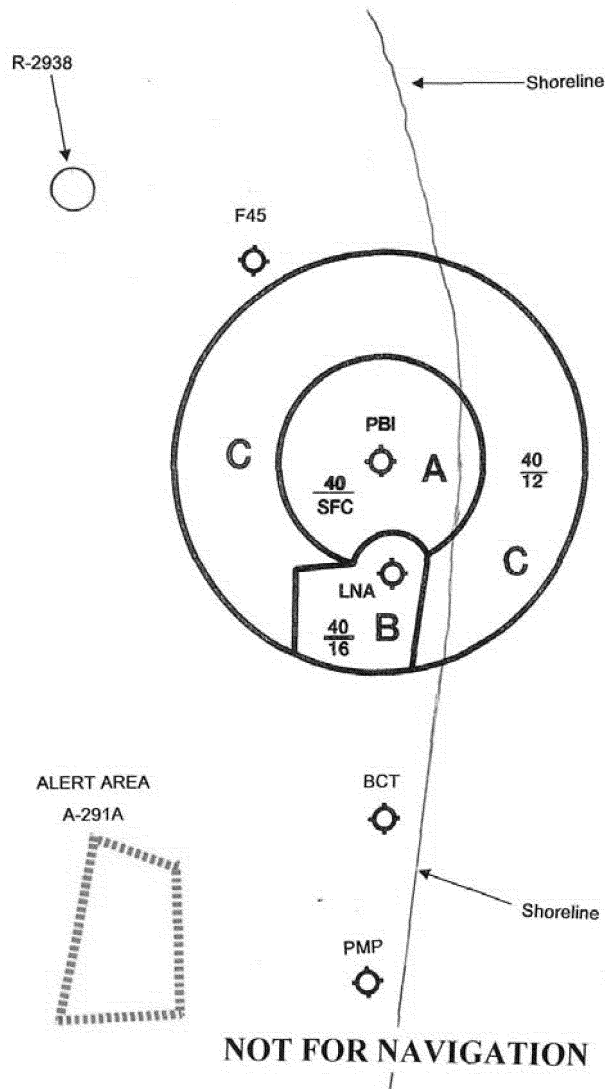


Proposed Modification of the Palm Beach International Airport Class C Airspace Area

Airspace Docket No. 11-AWA-2



[FR Doc. 2011-15407 Filed 6-20-11; 8:45 am]
BILLING CODE 4910-13-C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2011-0439; Airspace
Docket No. 11-ANM-10]

Proposed Amendment of Class D and Class E Airspace and Establishment of Class E Airspace; Casper, WY

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: This action proposes to amend Class D and Class E airspace at Casper, Natrona County International Airport, Casper, WY, by adjusting the geographic coordinates of the airport. This action also would establish Class E En Route Domestic airspace at the airport, to facilitate vectoring of Instrument Flight Rules (IFR) traffic from en route airspace to Casper, WY. The FAA is proposing this action to enhance the safety and management of aircraft operations at Casper, Natrona County International Airport.

DATES: Comments must be received on or before August 5, 2011.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366-9826. You must identify FAA Docket No. FAA-2011-0439; Airspace Docket No. 11-ANM-10, at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:
Eldon Taylor, Federal Aviation
Administration, Operations Support

Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203-4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA-2011-0439 and Airspace Docket No. 11-ANM-10) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at <http://www.regulations.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2011-0439 and Airspace Docket No. 11-ANM-10". The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5

p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the Class D and Class E airspace areas by adjusting the geographic coordinates of Casper, Natrona County International Airport to be in concert with the FAA's aeronautical database. Also, this action would establish Class E en route domestic airspace extending upward from 1,200 feet above the surface at the airport that would enhance the safety and management of IFR operations by vectoring IFR aircraft from en route airspace to the airport.

Class E airspace designations are published in paragraphs 5000, 6002, 6004, 6005 and 6006, respectively, of FAA Order 7400.9U, dated August 18, 2010, and effective September 15, 2010, 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 this Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (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 will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1,

Section 106, describes the authority for 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 creates additional controlled airspace at Casper, Natrona County International Airport, Casper, WY.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 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 14 CFR 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 part 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

ANM WY D Casper, WY [Amended]

Casper, Natrona County International Airport, WY

(Lat. 42°54'29" N., long. 106°27'52" W.)

That airspace extending upward from the surface to and including 7,800 feet MSL within a 4.3-mile radius of Natrona County 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 Airport/Facility Directory.

Paragraph 6002 Class E airspace designated as surface areas.

