Note: Guide 38 to Form N–3 does not and the amendments will not appear in the Code of Federal Regulations.

Form N–4 [Amended]

17. Part B, Item 21(a) of Form N–4 (referenced in §§ 239.17b and 274.11c) is amended by:

(a) Adding in paragraphs (i) and (ii) the phrase ''and income other than investment income'' after the phrase ''exclusive of capital changes'' in each paragraph.

(b) Adding at the end of Instruction 3 the following: ''Exclude income other than investment income.''

* * * * *

Note: Form N–4 does not and the amendments will not appear in the Code of Federal Regulations.

By the Commission.

Dated: December 10, 1996.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–31783 Filed 12–17–96; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1304

[DEA–143P]

RIN 1117–AA36

Establishment of Freight Forwarding Facilities for DEA Distributor Registrants

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: In response to industry concerns, the Drug Enforcement Administration (DEA) proposes to amend its regulations to define the term freight forwarding facility. DEA further proposes to amend its regulations to exempt certain freight forwarder facilities from registration requirements. These amendments will establish regulatory guidelines under which distributors registered with DEA may utilize freight forwarding facilities when shipping controlled substances to another DEA registrant.

DATES: February 18, 1996.

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: DEA 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:

I. Background

For many years, distributors registered with the DEA have utilized the services of common carriers to transport controlled substances to other registrants. These common carriers, who are not DEA registrants and therefore are not subject to the security and record keeping regulations promulgated pursuant to the Controlled Substances Act (CSA), often transfer the controlled substances from one conveyance to another at certain points during the shipment. In-transit losses due to theft of controlled substances have frequently occurred at these transfer points.

In discussions with DEA, distributors have expressed their interest in utilizing ''freight forwarding facilities,'' enabling them to employ proprietary or contracted shipping and better prevent in-transit losses. These controlled substance distributors represent that permitting distributors to utilize freight forwarding facilities will not only minimize in-transit losses, it will also facilitate more timely delivery of controlled substances and help lower health care costs.

To accomplish these goals, DEA proposes to permit distributors to extend their registrations to freight forwarding facilities operated by the distributor. In so doing, DEA is providing distributors an alternative means of delivery and allowing them to exercise direct control and responsibility for the controlled substances. By so extending the registration, the distributor will be required to comply with certain security and record keeping requirements proposed below.

Pursuant to these regulations, DEA proposes to allow distributors to use certain designated freight forwarding facilities as an extension of their registration. However, DEA has determined that due to security concerns, returns of controlled substances cannot be routed through the freight forwarding facilities because the registrant operating the facility will have no control over when drugs will be returned to the facility. Distributors who use freight forwarding facilities will not be required to obtain a separate registration for such facilities, but will be required to comply with record keeping and security requirements detailed below.

Distributors will be required to notify DEA in advance of their intent to utilize a freight forwarding facility. The distributor understands that if DEA approves the distributor's request, DEA will have the authority to conduct administrative inspections of the freight forwarding facility pursuant to 21 U.S.C. 822 and 880.

II. Notification of Use of a Freight Forwarding Facility

Although no separate DEA registration will be required for utilization of freight forwarding facilities for DEA distributor registrants, it will be necessary to notify DEA of their existence. DEA distributor registrants who intend to operate a freight forwarding facility must first notify both the DEA office in the area in which the distributor is located and the office in which the freight forwarding facility will be located. This facility must be for exclusive use of the named DEA distributor registrant and cannot be shared for use by another DEA registrant. Notification must be accomplished by registered letter, return receipt requested. If DEA does not communicate written disapproval within 21 days after confirmed receipt, the facility will be considered approved. Reasons for disapproval of a freight forwarding facility might include a registrant's failure to comply with DEA regulations or a history of losses.

Notification should consist of the distributor's DEA registration number, registered address and the address of the freight forwarding facility. A description of the operation of the freight forwarding facility should be included, listing such information as the hours of operation and the name, home address and date of birth of the designated responsible person. Information should be provided indicating what measures have been taken to limit accessibility to controlled substances at the facility. Notification should also include a description of the physical security in place at the facility. The physical security description should include a summary of the controlled substance temporary storage area including dimensions, specifications and alarm devices and identify the central station provider or delineation of the registrant's control station as specified in 21 CFR 1301.72(b)(4)(v).

A description of the recordkeeping procedures should also be included in the notification by providing an outline of recordkeeping procedures or copies of sample records.

III. Security of Freight Forwarding Facilities

The DEA distributor registrant utilizing a freight forwarding facility is

responsible for providing adequate security to guard against losses of controlled substances. DEA is proposing to amend 21 CFR Part 1301 by adding a new Section, 1301.77, outlining the security requirements. The new section requires either continuous observation of controlled substances stored in a segregated area by a designated responsible person(s) during the temporary storage, or by the installation of appropriate physical security measures. In some situations, a combination of the aforementioned two options may be permitted. The general security requirements currently found in 21 CFR 1301.71 are applicable and should be emphasized, since the freight forwarding facilities are located outside the normal realm of the distributor's registered location. It is necessary to pay special attention to security considerations, such as the extent of unsupervised public access and adequacy of supervision over employees within the facility. Definite procedures are required to be in place to control maintenance personnel and nonemployee service personnel.

Proposed physical security controls for all controlled substances routed through the freight forwarding facility, including Schedule II controlled substances, are those currently in place for Schedule III–V substances as set forth in 21 CFR 1301.72(b), unless the substances will remain under the constant observation of responsible person(s).

Access to controlled substances will be kept to an absolute minimum number of specifically authorized individuals. Only sealed containers, which do not identify controlled substances contents on the outside packaging, will be permitted to be temporarily stored or shipped through the freight forwarding facility. DEA distributor registrants will be permitted to utilize their proprietary fleet, or a specific contract carrier. Temporary storage at the freight forwarding facility will be permitted for a period of less than twenty-four (24) hours.

IV. Recordkeeping

There must be a clearly defined audit trail as part of the complete records maintained for all controlled substances transferred through the freight forwarding facility. DEA is proposing to amend the regulations by adding 21 CFR Section 1304.03(i), to specify the recordkeeping requirements. The records must contain dates, times of transfer, authorized signatures and number of cartons, crates, drums, or other packages in which commercial containers of controlled substances are shipped, to document the flow of controlled substances from the long distance conveyance through the freight forwarding facility to the local conveyance or from long distance conveyance directly to the local conveyance. These records must be traceable to a particular registrant invoice. The type of records to be kept can be designed by the individual registrant and must be kept for two years and stored at the freight forwarding facility. All other controlled substance recordkeeping requirements currently found in 21 CFR part 1304 are applicable. The freight forwarding facility will be exempt from all inventory requirements and ARCOS reporting.

The Deputy Assistant Administrator, Office of Diversion Control, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This proposal provides an alternative system that may allow some distributors a more efficient means of delivering controlled substances. Indeed, the regulated industry has represented that this procedure will benefit the industry by allowing it to lower costs associated with shipping controlled substances. Further, this regulation has been drafted and reviewed in accordance with Executive Order 12866, § 1(b), Principles of Regulations. 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 accordingly this rule has not been reviewed by the Office of Management and Budget. This regulation provides an exemption from certain requirements of the CSA for registrants operating freight forwarding facilities, thus allowing them a more efficient and cost effective means of doing business.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612 and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1301

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

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

For reasons set out above, DEA is proposing to amend 21 CFR parts 1301 and 1304 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, unless otherwise noted.

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

§ 1301.02 Definitions.

* * * * *

(m) The term *freight forwarding facility* means a separate facility operated by a DEA distributor registrant through which sealed, packaged controlled substances, in unmarked shipping containers, are stored for less than 24 hours while being routed to the ultimate DEA registrant consignee. A freight forwarding facility is a controlled premises as defined in § 1316.02 (c). The term does not include a facility through which controlled substance returners are processed.

* * * * *

3. Section 1301.23 is proposed to be amended by adding a new paragraph (b)(4) to read as follows:

§ 1301.23 Separate registrations for separate locations.

* * * * *

(b) * * *

(4) A freight forwarding facility operated by the registrant distributor through which the registered distributor transfers controlled substances from long distance conveyances to local conveyances, provided that the registrant has submitted written notice by registered mail, return receipt requested, of intent to operate the facility to the Administration's offices in the area in which the distributor is registered and in the area in which the facility will be located and that notice has been approved. Such notice shall detail the location of the facility, the hours of operation, the individual(s) responsible for the controlled substances, and the security and recordkeeping procedures that will be employed. The notice will be considered approved 21 days after receipt by the Administration provided the registrant has not been otherwise notified in writing by the Administration.

4. Section 1301.77 is proposed to be added under the undesignated center

heading ''Security Requirements'' as follows:

§ 1301.77 Security controls for freight forwarding facilities.

(a) All Schedule II–V controlled substances that will be temporarily stored/docked at the freight forwarding facility must be:

(1) Maintained under constant observation of the designated responsible individual(s) in a segregated area; or

(2) Where controlled substances will not be under the constant observation of the designated responsible individual(s), temporary storage in a caged area which meets the requirements of § 1301.72(b), and is secured by an alarm system operated by the registrant as specified in § 1301.72 (b)(4)(v), is required.

(b) Access to controlled substances must be kept to a minimum number of specifically authorized individuals.

(c) Only sealed, unmarked shipping containers will be permitted for transfer or temporary storage at the freight forwarding facility.

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. Section 1304.03 is proposed to be amended by adding a new paragraph (i) to read as follows:

§ 1304.03 Person required to keep records and file reports.

* * * * *

(i) A distributor registrant that utilizes a freight forwarding facility shall maintain records reflecting the transfer of controlled substances from the long distance conveyance, through the facility, to the local conveyance or from the long distance conveyance directly to the local conveyance. The records must contain the date, time of transfer, number of cartons, crates, drums or other packages in which commercial containers of controlled substances are shipped and authorized signatures for each transfer. The records of these shipments must be maintained at the facility for a period of two years.

Dated: December 6, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 96–32077 Filed 12–17–96; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

RIN 1010–AC12

Oil and Gas and Sulphur Operations in the Outer Continental Shelf

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule.

SUMMARY: The MMS proposes to amend the regulations governing quality assurance (QA) of safety and pollution prevention equipment (SPPE). The SPPE QA requirements currently fond in the regulations need refining to lessen the paperwork burden on MMS and industry and to ensure that Outer Continental Shelf operators continue to use the best available and safest equipment.

DATES: MMS will consider all comments we receive by February 18, 1997. We will begin reviewing comments then and may not fully consider comments we receive after February 18, 1997.

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

FOR FURTHER INFORMATION CONTACT: Bill Hauser, Engineering and Standards Branch, telephone (703)787–1600.

SUPPLEMENTARY INFORMATION:

Background

SPPE include the following equipment:

- Surface and underwater safety valves and their actuators,
- Subsurface safety valves and associated safety valve locks and landing nipples.

The current SPPE regulations, found at 30 CFR 250.126, require that lessees use SPPE certified by the manufacturer as having been produced under a QA program MMS recognizes. MMS currently recognizes two QA standards:

(1) American Society of Mechanical Engineers/American National Standards Institute Quality Assurance and Certification of Safety and Pollution Prevention Equipment Used in Offshore Oil and Gas Operations (ASME/ANSI SPPE–1).

(2) American Petroleum Institute (API) Specification for Quality Programs (Spec Q1).

MMS incorporated the QA requirements into the regulations in April 1988 when the offshore operating rules governing oil, gas, and sulphur exploration, development, and production on the OCS were consolidated. MMS required lessees to submit a list of all certified and noncertified SPPE in their inventory as of April 1, 1988, and to notify MMS when listed SPPE were removed from service for failure, malfunction, or remanufacture.

On July 6, 1988 (53 FR 25349), MMS proposed to recognize API's QA standard as an acceptable alternate or optional QA standard for the manufacture of SPPE. The API standard required manufacturers to meet API Spec Q1 in combination with API Specification for Subsurface Safety Valve Safety Equipment (Spec 14A) and API Specification for Surface Safety Valves and Underwater Safety Valves (Spec 14D). MMS evaluated the comments regarding the proposed rulemaking and determined that the API QA standard was an acceptable program. The API standard was recognized in a final rule dated March 22, 1990 (55 FR 10614). References to both API's and ASME/ANSI's QA standards were updated to incorporate the latest editions into the regulations on September 13, 1990 (55 FR 37709).

Regulatory Review

During a review of regulations, MMS evaluated the merit of continuing the SPPE QA requirements. The MMS examined the scope and effect of these requirements and determined that they were effective but needed revisions.

In January 1994, MMS decided to pursue a negotiated rulemaking to develop a proposed rule governing SPPE QA regulations. The preliminary steps of this effort included contacting interested parties (valve manufacturers, lessees, standards organizations, and environmental groups) to educate them on negotiated rulemaking and to determine their willingness to participate in the rulemaking effort. In April 1994, the ''convener'' held initial formal interviews with the interested parties. Over the next few months it became evident that, while MMS needed to revise the regulations, a negotiated rulemaking was not necessary.

This negotiated rulemaking exercise did succeed in getting the parties involved in the SPPE QA program to communicate. Misunderstandings between the parties were cleared up, and the consensus emerged that the SPPE QA program should continue for MMS and industry to ensure that the best available and safest technology and equipment are being used on the OCS.