

Duke Field

(Lat. 30°38'55" N., long. 86°31'19" W.)

Hurlburt Field

(Lat. 30°25'44" N., long. 86°41'20" W.)

Fort Walton Beach Airport

(Lat. 30°24'23" N., long. 86°49'45" W.)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Eglin Air Force Base, and within a 7.8-mile radius of Destin Executive Airport, and within a 7-mile radius of Duke Field, and within a 7-mile radius of Hurlburt Field, excluding a 1.5-mile radius of Fort Walton Beach Airport.

Issued in College Park, Georgia, on February 23, 2016.

Ryan W. Almasy,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2016-3108; Airspace Docket No. 15-ASO-16]

Proposed Establishment of Class E Airspace; Harlan, KY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Harlan, KY, to accommodate new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAPs) serving Tucker-Guthrie Memorial Airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Comments must be received on or before April 18, 2016.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Bldg Ground Floor, Rm W12-140, Washington, DC 20590-0001; Telephone: 1-800-647-5527; Fax: 202-493-2251. You must identify the Docket Number FAA-2016-3108; Airspace Docket No. 15-ASO-16, at the beginning of your comments. You may also submit and review received comments through the Internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday,

except Federal holidays. The Docket Office (telephone 1-800-647-5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at <http://www.faa.gov/airtraffic/publications/>. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 29591; 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 7400.9Z at NARA, call 202-741-6030, or go to <http://www.archives.gov/federal-register/code-of-federal-regulations/ibr-locations.html>.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-6364.

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 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 establish Class E airspace at Tucker-Guthrie Memorial Airport, Harlan, KY.

Comments Invited

Interested persons are invited to comment on this rule 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-2016-3108; Airspace Docket No. 15-ASO-16) 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>.

Persons 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 Docket No. FAA-2016-3108; Airspace Docket No. 15-ASO-16." The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. 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 from and comments submitted through <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 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 between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

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

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to establish Class E airspace extending upward from 700 feet above the surface within a 13-mile radius of Tucker-Guthrie Memorial Airport, Harlan, KY, providing the controlled airspace required to support the new RNAV (GPS) standard instrument approach procedures for Tucker-Guthrie Memorial Airport. Controlled airspace is necessary for IFR operations.

Class E airspace designations are published in Paragraph 6005, of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently 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 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 would 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.

Lists 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 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 Federal Aviation Administration Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

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

* * * * *

ASO KY E Harlan, KY [New]

Tucker-Guthrie Memorial Airport, KY
(Lat. 36°51'36" N., long. 83°21'31" W.)

That airspace extending upward from 700 feet above the surface within a 13-mile radius of Tucker-Guthrie Memorial Airport.

Issued in College Park, Georgia, on February 23, 2016.

Ryan W. Almasy,

*Acting Manager, Operations Support Group,
Eastern Service Center, Air Traffic
Organization.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2016–N–0400]

General and Plastic Surgery Devices; Reclassification of Blood Lancets

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to reclassify the following three types of blood lancets used to

puncture skin to obtain a drop of blood for diagnostic purposes from class I (general controls) exempt from premarket notification into class II (special controls) and subject to premarket review: Single use only blood lancets with an integral sharps injury prevention feature, single use only blood lancets without an integral sharps injury prevention feature, and multiple use blood lancets for single patient use only. FDA is identifying proposed special controls for these types of blood lancets that we believe are necessary to provide a reasonable assurance of safety and effectiveness. FDA is also proposing to reclassify multiple use blood lancets for multiple patient use from class I (general controls) exempt from premarket notification into class III (premarket approval). FDA is proposing the reclassification of these four types of blood lancets on its own initiative based on new information.

DATES: Submit either electronic or written comments on the proposed order by June 1, 2016. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) by April 4, 2016, (see the “Paperwork Reduction Act of 1995” section of this document). See section X of the **SUPPLEMENTARY INFORMATION** section of this document for the proposed effective date of any final order that may publish based on this proposal.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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