could be circumstances when the valuation is so qualified or subject to such limitations as to raise questions as to the reasonableness of such reliance on the opinion.

Accordingly, 17 CFR Part 241 is amended by adding this release thereto.

By the Commission.

George A. Fitzsimmons,

Secretary.

May 23, 1980.

[FR Doc. 80-16507 Filed 5-29-80; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 282

[Docket No. RM80-24; Order No. 85-A]

Permanent Rule Defining Small Existing Industrial Boiler Fuel Users Exempt From Incremental Pricing Surcharges

Issued: May 20, 1980.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: Order No. 85, which was issued in this docket on May 8, 1980 (45 FR 31980, May 15, 1980), adopted a final rule defining small existing industrial boiler fuel users permanently exempt from incremental pricing surcharges under section 206(a)(2) of the Natural Gas Policy Act of 1978. Order No. 85 also set forth deadlines and procedures for filing exemption affidavits to obtain a permanent exemption. The Federal Energy Regulatory Commission hereby amends its final regulations to extend by 60 days the deadlines established in Order No. 85 pertaining to exemption affidavits. The amended regulations provide that:

(1) an exemption on the basis of company records or previously-filed exemption affidavits continues until *August 31, 1980;*

(2) natural gas suppliers shall mail or otherwise supply exemption affidavits to appropriate facilities not later than *July 20, 1980;*

(3) executed affidavits shall be filed on or before *August 31, 1980.*

EFFECTIVE DATE: Effective May 20, 1980.

FOR FURTHER INFORMATION CONTACT: Alice Fernandez, Office of Producer and Pipeline Regulator , Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426 (202) 357-9095, or Carol M. Lane, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426 (202) 357-8114.

Permanent rule defining small existing industrial boiler fuel users exempt from incremental pricing under the Natural Gas Policy Act of 1978.

Order No. 85, which was issued in this docket on May 8, 1980 (45 FR 31980, May 15, 1980), adopted a final rule defining small existing industrial boiler fuel users permanently exempt from incremental pricing surcharges under section 206(a)(2) of the Natural Gas Policy Act of 1978. Order No. 85 also set forth deadlines and procedures for filing exemption affidavits to obtain a permanent exemption.

The Commission, upon its own motion, has determined that an undue administrative burden may be place upon natural gas suppliers and industrial end-users by the exemption affidavit portion of the order. Due to the immediacy of the filing deadlines, coupled with the large number of industrial end-users required to be served with affidavits, it may not be possible for all affected persons to meet the existing deadlines. It is therefore appropriate to extend the exemption affidavit deadlines established in Order No. 85 for a period of two months. Accordingly, Part 282 is amended to provide that:

(1) an exemption on the basis of company records or previously-filed exemption affidavits continues until *August 31, 1980;*

(2) natural gas suppliers shall mail or otherwise supply exemption affidavits to appropriate facilities not later than *July 20, 1980;*

(3) executed affidavits shall be filed on or before *August 31, 1980.*

The amendments adopted in this order relieve administrative burdens imposed on natural gas suppliers and industrial boiler fuel users; accordingly, the Commission finds there exists good cause to make them effective immediately.

(Natural Gas Policy Act of 1978, Pub. L. No. 95-621, 92 Stat. 3350, 15 U.S.C. 3301, *et seq.*)

In consideration of the foregoing, Part 282 of Subchapter I, Title 18, Code of Federal Regulations, is amended as set forth below, effective immediately.

By the Commission.

Kenneth F. Plumb,

Secretary.

1. In Section 282.204 paragraphs (c)(2), (d)(2)(i)(B), (d)(2)(ii)(B), and (d)(7)(i) (A) and (B) are revised to read as follows:

§ 282.204 Obtaining an exemption.

* * * * *

(c) *Exemption on the basis of company records until August 31, 1980.* * * *

(2) The natural gas supplier shall treat an industrial boiler fuel facility for which an affirmative determination is made under subparagraph (1) as exempt from incremental pricing under this part until August 31, 1980, without further action by the owner or operator of the facility.

(d) *Exemption on the basis of affidavit.* * * *

(2) *Availability from natural gas suppliers.*

(i) *Initial service.* * * *

(B) Not later than July 20, 1980, each natural gas supplier shall mail or otherwise supply an exemption affidavit, as described in paragraph (d)(3) of this section, to the owner or operator of each industrial boiler fuel facility on such supplier's system which obtained an exemption pursuant to § 282.203(a), as in effect from January 1 to August 31, 1980.

(ii) *Response date.* * * *

(B) Natural gas suppliers which supply exemption affidavits under clause (i)(B) shall request that executed affidavits be filed on or before August 31, 1980, in accordance with subparagraph (4).

* * * * *

(7) *Effective date of exemption.* * * *

(i) *Permanent exemption under 282.203(a).*

(A) If the owner or operator of an industrial boiler fuel facility files an exemption affidavit with the Commission in order to obtain a permanent exemption under § 282.203(a) and sends a copy to the facility's natural gas supplier on or before August 31, 1980, the facility shall be permanently exempt from incremental pricing in accordance with this part as of September 1, 1980.

(B) If the owner or operator of an industrial boiler fuel facility files an exemption affidavit with the Commission and sends a copy to the facility's natural gas supplier in order to obtain a permanent exemption under § 282.203(a) on or after September 1, 1980, the facility shall be exempt from incremental pricing under this part as of the beginning of the first full month following the date the exemption affidavit is filed with the Commission and received by the facility's natural gas supplier.

* * * * *

[FR Doc. 80-16408 Filed 5-29-80; 8:45 am]

BILLING CODE 6450-85-M

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 80-142]

19 CFR Parts 4, 144, 151, 159

Imports of Petroleum and Petroleum Products; Customs Regulations

AGENCY: U.S. Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations relating to imported petroleum and petroleum products to incorporate recommendations of a Customs Petroleum Imports Task Force for establishing standardized guidelines and procedures, including the use of public gaugers, for monitoring imports of petroleum and petroleum products. These amendments are being made to ensure proper control of imported petroleum and petroleum products and uniform, complete, and reliable statistics relating to the importation of these products. The amendments to the regulations are considered to be significant.

EFFECTIVE DATE: June 30, 1980.

FOR FURTHER INFORMATION CONTACT: Alice M. Rigdon, Cargo Processing Division, Office of Inspection, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229 (202-566-5354).

SUPPLEMENTARY INFORMATION:

Background

Controls and checks on the unlading and shore tank gauging of imported petroleum and petroleum products now are established by each district director of Customs under section 151.42, Customs Regulations (19 CFR 151.42). Depending on local conditions, the district director may employ any of the following methods of control:

(a) Complete and continuous supervision by a Customs officer when other methods are not considered adequate, or when the importer requests continuous supervision;

(b) Use of reports of public gaugers approved by the Commissioner of Customs in accordance with section 151.43, Customs Regulations (19 CFR 151.43);

(c) Use of positive displacement meters at installations where provided by the importer;

(d) Use of turbine-type meters at installations where provided by the importer;

(e) Sealing of all valves when practical; or

(f) Taking of vessel ullages before and after the discharge.

To ensure proper control of imported petroleum and petroleum products and uniform, complete, and reliable statistics relating to the importation of these products, a Customs Petroleum Imports Task Force was established to survey operations at selected Customs field locations and to formulate proposals to achieve these goals.

Survey teams conducted studies from July 2-20, 1979, in the 10 locations through which most petroleum and petroleum products imported into the United States are entered. The teams "* * * found that, in general, the Customs Service was providing proper controls and reporting reliable statistics." However, it was also discovered that "* * * there were isolated instances of insufficient controls and that the Customs Service was lacking in standardized national procedures and guidelines for various aspects of imported petroleum." Therefore, it was determined to be in the national interest, in light of the present energy situation, to develop standardized guidelines for processing petroleum and petroleum product importations.

On the basis of Task Force recommendations, and in accordance with Customs intent to maintain a permanent oversight function in regard to petroleum imports to ensure continued control in this vital area, the Customs Service published a notice in the **Federal Register** on November 7, 1979 (44 FR 64434), proposing to amend the Customs Regulations to establish standardized guidelines and procedures applicable to the appropriate methods of control and the use of public gaugers in monitoring imports of petroleum and petroleum products. These guidelines were similar to Customs procedures followed in most locations. Significant changes emphasize uniformity throughout Customs and tighter control through increased supervision of various gauging procedures, including controls on the use of public gaugers.

The notice invited interested persons to submit comments on or before December 7, 1979. At the request of an industry trade association, the period of time for the submission of comments was extended until December 14, 1979, by a notice published in the **Federal Register** on November 21, 1979 (44 FR 66835).

In response to the notices, 17 comments were received from corporations, cooperatives, industry representatives, refiners, and others. In addition, in accordance with requests from certain commenters for further discussion of the proposals prior to the issuance of a final rule, pursuant to a notice published in the **Federal Register** on December 21, 1979 (44 FR 75635), Customs held an open conference on January 8, 1980, for the discussion and clarification of the issues raised in the comments. Approximately 45 individuals representing various interested parties attended. Specific proposals were discussed, the Customs position on each was explained, and areas of misunderstanding were clarified.

