of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent loss of the metallic clamp or the engine exhaust ejector, damage to the main or tail rotor system, and subsequent loss of control of the helicopter, accomplish the following:

(a) Prior to further flight, in accordance with Part I of the Compliance Instructions in Agusta Bollettino Tecnico No. 109EP–3, dated December 22, 1998 (Technical Bulletin), inspect the exhaust ejector to ejector saddle locking system, the dampers at the bottom of the ejector saddle, and the torque of the metallic clamp, and install safety wire on the metallic clamp. If any damage is found as a result of the inspection, accomplish Part II of the Compliance Instructions in the Technical Bulletin prior to further flight.

(b) Within the next 10 hours time-in-service (TIS), inspect the dampers and metallic clamps, and reposition and modify the ejector saddle and the locking metallic clamp in accordance with Part II of the Compliance Instructions in the Technical Bulletin.

(c) Thereafter, at intervals not to exceed 25 hours TIS, inspect the metallic clamp, locking mechanism, and dampers in accordance with Part III of the Compliance Instructions in the Technical Bulletin.

(d) Before further flight after December 31, 2000, modify the engine exhaust ejectors, part number (P/N) 109–0601–51, by installing a kit, P/N 109–0822–94, in accordance with the Compliance Instructions in Agusta Technical Bulletin No. 109EP–5, dated December 22, 1999.

(e) Installing a kit, P/N 109–0822–94, is terminating action for the requirements of this AD.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through a FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Ente Nazionale per l'Aviazione Civile (Italy) AD No. 2000–001, dated January 4, 2000, and 2000–088, dated February 10, 2000.

Issued in Fort Worth, Texas, on September 15, 2000.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 00–24372 Filed 9–21–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ASO–35]

Proposed Amendment of Class D and Class E4 Airspace; Gainesville, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to amend Class D and Class E4 airspace at Gainesville, FL. The Gainesville VORTAC has been relocated and renamed. As a result the VHF Omni-directional Range (VOR) Standard Instrument Approach Procedure (SIAP) is amended. Therefore, the Class E4 extension to the Class D surface area will be rotated clockwise seven degrees. This proposed action will also remove the reference to the Gainesville VORTAC from the Class D airspace description.

DATES: Comments must be received on or before October 23, 2000.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 00–ASO–35, Manager, Airspace Branch, ASDO–520, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Regional Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5586.

FOR FURTHER INFORMATION CONTACT: Nancy B. Shelton, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5586.

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 the airspace docket number and be submitted in triplicate to the address listed above. Comments 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 Airspace Docket No. 00–ASO–35.'' 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 action may be changed in light of the comments received. All comments submitted will be available for examination in the Office of the Regional Counsel for Southern Region, Room 50, 1701 Columbia Avenue, College Park, Georgia 30337, 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

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO–520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR Part 71) to amend Class D airspace and Class E4 airspace at Gainesville, FL. Class D airspace designations for airspace areas extending upward from the surface and Class E4 airspace designations for airspace areas designated as an extension to a Class D airspace area are published in Paragraphs 5000 and 6004 respectively, of FAA Order 7400.9H, dated September 1, 2000 and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E4 airspace designations 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.

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, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; 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 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 500 Class D Airspace.

* * * * *

ASO FL D Gainesville, FL [Revised]

Gainesville Regional Airport, FL
(Lat. 29°41′24″N, long. 82°16′18″W)

That airspace extending upward from the surface to and including 2,700 feet MSL within a 4.3-mile radius of the Gainesville Regional 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 E4 Airspace Areas Designated as an Extension to a Class D Airspace Area

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ASO FL E4 Gainesville, FL [Revised]

Gainesville Regional Airport, FL
(Lat. 29°41′24″N, long. 82°16′18″W)
Gators VORTAC
(Lat. 29°34′20″N, long. 82°21′45″W)

That airspace extending upward from the surface within 2.4 miles each side of the Gators VORTAC 041° radial, extending from the 4.3-mile radius of Gainesville Regional Airport to 7 miles northeast of the VORTAC. This Class E4 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.

* * * * *

Issued in College Park, Georgia, on September 11, 2000.

Wade T. Carpenter,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 00–24294 Filed 9–21–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 00N–1457]

Medical Devices; Apnea Monitor; Special Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing a proposed rule to create a separate classification for the apnea monitor. The device currently is included in the generic type of device called breathing frequency monitors. The apnea monitor will remain in class II, but will be subject to a special control. The special control is an FDA guidance document that identifies minimum performance, testing, and labeling recommendations for the device. Elsewhere in this issue of the **Federal Register**, FDA is withdrawing a proposed mandatory standard for infant apnea monitors and is announcing the availability of a draft guidance document that will serve as the special control. FDA is taking these actions because it believes that they are necessary to provide reasonable assurance of the safety and effectiveness of the apnea monitor.

DATES: Submit written comments by December 21, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joanna H. Weitershausen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 164.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 10, 1982 (47 FR 39816), FDA classified devices intended to measure or monitor a patient's respiratory rate into class II (performance standards) as part of the generic group of devices known as breathing (ventilatory) frequency monitors (§ 868.2375 (21 CFR 868.2375)). Under the classification scheme set forth in section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the agency determined that performance standards were necessary to provide reasonable assurance of the safety and effectiveness of these devices.

After several initial steps, described in the notice published elsewhere in this issue of the **Federal Register** announcing the withdrawal of the proposed rule to establish a performance standard for the infant apnea monitor (withdrawal), FDA issued a proposed rule setting forth requirements for a performance standard for the infant apnea monitor (60 FR 9762, February 21, 1995). For the reasons discussed in the withdrawal, FDA determined that it is not necessary to establish a mandatory performance standard for the device.

In its place, FDA has developed a draft industry guidance document setting forth the agency's current position regarding minimum performance characteristics, test procedures and criteria, labeling, and, as appropriate, clinical testing for certain apnea monitors, i.e., the infant/child apnea monitor. The current draft guidance identifies the monitor used on this population because infants and children under 3 years old are particularly subject to the pathophysiological consequences of prolonged apneas lasting over 20 seconds in duration. The current draft guidance includes basic concepts set out in the proposed standard for the infant apnea monitor, but updates, consolidates, or eliminates certain