conditions, and other aircraft operating in visual weather conditions or instrument weather conditions. The Nucla NDB has not been certified and is, therefore, unusable.

The description of the transition area will require new points of reference for accuracy. The geographical area and associated airspace encompassed by the transition area will remain unchanged.

Since this action involves only editorial changes in the description of the transition area and makes no substantive change, notice and public procedure herein are unnecessary and good cause exists for making the amendment effective in less than 30 days.

FOR FURTHER INFORMATION CONTACT: Art Corwin, Airspace & Procedures Specialist, ANM–532, FAA Northwest Mountain Region, 17900 Pacific Highway South, C–68966, Seattle, Washington, 98168. The telephone number is (206) 431–2532.

List of Subjects in 14 CFR Part 71

Transition areas, Control zones, Aviation safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.181 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended effective 0901 G.m.t., when published, as follows:

§ 71.181 Nucla, Colorado [Revised]

That airspace extending from 700 feet above the surface within a 9.5 mile radius of the NUCLA-Hopkins Field (lat. 38°14'22" N; 108°33'42" W) and within the area bounded by a line beginning at the 9.5 mile radius at lat. 38°22'30" N; long. 108°34'00" W; to lat. 38°30'00" N; long. 108°40'00" W; to lat. 38°24'00" N; long. 108°53'30" W; to lat. 38°11'00" N; long. 108°43'00" W; where the line will intersect the 9.5 mile radius; and that airspace extending upward from 1,200 feet above the surface within the area bounded by a line beginning at lat. 38°34'00" N; long. 108°19'30" W; to lat. 37°34'00" N; long. 108°15'00" N; to lat. 37°32'30" N; long. 108°25'00" W; to lat. 37°57'30" N; long. 109°00'00" W; to lat. 38°34'00" N; long. 109°07'45" W; thence to the point of beginning.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); (49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); (Sec. 1165 of the Federal Aviation Regulations and 14 CFR 11.69))

Note.—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.

For this reason and the reasons given earlier in the preamble, it, therefore—(1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (14 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory elevation 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.

Issued in Seattle, Washington.

Wayne J. Barlow,

Acting Director, Northwest Mountain Region.

[FR Doc. 84–10283 Filed 4–17–84; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 399

[Docket No. 40444–4044]

Amendments to the Commodity Control List

AGENCY: Office of Export Administration International Trade Administration, Commerce.

ACTION: Final rule

SUMMARY: This rule, which neither expands nor limits the provisions of the Export Administration Regulations, amends export controls of the Commodity Control List (Supplement No. 1 to § 399.1) concerning restrictions on the use of General (export) License *GLV* and the availability of special licensing procedures for exporting certain commodities. These amendments are necessary due to the inadvertent insertion and/or elimination of text in the publication of a substantially revised format of the Commodity Control List (47 FR, December 29, 1982, 58122–58194).

EFFECTIVE DATE: April 18, 1984.

FOR FURTHER INFORMATION CONTACT: Vincent Greenwald, Exporter Services Division (telephone: (202) 377–3856).

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

In connection with various rulemaking requirements, the Office of Export Administration has determined that:

1. Since this regulation involves a foreign affairs function, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, the opportunity for public participation and a delay in effective date are inapplicable.

2. This rule does not impose a burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

3. This rule is not subject to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

4. This rule is exempt from the requirements of Executive Order No. 12291 (46 FR 13193, February 19, 1981), "Federal Regulation."

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

List of Subjects in 15 CFR Part 399

Exports.

Accordingly, Commodity Group 5, Electronics and Precision Instruments, of the Commodity Control List (Supplement No. 1 to §399.1) of the Export Administration Regulations (15 CFR Parts 368–399), is amended as follows:

1. ECCN 1502A is amended by revising the *Special Licenses Available* paragraph to read as follows:

1502A Communication, Detection or Tracking Equipment * * *

* * * * *

Special Licenses Available: A Distribution License is available for shipment of police model infrared viewers to countries listed in Supp. No. 2 to Part 373. Other special licenses, as well as a Distribution License, may be available for other equipment in the LIST below; see Part 373.

