

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2014-0305; Airspace
Docket No. 14-AWP-2]

**Proposed Establishment and
Amendment of Class D and E
Airspace; Santa Rosa, CA**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking
(NPRM).

SUMMARY: This action proposes to establish Class E airspace and modify Class D and E airspace at Charles M. Shultz-Sonoma County Airport, Santa Rosa, CA. This action, initiated by the FAA's biennial review of the airspace area, would enhance the safety and management of instrument flight rules (IFR) operations at the airport. Class D airspace would be amended to reflect the airport's name change.

DATES: Comments must be received on or before August 29, 2014.

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-2014-0305; Airspace Docket No. 14-AWP-2, at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203-4517.

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-2014-0305 and Airspace Docket No. 14-

AWP-2) 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-2014-0305 and Airspace Docket No. 14-AWP-2". 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 9:00 a.m. and 5:00 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 establishing Class E airspace designated as an extension and

modifying Class E airspace extending upward from 700 feet above the surface at Charles M. Schultz-Sonoma County Airport, Santa Rosa, CA. After a biennial review of the airspace, the FAA found modification of the airspace necessary for the safety and management of aircraft departing and arriving under IFR operations at the airport. Class E airspace designated as an extension to the Class D and Class E surface area would be established from the 4.3-mile radius of the airport to 14 miles northwest of the airport. Class E airspace extending upward from 700 feet above the surface would be modified with segments extending 23 miles northwest, 28 miles southeast, and 13 miles southwest of the airport. The description for the Class D airspace would reflect the airport name change from Santa Rosa/Sonoma County Airport to Charles M. Schultz-Sonoma County Airport.

Class D and E airspace designations are published in paragraph 5000, 6004, and 6005, respectively, of FAA Order 7400.9X, dated August 7, 2013, and effective September 15, 2013, 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 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 would amend controlled airspace at Charles M. Schultz-Sonoma County Airport, Santa Rosa, CA.

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

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 71.1 of the Federal Aviation Administration Order 7400.9X, Airspace Designations and Reporting Points, dated August 7, 2013, and effective September 15, 2013, is amended as follows:

Paragraph 5000 Class D Airspace

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AWP CA D Santa Rosa, CA [Amended]

Charles M. Schultz-Sonoma County Airport, CA

(Lat. 38°30'33" N., long. 122°48'46" W.)

That airspace extending upward from the surface to and including 2,600 feet MSL within a 4.3-mile radius of Santa Rosa/Sonoma County 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 6004 Class E Airspace Areas Designated As An Extension to Class D or Class E Surface Area

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AWP CA E4 Santa Rosa, CA [New]

Charles M. Shultz-Sonoma County Airport, CA

(Lat. 38°30'33" N., long. 122°48'46" W.)

That airspace extending upward from the surface within 2 miles either side of the 342° bearing from the Charles M. Shultz-Sonoma County Airport, CA, extending from the 4.3 mile radius of the airport to 14 miles northwest of the airport.

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

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AWP CA E5 Santa Rosa, CA [Modified]

Charles M. Shultz-Sonoma County Airport, CA

(Lat. 38°30'33" N., long. 122°48'46" W.)

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 38°53'25" N., long. 122°52'34" W.; to lat. 38°37'07" N., long. 122°46'02.00" W.; to 38°22'08" N., long. 122°38'28" W.; lat. 38°06'41" N., long. 122°29'59" W.; lat. 38°02'10" N., long. 122°44'09" W.; lat. 38°17'57" N., long. 122°54'37" W.; lat. 38°22'58" N., long. 123°02'34" W.; lat. 38°29'12" N., long. 122°56'32" W.; lat. 38°33'48" N., long. 123°00'47" W.; lat. 38°50'14" N., long. 123°07'20" W. thence to the point of origin; that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 45°49'00" N., long. 118°00'00" W.; to lat. 45°49'00" N., long. 119°45'00" W.; to lat. 47°00'00" N., long. 119°45'00" W.; to lat. 47°00'00" N., long. 118°00'00" W.; thence to the point of origin.

Issued in Seattle, Washington, on July 2, 2014.

Clark Desing,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2014-16636 Filed 7-14-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2014-N-0824]

Confidentiality of Interim Results in Cardiovascular Outcome Safety Trials; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing that will provide a forum to discuss confidentiality of interim results for certain cardiovascular outcomes trials (CVOTs) submitted to the Agency while the trials are still ongoing. The purpose of the public hearing is to initiate constructive discussion among regulators,

researchers, health care providers, representatives from the pharmaceutical industry and health care organizations, and the general public, about appropriate handling of interim analysis results of these ongoing CVOTs. FDA is also opening a public docket to receive comments on this topic.

DATES: The public hearing will be held on August 11, 2014, from 8 a.m. to 5 p.m. Individuals who wish to present at the public hearing must register by July 28, 2014. Section IV provides attendance and registration information. To ensure consideration, submit comments by July 28, 2014. Electronic or written comments will be accepted after the public hearing until October 10, 2014.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public hearing participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Indira Hills, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, rm. 4508, Silver Spring, MD 20993, 301-796-9686, FAX: 301-796-9907, email: indira.hills@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Requirement for Postmarketing Studies To Assess the Risk of a New Drug

In some cases, studies submitted to FDA as part of a new drug application or biologics license application will demonstrate that a drug is safe and effective for its intended use (i.e., that its benefits outweigh its identified risks), but the Agency will nevertheless require a sponsor to conduct additional postmarketing studies or trials under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)