

Dated: June 14, 2012.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2012-15163 Filed 6-21-12; 8:45 am]

BILLING CODE 4810-AM-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2012-0217; Airspace Docket No. 12-AEA-2]

Establishment of Class D Airspace and Amendment of Class E Airspace; East Hampton, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class D airspace and amends existing Class E airspace at East Hampton, NY, to accommodate the new mobile airport traffic control tower (ATCT) at East Hampton Airport. Controlled airspace enhances the safety and management of Instrument Flight Rules (IFR) operations at the airport. This action also updates the geographic coordinates of the airport's existing Class E airspace and eliminates Class E extensions that are no longer required.

DATES: Effective 0901 UTC, July 26, 2012. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments

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:

History

On March 15, 2012, the FAA published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) to establish Class D and E airspace and amend existing Class E airspace at East Hampton, NY, to accommodate a new air traffic control tower at East Hampton Airport (77 FR 15297). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. Two positive comments were received in support of the airspace. One negative comment letter was received.

One positive response was received from the Town of East Hampton. The other positive commenter, the East Hampton Aviation Association, observed that establishment of Class D airspace would provide greater safety to IFR operations during bad weather conditions. The FAA agrees with this observation.

The negative response comment was received from the Eastern Region Helicopter Council, Inc. (ERHC). ERHC made several observations in its comment letter. The FAA does not agree with this commenter's observations or conclusion. Each of the commenter's observations are outlined and addressed below.

The ERHC observed that the purpose of Class D airspace is to protect IFR operations; that the East Hampton tower will not have radar capabilities; that the tower will not have the authority to require helicopters to fly specific arrival/departure flight paths; and that most helicopter operations already comply with the voluntary noise abatement procedures; therefore, the commenter concludes that the airspace changes are not needed.

The FAA does not agree. The protection provided by Class D airspace to IFR operations is not based on the tower's ability to use radar to provide separation. Rather, the airspace establishes higher weather minima for VFR flights, thus restricting access of VFR flights to the airspace while IFR operations are in progress.

The ERHC commented that an unintended consequence of establishing Class D airspace would be increased noise impact from helicopters that are forced to wait outside the Class D airspace during adverse weather conditions.

While the FAA agrees that one-at-a-time Special VFR operations may have the potential for creating adverse effects, separation rules for Special VFR operations in Class D airspace allow for multiple helicopters to operate in Class D airspace at the same time, as long as they operate at a safe distance from IFR operations. Use of these rules requires the helicopter operators to enter into a Letter of Agreement (LOA) with the FAA. Use of these rules will allow the helicopter operators to minimize any delays they may experience due to the airspace, as well as provide a higher level of safety to all operations in adverse weather conditions.

The ERHC observed that one purpose of establishing a tower at East Hampton Airport is for helicopter noise mitigation purposes.

The FAA does not agree. The purpose of control towers and Class D airspace

is the safe and efficient use of airspace. Class D airspace provides controlled airspace to contain IFR arrival and departure operations. Further, Class D enhances safety by setting VFR weather minima specified in 14 CFR § 91.155 and the communications and other operating requirements in 14 CFR 91.129.

The Proposed Rule included a Class E surface area to be in effect when the control tower is closed. One prerequisite for the establishment of controlled airspace at the surface of an airport is the availability of hourly and special weather observations. Currently this prerequisite is only met during the dates and times when the tower will be operating. Therefore, the Class E surface area has been removed from this rule action.

The current Class E5 Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth (E5) includes two extensions for the support of IFR approach procedures. The approaches published for East Hampton Airport have been modified since this airspace was established and these extensions are no longer required for safe IFR operations. Therefore, they are being removed as part of the rule.

Class D and E airspace designations are published in Paragraphs 5000 and 6005, respectively, of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, 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 the Order.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class D airspace extending upward from the surface to and including 2,500 feet MSL within a 4.8-mile radius of East Hampton Airport, East Hampton, NY. Controlled airspace supports the new airport traffic control tower for continued safety and management of IFR operations at East Hampton Airport. This action also amends Class E airspace extending upward from 700 feet above the surface within a 7.3-mile radius of the airport. The geographic coordinates of the airport are adjusted to be in concert with the FAA's current aeronautical database.

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. Therefore, this 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 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 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 establishes and amends controlled airspace at East Hampton Airport, East Hampton, NY.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, “Environmental Impacts: Policies and Procedures,” paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 5000 Class D airspace.

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AEA NY D East Hampton, NY [NEW]

East Hampton Airport, NY
(Lat. 40°57′34″ N., long. 72°15′06″ W.)

That airspace extending upward from the surface up to and including 2,500 feet MSL within a 4.8-mile radius of East Hampton Airport. This Class D airspace area is effective during 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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AEA NY E5 East Hampton, NY [AMENDED]

East Hampton Airport, NY
(Lat. 40°57′34″ N., long. 72°15′06″ W.)

That airspace extending upward from 700 feet above the surface within a 7.3-mile radius of East Hampton Airport.

Issued in College Park, Georgia, on June 14, 2012.

Barry A. Knight,

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

[FR Doc. 2012–15279 Filed 6–21–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2011–N–0526]

Effective Date of Requirement for Premarket Approval for a Pacemaker Programmer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for pacemaker programmers. The Agency has summarized its findings regarding the

degree of risk of illness or injury designed to be eliminated or reduced by requiring this device to meet the statute’s approval requirements and the benefits to the public from the use of the devices. This action implements certain statutory requirements.

DATES: This rule is effective September 20, 2012.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1646, Silver Spring, MD 20993–0002, 301–796–5616.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and