TABLE 14—HEATING MODE TEST CONDITIONS FOR UNITS HAVING A VARIABLE-SPEED COMPRESSOR—Continued

Test description	Air entering indoor unit temperature (°F)		Air entering outdoor unit temperature (°F)		Compressor speed	Heating air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb		
$H1_N$ test (required, steady).	70	60(max)	47	43	Heating Full [5]	Heating Full-Load.[3]
$H1C_1$ test (optional, cyclic).	70	60(max)	47	43	Heating Minimum	([2]).
$H2_2$ test (optional)	70	60(max)	35	33	Heating Full [4]	Heating Full-Load.[3]
$H2_V$ test (required)	70	60(max)	35	33	Heating Intermediate	Heating Intermediate.[6]
$H3_2$ test (required, steady).	70	60(max)	17	15	Heating Full [4]	Heating Full-Load.[3]
$H4_2$ test (optional, steady).	70	60(max)	5	3(max)	Heating Full [7]	Heating Full-Load.[3]

[1] Defined in section 3.1.4.5 of this appendix.
[2] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during an ON period at the same pressure or velocity as measured during the $H1_1$ test.
[3] Defined in section 3.1.4.4 of this appendix.
[4] Maximum speed that the system controls would operate the compressor in normal operation in 17 °F ambient temperature. The $H1_2$ test is not needed if the $H1_N$ test uses this same compressor speed.
[5] Maximum speed that the system controls would operate the compressor in normal operation in 47 °F ambient temperature.
[6] Defined in section 3.1.4.6 of this appendix.
[7] Maximum speed that the system controls would operate the compressor in normal operation at 5 °F ambient temperature.

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[FR Doc. 2021–25539 Filed 12–1–21; 8:45 am]

BILLING CODE 6450–01–P

FARM CREDIT ADMINISTRATION

12 CFR Parts 614, 615, 620 and 628

RIN 3052–AD27

Regulatory Capital Rules: Tier 1/Tier 2 Framework

AGENCY: Farm Credit Administration.

ACTION: Notification of effective date.

SUMMARY: The Farm Credit Administration (FCA) issued a final rule to amend the regulatory capital requirements for Farm Credit System (System or FCS) institutions. The amendments clarified certain provisions in the Tier 1/Tier 2 Capital Framework and codified the guidance provided in an FCA bookletter.

DATES: *Effective date:* The final rule amending 12 CFR parts 614, 615, 620 and 628 published on October 1, 2021 (86 FR 54347), is effective on January 1, 2022.

FOR FURTHER INFORMATION CONTACT:

Technical information: Jeremy R. Edelstein, *EdelsteinJ@fca.gov,* Associate Director or Clayton D. Milburn, *MilburnC@fca.gov,* Senior Financial Analyst, Finance and Capital Markets Team, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4414, TTY (703) 883–4056 or *ORPMailbox@fca.gov;* or *Legal information:* Rebecca S. Orlich, *Orlichr@fca.gov,* Senior Counsel, or Jennifer A. Cohn, *Cohnj@fca.gov,* Assistant General Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: On October 1, 2021, FCA issued a final rule to amend the regulatory capital requirements for System institutions. The amendments clarified provisions in the Tier 1/Tier 2 Capital Framework, codified the guidance provided in FCA Bookletter BL–068, reduced administrative burden, and amended definitions pertaining to qualified financial contracts. In accordance with 12 U.S.C. 2252(c)(1), the final rule provided an effective date of the later to occur of January 1, 2022 or 30 days after the date of rule's publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulation is January 1, 2022.

Dated: November 29, 2021.

Ashley Waldron,

Secretary, Farm Credit Administration.

[FR Doc. 2021–26173 Filed 12–1–21; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0674; Airspace Docket No. 21–ASW–14]

RIN 2120–AA66

Amendment Class D and Class E Airspace; Ardmore, OK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects typographic errors in the final rule published in the **Federal Register** on October 26, 2021, amending the Class D and Class E airspace at Ardmore, OK.

DATES: Effective date 0901 UTC, January 27, 2022. The Director of the Federal Register approves this incorporation by reference action under Title 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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:

History

The FAA published a final rule in the **Federal Register** (86 FR 59015; October 26, 2021) for FR Doc. 2021–23008 amending the Class D and Class E

airspace at Ardmore, OK. Subsequent to publication, the FAA identified typographic errors that occurred when the notice to proposed rulemaking was transposed to the final rule in the Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area and Class E airspace extending upward from 700 feet above the surface airspace legal descriptions. This action corrects those errors.

Class D and Class E airspace designations are published in paragraph 5000, 6002, 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 Class E airspace designations listed in this document will be subsequently published in FAA Order JO 7400.11.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, Amendment Class D and Class E Airspace; Ardmore, OK, published in the **Federal Register** of October 26, 2021 (86 FR 59015), FR Doc. 2021–23008, is corrected as follows:

71.1 [Amended]

■ On page 59016, column 2, line 41, amend to read, ''Airport extending from the 4.3-mile radius of''.

■ On page 59016, column 2, line 60, amend to read, ''That airspace extending upward from''.

Issued in Fort Worth, Texas, on November 29, 2021.

Martin A. Skinner,

Acting Manager, Operations Support Group ATO Central Service Center.

[FR Doc. 2021–26187 Filed 12–1–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA–2021–N–0622]

Medical Devices; Anesthesiology Devices; Classification of the Isocapnic Ventilation Device

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 isocapnic ventilation device 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 isocapnic ventilation device'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 December 2, 2021. The classification was applicable on March 14, 2019.

FOR FURTHER INFORMATION CONTACT: Todd Courtney, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1216, Silver Spring, MD 20993–0002, 301–796–6371, *Todd.Courtney@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the isocapnic ventilation device 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 common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On August 18, 2017, Thornhill Research, Inc. submitted a request for De Novo classification of the ClearMate. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in