boss locations prior to the effective date of this AD in accordance with PW JT9D–7R4 Engine Manual, Section 72–41–02, Repair 28, perform an x-ray inspection of ten boss locations in accordance with the x-ray requirements of PW JT9D–7R4 Engine Manual, Section 72–41–02, Repair 28.

(ii) Determine if any previous weld repairs have been performed at any of the boss locations described in the above SB through reviewing maintenance records. If maintenance records cannot be located, or maintenance records indicate that a weld repair with a local stress relief has been performed at any of the boss locations, perform furnace stress relief, FPI, and shotpeen diffuser case assemblies in accordance with PW SB No. JT9D–7R4–72–469, Revision 2, dated April 25, 1994.

(b) For the purpose of this AD, an engine shop visit is defined as when the ''K'' and ''M'' flanges are separated so that the diffuser case is removed.

(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, Engine Certification Office. The request should be forwarded through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(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 aircraft to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on August 15, 1995.

James C. Jones,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 95–20851 Filed 8–22–95; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1303, 1304 and 1305

[DEA–108P]

RIN 1117–AA19

Definition and Registration of Disposers

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The DEA proposes to amend its regulations to define the term Disposer and establish a new category of manufacturer registration. DEA is also proposing to amend the regulations to exempt disposers from the quota requirements; to delineate the records and reports required of disposers; and to set out order form procedures for disposers. DEA is proposing these amendments in response to industry requests. The proposed amendments establish the regulatory guidelines under which disposers may handle controlled substances.

DATES: Comments and objections must be submitted by October 23, 1995.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537 Attention: Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Mr. G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: In years past, most pharmaceutical manufacturers and wholesalers, as a service to their customers, accepted returns of outdated/damaged controlled substances. Also, agencies such as DEA and state Boards of Pharmacy accepted surrendered drugs or witnessed their destruction by registrants.

Over the past several years, environmental concerns and regulations have eliminated many of the disposal options which had been available. As a result, drug manufacturers and government agencies alike are increasingly reluctant to be involved in the disposal process.

Pursuant to 21 CFR 1307.21, registrants may request permission to conduct disposal on their own without the benefit of DEA or State witness. In many cases, blanket permission is granted to manufacturers and distributors who have an ongoing need to dispose of unwanted substances. Their disposal must first have DEA authorization in writing, with a set schedule established. Other firms are granted disposal authority on a case by case basis.

In instances where DEA grants registrants authority to dispose of controlled substances, it is permissible for that registrant to utilize the services of an Environmental Protection Agency approved incinerator located in the area of the registrant's choice. The only caveat pursuant to DEA policy is that the registrant provide two designated responsible individuals to accompany the drugs to the disposal site and actually witness the destruction. The proposes registration of ''disposers'' will not alter the permissibility of this practice.

Traditionally, DEA has been opposed to granting DEA registrations to firms solely or primarily engaged in the disposal of controlled substances since they are not an essential link in the closed distribution system which the Controlled Substances Act established to control the flow of drugs from the manufacturer to the ultimate user. However, due to the changes in distribution patterns from local to a more national distribution, the time and resources expended by DEA in handling surrendered drugs, and the time expended by manufacturers, a disposer registration is becoming an essential link.

Title 21, CFR 1302.02(d) defines manufacture in part as ''the producing, preparation, propagation, compounding, or processing of a drug or substance. . .''. The section further defines a manufacturer as ''a person who manufactuers a drug or other substance . . . '' By its nature, a disposer processes a drug or other substance. Therefore, a disposer falls within the definition of manufacturer. However, due to the limited nature of the activity conducted by a disposer, a separate designation is necessary. Therefore, disposers will be registered as a subcategory of manufacturer.

The basic requirements for registration as a disposer will be similar to those currently imposed on all registrants at the manufacturer/distributor level. They include, but are not necessarily limited to: *Security;* all applicants must install at the registered premises physical security controls which meet the existing standards of 21 CFR 1301.71 and 1301.72. *Recordkeeping*; in accordance with 21 CFR 1304, periodic inventories and records of all controlled substances received, destroyed or distributed back to the original, registered manufacturers must be maintained. Due to the unique nature of this registration activity, the applicant must, consistent with 21 U.S.C. 823(a)(5), adequately describe the receipt and accountability methods and records to be employed to ensure the establishment of effective controls against diversion. *Order Forms* must be completed for all Schedule I and III items received and transferred *ARCOS* reports will be required. In addition to the DEA requirements, disposer applicants must obtain the appropriate state and federal approvals for controlled substance and disposal activities.

In conjunction with the proposed amendments outlined above, proposed

amendments are being made to a number of sections which currently are gender specific to make them gender appropriate.

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this purposed rule, initiated in the public interest is required to address disposers of controlled substances which are not covered by the existing regulations. This regulation will not have a significant economic impact on a substantial number of small entities; therefore no regulatory flexibility analysis is required in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 et. seq. The Deputy Assistant Administrator, Office of Diversion Control has determined that this rule is not a significant regulatory action under Executive Order 12866, Section 3(f) Regulatory Planning and Review, and therefore has not been reviewed by the Office of Management and Budget.

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

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1303

Administrative practice and procedure, Drug traffic control.

21 CFR Part 1304

Drug traffic control, Reporting requirements.

21 CFR Part 1305

Drug traffic control, Reporting requirements.

For reasons set out above, 21 CFR parts 1301, 1303, 1304, and 1305 are proposed to be amended as follows:

PART 1301—[AMENDED]

1. The authority citation for Part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

2. Section 1301.02 is proposed to be amended by redesignating paragraphs (f) through (m) as (g) through (n) and adding a new paragraph (f) as follows:

§ 1301.02 Definitions.

* * * * *

(f) The term disposer means a manufacturer (as defined in 1302.02(d)) who receives controlled substances for the sole or primary purpose of processing such substances to render them unusable.

* * * * *

3. Section 1301.22 is proposed to be amended by revising paragraphs (b)(1) and (b)(2) and adding new paragraph (b)(7) as follows:

§ 1301.22 Separate registration for independent activities.

* * * * *

(b) * * *

(1) A person registered to manufacture or import any controlled substance or basic class of controlled substance, except a person registered to dispose of any controlled substance, shall be authorized to distribute that substance or class, but no other substance or class which he/she is not registered to manufacture or import; a person registered to dispose of any controlled substance shall be authorized to distribute such substance only to the original registered manufacturer of the substance;

(2) A person registered to manufacture any controlled substance listed in Schedules II through V, except a person registered to dispose of any controlled substance, shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he/she is authorized to manufacture; a person registered to dispose of any controlled substance shall be authorized to conduct chemical analysis to ascertain that the substances received for disposal contain controlled substances;

* * * * *

(7) A person registered in any activity is authorized as a coincident activity to dispose of controlled substances in accordance with Section 1307.21.

* * * * *

4. Section 1301.26 is proposed to be amended by revising paragraphs (a)(1), (a)(2) and (b) and adding a new paragraph (a)(3) to read as follows:

§ 1301.26 Exemption of law enforcement officials.

(a) * * *

(1) Any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his or her official duties;

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to posses controlled substances in the course of his or her official duties; and

(3) Any person acting as an agent of the Administration or as an agent of any state or local law enforcement agency to dispose of controlled substances obtained from clandestine laboratories.

(b) Any official exempted by this section may, when acting in the course of his or her official duties, possess any controlled substance and distribute any such substance to any other official who is also exempted by this section and acting in the course of his or her official duties.

* * * * *

5. Section 1301.32 is proposed to be amended by revising paragraphs (a)(1) and (b)(1) to read as follows:

§ 1301.32 Application forms; contents; signature.

(a) * * *

(1) To manufacture, distribute, or dispose of controlled substances, he or she shall apply on DEA Form 225;

* * * * *

(b) * * *

(1) To manufacture, distribute, or dispose of controlled substances, he or she shall apply on DEA Form 225a;

* * * * *

6. In addition to the amendments set forth above in Section 1301.32, remove the words ''he shall apply'' and add, in their place ''he or she shall apply'' in each of paragraphs (a)(2) through (a)(8) and (b)(2) through (b)(8).

7. Section 1301.7 is proposed to be amended by revising paragraphs (b)(13) and (b)(14) and adding a new paragraph (b)(15) to read as follows:

§ 1301.71 Security requirements generally.

* * * * *

(b) * * *

(13) The availability of local police protection or of the registrant's or applicant's security personnel;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and

(15) The applicability of the security requirements contained in all Federal, state, and local laws and regulations governing the management of waste.

* * * * *

8. Section 1301.72 is proposed to be amended by revising paragraph (b)(7) to read as follows:

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

* * * * *

(b) * * *

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in Section 1301.71(b), (1) through (15);

* * * * *

PART 1303—[AMENDED]

1. The authority citation for Part 1303 continues to read as follows:

Authority: 21 U.S.C. 821, 826, 871(b).

2. Section 1303.12 is proposed to be amended by revising paragraphs (e)(2) and (e)(3) and adding a new paragraph (e)(4) to read as follows:

§ 1303.12 Procurement quotas.

* * * * *

(e) * * *

(2) Any person who is registered or authorized to conduct chemical analysis with controlled substances (for controlled substances to be used in such analysis only);

(3) Any person who is registered to conduct research with a basic class of controlled substance listed in Schedule I or II and who is authorized to manufacture a quantity of such class pursuant to Section 1301.22(b) of this chapter; and

(4) Any person who is registered solely as a disposer as defined in Section 1301.02(f) of this chapter.

* * * * *

PART 1304—[AMENDED]

1. The authority citation for Part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b) 958(d) 965, unless otherwise noted.

2. Part 1304 is proposed to be amended by adding new Section 1304.20 to read as follows:

§ 1304.20 Inventories of disposers.

Each person registered (by Section 1301.22(b) of this chapter) to dispose of controlled substances shall include in his inventory the same information required of manufacturers pursuant to Section 1304.15 (a), (c), and (d).

3. Part 1304 is proposed to be amended by adding new Section 1304.30 to read as follows:

§ 1304.30 Records for disposers.

Each person registered (by Section 1301.22(b) of this chapter) to dispose of controlled substances shall maintain records with the following information for each controlled substance:

(a) For each substance in bulk form,

(1) The name of the controlled substance;

(2) The total quantity of the controlled substance to the nearest metric unit weight consistent with unit size;

(3) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the controlled substance was received;

(4) The quantity distributed back to the original manufacturer of the controlled substance including the date of and quantity of each distribution and the name, address and registration number of the manufacturer to whom the controlled substance was distributed;

(5) The quantity disposed of including the date and manner of disposal, the quantity of the substance disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

(b) For each controlled substance in finished form,

(1) The name of the substance;

(2) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(3) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;

(4) The number of commercial containers of each such finished form distributed back to the original manufacturer of the substance, including the date of and number of containers in each distribution and the name, address, and registration number of the manufacturer to whom the containers were distributed;

(5) The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

4. Section 1304.34 is proposed to be amended by revising paragraphs (a) and (b) to read as follows:

§ 1304.34 Reports generally.

(a) All reports required by Sections 1304.35–1304.39 shall be filed with the ARCOS Unit, P.O. Box 28293, Central Station, Washington, D.C. 20005.

(b) Reports required by Sections 1304.35–1304.39 shall be filed on DEA Form 333, or on medial which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit.

* * * * *

5. Part 1304 is proposed to be amended by adding a new section 1304.39 to read as follows:

§ 1304.39 Reports from disposers.

Each person who is registered to dispose of controlled substances shall report as follows:

(a) Substances covered. Reports shall include data on each controlled substance listed in Schedules I and II and on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V). Data shall be presented in such a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.

(b) Transactions reported. Reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is e.g., by sale or transfer to the manufacturer, theft, destruction, or seizure by Government agencies). These reports shall be filed every month not later than the 15th day of the month succeeding the month for which it is submitted: except that a registrant may be given permission to file more frequently or less frequently (but not less than quarterly), depending on the number of transactions being reported each time by that registrant.

(c) Inventories reported. Reports shall provide data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year. These reports shall be filed no later than January 15 of the following year.

PART 1305—[AMENDED]

1. The authority citation for Part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

2. Section 1305.08 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1305.08 Persons entitled to fill order forms.

* * * * *

(b) A person who has obtained any controlled substance in Schedule I or II by order form may return such substance, or portion thereof, to the person from whom he/she obtained the substance, to the manufacturer of the substance, or to a registered disposer pursuant to the order form of the latter person;

* * * * *

Dated: August 17, 1995.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 95–20890 Filed 8–22–95; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 206 and 260

RIN 1010–AB93

Bidding Systems for Leases in the Outer Continental Shelf

AGENCY: Minerals Management Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Minerals Management Service (MMS) proposes an amendment to change the bidding systems for newly issued leases under the Outer Continental Shelf Lands Act (OCSLA). Four modifications of the existing alternative bidding systems are proposed that could lower the minimum prescribed royalty rate charged on newly issued Federal offshore leases from 12½ per centum to a rate greater than zero per centum; allow operating allowances in determining receipts subject to royalty rate; suspend or defer royalty for periods, volumes, or values of production; and extend the functional forms for calculating royalty rates under variable rate systems to include product prices as well as value and amount of production with the ability to apply different functional forms across time periods. The proposed rule does not affect existing leases.

This proposed rulemaking results from a review of alternative leasing policies conducted by MMS with constituent input, consistent with the Vice-President's Reinventing Government initiative. In particular, this change will grant the Secretary of the Interior (Secretary) the flexibility to improve the way MMS provides service to its customers and its ability to manage OCS oil and gas resources for the benefit of the public.

DATES: Comments must be received or postmarked no later than October 23, 1995 to be considered in this rulemaking.

ADDRESSES: Comments should be mailed or hand-carried to the Department of the Interior; Minerals Management Service; 381 Elden Street; Mail Stop 4700; Herndon, Virginia 22070–4817; Attention: Chief, Engineering and Standards Branch.

FOR FURTHER INFORMATION CONTACT: Dr. Marshall Rose, Chief, Economic Evaluation Branch, telephone (703) 787–1536.

SUPPLEMENTARY INFORMATION: Under the OCSLA, in section 8(a)(1), several bidding systems are authorized for new leases. The Secretary may grant a modification in the royalty rate to less than 12½ per centum upon application for existing leases. However, new leases are currently offered at a lease-specified royalty rate of no less than 12½ per centum, and it is for this class of leases that the proposed rule is applicable.

The OCSLA also provides authority to modify any bidding system currently authorized by the act if the Secretary determines the modification to be useful to accomplish the purposes and policies of the act (section 8(a)(1)).

MMS will consider using this more flexible royalty rate policy on specific types of new leases, including, but not limited to, those characterized by high development costs (deepwater leases in water depths of 200 meters or greater), relinquished tracts with qualifying wells but uneconomic reserves, or relinquished tracts that received high bonus bids but no exploration activity. Bidding systems that reflect a lower royalty than 12½ per centum are expected to increase competition for these tracts and, if discoveries are made, result in greater production in the future.

The proposed regulatory change would initiate actions to allow modification of the minimum royalty rate from 12½ per centum of the production amount or value to an effectively lower rate for all or a part of the tract's productive life as described in the lease terms portion of a sale's final notice. This lower rate could be designated over the life of the lease as a constant or variable measure or emerge as a result of fulfilling specified conditions (e.g., no royalties due until production reaches a designated level or a predetermined capital cost allowance is recovered). Further, the basis for determining the royalty rate under variable terms is expanded to include resource price as a potential variable. Thus, a smaller royalty rate could apply during periods of lower average product prices, and the precise relationship could vary between periods. This expansion will allow use of a simple price-royalty rate formula when unit operating costs are constant and can be estimated with some precision.

This proposed rule is the result of a review of alternate leasing policies conducted within MMS. MMS published a **Federal Register** Notice presenting possible alternate policies and received input from constituents, consistent with the Vice-President's Reinventing Government initiative.

The proposed actions will enable MMS to set royalty terms at time of sale for new leases that will adjust dynamically to changing market conditions prevalent in the oil and gas industry during exploration, development, and production. These actions are expected to result in increased competition for newly offered Federal offshore tracts, thereby contributing to the assurance of receipt of fair market value on leased tracts. These actions are also expected to increase the likelihood that a newly leased tract will be explored and developed. In sum, this change will grant the Secretary the flexibility to improve the way MMS provides service to its customers and its ability to manage OCS oil and gas resources for the benefit of the public.

Author: This document was prepared by Dr. Marshall Rose, Chief, Economic Revaluation Branch, MMS.

Executive Order (E.O.) 12866

This rule was reviewed under E.O. 12866. The rule was determined to not be significant under the criteria of E.O. 12866.

Regulatory Flexibility Act

The Department of the Interior (DOI) has determined that this proposed rule will not have a significant economic effect on a substantial number of small entities. Any direct effects of this rulemaking will primarily affect the Outer Continental Shelf (OCS) lessees and operators—entities that are not, by definition, small due to the technical complexities and financial resources necessary to conduct OCS activities. The indirect effect of this rulemaking on small entities that provide support for