

submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 97-SW-54-AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

97-26-09 Agusta S.p.A.: Amendment 39-10252. Docket No. 97-SW-54-AD.

Applicability: Model A109K2 helicopters with main transmission assembly, part number (P/N) 109-0400-03, serial number

(S/N) 005, 006, 007, 008, 010, 011, 012, 013, 014, 015, 016, 017, 018, 020, 022, 024, 027, 030, 031, 032, 033, 034, 035, 038, 039, 042, 047, 048, A2/1053, A2/1073, 2/1397, or B54895 e C347, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the main transmission Gleason crown (Gleason crown), failure of the main transmission and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 50 hours time-in-service (TIS) after the effective date of this AD, and thereafter at intervals not to exceed 300 hours TIS, perform a magnetic particle inspection of the Gleason Crown, P/N 109-0403-07, for cracks in accordance with steps 1 through 3 of Part II of the Compliance Instructions of Agusta Bollettino Tecnico (Technical Bulletin) No. 109K-16, dated April 24, 1997.

(b) If any crack is found, remove the Gleason crown and replace it with an airworthy Gleason crown, P/N 109-0403-07-103, S/N B58264 through S/N B58270, or S/N B58272 and subsequent (S/N B58271 is not an acceptable replacement part), and vibro-etch the main transmission tag with "S.M. 109-25094". Replacement of the Gleason crown with an airworthy Gleason crown, P/N 109-0403-07-103, S/N B58264 through S/N B58270 or S/N B58272 and subsequent, constitutes a terminating action for the requirements of this AD.

(c) 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, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

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

(d) 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.

(e) The inspections and replacement shall be done in accordance with Agusta Bollettino Tecnico (Technical Bulletin) No. 109K-16, dated April 24, 1997. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Agusta S.p.A., 21017 Cascina Costa di Samarate (VA), Via Giovanni Agusta 520, telephone (0331) 229111, fax (0331) 229605-222595. Copies may be inspected at the FAA, Office of Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on January 2, 1998.

Note 3: The subject of this AD is addressed in Registro Aeronautico Italiano (Italy) AD 97-122, dated April 29, 1997.

Issued in Fort Worth, Texas, on December 9, 1997.

Larry M. Kelly,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97-32992 Filed 12-16-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Airspace Docket No. 97-ANM-10]

RIN 2120-AA66

Change Controlling Agency for Restricted Areas R-6412A and R-6412B; Camp Williams, UT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action changes the published controlling agencies for Restricted Areas R-6412A and R-6412B, Camp Williams, UT. This is an administrative change initiated by the Northwest Mountain Region. There are no changes to the boundaries, altitudes, times of designation, or activities conducted within the restricted areas.

EFFECTIVE DATE: 0901 UTC, February 26, 1998.

FOR FURTHER INFORMATION CONTACT: Ken McElroy, Airspace and Rules Division, ATA-400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-7686.

SUPPLEMENTARY INFORMATION:

The Rule

This action amends 14 CFR part 73 by changing the published controlling

agencies for Restricted Areas R-6412A and R-6412B, Camp Williams, UT. This is an administrative change initiated by the Northwest Mountain Region. There are no changes to the boundaries, altitudes, times of designation, or activities conducted within the restricted areas.

Since this action simply changes the published controlling agency of the affected restricted areas, and does not involve a change in the dimensions or operating requirements of the restricted areas, the FAA finds that notice and public procedure under 5 U.S.C. 553(b) are unnecessary. Section 73.64 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8E, dated November 7, 1997.

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, it (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.

Environmental Review

In accordance with FAA Order 1050.1D, "Policies and Procedures for Considering Environmental Impacts," this action is not subject to environmental assessments and procedures.

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73, as follows:

PART 73—SPECIAL USE AIRSPACE

1. The authority citation for part 73 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

§ 73.64 [Amended]

2. § 73.64 is amended as follows:

* * * * *

R-6412A Camp Williams UT [Amended]

By removing "Controlling agency. FAA, Salt Lake City Tower" and substituting the following:

"Controlling agency. FAA, Salt Lake City TRACON."

R-6412B Camp Williams UT [Amended]

By removing "Controlling agency. FAA, Salt Lake City Tower" and substituting the following:

"Controlling agency. FAA, Salt Lake City TRACON."

* * * * *

Issued in Washington, DC, on December 2, 1997.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 97-32571 Filed 12-16-97; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 960712192-6192-01]

RIN 0648-AD85

Florida Keys National Marine Sanctuary Final Regulations

AGENCY: Sanctuaries and Reserves Division (SRD), Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Correction to final regulations.

SUMMARY: This document contains a correction to the final regulations which were published Thursday, January 30, 1997 (62 FR 4578). The regulations pertain to the Florida Keys National Marine Sanctuary and made revisions to the national marine sanctuary program regulations at 15 CFR Part 922.

EFFECTIVE DATE: December 17, 1997.

FOR FURTHER INFORMATION CONTACT: Michael Weiss (301) 713-2969, ext. 216.

SUPPLEMENTARY INFORMATION: Final regulations for the Florida Keys National Marine Sanctuary were published on Thursday, January 30, 1997 (62 FR 4578). These regulations were subsequently amended on June 12, 1997 (62 FR 32154). The January 30, 1997 **Federal Register** document made revisions to the national marine sanctuary program regulations at 15 CFR Part 922. The January 30, 1997 **Federal Register** document that is the subject of this correction contains amendatory language for § 922.48(b) of the national marine sanctuary program regulations, which pertains to national marine sanctuary permits. The amendatory instruction for paragraph (b) of section 922.48 was incorrect by failing to state

that only the introductory language to paragraph (b) was amended, thus leaving the remaining subparagraphs to paragraph (b) unchanged. Left uncorrected, the amendatory language would erroneously result in subparagraphs (1) through (5) of paragraph 922.48(b) being deleted from the Code of Federal Regulations.

Correction of Publication

Accordingly, the **Federal Register** document published on January 30, 1997 (62 FR 4578) is corrected by revising amendatory instruction 14 on page 4607, third column, to read as follows:

"14. Section 922.48 is amended by revising paragraph (a) and the introductory text of paragraph (b) as follows:"

Nancy Foster,

Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 97-32857 Filed 12-16-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 95P-0136]

Medical Devices; Reclassification of Tumor-Associated Antigen Immunological Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is codifying the reclassification of tumor-associated antigen immunological test systems intended as an aid in monitoring patients for disease progression or response to therapy or for the detection of recurrent or residual disease from class III (premarket approval) to class II (special controls). FDA is also announcing that it has issued an order in the form of a letter to Centocor, Inc., reclassifying serum tumor markers into class II. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

EFFECTIVE DATES: The reclassification was effective September 19, 1996. The codification becomes effective December 17, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices