

# **PART 6901—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

1. The authority citation for part 6901 is revised to read as follows:

**Authority:** 5 U.S.C. 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); 42 U.S.C. 2473(c)(1); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.403(a), 2635.802(a), 2635.803.

## **§ 6901.102 [Removed and Reserved]**

2. Section § 6901.102 is removed and reserved.

[FR Doc. 01–29424 Filed 11–26–01; 8:45 am]

**BILLING CODE 7510–01–P**

## **DEPARTMENT OF TRANSPORTATION**

### **Federal Aviation Administration**

#### **14 CFR Part 71**

[Airspace Docket No. 01–ASO–13]

#### **Amendment of Class E Airspace; Dayton, TN**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action amends Class E airspace at Dayton, TN. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP), helicopter point in space approach, has been developed for Bradley Memorial Hospital, Cleveland, TN. As a result, additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAP. This action amends the Class E5 airspace for Dayton, TN, to the south in order to include the point in space approach serving Bradley Memorial Hospital.

**EFFECTIVE DATE:** 0901 UTC, February 21, 2002.

**FOR FURTHER INFORMATION CONTACT:** Walter R. Cochran, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5627.

#### **SUPPLEMENTARY INFORMATION:**

#### **History**

On October 12, 2001, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending Class E airspace at Dayton, TN, (66 FR 52076). This

action provides adequate Class E airspace for IFR operations at the Bradley Memorial Hospital. Designations for Class E airspace extending upward from 700 feet or more above the surface are published in FAA Order 7400.9J, dated August 31, 2001, and effective September 16, 2001, which is incorporated by reference in 14 CFR part 71.1. The Class E designation listed in this document will be published subsequently in the Order.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

#### **The Rule**

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends Class E airspace at Dayton, TN, for the Bradley Memorial Hospital.

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. 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 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).

#### **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, CLASS B, CLASS C, CLASS D AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS**

1. The authority citation for 14 CFR part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; EO 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 7400.9J, Airspace Designations and Reporting Points, dated August 31, 2001, and effective September 16, 2001, is amended as follows:

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

\* \* \* \* \*

#### **ASO TN E5 Dayton, TN [Revised]**

Dayton, Mark Anton Airport, TN

(Lat. 35°29′10″N, long. 84°55′52″W)

Hardwick Field Airport (Lat. 35°13′12″N, long. 84°49′57″W)

Bledsoe County Hospital, Pikeville, TN

Point in Space Coordinates

(Lat. 35°37′34″N, long. 85°10′38″W)

Bradley Memorial Hospital, Cleveland, TN

Point in Space Coordinates

(Lat. 35°10′45″N, long. 84°52′56″W)

That airspace extending upward from 700 feet or more above the surface within a 12.5-mile radius of Mark Anton Airport, and that airspace within a 6.5-mile radius of Hardwick Field Airport, and that airspace within a 6-mile radius of the point in space (lat. 35°37′34″N, long. 85°10′38″W) serving Bledsoe County Hospital, Pikeville, TN, and that airspace within a 6-mile radius of the point in space (lat. 35°10′52″N, long. 84°52′56″W) serving Bradley Memorial Hospital Cleveland, TN; excluding that airspace within the Athens, TN, Class E airspace area.

\* \* \* \* \*

Issued in College Park, Georgia, on November 16, 2001.

**Wade T. Carpenter,**

*Acting Manager, Air Traffic Division, Southern Region.*

[FR Doc. 01–29480 Filed 11–26–01; 8:45 am]

**BILLING CODE 4910–13–M**

## **NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

### **14 CFR Part 1207**

**RIN 2700–AC37**

#### **Standards of Conduct**

**AGENCY:** National Aeronautics and Space Administration (NASA).

**ACTION:** Final rule; amendment.

**SUMMARY:** NASA is amending its standards of conduct regulations. These amendments: change the procedure for NASA employees requesting waivers of the conflict of interests statute at 18 U.S.C. 208 to reflect organizational changes; repeal the general conflict of interests waivers at 14 CFR 1207.102(b); and revise the designations of officials

authorized to perform ethics-related functions and move those designations from 5 CFR part 6901 to 14 CFR part 1207, Subpart A.

**EFFECTIVE DATE:** November 27, 2001.

**ADDRESSES:** Code GG, NASA Headquarters, Washington, DC 20546-0001.

**FOR FURTHER INFORMATION CONTACT:** Laurie P. Rafferty, Senior Ethics Attorney, NASA Headquarters, (202) 358-2028.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 2635.105 of 5 CFR authorizes executive agencies, with the concurrence of the Office of Government Ethics (OGE), to publish supplemental regulations necessary to implement their respective ethics programs. On September 28, 1994, NASA, with OGE's concurrence, published in the **Federal Register** a final rule establishing supplemental standards of ethical conduct for NASA employees (59 FR 49335-49338). In addition, on that date, NASA redesignated its preexisting Standards of Conduct regulations at 14 CFR part 1207, and limited the coverage of the latter part to conflict of interests waivers under 18 U.S.C. 208 and post-employment procedures under 18 U.S.C. 207(j)(5).

By separate publication in the **Federal Register**, NASA is deleting the designations of officials authorized to make ethics-related determinations from 5 CFR 6901.102. Designations of NASA officials authorized to make ethics-related determinations are being published in amended form at 14 CFR 1207.103 as part of NASA's conduct regulations. The amendments include the Associate Deputy Administrator and the Chief of Staff among those delegated authority to make ethics-related determinations under 5 CFR part 2635 as to NASA Headquarters employees and for matters affecting employees Agencywide.

The procedures for requesting conflict of interests waivers under 18 U.S.C. 208 are being revised to reflect organizational changes to clarify the officials with approving authority for various classes of NASA employees. Specifically, the amended regulation reserves to the Administrator approval authority for waivers requested by key officials, including members of the Senior Executive Service, other positions classified above the GS-15 level (or otherwise requiring the filing of Public Financial Disclosure Reports), astronauts, and other specified sensitive positions. For other employees, the

approval authority is established as the appropriate Center Director or, for Headquarters employees, the Associate Administrator for Headquarters Operations. Moreover, in light of the Governmentwide conflict of interests exemptions at subpart B of 5 CFR part 2640, NASA is deleting its superseded exemptions at 14 CFR 1207.102(b). Finally, in this rulemaking NASA is correcting a miscitation in the authority citation for this part 1207.

**II. Matters of Regulatory Procedure**

*Administrative Procedure Act*

Pursuant to 5 U.S.C. 553(a)(2), (b), and (d), NASA has determined that good cause exists for waiving the regular notice of proposed rulemaking, opportunity for public comments, and 30-day delayed effective date for this final rule amendment. This action is being taken because it is in the public interest that this rule, which concerns matters of agency management, personnel, organization, practice, and procedure, and which sets forth the procedure by which certain restrictions on NASA employees may be relieved, be effective on the date of publication.

*Small Entities*

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), NASA has considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. Pursuant to 5 U.S.C. 605(b), NASA certifies that this rule will not have a significant economic impact on a substantial number of small entities because the rule only affects the operations of NASA and its employees. Accordingly, no regulatory flexibility analysis is required.

*Executive Order 12866 Determination*

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, is not subject to review under section 3(d) of that Order because it is limited to NASA's organization, management and/or personnel matters, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

*Collection of Information*

This rule calls for no new collection of information under the Paperwork Reduction Act (44 U.S.C. 3501-3520).

*Federalism*

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. NASA has analyzed this rule under that Order and has determined that it does not have implications for federalism.

*Unfunded Mandates Reform Act*

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. NASA has determined that the rule will not result in expenditures by State, local, or tribal governments or by the private sector of \$100 million or more. The rule affects only the internal organization of NASA. Accordingly, NASA has not prepared a budgetary impact statement or specifically addressed regulatory alternatives.

**List of Subjects in 14 CFR Part 1207**

Administrative practice and procedure, Authority delegations (Government agencies), Conflict of interests, Ethical conduct, Organization and functions (Government agencies).

Dated: November 5, 2001.

**Daniel S. Goldin,**

*Administrator, National Aeronautics and Space Administration.*

For the reasons set out in the preamble, NASA amends 14 CFR part 1207, subpart A, as follows:

**PART 1207—STANDARDS OF CONDUCT**

**Subpart A—General Provisions**

1. The authority citation for part 1207 is revised to read as follows:

**Authority:** 5 U.S.C. 7301; 18 U.S.C. 207-208; 42 U.S.C. 2473(c)(1); 5 CFR 2635.102(b); 5 CFR part 2637; 5 CFR part 2640.

2. Revise § 1207.102 to read as follows:

**§ 1207.102 Waiver of prohibition in 18 U.S.C. 208.**

(a) *Prohibition.* Employees are prohibited by criminal statute, 18 U.S.C. 208(a), from participating personally and substantially in an official capacity in any particular matter in which, to their knowledge, they, or any person

whose interests are imputed to them under the statute, have a financial interest, if the particular matter will have a direct and predictable effect on that interest.

(b) *Specific waiver available.* A NASA employee may request a waiver of this prohibition. NASA may grant a specific waiver of the prohibition only if the Agency determines that the employee's financial interest is not so substantial as to be deemed likely to affect the integrity of the employee's services. The waiver must be obtained before the employee participates in the matter.

(c) *Officials authorized to make waiver determinations.* (1) For the employees listed below, waivers must be approved by the Administrator or Deputy Administrator. No further delegation is authorized.

(i) Employees who are required by 5 CFR 2634.202 to file Public Financial Disclosure Reports;

(ii) Employees who are appointed under authority of section 203(c)(2) ("NASA Excepted Positions") or section 203(c)(10) ("Alien Scientists") of the National Aeronautics and Space Act of 1958, as amended (42 U.S.C. 2473(c)(2) and 2473(c)(10));

(iii) Astronauts and astronaut candidates;

(iv) Chief Counsel; and

(v) Procurement Officers.

(2) For all other Headquarters employees, the Associate Administrator for Headquarters Operations may approve waivers of 18 U.S.C. 208. This authority may not be redelegated.

(3) For all other Center employees, the Center Director or Deputy Center Director may approve waivers of 18 U.S.C. 208. This authority may not be redelegated.

(d) *Procedures for specific waiver.* The employee's request for a waiver must be in writing. The request must describe the particular matter involved, the relevant duties of the employee, and the exact nature and amount of the disqualifying financial interest.

(1) *Headquarters employees.* (i) Those Headquarters employees described in paragraph (c)(1) of this section must submit their requests to the Official-in-Charge of the Headquarters office in which they are employed and to the General Counsel for concurrence. The Official-in-Charge will then submit the request to the Administrator with recommendations on the proposed waiver.

(ii) Other Headquarters employees must submit their requests to the Associate General Counsel (General) for concurrence, and to the Associate Administrator for Headquarters Operations for approval.

(2) *Center employees.* (i) Those Center employees described in paragraph (c)(1) of this section must submit their requests to the Center Chief Counsel for concurrence and then to the Director of the Center where they are employed. The Center Director will provide the request, with recommendations, to the appropriate Enterprise Associate Administrator and to the General Counsel for review and submission to the Administrator.

(ii) Other Center employees must submit their requests to the Center Chief Counsel for concurrence, and then to their Center Director or Deputy Center Director for approval.

(3) Copies of approved waivers must be forwarded to the Associate Administrator for Human Resources and Education, the General Counsel, and the Office of Government Ethics.

(e) *Cross-references.* For regulations concerning general waiver guidance and exemptions under 18 U.S.C. 208, see 5 CFR part 2640.

3. Add § 1207.103 to subpart A to read as follows:

**§ 1207.103 Designations of responsible officials.**

(a) *Designated Agency Ethics Official.* The General Counsel of NASA is the Designated Agency Ethics Official and is delegated the authority to coordinate and manage NASA's ethics program as set forth in 5 CFR 2638.203.

(b) *Alternate Designated Agency Ethics Official.* The Associate General Counsel (General) is the Alternate Designated Agency Ethics Official.

(c) *Deputy Ethics Officials.* The following officials are designated as Deputy Ethics Officials:

(1) The Deputy General Counsel;

(2) The Associate General Counsel (General);

(3) The Senior Ethics Attorney assigned to the Associate General Counsel (General); and

(4) The Chief Counsel at each NASA Center and Component Facility.

(d) *Agency Designee.* As used in 5 CFR part 2635, the term "Agency Designee" refers to the following:

(1) For employees at NASA Headquarters, or for matters affecting employees Agencywide, the Associate Deputy Administrator, the Designated Agency Ethics Official, the Alternate Designated Agency Ethics Official, or the Chief of Staff; and

(2) For Center employees, the Center Director, who may delegate specific responsibilities of the Agency Designee to the Center Chief Counsel or to another official who reports directly to the Center Director.

(e) *Cross-references.* For regulations on the appointment, responsibilities,

and authority of the Designated Agency Ethics Official, Alternate Designated Agency Ethics Official, and Deputy Ethics Officials, see 5 CFR part 2638. For the responsibilities of the Agency Designee, see 5 CFR part 2635.

[FR Doc. 01-29425 Filed 11-26-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 207, 607, and 807

[Docket No. 98N-1215]

RIN 0910-AB21

#### Foreign Establishment Registration and Listing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule to amend its regulations pertaining to the registration of foreign establishments and the listing of human drugs, animal drugs, biological products, and devices. The final rule requires foreign establishments whose products are imported or offered for import into the United States to register with FDA and to identify a United States agent. The final rule implements section 417 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) as it pertains to foreign establishment registration.

**DATES:** This rule is effective February 11, 2002.

**Compliance date:** FDA will begin enforcing the requirements in 21 CFR part 207 on May 28, 2002, and in 21 CFR part 807 on April 26, 2002.

**ADDRESSES:** Submit written or electronic comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Office of Policy, Planning, and Legislation (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

In the **Federal Register** of May 14, 1999 (64 FR 26330), FDA published a proposed rule to implement section 417