Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

**Lists 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, 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(f), 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 FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

*Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

* * * * *

**ASW OK E5 Hugo, OK [Amended]**

Stan Stamper Municipal Airport, OK
(Lat. 34°02′01″ N, long. 95°32′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Stan Stamper Municipal Airport.

Issued in Fort Worth, Texas, on January 31, 2022.

**Martin A. Skinner,**

*Acting Manager, Operations Support Group, ATO Central Service Center.*

[FR Doc. 2022–02272 Filed 2–3–22; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Docket No. FAA–2021–0814; Airspace Docket No. 21–AGL–30]**

**RIN 2120–AA66**

## Amendment of Class D and Class E Airspace and Revocation of Class E Airspace; Rochester and St. Cloud, MN

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

**ACTION:** Final rule.

**SUMMARY:** This action amends the Class D and Class E airspace at Rochester International Airport, Rochester, MN, and St. Cloud Regional Airport, St. Cloud, MN, and revokes the Class E airspace at Rochester International Airport. This action is the result of biennial airspace reviews. The geographic coordinates of St. Cloud Regional Airport are also being updated to coincide with the FAA's aeronautical database.

**DATES:** Effective 0901 UTC, May 19, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

**ADDRESSES:** FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

**SUPPLEMENTARY INFORMATION:**

**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace, the Class E surface airspace, and the Class E airspace extending upward from 700 feet above the surface at Rochester International Airport, Rochester, MN; revokes the Class E airspace designated as an extension to Class D and Class E surface areas at Rochester International Airport; amends the Class D airspace, the Class E surface area, the Class E airspace designated as an extension to Class D and Class E surface areas, and the Class E airspace extending upward from 700 feet above the surface at St. Cloud Regional Airport, St. Cloud, MN, to support instrument flight rule operations at these airports.

**History**

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 62750; November 12, 2021) for Docket No. FAA–2021–0814 to amend the Class D and Class E airspace at Rochester International Airport, Rochester, MN, and St. Cloud Regional Airport, St. Cloud, MN, and revoke Class E airspace at Rochester International Airport. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class D and E airspace designations are published in paragraphs 5000, 6002, 6004, and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

**Availability and Summary of Documents for Incorporation by Reference**

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E

airspace areas, air traffic service routes, and reporting points.

**Differences From the NPRM**

Subsequent to publication of the NPRM, the FAA discovered a typographic error in the St. Cloud, MN, Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area airspace legal description. The radius of the airport should be ''4.2-mile'' vice '4.4-mile.'' As this change does not affect the Class E airspace area as proposed, it is incorporated into this rule.

**The Rule**

This amendment to 14 CFR part 71:

Amends the Class D airspace to within a 4.4-mile (increased from a 4.3-mile) radius of Rochester International Airport, Rochester, MN; removes the Rochester VOR/DME from the airspace legal description as it is not required; and updates the outdated term ''Airport/Facility Directory'' to ''Chart Supplement'';

Amends the Class D airspace to within a 4.2-mile (increased from a 4.1-mile) radius of St. Cloud Regional Airport, St. Cloud, MN; updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and updates the outdated term ''Airport/Facility Directory'' to ''Chart Supplement'';

Amends the Class E surface area to within a 4.4-mile (increased from a 4.3-mile) radius of Rochester International Airport; removes the Rochester VOR/DME and associated extension from the airspace legal description as they are no longer required; and updates the outdated term ''Airport/Facility Directory'' to ''Chart Supplement'';

Amends the Class E surface area to within a 4.2-mile (increased from a 4.1-mile) radius of St. Cloud Regional Airport; removes the St. Cloud VOR/DME and associated extension from the airspace legal description as they no longer required; updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and updates the outdated term ''Airport/Facility Directory'' to ''Chart Supplement'';

Removes the Class E airspace designated as an extension to Class D and Class E surface areas at Rochester International Airport as it is no longer required;

Amends the Class E airspace designated as an extension to Class D and Class E surface areas at St. Cloud Regional Airport to within 2.4 miles each side of the St. Cloud VOR/DME 140° (previously 143°) radial extending from the 4.2-mile (increased from 4.1-mile) radius of the St. Cloud Regional Airport to 7 (decreased from 7.2) miles southeast of the St. Cloud VOR/DME (previously airport); and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Amends the Class E airspace extending upward from 700 feet above the surface to within a 6.9-mile (increased from a 6.8-mile) radius of Rochester International Airport; removes the Rochester VOR/DME and associated extension from the airspace legal description as they are no longer required; adds an extension within 2 miles each side of the 132° bearing from the airport extending from the 6.9-mile radius to 10.9 miles southeast of the airport; amends the southeast extension to within 4 miles each side of the 132° bearing from the Rochester Intl.: RWY 31–LOC (previously 5.3 miles northeast and 4 miles southwest of the Rochester southeast localizer course) extending from the 6.9-mile (increased from a 6.8-mile) radius to 7.5 miles (decreased from 17.3 miles) southeast of the airport; amends the northwest extension to within 3.9 miles each side of the 312° bearing from the Rochester Intl.: RWY 13–LOC (previously 5.3 miles southwest and 4 miles northeast of the Rochester northwest localizer course) extending from the 6.9-mile (increased from 6.8-mile) radius of the airport to 11.4 (decreased from 20) miles northwest of the airport;

And amends the Class E airspace extending upward from 700 feet above the surface to within a 6.7-mile (increased from 6.6-mile) radius of St. Cloud Regional Airport; amends the southeast extension to within 2.4 miles each side of the St. Cloud VOR/DME 140° (previously 143°) radial extending from the 6.7-mile (increased from 6.6-mile) radius of the airport to 7 (decrease from 7.2) miles southeast of the St. Cloud VOR/DME (previously airport); and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to biennial airspace reviews.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

**Regulatory Notices and Analyses**

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, is non-controversial and unlikely to result in adverse or negative comments. 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 only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

**Lists 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, 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(f), 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 FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

*Paragraph 5000 Class D Airspace.*

* * * * *

**AGL MN D Rochester, MN [Amended]**

Rochester International Airport, MN
(Lat. 43°54′30″ N, long. 92°30′00″ W)

That airspace extending upward from the surface to and including 3,800 feet MSL within a 4.4-mile radius of the Rochester International Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will

thereafter be published continuously in the Chart Supplement.

**AGL MN D St. Cloud, MN [Amended]**

St. Cloud Regional Airport, MN
(Lat. 45°32′46″ N, long. 94°03′34″ W)

That airspace extending upward from the surface to and including 3,500 feet MSL within a 4.2-mile radius of the St. Cloud Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

*Paragraph 6002 Class E Airspace Designated as a Surface Area.*

* * * * *

**AGL MN E2 Rochester, MN [Amended]**

Rochester International Airport, MN
(Lat. 43°54′30″ N, long. 92°30′00″ W)

Within a 4.4-mile radius of Rochester International Airport. This Class E airspace area is effective during the specific dates and times established by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

**AGL MN E2 St. Cloud, MN [Amended]**

St. Cloud Regional Airport, MN
(Lat. 45°32′46″ N, long. 94°03′34″ W)

Within a 4.2-mile radius of St. Cloud Regional Airport. This Class E airspace area is effective during the specific dates and times established by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

*Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.*

* * * * *

**AGL MN E4 Rochester, MN [Removed]**

**AGL MN E4 St. Cloud, MN [Amended]**

St. Cloud Regional Airport, MN
(Lat. 45°32′46″ N, long. 94°03′34″ W)
St. Cloud VOR/DME
(Lat. 45°32′58″ N, long. 94°03′31″ W)

That airspace extending upward from the surface within 2.4 miles each side of St. Cloud VOR/DME 140° radial extending from the 4.2-mile radius of St. Cloud Regional Airport to 7 miles southeast of the St. Cloud VOR/DME.

*Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

* * * * *

**AGL MN E5 Rochester, MN [Amended]**

Rochester International Airport, MN
(Lat. 43°54′30″ N, long. 92°30′00″ W)
Rochester Intl.: RWY 31–LOC
(Lat. 43°55′19″ N, long. 92°30′54″ W)
Rochester Intl.: RWY 13–LOC
(Lat. 43°54′06″ N, long. 92°29′02″ W)
Mayo Clinic-St. Mary's Hospital, MN
(Lat. 44°01′11″ N, long. 92°28′59″ W)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of the Rochester International Airport, and within 2 miles each side of the 132° bearing from the Rochester International Airport extending from the 6.9-mile radius of Rochester International Airport to 10.9 miles southeast of Rochester International Airport, and within 4 miles each side of the 132° bearing from the Rochester Intl.: RWY 31–LOC extending from the 6.9-mile radius of Rochester International Airport to 7.5 miles southeast of Rochester International Airport, and within 3.9 miles each side of the 312° bearing from the Rochester Intl.: RWY 13–LOC extending from the 6.9-mile radius of Rochester International Airport to 11.4 miles northwest of Rochester International Airport, and within a 6.4-mile radius of the Mayo Clinic-St. Mary's Hospital.

* * * * *

**AGL MN E5 St. Cloud, MN [Amended]**

St. Cloud Regional Airport, MN
(Lat. 45°32′46″ N, long. 94°03′34″ W)
St. Cloud VOR/DME
(Lat. 45°32′58″ N, long. 94°03′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of St. Cloud Regional Airport, and within 2.4 miles each side of the St. Cloud VOR/DME 140° extending from the 6.7-mile radius of the airport to 7 miles southeast of the St. Cloud VOR/DME.

Issued in Fort Worth, Texas, on January 31, 2022.

**Martin A. Skinner,**

*Acting Manager, Operations Support Group, ATO Central Service Center.*

[FR Doc. 2022–02276 Filed 2–3–22; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 866

**[Docket No. FDA–2021–N–0807]**

## Medical Devices; Immunology and Microbiology Devices; Classification of the System for Detection of Microorganisms and Antimicrobial Resistance Using Reporter Expression

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the system for detection of microorganisms and antimicrobial resistance using reporter expression into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the system for detection of microorganisms and antimicrobial resistance using reporter expression's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

**DATES:** This order is effective February 4, 2022. The classification was applicable on December 5, 2019.

**FOR FURTHER INFORMATION CONTACT:** Tobin Hellyer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3272, Silver Spring, MD 20993–0002, 301–796–6154, *Tobin.Hellyer@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

Upon request, FDA has classified the system for detection of microorganisms and antimicrobial resistance using reporter expression as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a