

Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2004-17426/Airspace Docket No. 04-ACE-26." The postcard will be date/time stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA as determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, 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

■ Accordingly, 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 7400.9L, dated September 2, 2003, and effective

September 16, 2003, is amended as follows:

* * * * *

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

* * * * *

ACE NE E5 Minden, NE

Minden, Pioneer Village Field, NE
(Lat. 40°30'54"N., long. 98°56'44"W.)

Kearney VOR

(Lat. 40°43'32"N., long. 99°00'18"W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Pioneer Village Field and within 3.5 miles each side of the Kearney VOR 168° radial extending from the 6.4-mile radius to 9.8 miles south of the airport.

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Issued in Kansas City, MO, on April 27, 2004.

Paul J. Sheridan

Acting Manager, Air Traffic Division, Central Region

[FR Doc. 04-10640 Filed 5-10-04; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2004-17425; Airspace Docket No. 04-ACE-25]

Modification of Class E Airspace; Holdrege, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends Title 14 Code of Federal Regulations, part 71 (14 CFR 71) by revising Class E airspace at Holdrege, NE. A review of controlled airspace for Brewster Field revealed it does not comply with the criteria for 700 feet above ground level (AGL) airspace required for diverse departures. The review also identified discrepancies in the legal description for the Holdrege, NE Class E airspace area. The area is modified and enlarged to conform to the criteria in FAA Orders.

DATES: This direct final rule is effective on 0901 UTC, August 5, 2004.

Comments for inclusion in the Rules Docket must be received on or before June 4, 2004.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC

20590-0001. You must identify the docket number FAA-2004-17425/Airspace Docket No. 04-ACE-25, at the beginning of your comments. You may also submit comments on the Internet at <http://dms.dot.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE-520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329-2524.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR part 71 modifies the Class E airspace area extending upward from 700 feet above the surface at Holdrege, NE. An examination of controlled airspace for Brewster Field revealed it does not meet the criteria for 700 feet AGL airspace required for diverse departures as specified in FAA Order 7400.2E, Procedures for Handling Airspace Matters. The criteria in FAA Order 7400.2E for an aircraft to reach 1200 feet AGL is based on a standard climb gradient of 200 feet per mile plus the distance from the airport reference point (ARP) to the end of the outermost runway. Any fractional part of a mile is converted to the next higher tenth of a mile. The examination identified discrepancies in the Brewster Field ARP used in the Class E airspace legal description and also that the legal description was not in compliance with FAA Order 8260.19C, Flight Procedures and Airspace. The limit of the Class E airspace area north extension should be defined as a distance from the Holdrege nondirectional radio beacon (NDB) and the bearing corrected. The limit of the Class E airspace area northeast extension should be extended and the Kearney very high frequency omnidirectional radio range (VOR) radial corrected. This amendment expands the airspace area from a 6-mile radius to a 6.6-mile radius of Brewster Field, corrects the ARP in the legal description, defines the north extension in relation to the Holdrege ND, corrects the NDB bearing from 016° to 014°, extends the northeast extension from 10.6 miles to 11 miles northeast of the airport, corrects the Kearney VOR radial from 220° to 222° and brings the legal description of the Holdrege, NE Class E airspace area into compliance with FAA

Orders 7400.2E and 8260.19C. This area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Interested parties are invited to participate in this rulemaking by submitting such written date, views, or arguments, as they may desire. comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2004-17425/Airspace Docket No. 04-ACE-25." The postcard

will be date/time stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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Adoption of the Amendment

■ Accordingly, 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 7400.9L, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

* * * * *

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

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ACE NE E5 Holdrege, NE
Holdrege, Brewster Field, NE

(Lat. 40°27'10" N., long. 99°20'14" W.)

Holdrege NDB

(Lat. 40°26'53" N., long. 99°20'27" W.)

Kearney VOR

(lat. 40°43'32" N., long. 99°00'18" W.)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Brewster Field and within 2.6 miles each side of the 014° bearing from the Holdrege NDB extending from the 6.6-mile radius of the airport to 7 miles north of the NDB and within 2.6 miles each side of the Kearney VOR 222° radial extending from the 6.6-mile radius to 11 miles northeast of the airport.

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Issued in Kansas City, MO, on April 27, 2004.

Paul J. Sheridan,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 04–10641 Filed 5–10–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2004P–0126]

Medical Devices; Immunology and Microbiology Devices; Classification of the Immunomagnetic Circulating Cancer Cell Selection and Enumeration System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Immunomagnetic Circulating Cancer Cell Selection and Enumeration System device into class II (special controls). The special control that will apply to the device is the guidance document entitled "Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System." 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 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of