Summary of Major Changes in Existing Regulations

1. Section 4.12 requires that manifest shortages and overages be reported to the district director. However, it does not state how great the discrepancy must be before a report is mandatory for bulk importations. Customs proposed that discrepancies exceeding one percent between the manifested quantity and the gross quantity unladen be reported on Customs Form 5931, signed by both the carrier and the importer, and that penalties otherwise provided by law be imposed if the required notification and explanation were not filed timely, or if the reasons for the discrepancy was not satisfactorily explained.

This proposal has been adopted and modified to delete the requirement that Customs Form 5931 be signed by both the carrier and the importer.

2. Sections 151.41 and 151.45(c) permit importers to estimate the amount of petroleum and petroleum products to be unladen for entry or withdrawal from bonded tanks if the exact quantity cannot be determined in advance. In order to obtain more accurate statistics regarding these imports, Customs proposed that this estimate not vary by more than one percent from the gross quantity unladen and that penalties otherwise provided by law be imposed if the required notification and explanation were not filed timely, or if the reason for the discrepancy was not satisfactorily explained.

This proposal has been adopted with the modification that the estimate may vary by three percent.

3. Section 151.42 provides that each district director shall establish controls and checks on the unlading and shore tank gauging of petroleum and petroleum products imported by vessel. Customs proposed to amend § 151.42 to include imports by truck, railroad car, pipeline, or other carrier.

This proposal has been adopted without modification.

Section 151.42 also permits the district director to exercise discretion in

determining which methods of control to use in the unlading and gauging of petroleum and petroleum products. Customs proposed that this section be amended to state that, where possible, two methods of control shall be used.

This proposal has been adopted. Accordingly, for control purposes, both shore measurements (§ 151.42(a)(1)) and vessel ullages (§ 151.42(a)(2)) shall be taken. For purposes of determining the gross quantity unladen, shore measurements will be used. Vessel ullages will not be used to determine the gross quantity unladen unless none of the methods of shore measurement are available or adequate.

At the suggestion of one commenter, weighing of trucks and railroad cars has been added as a method of control.

Consistent with an existing requirement that meters used in gauging petroleum and petroleum products be approved by Customs, it was proposed to amend § 151.42 (c) and (d) to provide that positive displacement meters and trubine-type meters used as methods of control in gauging petroleum and petroleum products must be of a type approved by Customs.

This proposal has been adopted without modification.

It was proposed further to amend § 151.42 to provide that Customs officers would perform or witness: (1) opening ullages of carriers; (2) closing ullages of all carriers which have not completely discharged cargo, or if an importer or carrier requests Customs to witness closing ullages due to special problems; (3) shore tank gauges performed by company or related party employees; (4) between 5 and 10 percent of shore tank gauges conducted by public gaugers; and (5) shore tank gauges, including those conducted by a public gauger, where no carrier ullages are taken. Because the sealing of valves is not a complete method of measurement and control, it was proposed to delete § 151.42(e), which refers to this method. Sealing of valves would continue to be used in shore tank gauging to the extent that it is safe and practicable.

These proposals have been adopted without modification.

Customs also proposed to add a new subsection to section § 151.42. The new subsection would require the reporting of discrepancies in manifests of petroleum and petroleum products imported by truck, railroad car, pipeline, or other carrier, if the discrepancy exceeds one percent.

This proposal has been adopted without modification.

4. Section 151.43(a) provides that the acceptance of public gauger quantity reports of imported petroleum and petroleum products is discretionary with the district director. Customs proposed to amend this section to permit acceptance of these reports for shore tank gauging and closing carrier ullages if Customs independently employed, as a second method of control, one of the other methods described in § 151.42(a), and there was no evidence that the public gauger failed to comply with the provisions of Part 151, Subpart C, Customs Regulations.

This proposal has been adopted. Therefore, Customs will accept public gaugers reports only when it has independently performed or witnessed opening and closing carrier ullages as prescribed in § 151.42(b).

5. Section 151.43(b) provides that in applying for Customs public gauger approval, an applicant must agree to avoid conflict-of-interest situations. In its notice of proposed rulemaking, Customs proposed to amend § 151.43(b) to require approved public gaugers to notify the Commissioner in writing within 60 days of any change of name, address of principal place of business, ownership, or financial condition, or, if a corporation, of any change in its articles of incorporation, officers, directors, or parent-subsidiary relationship.

It also was proposed that public gaugers be required to notify Customs of any (1) effort to influence or otherwise impede the performance of their duties in connection with proper gauging of petroleum or petroleum products, or (2) attempt to coerce them fraudulently to change or falsify records maintained by them in the course of their employment.

Both of these proposals have been adopted without modification.

6. Section 151.43(d) provides that a public gauger's Customs approval may be revoked for failure to comply with the provisions of that section but does not provide for the imposition of any other sanction. Customs proposed to amend this section to permit it to suspend approval or to assess liquidated damages under the public gauger bond described in § 113.13(b), Customs Regulations (19 CFR 113.13(b)).

This proposal has been adopted without modification.

7. Section 151.43(e)(1) provides that to be approved by Customs, all measuring and testing devices in use in a public gauger's operation shall be maintained in first-class condition. To clarify that sampling devices also are covered, it was proposed to amend § 151.43(e)(1) to include sampling devices with measuring and testing devices.

This proposal has been adopted without modification.

8. Section 151.43(e)(3) requires that as a condition of approval, public gaugers authorized to sign gauging reports must have a minimum of 6 months on-the-job training and experience. In the notice of proposed rulemaking, Customs proposed to amend § 151.43(e)(3) to require that public gaugers provide Customs with written certification of their training and experience.

This proposal has been adopted with the modification that each public gauger and each other person authorized to sign gauging reports shall furnish the required information.

9. The regulations do not require that a public gauger maintain records for Customs inspection pertaining to the measurement, gauging, testing, or sampling of imported petroleum or petroleum products performed in the course of his employment, nor for Customs verification of any records kept by him in the normal course of business. It was proposed to add new subsections (g) and (h) to § 151.43, establishing a recordkeeping requirement for public gaugers and providing a procedure for verification of these records by Customs.

This proposal has been adopted without modification.

10. Part 151, Subpart C, provides that Customs approval of a public gauger may be revoked for failure to comply with any of the provisions of that subpart. However, it is silent as to the public gauger's rights in such situations. Customs proposed to add a new subsection (i) to § 151.43, to provide an approved public gauger with due process before any revocation or suspension of his approval by Customs.

This proposal has been adopted without modification.

11. It was proposed to add a new subsection (j) to § 151.43 to state that in addition to (1) any penalty otherwise provided by law which may be incurred for failure to comply with the provisions of Part 151, Subpart C, or (2) any sanction which may be imposed against a public gauger approved by Customs under the provisions of that subpart, a monetary penalty also may be assessed under section 592, Tariff Act of 1930, as amended (19 U.S.C. 1592), if appropriate.

This proposal has been adopted without modification.

12. Section 151.44(c) provides that whenever practicable, the district director may require that the measurements and calibrations shown on the gauge tables of petroleum storage tanks be verified by a Customs officer. Because a district director may deem verification necessary at a time when no qualified Customs officer is available, it was proposed to amend this section to permit the district director to accept an independent certification verifying these

measurements and calibrations. The independent verification would be performed at the expense of the storage tank proprietor.

This proposal has been adopted with the modification that the district director may require verification of the measurements and calibrations shown on the gauge tables of petroleum tanks whenever he has reason to suspect their reliability, instead of whenever practicable.

Discussion of Comments

A majority of the commenters endorse, in principle, Customs proposals to ensure proper control of imported petroleum and petroleum products, to provide uniform, complete, and reliable statistics relative to the importation of these products, and to establish standardized guidelines applicable to the use of public gaugers for monitoring imports of petroleum and petroleum products. They are generally of the opinion that these guidelines will improve the reliability of public gaugers; promote greater uniformity and accuracy in the measurement of imported petroleum and petroleum products; ensure proper control of imported petroleum and petroleum products; ensure the availability of uniform, complete, and reliable statistics regarding these imports; and simplify the international transportation of petroleum and petroleum products.

However, the commenters criticized the proposals as inadequate, vague, too restrictive, and likely to increase both expenses and the burden of documentation for importers and Customs, which possibly could thwart the collection of accurate statistics and increase discrepancies for which importers would be penalized unfairly.

The specific comments are as follows:

I. Discrepancies

A. Reporting of One Percent Discrepancy

Fourteen commenters object to Customs proposal that discrepancies exceeding one percent between manifested and unladed quantities shall be reported on Customs Form 5931 and that penalties otherwise provided by law may be incurred automatically if the discrepancy exceeds one percent. A number of commenters believe that the one percent figure is too restrictive and suggest allowances ranging from 1.5 to five percent. Other commenters oppose the imposition of any reporting requirement. In their objections, the commenters state that the reporting of manifest discrepancies is impracticable because:

(1) Using at least two methods of measurement, one of which might be ullaging, may in itself guarantee discrepancies exceeding one percent;

(2) Discrepancies may result from factors beyond the control of the carrier or the importer, such as physical losses, temperature deviation, cargo remaining on board, measurement errors at either the loading or receiving port, inconsistent operations in foreign ports, vessel ullages taken at sea, and variables associated with pipelines;

(3) Other factors, such as imprecise gauge tables, and the presence of suspended water and sediment, may increase the likelihood of discrepancies; and

(4) Problems associated with split entries and the use of lightering vessels introduce variables in the determination and measurement of cargo which also may result in discrepancies.

The commenters contend that, for these reasons, the imposition of a penalty in every case in which a manifest discrepancy exceeds one percent would be unreasonable.

The addition of proposed paragraph (c) to § 4.12, Customs Regulations (19 CFR 4.12), does not change materially the requirement that a vessel master or agent is responsible for explaining manifest overages and shortages, but is a restatement of a longstanding Customs practice. Under the proposed amendments, the master or agent would manifest all cargo on board to be imported. The manifested quantity (gross quantity on board and to be unladen) would be compared to the gross quantity actually unladen, as determined in accordance with §§ 151.42(a) and 151.43(a). If there is a discrepancy in excess of one percent between the two figures, the master or agent would be required to file a report on Customs Form 5931 in accordance with § 4.12(a)(2) or (a)(3). It is not intended that a penalty will be imposed automatically if the discrepancy exceeds one percent. However, if the required notification and explanation are not filed timely, or if the reason for the discrepancy is not satisfactorily explained, an appropriate penalty will be imposed.

The net quantity unladen (the gross quantity unladen adjusted for excessive water and sediment) is the quantity which will be used for entry, licensing, and statistical purposes.

Because Customs recognizes that factors beyond the master's control may contribute to discrepancies, a one percent variable has been provided. The manifest is prepared by the vessel master and may be amended at any time before unlading. Accordingly, before unlading, the master may correct the manifest to take into account any variables of which he is aware. This may include correcting the manifest to reflect opening vessel ullages.

Customs has found that in those locations where vessel masters or agents now are required to report discrepancies exceeding one percent, no discrepancy reports were necessary in approximately 95 percent of the transactions.

B. Explanation of Manifest Discrepancies

Six commenters submit observations regarding Customs proposals to require discrepancy reports.

One commenter suggests that because there are reasons other than absorption of moisture, temperature, and faulty weighing at the port of lading, listed in § 4.12(a)(5)(b), which may account for discrepancies between the manifested quantity and the gross quantity unladen, the word "explainable" should be substituted for the word "similar" in the provision " * * * a correction in the manifest shall not be required in the case of bulk merchandise if the district director is satisfied that the difference between the manifested quantity and the quantity unladen is an ordinary and usual difference properly attributable to absorption of moisture, temperature, faulty weighing at the port of lading, or other similar reason."

Another commenter suggests that a correction of the manifest should not be required if discrepancies between the manifested quantity and the quantity unladen can be explained. Other commenters state that references to discrepancies of manifested entered quantities should be more specific as to which method of quantity determination shall be used and that the terms used be more specifically defined. One commenter also notes that carriers other than vessels, such as rail carriers, often are transient, and furnishing a report signed by both the carrier and the importer within 60 days of entry would be difficult.

Customs did not propose any changes to § 4.12(a)(5)(b) and believes that it is inappropriate to amend that section at this time. The section as written is sufficiently broad to take account of factors other than moisture absorption, temperature, and faulty weighing, which may contribute to discrepancies between quantities which are manifested and which are unladen.

The amendments to the Customs Regulations were proposed to ensure proper control of imported petroleum and petroleum products and uniform, complete, and reliable statistics relating

to the importation of these products. To carry out these purposes, proper carrier controls must be maintained. Accordingly, Customs is of the opinion that the provision requiring the correction of vessel manifests if there is a discrepancy of more than one percent between the manifested quantity and the gross quantity unladen is warranted.

As previously noted, vessel manifests may be amended at any time before unlading. Discrepancies will not be determined by comparing the entered quantity to the quantity unladen, but by comparing the quantity manifested to the quantity unladen, with both figures corrected to the same temperature coefficient—60° Fahrenheit.

Customs experience with rail carriers confirms that they are able to submit discrepancy reports within the 60 days provided. However, after further consideration, Customs has determined that it is unnecessary to require that manifest discrepancies reported on Customs Form 5931 be signed by both the carrier and the importer. Accordingly, the requirement has been deleted from proposed section 4.12(c).

II. Methods of Measurement

A. Ullages

Six commenters object to Customs proposal to use vessel ullages as a method of measurement. The commenters contend that the taking of vessel ullages is not a reliable basis for import reporting because it fails to take into account factors such as clingage, remains on board, the tank washing policy, differences in temperature above and below the waterline, and the inherent ship vs. shore measurement bias. It is suggested that ullage measurements be regarded only as an indication that a discrepancy may exist and not as a method for establishing a discrepancy for the purposes of imposing a penalty.

Customs agrees that vessel ullages are not the most accurate method of measuring the quantity unladen. The ullaged figure will not be used to determine quantity unladen for reporting purposes unless no other method of measurement is available or adequate. Nevertheless, vessel ullages shall be taken in every case unless the district director determines that it is unsafe to do so, or because technological factors, such as the presence of inert gas systems, prevent doing so. Customs intends to use the ullaged figure as an indication of the accuracy of the quantity manifested so as to afford the vessel master an opportunity to amend the manifest if a comparison between the quantity manifested and the ullaged figure shows a variance. Customs also will use the ullaged figure as an indication of the accuracy of shore metering and shore tank calibrations.

B. Meters

Four commenters address the proposal that positive displacement and turbine type meters used as methods of measurement be of a type approved by Customs. Two commenters suggest that applicable industry standards be used by Customs as criteria for approval of these meters. One commenter cautions that, in certain circumstances, meters may provide inaccurate measurements and suggests that gauging would be the most reliable means for measuring petroleum and petroleum products. Another commenter states that it is unnecessary for Customs to approve these meters, but if Customs chooses to do so, it should be required to provide approval within a specified time frame (i.e., 15 days) after the importer has requested approval.

Customs traditionally has used accepted industry standards in approving meters and intends to continue this practice. Experience has shown that Customs approved meters are generally as accurate or more accurate than gauging as a method of measurement. Furthermore, Customs may compare manifested quantities and quantities determined by opening ullages to metered quantities as an indication of the accuracy of the meter.

It is, and will continue to be, Customs policy to approve meters as rapidly as possible. Customs recognizes the need for timely approval of these devices and does not intend to inconvenience operators unnecessarily. However, Customs is of the opinion that it would be unduly restrictive to include a time constraint in the regulations.

C. Use of Two Methods of Measurement

Two commenters object to the proposal that, if possible, Customs use two methods of measurement to report imported petroleum and petroleum products. They state that there is no technical basis for assuming that the use of two equivalent measurement systems will give a more accurate reading than the use of one, that such use is expensive and redundant, will not increase the uniformity of controls, and only will generate an additional set of figures, thus creating an area of dispute.

Customs does not intend to use either an average or a combination of both figures for reporting purposes. The figure derived from the shore measurement will be the gross quantity unladen and ordinarily will be the basis for determining the net quantity unladen. The net quantity unladen, as determined by Customs, is the quantity used for entry, licensing, and statistical purposes in each case, whether or not there is a discrepancy between the quantity manifested and the gross quantity unladen. However, if shore measurements are unavailable or inadequate, Customs then will use vessel ullages to determine the gross quantity unladen.

Proposed § 151.42 has been modified to reflect this change.

D. Sealing of Valves

Three commenters oppose Customs proposal to eliminate sealing of valves as a method of control. One of the commenters states that although the sealing of valves is not a method of measurement, it is an effective means of controlling the flow of products into the measuring facility and that elimination of this method of control would remove a deterrent to both the intentional or inadvertent diversion of the product. Another commenter is concerned that eliminating the use of sealing of valves implies that segregation of a receiving system by installation of blinds will be required and that such a system would hinder normal terminal operations, especially lube oil operations.

Customs recognizes that the sealing of valves is an effective means of controlling the flow of products into measuring facilities. However, used alone, it is not a complete method of measurement. Accordingly, the sealing of valves has been deleted from the methods of measurement in proposed § 151.42(a)(1). However, sealing of valves shall continue as part of shore tank gauging to the extent safe and practicable.

Because the sealing of valves may be used in conjunction with the methods of measurement listed in § 151.42(a)(1), Customs does not anticipate that eliminating sealing of valves as a method of control will require the segregation of receiving systems by installing blinds.

E. Other

Additional commenters express reservations concerning use of the other methods of measurement proposed by Customs.

One commenter states that although Customs has set forth four methods of measurement which may be used in measuring imports of petroleum and petroleum products, it has not specified which shall be the ruling one for Customs outturn, license decrementation, and liquidation. The commenter suggests that the methods be given a rated priority of preference.

A second commenter recommends that only Customs inspectors perform ullaging and gauging. A third commenter notes that the only method of measurement discussed in the proposal is liquid gallons, but that many petroleum products, such as natural gas, greases, and waxes, are measured otherwise than in liquid gallons, and that weighing, an effective method for measuring the content of tank trucks and railroad cars, is not designated as a method of measurement.

Another commenter states that the shore tank gauge reading should be the only figure used for the determination of exact quantity discharged for statistical purposes and duty assessment where a partial quantity of a vessel's cargo is discharged at a particular port, and that a "bone dry certificate" from an independent surveyor should be required to determine that all of the material on board has been discharged in those instances where the vessel discharges all of the cargo on board.

