

operations in standard instrument approach and departure procedures at the airport.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, 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 will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "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

In consideration of the foregoing, 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(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 7400.11B, Airspace Designations and Reporting

Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

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

* * * * *

AWP AS E5 Pago Pago, AS [New]

Pago Pago International Airport, American Samoa
(Lat. 14°19'54" N, long. 170°42'41" W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Pago Pago International Airport and within 4 miles either side of the 071° bearing of the Pago Pago International Airport, extending from the 7-mile radius to 10.6 miles northeast of the airport, and within 4 miles either side of the 240° bearing of the airport extending from the 7-mile radius to 10.4 miles southwest of the airport; and that airspace extending upward from 1,200 feet above the surface within a 20 mile-radius of Pago Pago International Airport, excluding that airspace extending beyond 12 miles of the shoreline.

Issued in Washington, DC, on March 12, 2018.

Rodger A. Dean Jr.,
Manager, Airspace Policy Group.

[FR Doc. 2018–05585 Filed 3–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0195; Airspace Docket No. 17–AWP–15]

Proposed Amendment of Air Traffic Service (ATS) Route Q–5; Western United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend United States Area Navigation (RNAV) route Q–5 in the western United States. The route will now terminate at a waypoint (WP) that connects to an Oakland International Airport (OAK), Standard Terminal Arrival Route (STAR) near Oakland CA.

DATES: Comments must be received on or before May 7, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2018–0195 and Airspace Docket

No. 17–AWP–15 at the beginning of your comments. You may also submit comments through the internet at <http://www.regulations.gov>.

FAA Order 7400.11B, 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 7400.11B at NARA, call (202) 741–6030, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

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

FOR FURTHER INFORMATION CONTACT: Kenneth Ready, Airspace Policy Group, Office of Airspace Services, 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 would modify the route structure as necessary to support the safe and efficient flow of air traffic within the National Airspace System.

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-2018-0195 and Airspace Docket No. 17-AWP-15) and be submitted in triplicate to the Docket Management Facility (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-2018-0195, and Airspace Docket No. 17-AWP-15." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date 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 comment closing date. 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/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 **ADDRESSES** section for 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 office of the Western Service Center, Operations Support Group, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11B, airspace

Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

Route Q-5 was one of the original RNAV routes developed ushering in performance based navigation (PBN) into the United States. Route Q-5 provided a high altitude route from Seattle into the bay area of San Francisco and Oakland, CA. Route Q-5 tied in OAK airport via the RAIDR STAR from STIKM WP, which is the current southern boundary point on the route. The STAR was removed in 2017 and Q-5 no longer tied into the bay area. The FAA proposes to add a new boundary point of SPAMY, CA, WP, which serves two STARs; WNDSR TWO ARRIVAL and the AANET ONE ARRIVAL, with both serving OAK. Lastly, policy states odd numbered ATS routes list points south to north. Currently Q-5 lists the route north to south. This proposal corrects the direction and will be in line with current policy.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to modify RNAV route Q-5. The proposed route changes are outlined below. Q-5: Route Q-5 currently extends from HAROB, WA to STIKM, CA. The FAA proposes to start the route at SPAMY, CA, WP, thereby eliminating the STIKM, CA, WP and the HUPTU, CA, WP, to support STARs into OAK. Additionally, ATS route policy states, odd numbered routes will be listed south to north. Route Q-5 was originally listed north to south, and is proposed south to north. The amended route would, therefore, extend from SPAMY, CA to HAROB, WA.

United States Area Navigation Routes are published in paragraph 2006 of FAA Order 7400.11B dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The United States Area Navigation Routes listed in this document will be subsequently published in the Order.

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 will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

List of Subjects in 14 CFR Part 71

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The Proposed Amendment

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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 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017 and effective September 15, 2017, is amended as follows:

Paragraph 2006 United States Area Navigation Routes

Q-5 SPAMY, CA to HAROB, WA [Amended]

SPAMY, CA	WP	(Lat. 39°11'57.00" N, long. 122°37'58.00" W)
HOMEG, CA	WP	(Lat. 41°20'09.00" N, long. 122°51'05.00" W)
HARPR, OR	WP	(Lat. 42°28'50.00" N, long. 122°53'01.54" W)
HISKU, OR	WP	(Lat. 44°30'00.00" N, long. 122°56'39.00" W)
HAROB, WA	WP	(Lat. 47°14'36.00" N, long. 123°02'27.00" W)

Issued in Washington, DC, on March 13, 2018.

Rodger A. Dean Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2018-05584 Filed 3-20-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 4

[Docket No. FDA-2008-N-0424]

Postmarketing Safety Reporting for Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and FDA staff entitled "Postmarketing Safety Reporting for Combination Products." This draft guidance addresses certain means by which applicants may comply with the final rule on postmarketing safety reporting (PMSR) requirements for combination products that FDA issued on December 20, 2016.

Combination products are products composed of two or more different types of medical products (drug, device, and/or biological product). Although the PMSR regulations for drugs, devices, and biological products share many similarities, each set of regulations establishes distinct postmarketing reporting requirements, standards, and timeframes. The final rule provides clarity on the PMSR requirements for combination products to ensure consistent and complete reporting while avoiding duplication. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by June 19, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit either electronic or written comments on any

Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2008-N-0424 for "Postmarket Safety Reporting for Combination Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9

a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Combination Products, Food and Drug Administration, Bldg. 32, Rm. 5129, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section