* * * * *

2. ECCN 4516B is amended by deleting the word "modulators" in the *Units* paragraph.

3. The *Special Licenses Available* paragraph of ECCN 1522A is revised to read as follows:

1522A Lasers and Laser Systems, Including Equipment Containing Them

* * * * *

Special Licenses Available: See Part 373. (**Note:** Special licenses are *not* available for equipment of the following description: machine tools containing or designed to contain lasers described in ECCN 1522A; single aperture lasers with an output greater than one thousand Joules per nanosecond; and tunable diode lasers.)

* * * * *

4. ECCN 1555A is amended by revising the *Special Licenses Available* paragraph to read as follows:

1555A Electron Tubes and Specialized Components and Parts Therefor, * * *

* * * * *

Special Licenses Available: A Distribution License is available for shipment of equipment defined in paragraphs (a) and (c) of the LIST below to countries listed in Supp. Nos. 2 or 3 to Part 373. Other special licenses, as well as a Distribution license, may be available for other equipment in the LIST; see Part 373.

* * * * *

Authority: Secs. 203, 206 Pub. L. 95–223. Title II 91 Stat. 1626, 1628 (50 U.S.C. 1702, 1704) Executive Order No. 12470 of March 30, 1984 (49 FR 13099, April 3, 1984).

Dated: April 9, 1984.

John K. Boidock,

Director, Office of Export Administration, International Trade Administration.

[FR Doc. 84-10316 Filed 4-17-84; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 610, 620, 630, 640, 650, 660, and 680

[Docket No. 83N-0235]

General Biological Products Standards; Equivalent Methods

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to allow manufacturers of any licensed biological product to use modified test methods or manufacturing processes that are found by the Director, Office of Biologics Research and Review, Center for Drugs and Biologics, to be equal or superior to the test methods or manufacturing processes specified in the regulations under 21 CFR Parts 610 through 680. Because the regulation is applicable to all biological products, FDA also is removing from the additional standards for specific products all similar provisions for permitting equivalent methods or processes.

DATE: Effective May 18, 1984.

FOR FURTHER INFORMATION CONTACT: Michael L. Hooton, Center for Drugs and Biologics (formerly National Center for Drugs and Biologics) (HFN-368), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1306.

SUPPLEMENTARY INFORMATION: The biologics regulations prescribe test methods and manufacturing processes for licensed biological products to assure their safety, purity, potency, and effectiveness (21 CFR Parts 610 and 620 through 680). Most of the regulations for specific products now include provisions that permit manufacturers to use an alternative test method or manufacturing process, if the method or process is found by the Director, Office of Biologics Research and Review, Center for Drugs and Biologics, to be equal or superior to the method or process described in the regulations. These provisions are known as the "equivalent methods" provisions.

In the **Federal Register** of October 17, 1983 (48 FR 47009), FDA proposed to amend the biologics regulations to consolidate into new § 610.9 *Equivalent methods and processes* in Part 610 all of the equivalent methods provisions for specific products that are in Part 610 and Parts 620 through 680. FDA proposed that the requirements in new § 610.9 for obtaining FDA's approval for an equivalent method or process be essentially the same as the procedures that now are in Part 610 and Parts 620 through 680. FDA proposed that these equivalent methods provisions for specific products now in Part 610 and Parts 620 through 680 be removed.

The biologics regulations for certain specific tests, such as the test for Mycoplasma (21 CFR 610.30), now do not include provisions to permit the use of equivalent methods or processes. Also, the regulations for certain licensed biological products now do not include provisions to permit use of equivalent methods or processes. These products include Whole Blood (Human), Red Blood Cells (Human), Platelet Concentrate (Human), Single Donor Plasma (Human), Cryoprecipitated Antihemophilic Factor (Human), Immune Serum Globulin (Human), Antibody to Hepatitis B Surface Antigen, Reagent Red Blood Cells, Hepatitis B Surface Antigen, Limulus Amebocyte Lysate, Trivalent Organic Arsenicals, and Blood Group Substances. FDA proposed that equivalent methods or processes be permitted for the tests and products described above.

