

and expeditious flow of civil air traffic. The purpose of Article 12 and Annex 11 is to ensure that civil aircraft operations on international air routes are performed under uniform conditions.

The International Standards and Recommended Practices in Annex 11 apply to airspace under the jurisdiction of a contracting state, derived from ICAO. Annex 11 provisions apply when air traffic services are provided and a contracting state accepts the responsibility of providing air traffic services over high seas or in airspace of undetermined sovereignty. A contracting state accepting this responsibility may apply the International Standards and Recommended Practices that are consistent with standards and practices utilized in its domestic jurisdiction.

In accordance with Article 3 of the Convention, state-owned aircraft are exempt from the Standards and Recommended Practices of Annex 11. The United States is a contracting state to the Convention. Article 3(d) of the Convention provides that participating state aircraft will be operated in international airspace with due regard for the safety of civil aircraft. Since this action involves, in part, the designation of navigable airspace outside the United States, the Administrator is consulting with the Secretary of State and the Secretary of Defense in accordance with the provisions of Executive Order 10854.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

#### PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE 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 the FAA Order 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005, and effective September 15, 2005, is amended as follows:

*Paragraph 6007 Offshore airspace areas.*

\* \* \* \* \*

#### Control 1487L [Amended]

That airspace extending upward from 8,000 feet MSL within 149.5 miles of the Anchorage VOR/DME clockwise from the 090° radial to the 185° radial of the Anchorage VOR/DME; and that airspace extending upward from 5,500 feet MSL within the area bounded by a line beginning at lat. 58°19'58" N., long. 148°55'07" W.; to lat. 59°08'35" N., long. 147°16'04" W.; thence counterclockwise via the arc of a 149.5-mile radius centered on the Anchorage VOR/DME to the intersection of the 149.5-mile radius arc and a point 12 miles from and parallel to the U.S. coastline; thence southeast 12 miles from and parallel to the U.S. coastline to a point 12 miles offshore on the Vancouver FIR boundary; to lat. 54°32'57" N., long. 133°11'29" W.; to lat. 54°00'00" N., long. 136°00'00" W.; to lat. 52°43'00" N., long. 135°00'00" W.; to lat. 56°45'42" N., long. 151°45'00" W.; to the point of beginning; and that airspace extending upward from 1,200 feet MSL within the area bounded by a line beginning at lat. 59°33'25" N., long. 141°03'22" W.; thence southeast 12 miles from and parallel to the U.S. coastline to lat. 58°56'18" N., long. 138°45'19" W.; to lat. 58°40'00" N., long. 139°30'00" W.; to lat. 59°00'00" N., long. 141°10'00" W.; to the point of beginning, and that airspace within 85 miles of the Biorka Island VORTAC, and that airspace within 42 miles of the Middleton Island VOR/DME, and that airspace within 30 miles of the Glacier River NDB; and that airspace extending upward from 700 feet MSL within 14 miles of the Biorka Island VORTAC and within 4 miles west and 8 miles east of the Biorka Island VORTAC 209° radial extending to 16 miles southwest of the VORTAC. The portion within Canada is excluded.

\* \* \* \* \*

Issued in Washington, DC on May 31, 2006.

**Edith V. Parish,**

*Manager, Airspace and Rules.*

[FR Doc. E6–8848 Filed 6–6–06; 8:45 am]

**BILLING CODE 4910–13–P**

#### DEPARTMENT OF TRANSPORTATION

#### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA–2006–23708; Airspace Docket No. 06–AAL–1]

**RIN–2120–AA66**

#### Modification of Control 1234L Offshore Airspace Area; AK

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

**ACTION:** Final rule.

**SUMMARY:** This action amends Control 1234L offshore airspace area in Alaska. Specifically, this action modifies Control 1234L in the immediate vicinity of the Saint Paul Island Airport, AK, by

lowering the airspace floor from 2,000 feet above ground level (AGL) to 700 AGL. Additionally, outside the vicinity of the airport this action lowers the airspace floor from 2,000 AGL to 1,200 feet AGL within a 73-mile radius of the St. Paul Island Airport. The FAA is taking this action to provide additional controlled airspace for aircraft instrument flight rules (IFR) operations at the St. Paul Island Airport.

**DATES:** *Effective Date:* 0901 UTC, August 3, 2006.

**FOR FURTHER INFORMATION CONTACT:** Ken McElroy, Airspace and Rules, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

#### SUPPLEMENTARY INFORMATION:

#### History

On April 13, 2006, the FAA published in the **Federal Register** a notice of proposed rulemaking to modify the Control 1234L offshore airspace area in Alaska (71 FR 19148). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

Offshore Airspace Areas are published in paragraph 6007 of FAA Order 7400.9N dated September 1, 2005 and effective September 15, 2005, which is incorporated by reference in 14 CFR 71.1. The Offshore Airspace Areas listed in this document will be published subsequently in the Order.

