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SUPPLEMENTARY INFORMATION:

History

On April 24, 2000, a proposal to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise the Class E airspace at Barrow, AK, was published in the **Federal Register** (65 FR 21681). The proposal was necessary due to revisions to the instrument approaches to runway (RWY) 06 and RWY 24 at Wiley Post—Will Rogers Memorial Airport, Barrow, AK.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No public comments to the proposal were received, thus, the rule is adopted as written.

The area will 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 of FAA Order 7400.9G, *Airspace Designations and Reporting Points*, dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be revised and published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 revises the Class E airspace at Barrow, AK, through the revisions of instrument approaches to the Wiley Post—Will Rogers Memorial Airport, Barrow, AK. The area will be depicted on aeronautical charts for pilot reference. The intended effect of this proposal is to provide adequate controlled airspace for IFR operations at Wiley Post—Will Rogers Memorial Airport, Barrow, AK.

The FAA has determined that these proposed regulations only involve 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.

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, 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 7400.9G, *Airspace Designations and Reporting Points*, dated September 1, 1999, and effective September 16, 1999, 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 Barrow, AK [Revised]

Barrow/Wiley Post—Will Rogers Memorial Airport, AK

(Lat. 71°17'08" N, long. 156°45'58" W)

Barrow VORTAC

(Lat. 71°16'24" N, long. 156°47'18" W)

Barrow Localizer

(Lat. 71°17'08" N, long. 156°44'07" W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Barrow/Wiley Post—Will Rogers Memorial Airport and within 4 miles north and 6 miles south of the Barrow Localizer back course extending from the 6.6-mile radius to 14.6 miles east of the airport; and that airspace extending upward from 1,200 feet above the surface within a 77-mile radius of the airport extending clockwise from the Barrow VORTAC 101° radial to the 240° radial and within the area bounded by a line beginning at the Barrow VORTAC 240° radial 20 miles west to lat. 71°13' N long. 158° W, to lat. 71°23' N long. 157°48' W to lat. 71°25' N long. 156°55' W to lat. 71°20' N long. 155°40' W to lat. 71°14' N 155°40' W.

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Issued in Anchorage, AK, on June 27, 2000.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 00–16918 Filed 7–3–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–ASW–33]

RIN 2120–AA66

Realignment of Jet Route; TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published in the **Federal Register** on June 14, 2000 (Airspace Docket No. 99–ASW–33). The legal description of Jet Route 25 (J–25) contained an inadvertent error between the Corpus Christi, TX, Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC) and the San Antonio, TX, VORTAC. This action corrects that error.

EFFECTIVE DATE: July 5, 2000.

FOR FURTHER INFORMATION CONTACT: Bill Nelson, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION: On June 14, 2000, Airspace Docket No. 99–ASW–33, FR Doc. 00–14909, was published amending the legal description of J–25 between the Corpus Christi, TX, VORTAC and the San Antonio, TX, VORTAC (65 FR 37277). This rule inadvertently listed the true bearing between Corpus Christi, TX, and San Antonio, TX, as “166°.” The correct true bearing is “174°.” The correct true bearing was listed in the Notice of Proposed Rulemaking for this matter.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the legal description for J–25 as published in the **Federal Register** on June 24, 2000 (65 FR 37277), FR Doc. 00–14909, and incorporated by reference in 14 CFR 71.1, is corrected as follows:

§ 71.1 [Corrected]

Paragraph 2004 Jet Routes

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J-25 [Revised]

From the INT of the United States/Mexican Border and the Brownsville, TX, INT 221° radial via Brownsville; INT of the Brownsville 358° and the Corpus Christi, TX, 178° radials; Corpus Christi; INT of the Corpus Christi 311° and the San Antonio, TX, 174° radials; San Antonio; Centex, TX; Waco, TX; Ranger, TX; Tulsa, OK; Kansas City, MO; Des Moines, IA; Mason City, IA; Gopher, MN; Brainerd, MN; to Winnipeg, MB, Canada. The airspace within Canada is excluded. The airspace within Mexico is excluded.

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Issued in Washington, DC, on June 27, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division

[FR Doc. 00-16915 Filed 7-3-00; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Airspace Docket No. 97-ASO-18]

RIN 2120-AA66

Realignment and Establishment of VOR Federal Airways; KY and TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published in the **Federal Register** on June 2, 2000. The legal description of Federal Airway V-384 inadvertently listed incorrect radials. This action corrects that error.

EFFECTIVE DATE: July 5, 2000.

FOR FURTHER INFORMATION CONTACT:

Terry Brown, Airspace and Rules Division, ATA-400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION: On June 2, 2000, Airspace Docket No. 97-ASO-18, FR Doc. 00-13750, was published establishing V-384 between Livingston, TN, and Volunteer, TN. This rule included a legal description for V-384, which inadvertently listed incorrect radials. This action corrects this situation by omitting the radials in the legal description for V-384, thereby eliminating the error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the legal description for V-384 as published in the **Federal Register** on June 2, 2000 (65

FR 35272); FR Doc. 00-13750, and incorporated by reference in 14 CFR 71.1, is corrected as follows:

§ 71.1 [Corrected]

On page 35273, the legal description for V-384 is corrected as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

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V-384—[Revised]

From Livingston, TN; to Volunteer, TN.

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Issued in Washington, DC, on June 27, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 00-16914 Filed 7-3-00; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 884**

[Docket No. 95N-0084]

Medical Devices; Effective Date of Requirement for Premarket Approval for a Class III Preamendments Obstetrical and Gynecological Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for a Group 1 preamendments class III device, the obstetric data analyzer intended to analyze data from fetal and maternal monitors during labor and to warn of possible fetal distress. The agency has summarized its findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's approval requirements and the benefits to the public from the use of the devices.

DATES: This rule is effective July 5, 2000.

FOR FURTHER INFORMATION CONTACT:

Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA issued a notice of availability of a preamendments class III devices strategy document. The strategy document set forth FDA's plans for implementing the provisions of section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(i)) for preamendments class III devices for which FDA had not yet required premarket approval. FDA divided this universe of devices into three groups as referenced in the May 6, 1994, notice.

In the **Federal Register** of September 7, 1995 (60 FR 46718), FDA published a proposed rule to require the filing under section 515(b) of the act of a PMA or a notice of completion of a PDP for 43 preamendment class III devices, including the obstetric data analyzer. In accordance with section 515(b)(A)(2) of the act, FDA included in the preamble to the proposal the agency's tentative findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and the benefits to the public from use of the device. The September 7, 1995, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's findings. Under section 515(b)(2)(B) of the act, FDA provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the devices was required to be submitted by September 22, 1995. The comment period closed January 5, 1996.

FDA received one citizen petition requesting a change in the classification of the obstetrical data analyzer. FDA reviewed the petition, identified a deficiency in the petition, and issued a deficiency letter on March 7, 1996, to the petitioner. From the petitioner's response to the deficiency letter, it was apparent that the petitioner had misinterpreted the September 7, 1995, proposed rule because he believed that it was about another device and not the obstetrical data analyzer. In light of this petition, FDA has amended the identification of the device in § 884.2050(a) by changing the first two sentences to read as follows: "An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical diagnosis of fetal