One commenter suggests that specific procedures (e.g., frequency of audits or rotation of times that audits will be conducted) should be developed stating when the 5 to 10 percent of shore tank gauges conducted by public gaugers would be performed or witnessed by Customs.

One commenter states that with regard to stream-boarding of vessels, the decision whether or not to stream-board should be made by the individual inspector, not the district director.

As previously stated, Customs intends to employ only one method of mesurement (other than ullaging) to determine the gross quantity unladen. Customs does not believe that one method of shore measurement should be given preference over another because each port has different facilities, and a method used efficiently at one port may not be appropriate for use at another.

Because other Customs officers, such as warehouse officers, also may perform ullaging and gauging, Customs does not intend to authorize only inspectors to perform this function.

Although the measurement quantities discussed in the proposal included, but were not limited to, liquid gallons, the methods of control do not specify that measurements must be made in liquid gallons. It is Customs practice to measure merchandise in quantity units appropriate to each commodity.

Customs agrees that the weighing of tank trucks and rail cars is an effective measure and has determined to include it as a method of measurement in proposed § 151.42(a)(1), which has been modified accordingly.

The net amount unladen is the amount to be used for entry, licensing, and statistical purposes. Customs does not require a bone dry certificate because the burden is on the master to account for the entire cargo of the vessel whether or not the entire cargo is discharged at any particular port.

Specific procedures governing when the 5 to 10 percent of shore tank gauges conducted by public gaugers will be performed or witnessed by Customs have been developed. In addition, Customs intends to ensure the reliability and integrity of public gauger reports by random audits and by random on-site verification of quantities measured.

The Customs position, incorporated in an internal directive referencing safety problems, has been to allow each boarding officer to determine at the time of boarding whether or not it is safe to board a vessel in stream. This policy remains in effect. Customs does not intend to jeopardize the health and safety of its employees by requiring them to stream-board vessels under hazardous conditions.

III. Deduction for Basic Sediment and Water (BS&W)

Although the notice of proposed rulemaking did not address the subject, six commenters suggest that Customs amend the existing allowances for BS&W in suspension in imported petroleum and petroleum products.

Customs is amendable to suggestions and discussions leading to review of its BS&W claims policy. However, because no changes in existing policy were proposed in the notice, further consideration of comments regarding BS&E claims policy at this time is inappropriate.

IV. Public Gaugers

Seven commenters respond to Customs proposals regarding public gaugers.

Two commenters note that while Customs proposes to require that public gaugers maintain automatic sampling devices in first class condition, these devices normally are fixed shore installations owned and operated by the terminal operator, who is responsible for their maintenance. They suggest that gaugers be required to determine only that these devices be in first class condition.

One commenter recommends that a system for the verification of selected entries be instituted and that Customs investigate both public gaugers requesting Customs approval and gaugers who previously have been approved.

Another commenter suggests that the proposed amendments also provide for Customs approval of company-employed gaugers.

Two commenters note that while Customs would require each public gauger authorized to sign gauging reports to furnish Customs with a written certification that he has a minimum of six months on-the-job training and experience, there is no requirement that the person doing the gauging provide such certification. The commenter recommends that each gauger certified by Customs be required to carry identification stating that he is certified to perform gauging at any port his employer may send him.

One commenter questions whether, as part of Customs recordkeeping proposal, public gaugers must keep physical samples for a period of five years. The commenter suggests that maintaining these samples for six months or until liquidation of the entry would be sufficient.

One commenter is of the opinion that the provision that the Customs Office of Investigations shall investigate a gauger's fitness and reputation and verify the correctness of the statements made in his application at the direction of the Commissioner, as he deems necessary, vests too much discretion in the Commissioner. The commenter suggests that the provision should be modified to delete the section granting the Commissioner discretion in this situation.

One commenter suggests that if Customs exercises its discretion not to accept reports of public gaugers in certain situations, the volumes recorded for imports by a company and by Customs may vary. The company would employ an independent gauger to determine the discharged volume for accounting and reporting purposes, while Customs might record a different volume.

It has been Customs policy to require that gaugers maintain all of their measuring and testing equipment in first-class condition. In the proposed regulations, sampling devices also were included. However, the word "automatic" was inserted inadvertently in the notice of proposed rulemaking. Proposed § 151.43(e)(1) is modified to correct this error.

It is assumed that in recommending that a system for the verification of selected entries be instituted, the commenter is suggesting that Customs establish a means for ensuring the accuracy of public gaugers' reports. As previously noted, Customs intends to ensure the reliability and integrity of public gauger reports by random audits

and by random on-site verification of quantities measured.

All applicants who have received Customs approval previously have undergone Customs investigations to determine their fitness and reputation and to verify the correctness of the statements made in their applications. As set forth in § 151.43(c), this practice will be continued. Customs is of the opinion that re-investigating all public gaugers previously approved would require an unnecessary expenditure of money and manpower. Further, a revised agreement in the form set out in proposed § 151.43(b)(5) will not be required of previously-approved public gaugers. However, because the public gauger bond, posted by all previously-approved public gaugers is conditioned that the public gauger ". . . shall perform in accordance with standards and procedures of gauging as required by the Customs Regulations . . .", approved public gaugers have a continuing obligation to comply with changes in the regulations. Accordingly, they will be required to comply with new requirements set forth in this document. These include: conflict-of-interest requirements; recordkeeping requirements; the maintenance of sampling devices; and employee experience and training.

Customs does not agree that company-employed gaugers also should be approved by Customs and that Customs should accept reports made by company gaugers. Because company gaugers are directly employed by the concern for which the gauging is performed, Customs is of the opinion that accepting reports from company gaugers is not a form of independent verification because it may place the company gauger in a conflict-of-interest situation.

Customs agrees that both persons authorized to sign gauging reports and persons performing gauging should have a minimum of six months on-the-job training and experience. Accordingly, proposed § 151.43(e)(3) has been modified to reflect this change.

Customs does not agree, however, that it would be beneficial to require that each Customs approved gauger carry identification stating that he is certified to perform gauging at any port where his employer may send him because gaugers may perform gauging only in the district(s) for which they are approved. The district director in each district will verify which gaugers are approved to perform gauging within that district.

Public gaugers are not required to retain physical samples for a period of five years. The length of time for retaining physical samples is discretionary with the gauger. Customs maintains its own samples for analysis in cases where questions arise.

Even though in the past the Commissioner has directed that each applicant for Customs public gauger approval be investigated, Customs agrees that an automatic investigation would be beneficial. Accordingly, § 151.43(c) is modified to require that, in all cases, an applicant's fitness and reputation shall be investigated, and the correctness of the statements made in his application shall be verified.

Although an importer may determine his own policy for computing the quantity unladen, the net quantity unladen, as determined by Customs, is the amount to be used for entry license control and statistical purposes. When there is a variance between the quantitites recorded by the company and Customs, the quantity recorded by Customs will be used.

V. Foreign-Trade Zones

Two commenters note that procedures concerning the transfer into and out of, and the processing of petroleum within, foreign-trade zones are not addressed in the notice of proposed rulemaking. One suggests that foreign-trade zones be specifically exempt from the measuring requirements set forth in the notice. The other is of the opinion that operations in foreign-trade zones should be excluded from the proposed amendments except where these procedures can be applied effectively at the discretion of the district director.

The transfer of petroleum and petroleum products into and out of foreign-trade zones, and their processing within foreign-trade zones, were not addressed specifically in the notice of proposed rulemaking because the admission, handling, and removal of foreign-trade zone merchandise is subject to the requirements of Part 146, Subpart D, Customs Regulations (19 CFR Part 146, Subpart D). However, the transfer of petroleum and petroleum products into and out of foreign-trade zones also is subject to the provisions of Part 151, Subpart C, Customs Regulations, as amended by this document.

VI. Quantities Unladen

Three commenters remark on Customs proposal to use the amount of petroleum and petroleum products actually unladen as the quantity imported for statistical purposes.

One commenter suggests that because it is the most nearly correct expression of petroleum imports, the net quantity unladen should be used for all statistical purposes. The commenter further states that the requirement that an independent commercial laboratory must be used to determine the quantity is non-productive because receivers have extensive laboratory facilities for this purpose. This commenter suggests that Customs establish a method for ensuring that laboratory tests by receivers are in accordance with ASTM/API standards and, therefore, acceptable. A second commenter states that the wording used in proposed § 151.47(a) for determining the net quantity of petroleum unladen should refer to the table in § 151.46, instead of sediment and water in excess of 0.3 percent, and that in determining the net quantity unladen, reference should be made to § 158.13 and the need to file Customs Form 4315.

A third commenter is of the opinion that the parties responsible for securing and maintaining samples for testing in laboratories should be specified clearly to establish a chain of custody, and that a Customs laboratory should test all samples, including those tested in gaugers' laboratories.

As previously noted, the net quantity unladen is the amount which will be used for entry, licensing, and statistical purposes.

Customs does not agree that the provision in § 151.47(a) requiring that an independent commercial latoratory be used to determine the quantity should be changed at this time because it did not propose to change this requirement in the notice of proposed rulemaking. However, Customs would consider a request to change this provision at a later date.

