

Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX, 76177; telephone (817) 222-5857.

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 establishes controlled airspace at Park River-W C Skjerven Field, Park River, ND.

History

On May 24, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class E Airspace in the Park River, ND area. (81 FR 32679) FAA-2016-5856. 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 E airspace designations are published in paragraph 6005 of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 700 feet above the surface within a 7-mile radius of Park River-W C Skjerven Field, Park River, ND, to accommodate new standard instrument

approach procedures. Controlled airspace is needed for the safety and management of IFR operations at the airport. Additionally, this corrects the airport name to coordinate with the NASR, previously listed in the NPRM header and legal description as Park River Airport-WC Skjerven Field to Park River-W C Skjerven Field.

Class E airspace areas are published in Section 6005 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

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 5-6.5a. 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 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

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

* * * * *

AGL ND E5 Park River, ND [New]

Park River-W C Skjerven Field
(Lat. 48°23'39" N., long. 097°46'51" W.)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Park River-W C Skjerven Field.

Issued in Fort Worth, TX, on July 28, 2016.

Walter Tweedy,

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

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2016-4629; Airspace
Docket No. 16-AGL-8]

Amendment of Class E Airspace for the Following Michigan Towns; Alma, MI; Bellaire, MI; Cadillac, MI; Drummond Island, MI; Gladwin, MI; Holland, MI; and Three Rivers, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending upward from 700 feet above the surface at Gratiot Community Airport, Alma, MI; Antrim County Airport, Bellaire, MI; Wexford County Airport, Cadillac, MI; Drummond Island Airport, Drummond Island, MI; Charles C. Zettel Memorial Airport, Gladwin, MI; Park Township Airport and West Michigan Regional Airport, Holland, MI; and Three Rivers Municipal Dr. Haines Airport, Three Rivers, MI. Decommissioning of non-directional radio beacons (NDB),

cancellation of NDB approaches, or implementation of area navigation (RNAV) procedures have made this action necessary for the safety and management of Instrument Flight Rules (IFR) operations at the above airports. This action also updates the geographic coordinates of Three Rivers Municipal Dr. Haines Airport, and the name change of West Michigan Regional Airport (formerly Tulip City Airport) to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, November 10, 2016. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://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. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.9Z at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

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 Class E airspace at Gratiot Community Airport, Alma, MI; Antrim County Airport, Bellaire, MI; Wexford County Airport, Cadillac, MI; Drummond Island Airport, Drummond Island, MI; Charles C. Zettel Memorial Airport, Gladwin, MI; Park Township Airport and West Michigan Regional Airport, Holland, MI; and Three Rivers Municipal Dr. Haines Airport, Three Rivers, MI.

History

On May 3, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to modify Class E airspace at Gratiot Community Airport, Alma, MI; Antrim County Airport, Bellaire, MI; Wexford County Airport, Cadillac, MI; Drummond Island Airport, Drummond Island, MI; Charles C. Zettel Memorial Airport, Gladwin, MI; Park Township Airport and West Michigan Regional Airport, Holland, MI; and Three Rivers Municipal Dr. Haines Airport, Three Rivers, MI (81 FR 26501) Docket No. FAA-2016-4629. 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 E airspace designations are published in paragraph 6005 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class E airspace extending upward from 700 feet above the surface at the following airports:

Within a 6.5-mile radius of Gratiot Community Airport, Alma, MI;

Within a 6.5-mile radius of Antrim County Airport, Bellaire, MI, with a segment extending from the 6.5-mile radius to 6.9 miles south of the airport;

Within a 6.7-mile radius of Wexford County Airport, Cadillac, MI;

Within a 6.5-mile radius of Drummond Island Airport, Drummond Island, MI, with a segment extending from the 6.5-mile radius to 8.5 miles east of the airport;

Within a 6.5-mile radius of Charles C. Zettel Memorial Airport, Gladwin, MI;

Within a 6.5-mile radius of West Michigan Regional Airport (formerly Tulip City Airport), Holland, MI; Park Township Airport is removed as it no longer has instrument procedures and no longer requires Class E airspace; and

Within a 6.4 mile radius of Three Rivers Municipal Dr. Haines Airport, Three Rivers, MI, and updates the geographic coordinates of this airport to coincide with the FAA's aeronautical database.

These airspace reconfigurations are necessary due to the decommissioning of NDBs, cancellation of NDB approaches, or implementation of RNAV procedures at the above airports. Controlled airspace is necessary for the safety and management of the standard instrument approach procedures for IFR operations at the airports.