#### The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Control 1234L Offshore Airspace Area, AK by lowering the floor to 700 feet AGL in the vicinity of the St. Paul Island Airport, AK, and 1,200 feet AGL within a 73-mile radius of the airport. The action is to establish controlled airspace to support IFR operations at the St. Paul Island Airport, Alaska. The FAA Instrument Flight Procedures Production and Maintenance Branch developed new instrument approach procedures for the St. Paul Island Airport. New controlled airspace extending upward from 700 feet AGL and 1,200 feet AGL in international airspace is created by this action.

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 Department of Transportation (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 proposed 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.

#### ICAO Considerations

As part of this rule relates to navigable airspace outside the United States, the notice of this action is submitted in accordance with the International Civil Aviation Organization (ICAO) International Standards and Recommended Practices.

The application of International Standards and Recommended Practices by the FAA, Office of System Operations Airspace and AIM, Airspace & Rules, in areas outside the United States domestic airspace, is governed by the Convention on International Civil Aviation. Specifically, the FAA is governed by Article 12 and Annex 11, which pertain to the establishment of necessary air navigational facilities and services to promote the safe, orderly, and expeditious flow of civil air traffic. The purpose of Article 12 and Annex 11 is to ensure that civil aircraft operations on international air routes are performed under uniform conditions.

The International Standards and Recommended Practices in Annex 11 apply to airspace under the jurisdiction of a contracting state, derived from ICAO. Annex 11 provisions apply when air traffic services are provided and a contracting state accepts the responsibility of providing air traffic services over high seas or in airspace of undetermined sovereignty. A contracting state accepting this responsibility may apply the International Standards and Recommended Practices that are consistent with standards and practices utilized in its domestic jurisdiction.

In accordance with Article 3 of the Convention, state-owned aircraft are exempt from the Standards and Recommended Practices of Annex 11. The United States is a contracting state to the Convention. Article 3(d) of the Convention provides that participating state aircraft will be operated in international airspace with due regard for the safety of civil aircraft. Since this action involves, in part, the designation of navigable airspace outside the United

States, the Administrator is consulting with the Secretary of State and the Secretary of Defense in accordance with the provisions of Executive Order 10854.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

#### PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE 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 the FAA Order 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005, and effective September 15, 2005, is amended as follows:

*Paragraph 6007 Offshore airspace areas.*

\* \* \* \* \*

#### Control 1234L [Amended]

That airspace extending upward from 700 feet above the surface within 8 miles west and 6 miles east of the 360° bearing from the St. Paul Island Airport to 14 miles north of the St. Paul Island Airport, and within 6 miles west and 8 miles east of the 172° bearing from the St. Paul Island Airport to 15 miles south of the St. Paul Island Airport; and that airspace extending upward from 1,200 feet above the surface within a 73-mile radius of the St. Paul Island Airport, and the airspace extending upward from 1,200 MSL within a 72.8-mile radius of Chignik Airport, AK; and that airspace extending upward from 2,000 feet above the surface within an area bounded by a line beginning at lat. 58°06'57" N., long. 160°00'00" W., south along long. 160°00'00" W. until it intersects the Anchorage Air Route Traffic Control Center boundary; thence southwest, northwest, north, and northeast along the Anchorage Air Route Traffic Control Center boundary to lat. 62°35'00" N., long. 175°00'00" W.; to lat. 59°59'57" N., long. 168°00'08" W.; to lat. 57°45'57" N., long. 161°46'08" W.; to the point of beginning.

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Issued in Washington, DC on May 31, 2006.

**Edith V. Parish,**

*Manager, Airspace and Rules.*

[FR Doc. E6–8850 Filed 6–6–06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 50

RIN 0910–AC25

[Docket No. 2003N–0355]

#### Medical Devices; Exception From General Requirements for Informed Consent

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

**ACTION:** Interim final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this interim final rule to amend its regulations to establish a new exception from the general requirements for informed consent, to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The agency is taking this action because it is concerned that, during a potential terrorism event or other potential public health emergency, delaying the testing of specimens to obtain informed consent may threaten the life of the subject. In many instances, there may also be others who have been exposed to, or who may be at risk of exposure to, a dangerous chemical, biological, radiological, or nuclear agent, thus necessitating identification of the agent as soon as possible. FDA is creating this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational.

**DATES:** This rule is effective June 7, 2006. Submit written or electronic comments by August 7, 2006.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia M. Gaffey, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0496, ext. 109.

**SUPPLEMENTARY INFORMATION:**