

# Rules and Regulations

Federal Register

Vol. 85, No. 14

Wednesday, January 22, 2020

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA–2019–0662; Airspace Docket No. 19–AWA–2]

RIN 2120–AA66

#### Amendment of Class C Airspace; Lansing, MI

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

**ACTION:** Final rule.

**SUMMARY:** This action modifies the Lansing, MI, Class C airspace area by amending the effective hours to coincide with the associated radar approach control facility hours of operation. The designated boundaries and altitudes of the Lansing, MI, Class C airspace area are not changed. Class C airspace areas are predicated on an operational air traffic control tower serviced by a radar approach control facility. Additionally, this action establishes Class D airspace at Capital Region International Airport, MI, when the associated radar approach control facility is not in operation.

**DATES:** Effective date 0901 UTC, March 26, 2020. 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 7400.11 and publication of conforming amendments.

**ADDRESSES:** FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at [https://www.faa.gov/air\\_traffic/publications/](https://www.faa.gov/air_traffic/publications/). For further information, you can contact the Rules and Regulations 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 7400.11D at NARA, email: [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov) or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

**FOR FURTHER INFORMATION CONTACT:**

Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

**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 the 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 effective hours of the Lansing, MI, Class C airspace to coincide with the associated radar approach control facility hours of operation and establishes Class D airspace at Capital Region International Airport, MI, when the associated radar approach control facility is not in operation.

**History**

The FAA published a notice of proposed rulemaking for Docket No. FAA–2019–0662 in the **Federal Register** (84 FR 50346; September 25, 2019), amending the effective hours of the Lansing, MI, Class C airspace to coincide with the associated radar approach control facility hours of operation and establish Class D airspace at Capital Region International Airport, MI, when the associated radar approach control facility is not in operation. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

Class C airspace areas are published in paragraph 4000 and Class D airspace areas are published in paragraph 5000 of FAA Order 7400.11D, dated August 8,

2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The Class C airspace area modification and Class D airspace establishment proposed in this document will be published subsequently in the Order.

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

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

This document amends FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

**The Rule**

This rule amends Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying the Lansing, MI, Class C airspace effective hours to coincide with the associated radar approach control facility’s hours of operation. The designated boundaries and altitudes of the Class C airspace area are not changed. Additionally, this rule establishes the Lansing, MI, Class D airspace area at the Capital Region International Airport to provide controlled airspace for airport operations and instrument approach and departure procedures when the associated radar approach control facility is not in operation.

**Regulatory Notices and Analyses**

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 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 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 the actions of modifying the Lansing, MI, Class C airspace area by amending the effective hours to coincide with the associated radar approach control facility hours of operation, and establishing Class D airspace at Capital Region International Airport, MI when the associated radar approach control facility is not in operation, have no potential to cause significant environmental impacts. Therefore, because these airspace actions do not change the boundaries, altitudes, or operating requirements of the Lansing, MI, Class C airspace area, they have been categorically excluded from further environmental impact review in accordance with the National Environmental Policy Act (NEPA) and its implementing regulations at 40 CFR parts 1500–1508, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review, rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). In accordance with FAAO 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, this action has been reviewed for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis, and it is determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment.

#### 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(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 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

*Paragraph 4000—Subpart C—Class C Airspace.*

\* \* \* \* \*

#### AGL MI C Lansing, MI [Amended]

Capital Region International Airport, MI (Lat. 42°46'43" N, long. 84°35'10" W)

That airspace extending upward from the surface to and including 4,900 feet MSL within a 5-mile radius of Capital Region International Airport; and that airspace extending upward from 2,100 feet MSL to and including 4,900 feet MSL within a 10-mile radius of Capital Region International Airport. This Class C airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

\* \* \* \* \*

*Paragraph 5000—Subpart D—Class D Airspace.*

\* \* \* \* \*

#### AGL MI D Lansing, MI [New]

Capital Region International Airport, MI (Lat. 42°46'43" N, long. 84°35'10" W)

That airspace extending upward from the surface to and including 3,400 feet MSL within a 5-mile radius of Capital Region 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 date and time will thereafter be continuously published in the Chart Supplement.

\* \* \* \* \*

Issued in Washington, DC, on January 15, 2020.

**Scott M. Rosenbloom,**

*Acting Manager, Rules and Regulations Group.*

[FR Doc. 2020–00992 Filed 1–21–20; 8:45 am]

**BILLING CODE 4910–13–P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Part 892

[Docket No. FDA–2019–N–5610]

#### Medical Devices; Radiology Devices; Classification of the Radiological Computer-Assisted Diagnostic Software for Lesions Suspicious for Cancer

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

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

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the radiological computer-assisted diagnostic (CADx) software for lesions suspicious for cancer 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 radiological CADx software for lesions suspicious for cancer'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, in part by reducing regulatory burdens.

**DATES:** This order is effective January 22, 2020. The classification was applicable on July 19, 2017.

**FOR FURTHER INFORMATION CONTACT:** Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD, 20993–0002, 240–402–6357, [ryan.lubert@fda.hhs.gov](mailto:ryan.lubert@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA has classified the CADx software for lesions suspicious for cancer 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, in part by reducing regulatory burdens 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