FDA provided 60 days for interested persons to submit comments on the proposal of October 17, 1983, and FDA received two letters of comment. Both letters supported adoption of the proposed rule and both also suggested inclusion of additional requirements.

1. One comment recommended that proposed § 610.9 be revised to include the criteria that FDA uses to determine the suitability of equivalent methods for each of various groups of products, such as vaccines and blood products composed of complex substances of biological origin, or products composed essentially of a single active chemical substance, such as products produced by recombinant DNA technology.

FDA disagrees with the comment. FDA does not believe that it is possible or practical to provide in the regulations the criteria suggested by the comment. For example, FDA may approve a manufacturer's product license application for a product. A second manufacturer later may submit, and FDA may approve, a product license application for the same product but using a different manufacturing process. Thus, because of the diversity of approved methods and processes, the criteria used by the agency to review and approve equivalent methods for products are not suitable for codification in the Code of Federal Regulations.

2. One comment suggested that proposed § 610.9 be revised to include several requirements in addition to those that were proposed. Some of these suggested additions are consistent with FDA's proposed "NDA Rewrite" published in the **Federal Register** of October 19, 1982 (47 FR 46622). The comment suggested that a manufacturer with an approved product license for a product should be allowed to implement minor changes in test methods or manufacturing processes for the product without obtaining prior agency approval through submission of a product license amendment. When such minor changes are made, the manufacturer should be required to describe in a periodic report to FDA each of the changes made and its date of implementation. However, before a manufacturer implements a major change, such as a new analytical method or a new manufacturing process, the manufacturer should submit to FDA a product license amendment and obtain agency approval. If within 45 days after its filing FDA does not deny approval of a manufacturer's product license amendment, the manufacturer should be allowed to implement the amendment without FDA approval.

FDA believes that the suggestions have merit, but rejects them at this time. These and similar suggestions currently are being evaluated as part of FDA's retrospective review of all of the general regulations for biological products. (See the **Federal Register** of July 14, 1981; 46 FR 36333.) When the retrospective review is completed, FDA's proposed changes in the regulations, if any, will be published in the **Federal Register** for public comment. Furthermore, these suggested changes are outside the scope of this rulemaking.

FDA finds that both comments support adoption of this proposal as a first step in improving the regulations for biologic products. Accordingly, FDA is adopting the proposal without change, except that in the final rule the reference to the Director, Office of Biologics, is changed to read the Director, Office of Biologics Research and Review, to reflect a recent reorganization within FDA's Center for Drugs and Biologics (See 49 FR 10168; March 19, 1984.)

The agency has determined pursuant to 21 CFR 25.24(d)(10) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The agency has reexamined the economic impact of this rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis as defined in the Regulatory Flexibility Act (Pub. L. 96-354). Specifically, this rule will provide manufacturers of all licensed biological products an opportunity to apply for use of a test method or manufacturing process that is modified from that prescribed in the biologics regulations. Although the immediate effect of the rule is neutral; i.e., it neither adds nor removes requirements from the standards for licensed biological products, a manufacturer may benefit from the flexibility permitted under the rule by gaining FDA approval of a modified method or process other than that prescribed under the biologics regulations. Therefore, the agency concludes that the rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act.

List of Subjects in 21 CFR Parts 610 through 680

Biologics, Blood, Labeling.

Therefore, under the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 610, 620, 630, 640, 650, 660, and 680 are amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. In Part 610:

a. By adding new § 610.9 to Subpart B to read as follows:

§ 610.9 Equivalent methods and processes.

Modification of any particular test method or manufacturing process or the conditions under which it is conducted as required in this part or in the additional standards for specific biological products in Parts 620 through 680 of this chapter shall be permitted only under the following conditions:

(a) The manufacturer presents evidence, in the form of a product license amendment, demonstrating that the modification will provide assurances of the safety, purity, potency, and effectiveness of the biological product equal to or greater than the assurances provided by the method or process specified in the general standards or additional standards for the biological product; and

(b) Approval of the modification is received in writing from the Director, Office of Biologics Research and Review (HFN-800), Center for Drugs and Biologics, 5600 Fishers Lane, Rockville, MD 20857.

§ 610.11 [Amended]

b. In § 610.11 *General safety*, by removing paragraph (f) and marking it "reserved."

§ 610.12 [Amended]

c. In § 610.12 *Sterility*, by removing paragraph (g)(3) and marking it "reserved."

§ 610.13 [Amended]

d. In § 610.13 *Purity*, by removing paragraph (c).

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

§§ 620.7, 620.15, 620.25, 620.36, and 620.49 [Removed]

2. In Part 620, by removing §§ 620.7, 620.15, 620.25, 620.36, and 620.49. (All are titled "Equivalent methods.")

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

§§ 630.6, 630.18, 630.37, 630.57, 630.67, 630.76, and 630.87 [Removed]

3. In Part 630, by removing §§ 630.6, 630.18, 630.37, 630.57, 630.67, 630.76, and 630.87. (All are titled "Equivalent methods.")

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

4. In Part 640:

§ 640.2 [Amended]

a. In § 640.2 *General requirements*, by removing the last sentence in paragraph (b).

§§ 640.86 and 640.96 [Removed]

b. By removing §§ 640.86 and 640.96. (Both are titled "Equivalent methods.")

PART 650—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR DERMAL TESTS

§§ 650.7 and 650.16 [Removed]

5. In Part 650, by removing §§ 650.7 and 650.16. (Both are titled "Equivalent methods.")

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

§ 660.25 [Amended]

6. In Part 660, by removing paragraph (d) from § 660.25 *Potency test without reference preparations.*

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

§ 680.5 [Removed]

7. In Part 680, by removing § 680.5 *Equivalent methods.*

Effective date. This regulation is effective on May 18, 1984.

(Sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262))

Dated: April 5, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-10298 Filed 4-17-84; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 51 and 150

[T.D. 7905]

Excise Tax Regulations Under the Crude Oil Windfall Profit Tax Act of 1980; Base Prices of Tier 2 and 3 Oil

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to final rule.

SUMMARY: This document contains corrections to the Federal Register publication beginning at 48 FR 35092 of the final regulations that were the subject of Treasury Decision 7905. T.D. 7905 relates to the determination of base prices of tier 2 and 3 oil for purposes of the windfall profit tax on domestically produced crude oil imposed by title I of

the Crude Oil Windfall Profit Tax Act of 1980.

EFFECTIVE DATE: Except as otherwise stated in the amendments that constitute T.D. 7905, the regulations that are the subject of this correction are effective with respect to tax liability for windfall profit tax on crude oil removed from the premises after September 30, 1980.

FOR FURTHER INFORMATION CONTACT: Donald W. Stevenson of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, Washington, D.C. 20224 (Attn: CC:LR:T), telephone 202–566–3297 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On August 3, 1983, the **Federal Register** published final regulations (48 FR 35092) relating to the determination of base prices of tier 2 and 3 oil for purposes of the windfall profit tax on domestically produced crude oil imposed by title I of the Crude Oil Windfall Profit Tax Act of 1980. The regulations were issued under the authority of sections 4989(d), 4997(b) and 7805 of the Internal Revenue Code of 1954 (94 Stat. 233, 26 U.S.C. 4989(d); 94 Stat. 249, 26 U.S.C. 4997(b); 68A Stat. 917, 26 U.S.C. 7805).

Need for a Correction

As published, the amendatory language of T.D. 7905, beginning at the bottom of page 35093, right column, has raised some questions with regards to the 1984 revision of Title 26 CFR. This correction notice restates the amendatory language of T.D. 7905 in a format that resolves those uncertainties.

Correction of Publication

Accordingly, the publication of Treasury Decision 7905, which was the subject of FR Doc. 83–21096, is corrected by revising the amendatory language that begins at the bottom of the right column on page 35093 to read as follows:

PART 51—[AMENDED]

§ 51.4989–1 [Amended]

Paragraph 1. The proposed regulations under section 4989(d)(1) of the Internal Revenue Code of 1954, the text of which is set out as temporary regulations § 150.4989–1(c)(1)–(7), are adopted as final regulations under § 51.4989–1(c)(1)–(7).

Par. 2. Paragraph (c)(2) of § 51.4989–1 is amended by removing "March 1, 1980." and adding in its place "April 1, 1980.", and by removing "§ 150.6050C–1" and adding in its place "§ 51.6050C–1".

Par. 3. Paragraph (c)(3) of § 51.4989–1 is amended by removing "March 1, 1980." and adding in its place "April 1, 1980.".

Par. 4. Paragraph (c)(7) of § 51.4989–1 is amended by removing "§ 150.4995–1" everywhere it appears and adding in those places "§ 51.4995–1", and by removing "§ 150.4995–3" everywhere it appears and adding in those places "§ 51.4995–3".

§ 150.4989–1 [Amended]

Par. 5. Paragraphs (c)(1)–(7) of § 150.4989–1 are removed.

Dated: April 13, 1984.

George H. Jelly,

Director, Legislation and Regulations Division.

[FR Doc. 84–10328 Filed 4–17–84; 8:45 am]

BILLING CODE 4830–01–M

Office of the Secretary

31 CFR Part 10

Regulations Governing the Practice of Attorneys, Certified Public Accountants, Enrolled Agents, and Enrolled Actuaries Before the Internal Revenue Service; Clarification of Effective Date

AGENCY: Department of the Treasury.

ACTION: Clarification of effective date.

SUMMARY: This notice clarifies the effective date of the final regulations governing practice before the Internal Revenue Service in 31 CFR Part 10 to set standards for providing opinions used in the promotion of tax shelters. Such regulations were published in the **Federal Register** on February 23, 1984 (49 FR 6719).

FOR FURTHER INFORMATION CONTACT: Mr. Leslie S. Shapiro, Director of Practice, Department of the Treasury, Washington, D.C. 20220, (202) 535–6787 (non toll free).

SUPPLEMENTARY INFORMATION:

Clarification

A number of inquiries have been received concerning the effective date of the final tax shelter opinion regulations. The final rule states the following:

These final regulations are effective with respect to tax shelter opinions provided after May 23, 1984. This is interpreted to mean that the regulations will apply only to tax shelter opinions provided by practitioners to clients after May 23, 1984. Opinions furnished clients before that time will not be subject to the provisions of the regulations. However, any tax shelter offering material or sales promotion effort used before May 24, 1984 and modified on or after that date will require compliance with the regulations by a practitioner if the modification relates to a matter which is required to be included in any tax shelter opinion issued after May 23, 1984.

Dated: April 13, 1984.

Peter J. Wallison,

General Counsel, Department of the Treasury.

[FR Doc. 84–10345 Filed 4–17–84; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Secretary of the Navy: (1) Has determined that USS RENTZ (FFG 46) and USS ROBERT G. BRADLEY (FFG 49) are vessels of the Navy which, due to their special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with their special functions as naval frigates and (2) has found that USS RENTZ (FFG 46) and USS ROBERT G. BRADLEY (FFG 49) are members of the FFG 7 class of ships, certain exemptions for which have been previously granted under 72 COLREGS, Rule 38. The intended effect of this rule is to warn mariners in waters where the 72 COLREGS apply.

EFFECTIVE DATE: April 5, 1984.

FOR FURTHER INFORMATION CONTACT: Captain Richard J. McCarthy, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332, Telephone number: (202) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in Executive Order 11964 and 33 U.S.C. 1605, the Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the Secretary of the Navy has certified that USS RENTZ (FFG 46) and USS ROBERT G. BRADLEY (FFG 49) are vessels of the Navy which, due to their special construction and purpose, cannot comply fully with 72 COLREGS: Rule 21(a) regarding the arcs