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ANM WY E2 Casper, WY [Amended]

Casper, Natrona County International Airport, WY

(Lat. 42°54'29" N., long. 106°27'52" W.)

Within a 4.3-mile radius of Natrona County International Airport. This Class E 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 Airport/Facility Directory.

Paragraph 6004 Class E airspace designated as an extension to a Class D surface area.

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ANM WY E4 Casper, WY [Amended]

Casper, Natrona County International Airport, WY

(Lat. 42°54'29" N., long. 106°27'52" W.)

Muddy Mountain VORTAC

(Lat. 43°05'27" N., long. 106°16'37" W.)

Johno LOM

(Lat. 42°54'26" N., long. 106°34'12" W.)

That airspace extending upward from the surface within 4.3 miles each side of the Muddy Mountain VORTAC 216° radial extending from the VORTAC to 29 miles southwest of the VORTAC, and within 2.7 miles each side of the ILS localizer west course extending from .9 miles east to 9 miles west of the Johno LOM. This Class E 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 Airport/Facility Directory.

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

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ANM WY E5 Casper, WY [Amended]

Casper, Natrona County International Airport, WY

(Lat. 42°54'29" N., long. 106°27'52" W.)

Muddy Mountain VORTAC

(Lat. 43°05'27" N., long. 106°16'37" W.)

Casper ASR

(Lat. 42°55'16" N., long. 106°27'15" W.)

That airspace extending upward from 700 feet above the surface within a 23.5-mile radius of the Casper ASR; that airspace extending upward from 1,200 feet above the surface within the 37.5-mile radius of the Casper ASR, and within an area extending from the 37.5-mile radius to the 36.6-mile radius of the Muddy Mountain VORTAC, bounded on the north by the Muddy Mountain VORTAC 060° radial and on the south by the Muddy Mountain VORTAC 111° radial; that airspace extending upward from 11,500 feet MSL extending from the 37.5-mile radius to the 52.2-mile radius of the Muddy Mountain VORTAC, bounded on the east by the west edge of V-19 and on the south by the north edge of V-298.

Paragraph 6006 En route domestic airspace areas.

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ANM WY E6 Casper, WY [New]

Casper, Natrona County International Airport, WY

(Lat. 42°54'29" N., long. 106°27'52" W.)

That airspace extending upward from 1,200 feet above the surface within a 85-mile

radius of Natrona County International Airport; excluding existing controlled airspace 7,100 feet MSL and above.

Issued in Seattle, Washington, on June 14, 2011.

William Buck,

Acting Manager, Operations Support Group, Western Service enter.

[FR Doc. 2011-15393 Filed 6-20-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 610, and 680

[Docket No. FDA-2011-N-0080]

Amendments to Sterility Test Requirements for Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the sterility test requirements for biological products. This proposed rule is intended to provide manufacturers of biological products greater flexibility and to encourage use of the most appropriate and state-of-the-art test methods for assuring the safety of biological products. We are taking this action as part of our continuing effort to review and, as necessary, update the biologics regulations.

DATES: Submit either electronic or written comments on this proposed rule by September 19, 2011. See section X of this document for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0080, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and

Docket No. FDA-2011-0080 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Any product that purports to be sterile should be free of viable contaminating microorganisms to assure product safety (§ 600.3(q) (21 CFR 600.3(q)). Absolute sterility of a lot cannot be practically demonstrated without complete destruction of every finished article in that lot (United States Pharmacopeia (USP) Chapter 1211). Therefore, sterility assurance is accomplished primarily by validation of the sterilization process or of the aseptic processing procedures under current good manufacturing practice (CGMP), and is supported by sterility testing using validated and verified test methods. (See *e.g.*, USP Chapter 71>, European Pharmacopeia 2.6.2.)

In the **Federal Register** of November 20, 1973 (38 FR 32048), we reorganized and republished the biologics regulations, which included regulations governing sterility testing, as title 21 of the Code of Federal Regulations (CFR), subchapter F, parts 600 through 680 (21 CFR parts 600 through 680). Section 610.12 currently requires manufacturers to perform sterility tests for both bulk and final container material of most biological products¹ for the detection of

¹ Sterility tests are not currently required to be performed for Whole Blood, Cryoprecipitated Antihemophilic Factor (AHF), Platelets, Red Blood Cells, Plasma, Source Plasma, Smallpox Vaccine, Reagent Red Blood Cells, Anti-Human Globulin, or Blood Grouping Reagents; or in cases where the Director of the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER), as appropriate, determines that the mode of administration, method of