

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 806**

[Docket No. 91N-0396]

Medical Devices; Reports of Corrections and Removals; Stay of Effective Date of Information Collection Requirements**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Stay of effective date of a final regulation.

SUMMARY: The Food and Drug Administration (FDA) is staying the effective date of the information collection requirements of a final rule to implement the provisions of the Safe Medical Devices Act of 1990 (the SMDA) regarding reports of corrections and removals of medical devices. FDA is taking this action because the information collection requirements in the final rule have not yet been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). In the **Federal Register** of November 26, 1997, FDA announced that it sent the proposed information collection to OMB for review and clearance.

DATES: Effective November 17, 1997, sections 806.10 and 806.20, which contain information collection requirements published at 62 FR 27183, May 19, 1997, are stayed pending OMB clearance of the information collection requirements. FDA will announce the effective date of these sections in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2974.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 19, 1997 (62 FR 27183), FDA issued a final rule implementing the provisions of the SMDA concerning reports of corrections and removals of medical devices. The rule was scheduled to become effective on November 17, 1997. In the preamble to the final rule, FDA provided for a 60-day comment period on the information collection requirements of the rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), which was enacted after the publication of the proposed rule on reports of corrections and removals of medical devices.

In the preamble to the final rule, FDA announced that it would review the

comments received, make revisions as necessary to the information collection requirements, and submit the requirements to OMB for approval. FDA received four comments and has reviewed and responded to them and has submitted the information collection requirements to OMB for approval. A notice published in the **Federal Register** of November 26, 1997 (62 FR 63182), informs the public how to address comments on the information collection provisions to OMB.

The Administrative Procedure Act and FDA regulations provide that the agency may issue a regulation without notice and comment procedures when the agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(3)(B); 21 CFR 10.40(e)(1)). FDA finds there is good cause for dispensing with notice and comment procedures on this amendment to stay the effective date of the information collection requirements of the final rule on reports of corrections and removals until such time as OMB approves these requirements. Engaging in notice and comment rulemaking is unnecessary because the information collection provisions cannot become effective until such time as FDA obtains OMB approval of them. Moreover, notice and comment rulemaking is impracticable and contrary to the public interest in this case. There is not enough time to solicit a new round of notice and comment on the issue of establishing a delayed effective date for these information collection requirements without further delaying the implementation of this provision of the SMDA. Dispensing with notice and comment rulemaking provides that the information collection requirements of the reports of corrections and removals rule will go into effect at the earliest possible date after OMB review and clearance. FDA will announce the effective date of the information collection requirements of the final rule in a future issue of the **Federal Register**.

List of Subjects in 21 CFR Part 806

Corrections and removals, Medical devices, Reporting and recordkeeping requirements.

Therefore, under sections 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-393) and under authority delegated to the Commissioner of Food and Drugs, §§ 806.10 and 806.20, published in the **Federal Register** of May 19, 1997 (62 FR 27183), are stayed until further notice.

Dated: December 16, 1997.

William K. Hubbard,*Associate Commissioner for Policy Coordination.*

[FR Doc. 97-33418 Filed 12-23-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF STATE**22 CFR Parts 120, 123, 124, 126, 127, and 129**

[Public Notice 2602]

Bureau of Political-Military Affairs; Amendments to the International Traffic in Arms Regulations**AGENCY:** Department of State.**ACTION:** Final rule.

SUMMARY: This rule amends certain provisions of the International Traffic in Arms Regulations (ITAR) in order to reflect recent changes to the Arms Export Control Act (AECA).

EFFECTIVE DATE: December 24, 1997.**FOR FURTHER INFORMATION CONTACT:**

Mary F. Sweeney, Compliance and Enforcement Branch, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State (703) 875-6644.

SUPPLEMENTARY INFORMATION: Section 1045(a) of the National Defense Authorization Act for Fiscal Year 1997 (Public Law 104-201) added a new paragraph 12 to section 36(a) of the AECA requiring a report on all concluded agreements involving coproduction or licensed production outside of the United States of defense articles of United States origin.

Section 141 of the Defense and Security Assistance Improvements Act of 1996 (Public Law 104-164) amended and restated the requirements in section 36(c) and (d) of the AECA for certification to Congress of certain proposed exports and technical assistance or manufacturing license agreements, generally reducing the time for transfers involving member countries of the North Atlantic Treaty Organization, Australia, Japan and New Zealand.

Section 151 of Public Law 104-164 added a new clause (ii) to Subsection (b)(1)(A) of section 38 of the AECA requiring the registration and licensing of persons who engage in the business of brokering activities of defense articles and defense services.

Section 156 of Public Law 104-164 amended section 38(e) of the AECA, providing that certain types of information shall not be withheld from public disclosure unless the President

determines that the release of such information would be contrary to the national interest.

Section 144 of Public Law 104-164 amended and restated certain definitions contained in Section 47 of the AECA.

The civil penalty amount is in accordance with 22 U.S.C. 2778, 2779a and 2780.

In order to ensure consistent application of the ITAR as provided in law, Parts 120, 123, 124, 126, and 127 are being amended and a new Part 129 is being established.

Part 129 contains guidance concerning persons required to register as brokers and the types of brokering activities that require prior approval of the Department of State. As a general matter, any person in the United States or otherwise subject to U.S. jurisdiction who is in the business of brokering transfers of defense articles or services is required to register and pay a fee. This would include for example, persons who act as agents for others in arranging arms deals, as well as so-called finders and other persons who facilitate such deals. Certain exemptions to this requirement are also established, however, such as persons exclusively in the business of financing or transporting defense articles whose business activities do not include brokering arms deals. Certain prohibitions are also established in Part 129 concerning brokering activities associated with defense articles and defense services involving ineligible countries or persons, such as those countries for which the United States maintains an arms embargo and those persons debarred from receiving U.S. munitions licenses owing to previous violations of U.S. law. Part 129 identifies those circumstances or defense articles for which either prior written approval by, or prior notification to, the Department of State is necessary, and also specifies exemptions to these requirements. Further, Part 129 provides a procedure by which persons may seek guidance from the Department of State in respect to the possible application of these requirements to their activities.

These amendments involve a foreign affairs function of the United States. They are excluded from review under Executive Order 12866 (69 FR 51735) and 9 U.S.C. 553 and 554, but have been reviewed internally by the Department to ensure consistency with the purposes thereof.

In accordance with 5 U.S.C. 808, as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (the "Act"), the Department of State has found for foreign policy reasons that

notice and public procedure under section 251 of the Act is impracticable and contrary to the public interest. However, interested parties are invited to submit written comments to the Department of State, Office of Defense Trade Controls, ATTN: Regulatory Change, Room 200, SA-6, Washington, D.C. 20520-0602.

List of Subjects

22 CFR Part 120

Arms and munitions, Exports, Technical assistance.

22 CFR Part 123

Arms and munitions, Exports, Technical assistance.

22 CFR Part 124

Arms and munitions, Exports, Technical assistance.

22 CFR Part 126

Arms and munitions, Exports.

22 CFR Part 127

Arms and munitions, Exports.

22 CFR Part 129

Arms and munitions, Exports, Technical assistance.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Parts 120, 123, 124, 126 and 127 are amended and Part 129 is established as follows:

PART 120—PURPOSE AND DEFINITIONS

1. The authority citation for part 120 is revised to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2794; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2658.

2. In § 120.7 paragraph (a) is revised to read as follows:

§ 120.7 Significant military equipment.

(a) *Significant military equipment* means articles for which special export controls are warranted because of their capacity for substantial military utility or capability.

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3. Section 120.9 is revised to read as follows:

§ 120.9 Defense service.

(a) *Defense service* means:

(1) The furnishing of assistance (including training) to foreign persons, whether in the United States or abroad in the design, development, engineering, manufacture, production, assembly, testing, repair, maintenance,

modification, operation, demilitarization, destruction, processing or use of defense articles;

(2) The furnishing to foreign persons of any technical data controlled under this subchapter (see § 120.10), whether in the United States or abroad; or

(3) Military training of foreign units and forces, regular and irregular, including formal or informal instruction of foreign persons in the United States or abroad or by correspondence courses, technical, educational, or information publications and media of all kinds, training aid, orientation, training exercise, and military advice. (See also § 124.1.)

(b) [Reserved]

PART 123—LICENSES FOR THE EXPORT OF DEFENSE ARTICLES

4. The authority citation for part 123 is revised to read as follows:

Authority: Secs. 2 and 38, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778); 22 U.S.C. 2753; E.O. 11958, 42 FR 4311; 3 CFR 1977 Comp. 79; 22 U.S.C. 2658.

5. Section 123.15 is revised to read as follows:

§ 123.15 Congressional notification for licenses.

(a) All exports of major defense equipment, as defined in § 120.8 of this subchapter, sold under a contract in the amount of \$14,000,000 or more, or exports of defense articles and defense services sold under a contract in the amount of \$50,000,000 or more, may take place only after the Office of Defense Trade Controls notifies the exporter through issuance of a license or other approval that Congress has not enacted a joint resolution prohibiting the export and:

(1) In the case of a license for an export to the North Atlantic Treaty Organization, any member country of that Organization, or Australia, Japan or New Zealand, 15 calendar days have elapsed since receipt by the Congress of the certification required by 22 U.S.C. 2776(c)(1); or

(2) In the case of a license for an export to any other destination, 30 calendar days have elapsed since receipt by the Congress of the certification required by 22 U.S.C. 2776(c)(1).

(b) Persons who intend to export defense articles and defense services pursuant to any exemption in this subchapter (e.g., § 126.5 of this subchapter) under the circumstances described in the first sentence of paragraph (a) of this section must notify the Office of Defense Trade Controls by letter of the intended export and, prior to transmittal to Congress, provide a

signed contract and a DSP-83 signed by the applicant, the foreign consignee and end-user.

PART 124—AGREEMENTS, OFFSHORE PROCUREMENT AND OTHER DEFENSE SERVICES

6. The authority citation for Part 124 continues to read as follows:

Authority: Secs. 2, 38 and 71, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); E.O. 11958, 42 FR 4311; 3 CFR 1977 Comp. p. 79; 22 U.S.C. 2658.

7. Section 124.4 is revised to read as follows:

§ 124.4 Deposit of signed agreements with the Office of Defense Trade Controls.

(a) The United States party to a manufacturing license or a technical assistance agreement must file one copy of the concluded agreement with the Office of Defense Trade Controls not later than 30 days after it enters into force. If the agreement is not concluded within one year of the date of approval, the Office of Defense Trade Controls must be notified in writing and be kept informed of the status of the agreement until the requirements of this paragraph or the requirements of (124.5 are satisfied.

(b) In the case of concluded agreements involving coproduction or licensed production outside of the United States origin, a written statement must accompany filing of the concluded agreement with the Office of Defense Trade Controls, which shall include:

(1) The identity of the foreign countries, international organization, or foreign firms involved;

(2) A description and the estimated value of the articles authorized to be produced, and an estimate of the quantity of the articles authorized to be produced;

(3) A description of any restrictions on third-party transfers of the foreign-manufactured articles; and

(4) If any such agreement does not provide for United States access to and verification of quantities of articles produced overseas and their disposition in the foreign country, a description of alternative measures and controls to ensure compliance with restrictions in the agreement on production quantities and third-party transfers.

8. Section 124.11 is revised to read as follows:

§ 124.11 Certification to Congress for agreements.

Regardless of dollar value, a Technical Assistance Agreement or a Manufacturing License Agreement that

involves the manufacture abroad of any item of significant military equipment (as defined in § 120.7 of this subchapter) shall be certified to Congress by the Department as required by 22 U.S.C. 2776(d). Additionally, any technical assistance agreement or manufacturing license agreement providing for the export of major defense equipment, as defined in § 120.8, sold under a contract in the amount of \$14 million or more, or of defense articles or defense services sold under a contract in the amount of \$50 million or more, shall be certified to Congress by the Department as required by 22 U.S.C. 2776(c)(1). The Office of Defense Trade Controls will not approve agreements requiring Congressional notification unless Congress has not enacted a joint resolution prohibiting the agreement and:

(a) In the case of an agreement for or in a country which is a member of the North Atlantic Treaty Organization or Australia, Japan, or New Zealand, at least 15 calendar days have elapsed since receipt by the Congress of the certification required by 22 U.S.C. 2776(d); or

(b) In the case of an agreement for or in any other country, at least 30 calendar days have elapsed since receipt by the Congress of the certification required by 22 U.S.C. 2776(d).

PART 126—GENERAL POLICIES AND PROVISIONS

9. The authority citation for Part 126 is revised to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); 22 U.S.C. 2778; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp., p. 79; 22 U.S.C. 2658; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899.

10. In § 126.10 paragraph (b) is revised to read as follows:

§ 126.10 Disclosure of information.

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(b) *Determinations required by law.* Section 38(e) of the Arms Export Control Act (22 U.S.C. 2778) provides by reference to certain procedures of the Export Administrative Act that certain information required by the Department of State in connection with the licensing process may generally not be disclosed to the public unless certain determinations relating to the national interest are made in accordance with the procedures specified in that provision, except that the names of the countries and the types and quantities of defense articles for which licenses are issued under this section shall not be withheld

from public disclosure unless the President determines that release of such information would be contrary to the national interest. Determinations required by section 38(e) shall be made by the Assistant Secretary for Political-Military Affairs.

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PART 127—VIOLATIONS AND PENALTIES

11. The authority citation for part 127 is revised to read as follows:

Authority: Secs. 2, 38, and 42, Pub. L. 90-629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2791); E.O. 11958, 42 FR 4311, 3 CFR, 1977 Comp., p. 79; 22 U.S.C. 401; 22 U.S.C. 2658; 22 U.S.C. 2779a; 22 U.S.C. 2780.

12. In § 127.10 paragraph (a) is revised to read as follows:

§ 127.10 Civil penalty.

(a) The Assistant Secretary of State for Political-Military Affairs, Department of State, is authorized to impose a civil penalty in an amount not to exceed that authorized by 22 U.S.C. 2778, 2779a and 2780 for each violation of 22 U.S.C. 2778, 2779a and 2780, or any regulation, order, license or approval issued thereunder. This civil penalty may be either in addition to, or in lieu of, any other liability or penalty which may be imposed.

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13. Part 129 is added to read as follows:

PART 129—REGISTRATION AND LICENSING OF BROKERS

Sec.

- 129.1 Purpose.
- 129.2 Definitions.
- 129.3 Requirement to register.
- 129.4 Registration statement and fees.
- 129.5 Policy on embargoes and other proscriptions.
- 129.6 Requirement for license/approval.
- 129.7 Prior approval (license).
- 129.8 Prior notification.
- 129.9 Reports.
- 129.10 Guidance.

Authority: Sec. 38, Pub. L. 104-164, 110 Stat. 1437, (22 U.S.C. 2778).

§ 129.1 Purpose.

Section 38(b)(1)(A)(ii) of the Arms Export Control Act (22 U.S.C. 2778) provides that persons engaged in the business of brokering activities shall register and pay a registration fee as prescribed in regulations, and that no person may engage in the business of brokering activities without a license issued in accordance with the Act.

§ 129.2 Definitions.

(a) *Broker* means any person who acts as an agent for others in negotiating or

arranging contracts, purchases, sales or transfers of defense articles or defense services in return for a fee, commission, or other consideration.

(b) *Brokering activities* means acting as a broker as defined in § 129.2(a), and includes the financing, transportation, freight forwarding, or taking of any other action that facilitates the manufacture, export, or import of a defense article or defense service, irrespective of its origin. For example, this includes, but is not limited to, activities by U.S. persons who are located inside or outside of the United States or foreign persons subject to U.S. jurisdiction involving defense articles or defense services of U.S. or foreign origin which are located inside or outside of the United States. But, this does not include activities by U.S. persons that are limited exclusively to U.S. domestic sales or transfers (e.g., not for export or re-transfer in the United States or a foreign person).

(c) The term "foreign defense article or defense service" includes any non-United States defense article or defense service of a nature described on the United States Munitions List regardless of whether such article or service is of United States origin or whether such article or service contains United States origin components.

§ 129.3 Requirement to Register.

(a) Any U.S. person, wherever located, and any foreign person located in the United States or otherwise subject to the jurisdiction of the United States (notwithstanding § 120.1(c)), who engages in the business of brokering activities (as defined in this part) with respect to the manufacture, export, import, or transfer of any defense article or defense service subject to the controls of this subchapter (see § 121) or any "foreign defense article or defense service" (as defined in § 129.2) is required to register with the Office of Defense Trade Controls.

(b) Exemptions. Registration under this section is not required for:

- (1) Employees of the United States Government acting in official capacity.
- (2) Employees of foreign governments or international organizations acting in official capacity.
- (3) Persons exclusively in the business of financing, transporting, or freight forwarding, whose business activities do not also include brokering defense articles or defense services. For example, air carriers and freight forwarders who merely transport or arrange transportation for licensed United States Munitions List items are not required to register, nor are banks or credit companies who merely provide

commercially available lines or letters of credit to persons registered in accordance with Part 122 of this subchapter required to register.

However, banks, firms, or other persons providing financing for defense articles or defense services would be required to register under certain circumstances, such as where the bank or its employees are directly involved in arranging arms deals as defined in § 129.2(a) or hold title to defense articles, even when no physical custody of defense articles is involved.

§ 129.4 Registration statement and fees.

(a) *General.* The Department of State Form DSP-9 (Registration Statement) and a transmittal letter meeting the requirements of § 122.2(b) of this subchapter must be submitted by an intended registrant with a payment by check or money order payable to the Department of State of one of the fees prescribed in § 122.3(a) of this subchapter. The Registration Statement and transmittal letter must be signed by a senior officer who has been empowered by the intended registrant to sign such documents. The intended registrant shall also submit documentation that demonstrates that it is incorporated or otherwise authorized to do business in the United States.

(b) A person required to register under this part who is already registered as a manufacturer or exporter in accordance with part 122 of this subchapter must also provide notification of this additional activity by submitting to the Office of Defense Trade Controls by registered mail a transmittal letter meeting the requirements of § 122.2(b) and citing the existing registration, and must pay an additional fee according to the schedule prescribed in § 122.3(a). Any person who registers coincidentally as a broker as defined in § 129.2 of this subchapter and as a manufacturer or exporter must submit a Registration Statement that reflects the brokering activities, the § 122.2(b) transmittal letter, as well as the additional fee for registration as a broker.

(c) Other provisions of part 122, in particular, § 122.4 concerning notification of changes in information furnished by registrants and § 122.5 concerning maintenance of records by registrants, apply equally to registration under this part (part 129).

§ 129.5 Policy on embargoes and other proscriptions.

(a) The policy and procedures set forth in this subparagraph apply to brokering activities defined in § 129.2 of this subchapter, regardless of whether the persons involved in such activities

have registered or are required to register under § 129.3 of this subchapter.

(b) No brokering activities or brokering proposals involving any country referred to in § 126.1 of this subchapter may be carried out by any person without first obtaining the written approval of the Office of Defense Trade Controls.

(c) No brokering activities or proposal to engage in brokering activities may be carried out or pursued by any person without the prior written approval of the Office of Defense Trade Controls in the case of other countries or persons identified from time to time by the Department of State through notice in the **Federal Register**, with respect to which certain limitations on defense articles or defense services are imposed for reasons of U.S. national security or foreign policy (e.g., Cyprus, Guatemala, Yemen) or law enforcement interests (e.g., an individual subject to debarment pursuant to § 127.7 of this subchapter).

(d) No brokering activities or brokering proposal may be carried out with respect to countries which are subject to United Nations Security Council arms embargo (see also § 121.1(c)).

(e) In cases involving countries or persons subject to paragraph (b), (c), or (d), above, it is the policy of the Department of State to deny requests for approval, and exceptions may be granted only rarely, if ever. Any person who knows or has reason to know of brokering activities involving such countries or persons must immediately inform the Office of Defense Trade Controls.

§ 129.6 Requirement for License/Approval.

(a) No person may engage in the business of brokering activities without the prior written approval (license) of, or prior notification to, the Office of Defense Trade Controls, except as follows:

(b) A license will not be required for:

- (1) Brokering activities undertaken by or for an agency of the United States Government—

- (i) for use by an agency of the United States Government; or

- (ii) for carrying out any foreign assistance or sales program authorized by law and subject to the control of the President by other means.

- (2) Brokering activities that are arranged wholly within and destined exclusively for the North Atlantic Treaty Organization, any member country of that Organization, Japan, Australia, or New Zealand, except in the case of the defense articles or defense services specified in § 129.7(a) of this

subchapter, for which prior approval is always required.

§ 129.7 Prior Approval (License).

(a) The following brokering activities require the prior written approval of the Office of Defense Trade Controls:

(1) Brokering activities pertaining to certain defense articles (or associated defense services) covered by or of a nature described by Part 121, to or from any country, as follows:

(i) Fully automatic firearms and components and parts therefor;

(ii) Nuclear weapons strategic delivery systems and all components, parts, accessories, attachments specifically designed for such systems and associated equipment;

(iii) Nuclear weapons design and test equipment of a nature described by Category XVI of Part 121;

(iv) Naval nuclear propulsion equipment of a nature described by Category VI(e);

(v) Missile Technology Control Regime Category I items (§ 121.16);

(vi) Classified defense articles, services and technical data;

(vii) Foreign defense articles or defense services (other than those that are arranged wholly within and destined exclusively for the North Atlantic Treaty Organization, Japan, Australia, or New Zealand (see §§ 129.6(b)(2) and 129.7(a)).

(2) Brokering activities involving defense articles or defense services covered by, or of a nature described by, Part 121, in addition to those specified in § 129.7(a), that are designated as significant military equipment under this subchapter, for or from any country not a member of the North Atlantic Treaty Organization, Australia, New Zealand, or Japan whenever any of the following factors are present:

(i) The value of the significant military equipment is \$1,000,000 or more;

(ii) The identical significant military equipment has not been previously licensed for export to the armed forces of the country concerned under this subchapter or approved for sale under the Foreign Military Sales Program of the Department of Defense;

(iii) Significant military equipment would be manufactured abroad as a result of the articles or services being brokered; or

(iv) The recipient or end user is not a foreign government or international organization.

(b) The requirements of this section for prior written approval are met by any of the following:

(1) A license or other written approval issued under parts 123, 124, or 125 of

this subchapter for the permanent or temporary export or temporary import of the particular defense article, defense service or technical data subject to prior approval under this section, provided the names of all brokers have been identified in an attachment accompanying submission of the initial application; or

(2) A written statement from the Office of Defense Trade Controls approving the proposed activity or the making of a proposal or presentation.

(c) Requests for approval of brokering activities shall be submitted in writing to the Office of Defense Trade Controls by an empowered official of the registered broker; the letter shall also meet the requirements of § 126.13 of this subchapter.

(d) The request shall identify all parties involved in the proposed transaction and their roles, as well as outline in detail the defense article and related technical data (including manufacturer, military designation and model number), quantity and value, the security classification, if any, of the articles and related technical data, the country or countries involved, and the specific end use and end user(s).

(e) The procedures outlined in § 126.8(c) through (g) are equally applicable with respect to this section.

§ 129.8 Prior Notification.

(a) Prior notification to the Office of Defense Trade Controls is required for brokering activities with respect to significant military equipment valued at less than \$1,000,000, except for sharing of basic marketing information (e.g., information that does not include performance characteristics, price and probable availability for delivery) by U.S. persons registered as exporters under Part 122.

(b) The requirement of this section for prior notification is met by informing the Office of Defense Trade Controls by letter at least 30 days before making a brokering proposal or presentation. The Office of Defense Trade Controls will provide written acknowledgment of such prior notification to confirm compliance with this requirement and the commencement of the 30-day notification period.

(c) The procedures outlined in § 126.8(c) through (g) are equally applicable with respect to this section.

§ 129.9 Reports.

(a) Any person required to register under this part shall provide annually a report to the Office of Defense Trade Controls enumerating and describing its brokering activities by quantity, type, U.S. dollar value, and purchaser(s) and

recipient(s), license(s) numbers for approved activities and any exemptions utilized for other covered activities.

§ 129.10 Guidance.

(a) Any person desiring guidance on issues related to this part, such as whether an activity is a brokering activity within the scope of this Part, or whether a prior approval or notification requirement applies, may seek guidance in writing from the Office of Defense Trade Controls. The procedures and conditions stated in § 126.9 apply equally to requests under this section.

Dated: November 24, 1997.

Strobe Talbott,

Acting Secretary of State.

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BILLING CODE 4710-25-P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 250 and 251

RIN 1010-AC10

Geological and Geophysical (G&G) Explorations of the Outer Continental Shelf

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: This rule revises MMS' regulations and expands the Notice requirement to include all oil, gas, and sulphur related G&G scientific research not conducted under a permit. The revisions also update the addresses for applying for a permit or filing a Notice, standardize definitions, describe the procedures for protecting archaeological resources, reflect changes in technology, and clarify the obligations of third parties who obtain G&G data and information collected under a permit. These revisions are being made because there have been instances of commercial G&G exploration being conducted by academia without a permit, the addresses for all the MMS regions have changed, changes in technology need to be incorporated, and permittees and third parties have questioned MMS access to certain G&G data and information that were collected under a permit and further processed by third parties. The modifications will enable MMS to better ensure safe use and environmental protection of the outer continental shelf (OCS) for all G&G related operations, expedite permit applications and Notices to MMS, and make the regulatory language clearer