

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

[Airspace Docket No. 00-ASO-41]

Amendment of Class E Airspace; New Bern, NC**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.

SUMMARY: This action amends the Class E2 airspace at New Bern, NC, from continuous to part time. A Federal Contract Tower is operational at Craven County Regional Airport, NC. Class D airspace has been established for the airport during the tower hours of operation. Therefore, the Class E2 airspace is amended from continuous to part time.

EFFECTIVE DATE: 0901 UTC, January 25, 2001.

FOR FURTHER INFORMATION CONTACT:

Wade T. Carpenter, Jr., Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5627.

SUPPLEMENTARY INFORMATION:**History**

On August 28, 2000, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by establishing Class D airspace at New Bern, NC, (65 FR 52375) as a Federal Contract Tower has opened. This action will provide Class D airspace designated as surface area to accommodate IFR operations at Craven County Regional Airport when the control tower is open. Therefore, the Class E2 airspace at New Bern, NC, must be amended from continuous to part time. Class E airspace designations are published in Paragraph 6002 of FAA Order 7400.9H, dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1, dated September 1, 1999. The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) amends Class E2 airspace at New Bern, NC.

The FAA has determined that this 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 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; EO 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

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ASO NC E2 New Bern, NC [Revised]

Craven County Regional Airport, NC
(Lat. 35°04'23"N, long. 77°02'35"W)

New Bern, VOR/DME

(Lat. 35°04'23"N, long. 77°02'42"W)

Within a 4-mile radius of Craven County Regional Airport and within 2.4-miles each side of New Bern VOR/DME 038° and 210° radials, extending from the 4-mile radius to 7 miles northeast and southwest of the VOR/DME. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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Issued in College Park, Georgia, on November 16, 2000.

Wade T. Carpenter,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 00-29908 Filed 11-21-00; 8:45 am]

BILLING CODE 4910-13-M

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

[Airspace Docket No. 00-AAL-02]

RIN: 2120-AA66**Establishment of VOR Federal Airway; AK****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.

SUMMARY: This action establishes a Very High Frequency Omnidirectional Range (VOR) Federal airway (V-457) in Alaska. The FAA is establishing this Federal airway for the following reasons: (1) The conversion of this uncharted nonregulatory route to a VOR Federal airway will add to the instrument flight rules (IFR) airway and route infrastructure in Alaska; (2) pilots will be provided with minimum en route altitudes and minimum obstruction clearance altitudes information; (3) this amendment establishes controlled airspace, thus eliminating some of the commercial IFR operations in uncontrolled airspace; and (4) the addition of this route improves the management of air traffic operations and thereby enhances safety.

EFFECTIVE DATE: 0901 UTC, January 25, 2001.

FOR FURTHER INFORMATION CONTACT: Ken McElroy, 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:**Background**

On June 28, 2000, the FAA proposed to amend Title 14 of the Code of Federal Regulations part 71 (part 71) to establish VOR Federal Airway, V-457, in Alaska (65 FR 39834). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

The Rule

This action amends part 71 by establishing VOR Federal Airway V-457 in Alaska. Presently, there is an uncharted nonregulatory route using the same routings as the V-457 which becomes effective January 25, 2001. The FAA is establishing V-457 for the following reasons: (1) The conversion of this uncharted nonregulatory route to a VOR Federal airway adds to the IFR airway and route infrastructure in Alaska; (2) pilots will be provided with minimum en route altitudes and minimum obstruction clearance altitudes information; (3) this amendment establishes controlled airspace, thus eliminating some of the commercial IFR operations in uncontrolled airspace; and (4) the addition of this route improves the management of air traffic operations and thereby enhance safety.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (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.

Alaskan VOR Federal airways are published in paragraph 6010(b) of FAA Order 7400.9H dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Alaskan VOR Federal airway listed in this document will be published subsequently in the order.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Rule

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 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 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6010(b) Alaskan VOR Federal Airways

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V-457 [New]

From Iliamna, AK, NDB; to Kenai, AK.

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Issued in Washington, DC, on November 15, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 00-29906 Filed 11-21-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 00N-1565]

Immunology and Microbiology Devices; Classification of Anti-Saccharomyces cerevisiae (S. cerevisiae) Antibody (ASCA) Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Anti-Saccharomyces cerevisiae (S. cerevisiae) antibody (ASCA) test system into class II (special controls). The special control that will apply to this device is a guidance document entitled "Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (S. cerevisiae) Antibody (ASCA) Premarket Notifications." Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this

guidance document. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of the safety and effectiveness of the devices.

DATES: This rule is effective December 22, 2000.

FOR FURTHER INFORMATION CONTACT:

Deborah M. Moore, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.