Customs agrees that proposed § 151.47(a), the provision for determining the net quantity of petroleum unladen, should be expanded to refer to the table in § 151.46, instead of sediment and water in excess of 0.3 percent. Customs also agrees that in determining the net quantity unladen, reference should be made to § 158.13 and the need to file Customs Form 4315. Proposed § 151.47(a) is modified accordingly.

Because when a claim is made, independent laboratory reports are verified by Customs laboratory tests using Customs own samples, Customs is of the opinion that it is not necessary to establish a chain of custody for samples tested in commercial laboratories.

Customs does not believe that it should routinely test all samples. To do so would not be cost effective. However, Customs now tests, and will continue to test, all samples subject to a claim filed on Customs Form 4315.

VII. Storage Tanks

Four commenters address Customs proposals to amend sections 151.44 and 151.45, relating to storage tanks.

One commenter objects to the provision in proposed § 151.44(c) that if no qualified Customs officer is available, the district director may accept an independent certification of the measurements and calibrations of storage tanks, performed at the expense of the storage tank proprietor. The commenter states that the provision should state more specifically when a verification is called for and what it is to consist of, and that Customs, not the proprietor, should bear the expense of an independent verification.

A second commenter states that Customs should require certification of carrier tanks when gauge tables are to be used for vessel ullages. Although customs proposed no change to § 151.45(b), a third commenter notes that although this section states that under certain circumstances, non-bonded petroleum may be required to be completely removed from bonded storage tanks, this is not practicable or possible in all situations and that some method of accommodation should be provided.

Another commenter states that if Customs discovers through independent survey that tanks do not contain accurate measurements and calibrations, and it can be proven that the tank proprietor was negligent in reporting suspected inaccuracies to Customs before the survey, a penalty should be assessed against the proprietor.

Customs agrees that proposed § 151.44(c) should state more specifically when verification is called for. Customs is of the opinion that the district director should have discretion to require verification of the measurements and calibrations shown on the gauge tables whenever he has reason to suspect their reliability. Proposed § 151.44(c) is modified accordingly.

Customs believes that it is justified in requiring that independent certification of the measurements and calibrations of storage tanks be performed at the expense of the storage tank operator when no Customs officer is available. The proper maintenance of storage tanks and gauge tables is the responsibility of the owner and, therefore, it is the owner who should bear the expense of properly maintaining them. Further, because Customs allows importers the convenience of unlading at their own facilities, Customs must be assured that provisions for determining the quantities unladen are adequate.

Customs has concluded that certification of carrier tanks when gauge tables are to be used for vessel ullages would cause an unnecessary expense to the carrier in view of the fact that ullages ordinarily will not be used to determine the actual quantity unladen unless none of the other methods of control in proposed § 151.42(a)(1) is available or shore measuring facilities are inadequate.

Customs must be assured that only bonded cargo is stored in storage tanks bonded as warehouses. Accordingly, it is not unreasonable to require removal of non-bonded petroleum from bonded tanks.

Customs is of the opinion that current law provides for the imposition of a penalty if a storage tank proprietor is negligent in reporting suspected inaccuracies to Customs before a survey of his tanks.

VIII. Hearing, Meeting and Study Committee

Three commenters state that, before implementing a final rule, Customs should provide the public with an opportunity to discuss and comment on the proposed changes One commenter suggests that Customs hold a public hearing; the second commenter suggests that Customs establish a study committee consisting of Customs officials, industry representatives, and experts in the science of petroleum management and statistics to study the proposals; and the third commenter suggests that Customs meet with industry personnel to discuss the proposals.

As previously noted, on January 8, 1980, Customs held an open conference with interested members of the public to further discuss and clarify the issues raised by the commenters. At the conference an attempt was made to resolve objections to the proposed regulations to the satisfaction of all participants.

IX. Vagueness of Terms—Need for Further Definition

Seven commenters state that terms used in the proposed regulations are either vague or inadequately defined.

Two commenters state that proposed § 151.42 is vague in that it does not specifically state under what conditions two methods of control are to be used and who is to determine when it is possible to use two methods of control.

Five commenters state that terms such as "petroleum and petroleum products," "gross quantity landed," "net quantity landed," "net quantity," "manifest," "public gauger," "verification," and "acceptance" should be better defined.

As previously stated, Customs has determined that only one method of measurement will be used to determine the amount of petroleum and petroleum products unladen and has modified the proposed regulations accordingly.

Customs is of the opinion that the terms "public gauger," "verification," and "accepted," do not require further definition because their meanings in the context of the regulations are well known to the importing and transportation communities. However, to aid in understanding the regulations, the following definitions are provided:

1. "Petroleum and petroleum products" includes, but is not limited to, those items found in Schedule 4, Part 10, Tariff Schedules of the United States (TSUS) (19 U.S.C. 1202), and those items in Schedule 4, Part 2, TSUS, if comprised of hydrocarbons derived from pertroleum. Customs reserves the right to determine the application of the term on a case-by-case basis.

2. "Gross quantity unladen" or "gross quantity" is the amount directly unladen (landed) from vessel to shore without allowance for excessive water and sediment (BS&W).

3. "Net quantity unladen" or "net quantity" is the gross quantity unladen (landed) adjusted for excessive water and sediment (BS&W) in accordnace with § 151.46, Customs Regulations.

4. "Manifest" is an invoice of the cargo on board a carrier. The form of the manifest and the information therein varies according to the type of carrier. Customs manifest requirements are found in sections 4.7 and 4.7a and Part 123, Customs Regulations (19 CFR 4.7, 4.7a, Part 123) and 19 U.S.C. 1431.

X. Miscellaneous

One commenter is of the opinion that (1) requiring that estimates of petroleum and petroleum products unladen or withdrawn from bonded tanks not vary by more than one percent from the actual gross quantity unladen or withdrawn, and (2) the assessment of a penalty in cases where the variance exceeds one percent, are unreasonable considering the difficulty in measuring certain products or unusually small quantities of a product. A second commenter believes that a difference of three percent should be allowed between estimation and delivery because there are many variables (such as problems in the use of common pipelines to supply fuels to bonded tanks) which make it impossible to meet the one percent requirement.

Another commenter states that, in reference to proposed § 151.41,

"Information on Entry Summary," the explanatory material refers to an estimate of the quantity unladen, but the proposed regulation itself requires a notation of the API gravity, which is redundant because petroleum is graded by API gravity for tariff schedule purposes. One commenter questions whether and to what extent the proposed amendments imply recalibration (restrapping).

Customs recognizes the difficulties involved, and in order to allow importers greater latitude in preparing estimates required in proposed §§ 151.41 and 151.45, the regulations have been modified to provide for a three percent variance between the estimated quantity and the net quantity unladen before a penalty may be incurred.

Although § 151.41 requires that the importer show API gravity at 60° Fahrenheit, that and the estimate of the volumetric quantity landed are two distinctly different figures and both must be provided.

Customs does not anticipate that any additional recalibration or restrapping will be required as a result of these amendments.

Drafting Information

The principal author of this document was Lawrence P. Dunham, Regulations and Research Division, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices of the Customs Service and the Department of the Treasury participated in its development.

Adoption of the Proposed Regulations

The proposed regulations set forth in the notice of proposed rulemaking published on November 7, 1979 (44 FR 64434), are adopted subject to the revisions made below.

Amendments to the Regulations

Parts 4, 144, 151, and 159, Customs Regulations (19 CFR Parts 4, 144, 151, 159), are amended as set forth below.

R. E. Chasen,

Commissioner of Customs.

Approved: April 24, 1980.

Richard J. Davis,

Assistant Secretary of the Treasury.

Amendments to the Customs Regulations

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

Section 4.12 is amended to read as follows:

§ 4.12 Explanation of manifest discrepancy.

(a)(1) Vessel masters or agents shall notify the district director on Customs Form 5931 of shortages (merchandise manifested, but not found) or overages (merchandise found, but not manifested) of merchandise.

(2) Shortages shall be reported to the district director by the master or agent of the vessel by endorsement on the importer's claim for shortage on Customs Form 5931 as provided for in § 158.3 of this chapter, or within 60 days after the date of entry of the vessel, whichever is later. Satisfactory evidence to support the claim of nonimportation [23] or of proper disposition or other corrective action (see section 4.34) shall be obtained by the master or agent and shall be retained in the carrier's file for one year.

(3) Overages shall be reported to the district director within 60 days after the date of entry of the vessel by completion of a post entry [24] or suitable explanation of corrective action (see section 4.34) on the Customs Form 5931.

(4) The district director shall immediately advise the master or agent of those discrepancies which are not reported by the master or agent. Notification may be in any appropriate manner, including the furnishing of a copy of Customs Form 5931 to the master or agent. The master or agent shall satisfactorily resolve the matter within 30 days after the date of such notification, or within 60 days after entry of the vessel, whichever is later.

(5)(a) Unless the required notification and explanation is made timely and the district director is satisfied that the discrepancies resulted from clerical error or other mistake and that there has been no loss of revenue (and in the case of a discrepancy not initially reported by the master or agent that there was a valid reason for failing to so report), applicable penalties under section 584, Tariff Act of 1930, as amended (19 U.S.C. 1584), shall be assessed (see § 162.31 of this chapter). For purposes of this section, the term "clerical error" is defined as a non-negligent, inadvertent, or typographical mistake in the preparation, assembly, or submission of the manifest. However, repeated similar manifest discrepancies by the same parties may be deemed the result of negligence and not clerical error or other mistake. For the purpose of assessing applicable penalties, the value of the merchandise shall be determined as prescribed in § 162.43 of this chapter. The fact that the master or owner had no knowledge of a discrepancy shall not relieve him from the penalty.

(b) Except as provided in paragraph (c) of this section, a correction in the manifest shall not be required in the case of bulk merchandise if the district director is satisfied that the difference between the manifested quantity and the quantity unladen, whether the difference constitutes an overage or a shortage, is an ordinary and usual difference properly attributable to absorption of moisture, temperature, faulty weighing at the port of lading, or other similar reason. A correction in the manifest shall not be required because of discrepancies between marks or numbers on packages of merchandise and the marks or numbers for the same packages as shown on the manifest of the importing vessel when the quantity and description of the merchandise in such packages are correctly given.

(c) Manifest discrepancies (shortages and overages) of petroleum and petroleum products imported in bulk shall be reported on Customs Forms 5931, if the discrepancy exceeds one percent.

(R.S. 251, as amended, secs. 440, 584, 624, 46 Stat. 712, as amended, 748, as amended, 759 (19 U.S.C. 88, 1440, 1584, 1624))

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(R.S. 251, as amended, sec. 624, 46 Stat. 759 (19 U.S.C. 66, 1624))

PART 144—WAREHOUSE AND REWAREHOUSE ENTRIES AND WITHDRAWALS

Section 144.37(e) is amended by changing the spelling of the word "gage" to "gauge" wherever it appears.

(R.S. 251, as amended, sec. 624, 46 Stat. 759 (19 U.S.C. 66, 1624))

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[23] * * * "If any merchandise described in such manifest is not found on board the vessel or vehicle the master or other person in charge or the owner of such vessel or vehicle or any person directly or indirectly responsible for any discrepancy between the merchandise and said manifest shall be subject to a penalty of $500: *Provided*, That if the appropriate Customs officer shall be satisfied that the manifest * * * is incorrect by reason of clerical error or other mistake and that no part of the merchandise not found on board was unshipped or discharged except as specified in the report of the master, said penalties shall not be incurred. * * *, the term 'clerical error' means a non-negligent, inadvertent, or typographical mistake in the preparation, assembly or submission of the manifest. * * *" (Tariff Act of 1930, sec. 584, as amended, 19 U.S.C. 1584).

[24] "If there is any merchandise or baggage on board such vessel which is not included in or which does not agree with the manifest, the master of the vessel shall make a post entry thereof, and mail or deliver a copy to such employee as the Secretary of the Treasury shall designate and for failure so to do shall be liable to a penalty of $500." (Tariff Act of 1930, sec. 440, as amended; 19 U.S.C. 1440).

PART 151—EXAMINATION, SAMPLING, AND TESTING OF MERCHANDISE

1. Section 151.28 is amended by changing the spelling of the words "gage" and "gaging" to " gauge" and "gauging", respectively, wherever the words appear.

2. Subpart C is amended to read as follows:

Subpart C—Petroleum and Petroleum Products

§ 151.41 Information on entry summary.

On the entry summary for petroleum or petroleum products in bulk, the importer shall show the API gravity at 60° Fahrenheit, in accordance with the current edition of the ASTM–IP Petroleum Measurement Tables (American Edition), published by the American Society for Testing and Materials. The appropriate unabridged table shall be used in the reduction of volume to 60° F. If the exact volumetric quantity cannot be determined in advance, the entry summary may be made for "—— United States gallons, more or less", but in no case may the estimate vary by more than three percent from the gross quantity unladen. The information required by this section also shall be shown on the entry summary permit if the entry summary is filed at the time of entry, and on each entry summary continuation sheet regardless of when the entry summary is filed.

§ 151.42 Controls on unlading and gauging.

(a) *Methods of control.*

(1) Each district director shall establish controls and checks on the unlading and measurement of petroleum and petroleum products imported in bulk by vessel, truck, railroad car, pipeline, or other carrier. One of the following methods of control shall be employed:

(i) Customs approved positive displacement meters at installations where provided by the importer;

(ii) Customs approved turbine-type meters at installations where provided by the importer;

(iii) Shore tank gauging; or

(iv) Weighing for trucks and railroad cars.

(2) Vessel ullages shall be taken in every case unless the district director determines that it is impracticable to do so for safety or technological reasons. Ullages may be taken for trucks and railroad cars if weighing or shore tank gauging is not available as a method of control. Vessel ullages will not be used to determine the quantity unladen unless none of the other methods provided for in this paragraph is available or adequate.

(b) *Duties of Customs officers.* Customs officers shall perform or witness ullaging and gauging as follows:

(1) Opening ullages.

(2) Closing ullages of carriers which have not completely discharged cargo, or if an importer or carrier requests Customs to witness closing ullages because of special problems.

(3) Shore tank gauges performed by company or related-party employees.

(4) Between 5 and 10 per cent of shore tank gauges performed by public gaugers.

(5) Shore tank gauges, including those conducted by a public gauger if no carrier ullages are taken.

(c) *Manifest discrepancies.* Manifest discrepancies (shortages and overages) shall be reported by or on behalf of the carrier in the manner specified in section 4.12 of this chapter. If a reported discrepancy is not explained to the satisfaction of the district director, the master or other person in charge, or the owner of the vessel or vehicle, or any person directly or indirectly responsible for the discrepancy, will be subject to the imposition of the appropriate penalty under section 460, 584, or 592, Tariff Act of 1930, as amended (19 U.S.C. 1460, 1584, 1592).

§ 151.43 Public gaugers.

(a) *Acceptance of quantity reports.* Subject to such controls and checks as he may deem necessary, the district director may accept, for shore tank gauging and closing carrier ullages, the reports of quantities of imported petroleum and petroleum products made by public gaugers approved by the Commissioner in accordance with this section, provided—

(1) Customs officers have exercised the supervision required by section 151.42(b) of this part, and

(2) There is no evidence that the public gauger has failed to comply with the provisions of this subpart.

(b) *Application.* Any public gauger desiring approval shall submit an application, which may be in the form of a letter, to the Commissioner of Customs, Washington, D.C. 20229. The application shall contain or be accompanied by the following:

(1) The applicant's name, address, and ownership, and a statement of financial condition.

(2) If a corporation, a copy of its articles of incorporation, a list of its officers and directors, and details of any parent-subsidiary relationship.

(3) A detailed statement of the applicant's qualifications.

(4) The Customs district(s) for which approval is requested.

(5) A written agreement in the following form to avoid conflict-of-interest situations and to comply with operating requirements prescribed by Customs:

Public Gauger Agreement

As conditions for the approval of this application, I undertake and agree:

(1) To have no financial interest or other connection (except for acceptance of the usual fees for gauging services) with any business or other activity which might be considered to affect the unbiased performance of my duties as a public gauger for Customs purposes, in accordance with the standards and procedures approved by the Commissioner of Customs.

(2) To comply with the requirements of Part 151, Subpart C, Customs Regulations (19 CFR Part 151, Subpart C), and with any procedures prescribed by the Commissioner or district director of Customs pursuant to that subpart.

(3) To notify the Commissioner and district director of Customs in writing within 60 days of any change of name, address, ownership, or financial condition, and, if a corporation, of any change in its articles of incorporation, officers, directors, or parent subsidiary relationship.

(4) To communicate immediately to the Commissioner and district director of Customs notice of any—

(i) Effort to influence, or otherwise impede, the performance of my duties in connection with the proper gauging of petroleum or petroleum products, or

(ii) Attempt to coerce me fraudulently to change or falsify records maintained in the course of my employment.

(6) A bond in the amount of $10,000 to insure that the gauging will be in conformance with the approved standards and procedures, and with such procedures as may be prescribed by the district director pursuant to paragraph (f) of this section. The form of the required bond will be available from any district director.

(c) *Investigation of applicant.* The Commissioner shall direct the Office of Investigations to determine the applicant's fitness and reputation, and to verify the correctness of the statements made in the application.

(d) *Notice of approval, disapproval, suspension, or revocation.* When the investigation is completed, the applicant will be advised of the approval of his application, or, if disapproved, of the reasons for such action. An approval may be suspended or revoked by the Commissioner for failure to comply with any of the provisions of this subpart, or liquidated damages may be assessed under the public gauger bond described in section 113.13(b) of this chapter. Notice of approvals or suspensions or revocations of approval will be

published from time to time in the Customs Bulletin.

(e) *Requirements for operations.* To be approved for Customs purposes, a public gauger's operations shall conform to the following requirements.

(1) All measuring, testing, and sampling devices in use shall be maintained in first-class condition. Each device shall be calibrated before the first use, and checked at regular intervals thereafter, against standards whose accuracy is traceable to standards issued by the National Bureau of Standards. In making calibrations and checks, the applicable methods of the American Society for Testing and Materials or the American Petroleum Institute shall be used.

(2) All measuring, testing, and sampling procedures shall be in conformance with published industry standards, such as those of the American Petroleum Institute or the American Society for Testing and Materials, and shall conform to such specific procedures as may be required by the district director in accordance with paragraph (f) of this section.

(3) Each public gauger and each other person authorized to sign gauging reports shall furnish Customs with a written certification that he has a minimum of 6 months on-the-job training and experience.