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 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, 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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AGL MI E5 Alma, MI [Amended]

Alma, Gratiot Community Airport, MI (Lat. 43°19'20" N., long. 84°41'17" W.)
Mount Pleasant VOR/DME (Lat. 43°37'22" N., long. 84°44'14" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Gratiot Community Airport, and within 2.0 miles either side of a 270° bearing from the airport extending from the 6.5-mile radius to 10.1 miles west of the airport, and within 1.5 miles either side of the Mount Pleasant VOR/DME 178° radial extending from the 6.5-mile radius to 10.3 miles north of the airport.

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AGL MI E5 Bellaire, MI [Amended]

Bellaire, Antrim County Airport, MI (Lat. 44°59'19" N., long. 85°11'54" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Antrim County Airport, and within 1.9 miles each side of the 197° bearing from the airport extending from the 6.5-mile radius to 6.9 miles south of the airport.

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AGL MI E5 Cadillac, MI [Amended]

Cadillac, Wexford County Airport, MI (Lat. 44°16'31" N., long. 85°25'08" W.)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of the Wexford County Airport.

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AGL MI E5 Drummond Island, MI [Amended]

Drummond Island Airport, MI

(Lat. 46° 00'34" N., long. 83° 44'38" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Drummond Island Airport, and within 4 miles each side of the 072° bearing from the airport extending from the 6.5-mile radius to 8.5 miles east of the airport; that airspace extending upward from 1,200 feet above the surface bounded by long. 83° 57'00" W., on the west; long. 83° 26'00" W., on the east; lat. 46° 05'00" N., on the north; and lat. 45° 45'00" N., on the south, excluding that airspace within Canada.

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AGL MI E5 Gladwin, MI [Amended]

Charles C. Zettel Memorial Airport, MI (Lat. 43°58'14" N., long. 84°28'30" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Charles C. Zettel Memorial Airport.

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AGL MI E5 Holland, MI [Amended]

West Michigan Regional Airport, MI (Lat. 42°44'34" N., long. 86°06'28" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the West Michigan Regional Airport.

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AGL MI E5 Three Rivers, MI [Amended]

Three Rivers Municipal Dr Haines Airport, MI (Lat. 41°57'35" N., long. 85°35'35" W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Three Rivers Municipal Dr Haines Airport, excluding that airspace within the Sturgis, Kirsch Municipal Airport, MI, Class E airspace area.

Issued in Fort Worth, Texas, on July 29, 2016.

Walter Tweedy,

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

[FR Doc. 2016–18777 Filed 8–10–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 16

[Docket No. FDA–2016–N–0011]

Regulatory Hearing Before the Food and Drug Administration; General Provisions; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its

regulations to correct an error in the lists of statutory and regulatory provisions that provide an opportunity for an informal hearing so that the lists correctly reference the statutory and regulatory provisions that provide such an opportunity in connection with a ban of a device. This action is being taken to align the regulations with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and avoid any potential confusion the erroneous lists may cause.

DATES: This rule is effective August 11, 2016.

FOR FURTHER INFORMATION CONTACT: Ian Ostermiller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5515, Silver Spring, MD 20993–0002, 301–796–5678.

SUPPLEMENTARY INFORMATION: FDA is correcting an error in the regulations that identify the statutory and regulatory provisions that provide an opportunity for a regulatory hearing, also known as an informal hearing (§ 16.1 (21 CFR 16.1)). In the list of statutory provisions at § 16.1(b)(1), the Agency is adding a reference to subsection (b) of section 516 of the FD&C Act (21 U.S.C. 360f), which provides for a reasonable opportunity for an informal hearing when FDA proposes a medical device ban with a special effective date (21 U.S.C. 360f(b)(2)). The list of statutory provisions does not currently specify subsection (b) of section 516 of the FD&C Act, and it incorrectly refers to 21 CFR 895.21(d). An opportunity for a hearing is not required under section 516 of the FD&C Act or part 895 (21 CFR part 895) for bans that do not have a special effective date.

Further, the list of regulatory provisions at § 16.1(b)(2) does not include any reference to part 895. We are correcting this by adding a reference to § 895.30(c), which provides for an opportunity for an informal hearing under 21 CFR part 16 when FDA proposes a medical device ban with a special effective date. These corrections will align § 16.1(b) with section 516 of the FD&C Act and part 895 to avoid confusion regarding when an opportunity for hearing is required for a device ban.

Prior to the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629), the FD&C Act required the Secretary of Health and Human Services to afford an opportunity for informal hearings about any proposed rule to ban a medical device, regardless of effective date. One of the SMDA’s provisions removed the requirement that FDA provide an opportunity for an informal hearing when FDA does not establish a special