

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.

#### 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 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 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

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

\* \* \* \* \*

#### ASO TN E5 Hohenwald, TN [New]

John A. Baker Field, TN

(Lat. 35°32'46" N, long. 87°35'58" W)

That airspace extending upward from 700 feet or more above the surface within a 6.4-mile radius of John A. Baker Field.

\* \* \* \* \*

Issued in College Park, Georgia, on March 6, 1998.

**Wade T. Carpenter,**

*Acting Manager, Air Traffic Division,  
Southern Region.*

[FR Doc. 98–9515 Filed 4–9–98; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Airspace Docket No. 98–AAL–5]

#### Proposed Revision of Class E Airspace; Kotzebue, AK

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This action revises Class E airspace at Kotzebue, AK. The establishment of Global Positioning System (GPS) instrument approaches to runway (RWY) 8 and RWY 26 at Kotzebue, AK, has made this action necessary. Adoption of this proposal would result in the provision of adequate controlled airspace for Instrument Flight Rules (IFR) operations at Kotzebue, AK.

**DATES:** Comments must be received on or before May 26, 1998

**ADDRESSES:** Send comments on the proposal in triplicate to: Manager, Operations Branch, AAL–530, Docket No. 98–AAL–5, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

The official docket may be examined in the Office of the Regional Counsel for the Alaskan Region at the same address.

An informal docket may also be examined during normal business hours in the Office of the Manager, Operations Branch, Air Traffic Division, at the address shown above and on the Internet at Alaskan Region's homepage at <http://www.alaska.faa.gov/at> or at address <http://162.58.28.41/at>.

**FOR FURTHER INFORMATION CONTACT:** Robert van Haastert, Operations Branch, AAL–538, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5863; fax: (907) 271–2850; email: [Robert.van.Haastert@faa.dot.gov](mailto:Robert.van.Haastert@faa.dot.gov). Internet address: <http://www.alaska.faa.gov/at> or at address <http://162.58.28.41/at>.

#### SUPPLEMENTARY INFORMATION:

#### Comments Invited

Interested parties are invited to participate in this proposed rulemaking

by submitting such written data, 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 the airspace docket number 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 Airspace Docket No. 98–AAL–5." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Operations Branch, Air Traffic Division, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK, 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 NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Operations Branch, AAL–530, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

#### The Proposal

The FAA proposes to amend 14 CFR part 71 by revising the Class E airspace at Kotzebue, AK, due to the establishment of GPS instrument approaches to RWY 8 and RWY 26. The area would be depicted on aeronautical charts for pilot reference. The intended effect of this proposal is to provide adequate controlled airspace for IFR operations at Kotzebue, AK.

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 7400.9E, *Airspace Designations and Reporting Points*, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1 (62 FR 52491; October 8, 1997). The Class E airspace designation listed in this document would be revised and published subsequently in the Order.

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.

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#### 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:

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##### § 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, *Airspace Designations and Reporting Points*, dated September 10, 1997, and effective September 16, 1997, 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 Kotzebue, AK

Kotzebue, Ralph Wien Memorial Airport, AK  
(Lat. 66°53'05" N, long. 162°35'55" W)  
Kotzebue VOR/DME  
(Lat. 66°53'08" N, long. 162°32'24" W)  
Hotham NDB  
(Lat. 66°54'05" N, long. 162°33'52" W)

That airspace extending upward from 700 feet above the surface within a 6.8 mile radius of the Ralph Wien Memorial Airport and within 14 miles of the Kotzebue VOR/DME extending clockwise from the 206° radial to the 130° radial and within 4 miles southeast and 8 miles northwest of the Hotham NDB 039° bearing extending from the NDB to 16 miles northeast of the NDB and within 4 miles north and 8 miles south of the Kotzebue VOR/DME 278° radial extending from the VOR/DME to 20 miles west of the VOR/DME; and that airspace extending upward from 1,200 feet above the surface within 18 miles of the Kotzebue VOR/DME clockwise from the 020° radial to the 130° radial and within 38 miles of the Kotzebue VOR/DME clockwise from the 130° radial to the 314° radial and within 4.3 miles each side of the Kotzebue VOR/DME 103° radial extending from the VOR/DME to 34 miles east of the VOR/DME; and that airspace extending upward from 5,500 feet MSL within 4.3 miles each side of the Kotzebue VOR/DME 103° radial extending from 34 miles east of the VOR/DME to 51.3 miles east of the VOR/DME; and that airspace extending upward from 7,500 feet MSL within 4.3 miles each side of the Kotzebue VOR/DME 103° radial at 51.3 miles east of the Kotzebue VOR/DME widening to 7.4 miles each side of the 103° radial at 96 miles east of the Kotzebue VOR/DME.

\* \* \* \* \*

Issued in Anchorage, AK, on April 3, 1998.

**Willis C. Nelson,**

*Manager, Air Traffic Division, Alaskan Region.*

[FR Doc. 98–9510 Filed 4–9–98; 8:45 am]

BILLING CODE 4910–13–M

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Part 26

[Docket No. 95N–0185]

RIN 0910–ZA11

#### Mutual Recognition of the Food and Drug Administration and European Community Member State Conformity Assessment Procedures; Pharmaceutical GMP Inspection Reports, Medical Device Quality System Evaluation Reports, and Certain Medical Device Premarket Evaluation Reports

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations pursuant to an international agreement that is expected to be concluded between the United States and the European Community (EC) (Ref. 1). Under the terms of that agreement, FDA may normally endorse good manufacturing practice (GMP) inspection reports for pharmaceuticals provided by equivalent EC Member State regulatory authorities and medical device quality system evaluation reports and certain medical device premarket evaluation reports provided by equivalent conformity assessment bodies. FDA is taking this action to enhance its ability to ensure the safety and efficacy of pharmaceuticals and medical devices through more efficient and effective utilization of its regulatory resources. The agency is requesting comments on the proposed rule.

**DATES:** Comments by May 11, 1998. Comments must be received by the Dockets Management Branch (address below) by 4:30 p.m. Eastern Standard Time on May 11, 1998.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, fax 301–594–3215.

**FOR FURTHER INFORMATION CONTACT:** Merton V. Smith, Office of International Affairs (HFG–1), Office of External Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0910, or E-mail: “MSmith@bangate.fda.gov”.

#### SUPPLEMENTARY INFORMATION:

#### I. Background and History

On June 20, 1997, the United States and the EC concluded negotiations of an agreement entitled “Agreement on Mutual Recognition between the United States of America and the European Community” (also called “the MRA”). The MRA includes two sectoral annexes covering products regulated by FDA. The medical device sectoral annex covers medical device quality system-related inspection reports and premarket evaluation reports. The pharmaceutical GMP sectoral annex covers pharmaceutical GMP inspection reports. The MRA also includes sectoral annexes covering products regulated by other U.S. regulatory agencies, including telecommunication equipment, electromagnetic compatibility, electrical safety, and recreational craft. Finally, the MRA includes an “umbrella” agreement that contains general provisions applicable