(4)(i) The public gauger shall investigate promptly any apparent irregularities, procedural difficulties, or indications of systematic bias called to his attention by the district director, or of which he otherwise may become aware, and immediately shall take corrective measures if indicated. The public gauger shall notify the district director of any such matter of which he may become aware.

(ii) The district director shall notify the Commissioner of each such matter that he brings to the attention of the public gauger, or which the public gauger brings to his attention, and of the corrective measures taken.

(f) *Procedures prescribed by district director.* The district director is authorized to prescribe general or specific procedures to be followed by each approved public gauger at each of the discharging facilities in the district.

(g) *Recordkeeping requirement.* Records of the public gauger of the type normally kept in the ordinary course of business, pertaining to the measurement, gauging, testing, and sampling of imported petroleum and petroleum products, shall be maintained for 5 years in accordance with sections 162.1a and 162.1c of this chapter.

(h) *Verification requirement.*

(1) *Compliance.* To ensure compliance with the provisions of this subpart and accuracy and uniformity in the information submitted by public gaugers, the district director shall verify by integrity checks, audits, and, if necessary, investigations, the gauging operations in his district. Any discrepancy between the quantity reported by the gauger and the quantity found by Customs shall be resolved in favor of Customs unless the gauger produces clear and convincing evidence that Customs is in error.

(2) *Sanctions.* If a public gauger's reports are repeatedly inaccurate to a significant degree, the gauger may be subject to sanctions in accordance with sections 151.43(d) and (i).

(i) *Suspension or revocation of Customs approval.*—(1) *Grounds.* Failure to comply with the provisions of this subpart may be grounds for suspension or revocation of Customs approval of a public gauger.

(2) *Notice.* The district director shall give written notice of the proposed suspension or revocation to the public gauger. The notice shall be in the form of a statement setting forth specific grounds for the proposed action and shall become final unless the public gauger files a written reply in accordance with paragraph (3) of this subsection. An information copy of the notice shall be forwarded by the district director to Headquarters.

(3) *Reply.* The public gauger may file a written reply with the district director within 10 days following receipt of the notice. An extension of time to reply beyond the 10-day period may be granted for good cause. The reply shall be filed in duplicate and shall set forth the response of the public gauger, including his answers to the allegations and rebuttal evidence, if any. The district director upon request, may allow an oral presentation as to why approval should not be suspended or revoked.

(4) *Action on reply.* If the district director determines that the allegations set forth in the notice have not been proved, he shall notify the public gauger that suspension or revocation no longer is contemplated, and the case shall be closed. Otherwise, the approval shall be suspended or revoked, in which case the district director shall notify the gauger that he may request review of the suspension or revocation by the Commissioner in accordance with paragraph (6). An information copy of the district director's action shall be forwarded to Headquarters.

(5) *Stay of suspension or revocation.* The decision of the district director to suspend or revoke approval shall be stayed until the time for the gauger to file a petition for review by Headquarters has passed and no action has been taken on his part or, if a petition for review has been filed in accordance with paragraph (6), until Headquarters affirms the decision of the district director.

(6) *Review of suspension or revocation of approval.* Petitions for review of suspension or revocation of a public gauger's Customs approval by the district director shall be addressed to the Commissioner and filed in duplicate with the appropriate district director for transmission to Headquarters. Petitions for review shall be filed within 30 days from the date of suspension or revocation of approval and shall state the facts and circumstances relied upon by the petitioner in seeking review of the district director's order. The petition shall be reviewed by the Commissioner or his designee. Upon completion of the review, a written decision shall be forwarded to the district director for delivery to the public gauger.

(7) *Publication.* Notice of any final action by the district director or the Commissioner suspending or revoking approval of a public gauger shall be published in the **Federal Register** and the Customs Bulletin.

(j) *Penalties.* In addition to—

(i) Any penalty otherwise provided by law which may be incurred for failure to comply with the provisions of this subpart, or

(ii) Any sanction which may be imposed against a public gauger approved by Customs under the provisions of this subpart, a monetary penalty also may be assessed under section 592, Tariff Act of 1930, as amended (19 U.S.C. 1592), if appropriate.

§ 151.44 Storage tanks.

(a) *Plans and gauge tables.* When petroleum or petroleum products subject to duty at a specific rate per gallon are imported in bulk in tank vessels and are to be transferred into shore storage tanks, both the plans of each shore tank showing all outlets and inlets and the gauge table for each tank showing its capacity in U.S. gallons per inch or fraction of an inch of height shall be certified as correct by the proprietor of the tank. One set of these plans and gauge tables so certified shall be kept on file at the plant of the oil company and shall be available at all times to Customs officers. Another certified set of the shore tank plans and gauge tables shall be filed with the district director for use in verifying the Customs officers' reports. The district director may require such additional sets of shore tank plans, including subsidiary pipeline plans, and gauge tables as he may deem necessary.

The storage tank proprietor shall maintain the plans and gauge tables for 3 years after discontinuing use of the storage tanks as bonded warehouses for the storage of imported petroleum or petroleum products.

(b) *Tags required on valves.* The inlet and outlet valves of each tank shall have tags of a permanent type affixed by the proprietor or lessee indicating the use of the valves.

(c) *Verification of gauge tables.* Whenever he has reason to suspect their reliability, the district director may require the measurement and calibrations shown on the gauge tables to be verified by a Customs officer. If no qualified Customs officer is available, the district director may accept an independent certification verifying the measurements and calibrations. The independent verification shall be performed at the expense of the storage tank proprietor.

§ 151.45 Storage tanks bonded as warehouses.

(a) *Application.* Tanks for the storage of imported petroleum or petroleum products in bulk may be bonded as warehouses of class 2 if to be used exclusively for the storage of petroleum or petroleum products belonging or consigned to the owner or lessee of the tank. In addition to the documents and bonds required to be filed with the application to bond (see section 19.2 of this chapter), the certified plans and gauge tables required by section 151.43 shall be filed.

(b) *Removal of nonbonded petroleum.* If a bonded tank is not empty at the time the first importation of bonded petroleum or petroleum products is to be stored therein, the amount of nonbonded petroleum or petroleum products in the tank shall be withdrawn by the proprietor as soon as possible. The request to withdraw shall be in the form of a letter and no formal withdrawal need be filed. Domestic or duty-paid petroleum or petroleum products shall not thereafter be stored in the tank as long as the tank remains bonded.

(c) *Information on warehouse withdrawal.* Warehouse withdrawals of petroleum or petroleum products from bonded tanks shall show the information specified in section 151.41, as well as the designation of the tank from which the merchandise is to be withdrawn. Such withdrawals may be made for "—— U.S. gallons, more or less", but in no case may the estimate vary by more than three percent from the gross quantity unladen.

§ 151.46 Allowance for excessive water and sediment.

Allowance for excessive moisture or other impurities in imported petroleum or petroleum products shall be made in accordance with section 158.13 of this chapter for the quantity of water and sediment, established to be in excess of that usually found in such merchandise, as set forth in the following table:

Merchandise	*Quantity (percent)*
Crude petroleum	0.3
Petroleum products having an API gravity at 60° or less than 22°	0.5
22° to 30°	0.3
More than 30°	0.0

§ 151.47 Entered quantities of petroleum or petroleum products released under entry or immediate delivery.

(a) *Optional entry of net quantity landed.* As an alternative to stating on the entry summary the gross quantity of petroleum or petroleum products released under the immediate delivery procedure in § 142.21 of this chapter, or under the entry documentation in § 142.3(a), the importer may file an entry summary for the net quantity of petroleum or petroleum products unladen. The net quantity shall be determined in accordance with section 158.13 of this chapter, with an allowance made for sediment and excessive water present, as prescribed in the table found in section 151.46, and reported in a laboratory test made by an independent commercial laboratory which has been approved by the Commissioner. The commercial laboratory report shall be filed with the entry summary.

(b) *Approval of independent commercial laboratories.* Applications of independent commercial laboratories for approval of the use of their tests in determining the net landed quantity of petroleum or petroleum products shall be sent to the Commissioner of Customs, Washington, D.C. 20229. For the purposes of this section, the approval of a public gauger by the Commissioner in accordance with § 151.43 shall constitute approval of the commercial laboratories operated by the public gauger as a part of the services rendered by him for his customers.

(c) *Use of Customs laboratory tests for liquidation.* Where there is a difference between the quantity reported by the Customs laboratory and the quantity reported by the approved independent commercial laboratory, the results of the Customs laboratory test shall be used in the liquidation of the entry and in determining the quantity chargeable against the importer's oil import license, unless the difference is within the limits set forth in paragraph (d) of this section.

(d) *Use of commercial laboratory tests for liquidation.* The quantity reported by the approved independent commercial laboratory shall be used in the liquidation of the entry and in determining the quantity chargeable against the importer's oil import license if the difference between the commercial laboratory test and the Customs laboratory test do not exceed the differences set forth in the following table (adapted from ASTM Designation D1796, Fig. 3):

Percentage of water and sediment found by Customs laboratory	Maximum percentage difference allowable
0.05 to 0.50	0.1
0.51 to 1.50	0.2
More than 1.50	0.3

(Sec. 507, 46 Stat. 732 (19 U.S.C. 1507)) (R.S. 251, as amended, sec. 624, 46 Stat. 759, 77A Stat. 14 (19 U.S.C. 66, 1202 (Gen. Hdntes. 11, 12), 1624))

PART 159—LIQUIDATION OF DUTIES

Section 159.21(a) is amended by changing the spelling of the word "gage" to "gauge" in the first sentence.

