repairable and must be replaced. If FedEx finds that the transponders must be replaced after its exemption terminates, it must do so in accordance with the regulations and install a Mode S transponder. The FAA proposed the March 2007 date to provide a reasonable time for operators to plan for the need to replace outdated equipment when necessary. The FAA did not suggest this date to provide a vehicle for operators to quickly seek an exemption or extension to bide more time for which to equip their aircraft. We do not find that the public interest is served by simply granting additional exemptions for yet another year.

It appears to be a business decision by FedEx to have two transponders installed in its aircraft. This is not a regulatory requirement. Consequently, if FedEx needs to install a Mode S transponder in its aircraft, it only needs

to install one transponder under the regulations. Any election to install a second transponder is at FedEx's discretion.

An individual commented that the ADS-B system is far superior to Mode S because it has the capability to receive other traffic and weather information and urged the adoption of a nationwide Capstone policy to benefit all operators (including general aviation) as opposed to enforcing outdated Mode S equipment. Also, RAA commented it would expect the Mode S requirement to be consistent with the FAA's long term objectives for ADS-B to avoid costly retrofits.

Capstone is a successful initiative, but is a limited concept for a defined and remote area in southwest Alaska. Capstone does not rely on ADS-B technology but rather on Global Positioning Systems (GPS) and Wide Area Augmentation Systems (WAAS) in areas where ground sensors are not yet available. ADS-B is not considered an alternative to the more mature Mode S technology at this time due to the uncertain timeframe of widespread availability of the technology. FAA plans for expanding the ADS-B technology to the lower 48 states are still under review. Lastly, any requirement to equip and use ADS-B technology must be established through rulemaking.

RAA requested that the agency complete a cost benefit analysis of the Mode S policy and provide an opportunity for public comment on that analysis.

The FAA is required to economically analyze its intended regulations.¹ (A regulatory evaluation, including cost-benefit analysis, was completed for both the final rule adopting the Mode S requirement² and the notice proposing to withdraw the requirement.³) The FAA is not required to conduct an economic review because it determines not to proceed with a proposed regulation. A number of exemptions were granted between 1996 and 2005. The FAA could have simply denied all requests for exemptions until the Mode S transponder equipment requirement was in fact rescinded. However, we did not view this as supporting the public interest and concluded that certain exemptions were justified given the agency position on Mode S in 1996. Several operators have benefited from

¹ Executive Order 12866, Regulatory Flexibility Act of 1980 (5 U.S.C. 5601, et seq.), Trade Agreements Act (19 U.S.C. 4 §§ 2531-2533, Unfunded Mandate Reform Act of 1995 (Pub. L. 104-4).

² 52 FR 3380; February 3, 1987.

³ 61 FR 26036; May 23, 1996.

the exemptions and were able to defer the equipage costs for several years. Since that time, technology developments and the availability of Mode S avionics dictate that we revise our policy. As we are retaining the Mode S transponder requirements, the basis for the current exemptions no longer exists. Operators are not entitled to an exemption as a matter of right. Consequently, we do not agree with RAA's assertion that the previous grant of exemptions is tantamount to a rule and thus deserving of a cost-benefit analysis. We did view, as critical and warranting public input, the appropriate date for which the exemptions would terminate and that affected operators would be required to install a Mode S transponder if their Mode C or Mode A transponder could not be repaired and specifically requested comment on that aspect.

RAA also stated that there are more than 130,000 general aviation users who are not required to install Mode S and questioned why the Mode S transponder are required for part 135 operators.

The Mode S transponder requirement for part 91 operations was rescinded in 1992 (57 FR 34614; August 5, 1992). The agency concluded that the expense of requiring the equipment for all part 91 operators could not be justified since the vast majority of general aviation operators do not operate in congested airspace. Furthermore, to impose a Mode S requirement on all such operators would be unduly burdensome with little safety benefit. At this time, we do not see evidence that this rationale is no longer valid.

As stated previously, any new exemption or request for extension will be evaluated carefully as to whether it would serve the public interest. Requesting an exemption simply because previous exemptions have been granted is not considered in the public interest.

Adoption of the March 1, 2007 Date

The FAA concludes that March 1, 2007, provides a reasonable timeframe for the exemptions to terminate. We intend to judiciously exercise our authority in reviewing any petitions for exemption or requests for extension under 14 CFR 11.81.

Operators are advised that this policy does not require the installation of Mode S transponders on March 1, 2007. Operators may continue to use Mode A and Mode C transponders beyond the expiration of their exemption and past March 1, 2007, until they can no longer be repaired and must be replaced.

Issued in Washington, DC, on February 9, 2006.

James J. Ballough,

Director, Flight Standards Service.

[FR Doc. E6-2178 Filed 2-14-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 2005N-0467]

Medical Devices; Radiology Devices; Reclassification of Bone Sonometers

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing a proposed rule to reclassify bone sonometer devices from class III into class II, subject to special controls. A bone sonometer is a device that transmits ultrasound energy into the human body to measure acoustic properties of bone that indicate overall bone health and fracture risk. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document entitled "Class II Special Controls Guidance Document: Bone Sonometers" that the agency proposes to use as a special control for these devices.

DATES: Submit comments by May 16, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2005N-0467, by any of the following methods:
Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-

mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212, ext. 130.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authority

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101-629), and the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments