

RWY 19 SIAPs to serve the Stockton Municipal Airport, Stockton, MO.

The amendment to Class E airspace at Stockton, MO, will provide additional controlled airspace at and above 700 feet AGL in order to contain the new SIAPs within controlled airspace, and thereby facilitate separation of aircraft operating under Instrument Flight Rules. The 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 7400.9F, dated September 10, 1998, and effective September 16, 1998, 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. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. 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

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket

number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 99-ACE-7." The postcard will be date stamped and returned to the commenter.

#### Agency Findings

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulations is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulations (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 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

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

\* \* \* \* \*

#### ACE MO E5 Stockton, MO [Revised]

Stockton Municipal Airport, MO  
(lat. 37°39'37"N., long. 93°49'01"W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Stockton Municipal Airport.

\* \* \* \* \*

Issued in Kansas City, MO, on February 17, 1999.

**Herman, J. Lyons, Jr.,**

*Manager, Air Traffic Division, Central Region.*

[FR Doc. 99-5604 Filed 3-5-99; 8:45 am]

BILLING CODE 4910-13-M

#### DEPARTMENT OF TRANSPORTATION

#### Federal Aviation Administration

#### 14 CFR Part 71

[Airspace Docket No. 99-ACE-11]

#### Amendment to Class E Airspace; Neosho, MO

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

**ACTION:** Direct final rule; request for comments.

**SUMMARY:** This action amends Class E airspace area at Hugh Robinson Airport, Neosho, MO. A review of the Class E airspace area for Hugh Robinson Airport indicates it does not comply with the criteria for 700 feet Above Ground Level (AGL) airspace required for diverse departures as specified in FAA Order 7400.2D. The Class E airspace has been

enlarged to confirm to the criteria of FAA Order 7400.2D.

In addition, the name of Neosho Municipal Airport has been changed to Neosho, Hugh Robinson Airport.

The intended effect of this rule is to provide additional controlled Class E airspace for aircraft operating under Instrument Flight Rules (IFR), change the airport name, and comply with the criteria of FAA Order 7400.2D.

**DATES:** Effective date: 0901 UTC, July 15, 1999.

Comments for inclusion in the Rules Docket must be received on or before April 15, 1999.

**ADDRESSES:** Send comments regarding the rule in triplicate to: Manager, Airspace Branch, Air Traffic Division, ACE-520, Federal Aviation Administration, Docket Number 99-ACE-11, 601 East 12th Street, Kansas City, MO 64106.

The official docket may be examined in the Office of the Regional Counsel for the Central Region at the same address between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

An informal docket may also be examined during normal business hours in the Air Traffic Division at the same address listed above.

**FOR FURTHER INFORMATION CONTACT:** Kathy Randolph, Air Traffic Division, Airspace Branch, ACE-520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, MO 64106; telephone: (816) 426-3408.

**SUPPLEMENTARY INFORMATION:** This amendment to 14 CFR 71 revises the Class E airspace at Neosho, MO. A review of the Class E airspace for Hugh Robinson Airport, MO, indicates it does not meet the criteria for 700 feet AGL airspace required for diverse departures as specified in FAA Order 7400.2D. The criteria in FAA Order 7400.2D 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 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 amendment at Neosho, Hugh Robinson Airport, MO, will provide additional controlled airspace for aircraft operating under IFR, change the airport name, and comply with the criteria of FAA Order 7400.2D. The 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 7400.9F, dated September 10, 1998, and effective September 16, 1998, 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. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. 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**

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and are submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the

effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 99-ACE-11." The postcard will be date stamped and returned to the commenter.

#### **Agency Findings**

The regulations adopted herein will not have substantial direct 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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.

#### **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 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

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

\* \* \* \* \*

**ACE MO E5 Neosho, MO [Revised]**

Neosho, Hugh Robinson Airport, MO  
(lat. 36°48'39"N., long. 94°23'30"W.)

Neosho VORTAC

(lat. 36°50'33"N., long. 94°26'08"W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Neosho, Hugh Robinson Airport and within 1.8 miles each side of the Neosho VORTAC 310° radial extending from the 6.5-mile radius to 7 miles northwest of the airport.

Issued in Kansas City, MO, on February 16, 1999.

**Herman J. Lyons, Jr.,**

*Manager, Air Traffic Division, Central Region.*  
[FR Doc. 99–5603 Filed 3–5–99; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 50 and 812**

[Docket No. 96N–0158]

RIN 0910–AA60

**Protection of Human Subjects; Informed Consent; Technical Amendment**

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending a final rule that appeared in the **Federal Register** of October 2, 1996 (61 FR 51498) on informed consent. The document was published with some

inadvertent errors in the codified section. This document corrects those errors to ensure the accuracy and consistency of the agency's regulations. **EFFECTIVE DATE:** March 8, 1999.

**FOR FURTHER INFORMATION CONTACT:** Bonnie M. Lee, Office of the Executive Secretariat (HF–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–4450.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Wednesday, October 2, 1996 (61 FR 51498), an amendment for § 50.20 (21 CFR 50.20) was inadvertently omitted. Section 50.20 now provides for two exceptions to obtaining informed consent; one exception is contained in § 50.23 (21 CFR 50.23) and the other is contained in § 50.24 (21 CFR 50.24). Accordingly this document conforms § 50.20 to the final regulations. Additionally, an amendment for § 812.47(b) (21 CFR 812.47(b)) inadvertently omitted commas which could cause confusion in understanding the meaning of the last sentence in that paragraph. Accordingly, FDA is amending the last sentence in § 812.47(b) to include two commas so that it will state “The sponsor promptly shall provide this information in writing to FDA, investigators who are asked to participate in this or a substantially equivalent clinical investigation, and other IRB’s that are asked to review this or a substantially equivalent investigation.” Also, the final rule on informed consent amended the Investigational New Drug Application (IND) regulations and the Investigational Device Exemption (IDE) regulations. In the **Federal Register** of June 16, 1997, FDA amended its IND regulations to clarify that, within 30 days after receipt of an IND for any clinical investigation involving an exception from informed consent, FDA will provide a written determination as to whether the investigation may begin. The agency inadvertently omitted a conforming amendment for the IDE regulations in § 812.20 (21 CFR 812.20). Current IDE regulations at § 812.20(a)(4)(i) require sponsors to submit a separate IDE for any clinical investigation involving an exception from informed consent under § 50.24. This requirement is to ensure that FDA has an opportunity to review the protocol and supporting information before the investigation begins. Section 812.20(a)(4)(i) also provides that the clinical investigation may not proceed without prior written authorization from FDA. The statement in § 812.20(a)(4)(i) that “FDA shall provide such written authorization 30 days after FDA receives the IDE or earlier” might be misread as suggesting that the agency may only

grant permission for investigations to begin. To clarify the agency's intent, FDA is amending the last sentence in § 812.20(a)(4)(i) to state that “FDA shall provide a written determination 30 days after FDA receives the IDE or earlier.”

**List of Subjects**

*21 CFR Part 50*

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

*21 CFR Part 812*

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 50 and 812 are amended as follows:

**PART 50—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 21 CFR part 50 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 346, 346a, 348, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

2. Section 50.20 is amended by revising the first sentence to read as follows:

**§ 50.20 General requirements for informed consent.**

Except as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. \* \* \*

**PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS**

3. The authority citation for 21 CFR part 812 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

4. Section 812.20 is amended by revising the last sentence of paragraph (a)(4)(i) to read as follows:

**§ 812.20 Application.**

(a) \* \* \*

(4)(i) \* \* \* FDA shall provide a written determination 30 days after FDA receives the IDE or earlier.

\* \* \* \* \*

5. Section 812.47 is amended by revising the last sentence of paragraph (b) to read as follows: