

International Airport, Duluth, MN. Controlled airspace is needed for the safety and management of IFR operations at the airport. Geographic coordinates would also be updated to coincide with the FAA's aeronautical database.

Class E airspace areas are published in Paragraphs 6004 and 6005, respectively, of FAA Order 7400.9U, dated August 18, 2010 and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

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 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.

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 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 amend controlled airspace at Duluth International Airport, Duluth, MN.

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 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 FAA Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010, is amended as follows:

Paragraph 6004 Class E Airspace areas designated as an extension to a Class D or Class E Surface Area.

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AGL MN E4 Duluth, MN [Amended]

Duluth International Airport, MN
(Lat. 46°50'32" N., long. 92°11'37" W.)
Duluth VORTAC

(Lat. 46°48'08" N., long. 92°12'10" W.)

That airspace extending upward from the surface within 3.4 miles each side of the Duluth VORTAC 193° radial extending from the 4.9-mile radius of Duluth International Airport to 14.2 miles south of the VORTAC, and within 3.6 miles each side of the 267° bearing from Duluth International Airport extending from the 4.9-mile radius of the airport to 9.7 miles west 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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AGL MN E5 Duluth, MN [Amended]

Duluth International Airport, MN
(Lat. 46°50'32" N., long. 92°11'37" W.)

That airspace extending upward from the 700 feet above the surface within a 7.1-mile radius of Duluth International Airport, and within 4.4 miles each side of the 267° bearing from the airport extending from the 7.1-mile radius to 7.7 miles west of the airport.

Issued in Fort Worth, TX, on March 15, 2011.

Richard J. Kerwin, Jr.,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2011–6847 Filed 3–22–11; 8:45 am]

BILLING CODE 4901–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Chapter 1

Notice of Policy Regarding Civil Aircraft Operators Providing Contract Support to Government Entities (Public Aircraft Operations)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notification of policy change; request for comments.

SUMMARY: This notice states the Federal Aviation Administration's (FAA) policy pertaining to civil aircraft operators that provide contract support to government entities.

DATES: Comments must be received before April 22, 2011.

ADDRESSES: This is a statement of policy only. We are accepting comments concerning the implementation of this policy only from government entities via e-mail at PublicAircraft@faa.gov.

FOR FURTHER INFORMATION CONTACT: Monica C. Buenrostro, General Aviation and Commercial Division, Flight Standards Service, AFS–800, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8212; e-mail: monica.c.buenrostro@faa.gov.

SUPPLEMENTARY INFORMATION: Title 49 of the United States Code (U.S.C), section 40102 (a)(41) provides the definition of "Public Aircraft" and Title 49 U.S.C 40125 provides the Qualifications for Public Aircraft Status. These statutory provisions provide the legal basis for public aircraft operations in the United States.

The FAA recognizes that these statutory provisions are difficult to apply to aircraft operations conducted by civil contractors for government entities. The FAA is therefore clarifying its policy toward these operators by better defining the responsibilities of the parties affected by these contracts.

Public Aircraft Operation is limited by the statute to certain government operations within U.S. airspace. Although these operations must comply with certain general operating rules (including those applicable to all aircraft in the National Airspace System), other civil certification and safety oversight regulations do not apply. Whether an operation may be considered public is determined on a flight-by-flight basis, under the terms of the statute (49 U.S.C 40102 and 49 U.S.C 40125) and considers aircraft

ownership, operator, the purpose of the flight and the persons on board the aircraft.

FAA Policy

- Public aircraft status is not an “automatic” status granted by the existence of a contract between a civil operator and a government agency.
- The FAA considers ALL contracted operations to be civil aircraft operations, unless:
 - The contracting government entity provides the operator with a written declaration (from the contracting officer or higher-level official) of public aircraft status for designated, qualified flights;
 - The contracted operator notifies the FAA Flight Standards District Office (FSDO) having oversight of the operator (or the operation, as appropriate) that it has contracted with a government entity to conduct “eligible” public aircraft operations;
 - The contracted operator submits the written declaration to the FSDO with jurisdiction having oversight;
 - The flight(s) in question are determined to be legitimate public aircraft operations under the terms of the statute; and
 - The declaration is made in advance of the proposed public aircraft flight.
 - To implement this policy and collect data, the FSDO having oversight of the contracted operator will record receipt of these declarations by electronic means.

Contracted government entities are cautioned that public aircraft operations performed by civil operators create a significant transfer of liability to the contracting government entity, and that FAA oversight ceases.

Civil operators are cautioned that unless there is a declaration of public aircraft status, all operations must be conducted in accordance with all applicable civil aviation regulations, and that the FAA retains oversight and enforcement authority for any deviation from the provisions of Title 14 of the Code of Federal Regulations (14 CFR). Operators are also cautioned that it is their responsibility to refuse a contract to perform operations that violate 14 CFR if they cannot ensure that the government entity offering the contract has declared that operation as a public aircraft operation and that such flight meets the public aircraft eligibility requirements as outlined in the statute.

The FAA is revising Advisory Circular 00.1–1, Government Aircraft Operations, and FAA Order 8900.1, Flight Standards Information Management System. These revisions will more fully address public aircraft policy issues and implementation.

Government entities with experience using civil operators under contract are invited to share their experience and suggestions concerning implementation of this policy. Government entities may submit comments to PublicAircraft@faa.gov to be considered as the FAA continues to refine the public aircraft operations policy.

Issued in Washington, DC, on March 17, 2011.

John W. McGraw,

Acting Director, Flight Standards Service.

[FR Doc. 2011–6894 Filed 3–22–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2010–N–0029]

Medical Devices; Ovarian Adnexal Mass Assessment Score Test System; Labeling; Black Box Restrictions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulation classifying ovarian adnexal mass assessment score test systems to restrict these devices so that a prescribed warning statement that addresses a risk identified in the special controls guidance document must be in a black box and must appear in all labeling, advertising, and promotional material. The black box warning mitigates the risk to health associated with off-label use as a screening test, stand-alone diagnostic test, or as a test to determine whether or not to proceed with surgery. Elsewhere in this issue of the **Federal Register**, FDA is announcing a final rule that classifies the ovarian adnexal mass assessment score test system into class II (special controls).

DATES: Submit either electronic or written comments by May 23, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0029, 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–2010–N–0029. 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: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5543, Silver Spring, MD 20993–0002, 301–796–6217.

SUPPLEMENTARY INFORMATION:

I. What is the background of this proposed rule?

A. Ovarian Adnexal Mass Assessment Score Test System

An ovarian adnexal mass assessment score test system measures one or more analytes in serum and combines the values into a single score that is then used to determine the likelihood that the pre-surgical adnexal mass in a woman not yet referred to an oncologist, is malignant. An ovarian adnexal mass assessment score test system is intended for use in those patients for whom surgery is planned, and should not be used to decide whether or not a patient should receive surgery. The test is used in conjunction with a clinical and radiological evaluation of the patient by physicians in determining whether the patient should be referred to a gynecologic oncologist for surgery.

B. Identified Risk to Health

The ovarian adnexal mass assessment score test system is not indicated for use as a screening or diagnostic test for ovarian cancer. Off-label use of the test (*e.g.*, in patients who are not already