(R.S. 251, as amended, sec. 624, 46 Stat. 759 (19 U.S.C. 66, 1624))

[FR Doc. 80-16520 Filed 5-29-80; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 50

[Docket No. 78N-0049]

Protection of Human Subjects; Prisoners Used as Subjects in Research

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document establishes regulations to provide protection for prisoners involved in research activities that fall within the jurisdiction of the Food and Drug Administration (FDA). These regulations implement the recommendations of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (National Commission) on research involving prisoners. These regulations restrict the use of prisoners in research within the jurisdiction of FDA and establish requirements for the composition of and additional duties for institutional review boards when prisoners are involved in the research.

EFFECTIVE DATE: June 1, 1981.

FOR FURTHER INFORMATION CONTACT: Roger Barnes, Office of Health Affairs (HFV–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: Under the National Research Act (Pub. L. 93–348), the National Commission was charged with, among other duties, identifying the requirements for informed consent by prisoners for participation in biomedical and behavioral research. On the basis of its investigation and study of this issue (see paragraph 7), the National Commission identified the requirements for informed consent and made recommendations to the Secretary of Health and Human Services (HHS) about appropriate administrative actions to ensure that those requirements would be met in research subject to the Department's jurisdiction. The National Commission's recommendations covered research conducted or supported under programs administered by the Secretary and research reported to the Secretary in fulfillment of regulatory requirements (42 FR 3076, 3079, January 14, 1977).

Section 205 of the National Research Act, however, only required the Secretary to determine whether the National Commission's recommendations were appropriate to assure the protection of prisoners as subjects of biomedical or behavioral research conducted or supported under the programs the Secretary administered. (In the **Federal Register** of January 8, 1978 (43 FR 1050), the Secretary announced that the Department was adopting the National Commission's recommendations for such research and was proposing regulations implementing this determination. These regulations were adopted in final form on November 16, 1978 (43 FR 53652).) Section 205 did not explicitly impose an obligation on the Secretary to respond to the National Commission's recommendations with regard to research reported in fulfillment of regulatory requirements.

Nevertheless, the Secretary believed that a determination should be made as to whether the National Commission's recommendations should be adopted for non-HHS supported research that is submitted to FDA to satisfy its regulatory requirements. Because rulemaking authority with respect to FDA activities has been delegated to the Commissioner of Food and Drugs, the Secretary directed the Commissioner to take appropriate action on these recommendations (43 FR 1051).

In the **Federal Register** of May 5, 1978, the Commissioner announced the tentative decision to adopt the findings of both the National Commission and the Secretary regarding the inherently coercive nature of the prison environment and the need for special protections for prisoners involved as subjects of clinical research (43 FR 19417, 19418). Therefore, on the basis of the authority granted under the Federal Food, Drug, and Cosmetic Act (the act), the Commissioner proposed these regulations to establish those special protections.

FDA allowed 60 days for comment on the proposed regulations. The agency received more than 40 letters with comments directed to the proposal. These comments were from government officials, prisoners, clinical investigators, trade associations, professional societies, academic research institutions, drug companies, members of Congress on behalf of constituents, and other private citizens. The substantive comments received and the agency's conclusions about them are discussed below.

In addition, the reasoning in the preambles to HHS's proposed rulemaking (43 FR 1050) and rulemaking on adopting "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects" (43 FR 53652) has been considered by FDA and is incorporated as part of this record.

Comments on the Advance Notice of Proposed Rulemaking and the Proposed Rule

1. Several comments challenged FDA's authority to issue these regulations.

A thorough discussion of FDA's authority was provided in the preamble to the proposed rule (see 43 FR 19419). FDA believes it is unnecessary to reproduce that discussion here. Some comments on the proposed regulations challenged the agency's analysis of its authority. FDA has studied them carefully, and FDA continues to believe that its assessment is accurate. However, in the interest of responsiveness, FDA will reply to each objection relating to its authority.

2. Two comments stated that FDA lacks authority to promulgate regulations concerning the validity of informed consent based on prisoner status.

FDA rejects these comments. As discussed in the preamble to the May 5, 1978 proposal, sections 505(i), 507(d), and 520(g) (21 U.S.C. 355(i), 357(d), and 360j(g)) of the act require that FDA promulgate regulations for the exemption of drugs and devices for investigational use. These sections of the act direct FDA to issue regulations that protect the public health in the course of clinical investigations and that provide that informed consent will be obtained from the human subjects of the investigations.The act also requires these regulations, in the case of drugs, have due regard for the interests of patients (21 U.S.C. 355(j)(1) and 21 U.S.C. 357(g)(1)) or, in the case of devices, be consistent with ethical standards (21 U.S.C. 360j(g)(1)).

FDA believes that there is significant evidence that additional regulations are necessary to protect adequately the interests of prisoners who participate as human subjects of research within its jurisdiction. FDA notes that the legislative history of the National Research Act indicates that it was passed in reaction to abuses in the field of human experimentation, including prison research. See 1974 U.S. Code Cong. & Admin. News, 93rd Cong., 2d Sess., 3634, 3650 (S. Rep. 93–381). As at least one court has stated, a particular concern to the drafters of the National Research Act was that a subject's consent be based on full disclosure and be free of any form of coercion. *Clay* v. *Martin*, 509 F.2d 109, 173 (2d Cir. 1975), citing 1974 U.S. Code Cong. & Admin. News, *supra*, at 3657. Yet the National Commission found, which finding FDA has adopted, that the prison environment is inherently coercive.

Therefore, FDA has decided that due regard for the interests of prisoners as subject and for appropriate ethical standards, as well as for the protection of the public health and safety, requires that special protections be adopted for prisoners involved in clinical investigations. Under the authority granted to it in sections 505(i), 505(j), 507(d), 507(g), and 520(g) of the act FDA is promulgating these regulations that restrict the circumstances in which prisoners can be used as subjects in the research that is under the jurisdiction of FDA.

3. One comment stated that the act requires FDA to accept all clinical investigations that are submitted to the agency to support marketing of a new drug or device pursuant to sections 505(i), 507(d), and 520(g) of the act. The comment went on to suggest that FDA lacks the rulemaking authority to reject private scientific research on the basis that such research was conducted on prisioners.

FDA rejects this comment. No legal basis for the propositions asserted is cited in the comment, and none exists in the act. The agency's authority to define what clinical investigations it will eccept is well-established and is discussed at length in the preamble to

the proposed regulations (See 43 FR 19419).

4. Two comments argued that nothing in the act provides FDA with statutory authority to ban all privately supported and conducted scientific research involving prisoner volunteers.

These comments misconstrue the effect of these regulations. These reglations apply to all clinical investigations regulated by FDA under sections 505(i), 507(d), and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA. However, the regulations do not affect privately supported and conducted scientific research on prisoner volunteers that is not subject to FDA jurisdiction.

5. One comment stated that the proposed regulations are an impermissible intrusion upon the rights of the States to manage their own prison systems. Two comments contended that FDA's regulations would vilolate a California law that permits prisoner research.

FDA disagrees with these comments. These regulations impose no obligations on State prison authorities. They state that except in limited circumstances, the agency will not permit the use of prisoners in the clinical investigations it regulates under sections 505(i), 507(d), and 520(g) of the act or accept clinical investigations that involved prisoner subjects in support of applications for research or marketing permits for products regulated by FDA.

6. Several comments stated that FDA was "taking away a prisoner right" to participate in research, and that these regulations denied equal protection of the law to prisoners by taking away that right.

FDA rejects these comments. Participation in research, which has been a source of income for prisoners, will be greatly restricted by these regulations. However, FDA believes that any deprivation to prisoners that results is clearly outweighed by the fact that these regulations are necessary to assure that the interests of prisoners who participate in research subject to FDA's jurisdiction are adequately protected (see also paragraph 12 of this preamble). It is relevant to point out, as noted in HHS's final rule published in the **Federal Register** of November 16, 1978 (43 FR 53652, 53654), that medical and medically related research involving prisoners: (1) has already been prohibited in all Federal prisons; (2) has been prohibited in eight States; and (3) is conducted only in about seven of the States that either permit it or do not regulate it. These prohibitions have been based on the demonstrable inequities of such research and on the questionable voluntariness of prisoner consent.

7. Many comments objected to the recommendations of the National Commission. The comments argued that the National Commission had no basis to conclude that research conducted with prisoner subjects was unsafe or coercive. Several comments stated that the only rationale for the National Commission's recommendations was an emotional bias against research involving prisoners. These comments suggested that FDA reject the National Commission's recommendations and allow prisoners to continue to be subjects of clinical investigations subject to FDA's jurisdiction.

FDA rejects these comments. The National Commission's findings and recommendations were based on extensive research. The National Commission visited prison research facilities, interviewed many prisoners, and discussed prison procedures with prison officials. In addition, to ensure that viewpoints of minorities were heard, the National Commission contracted with the National Urban Coalition to organize a conference on human experimentation which was held in January 1977. The National Commission also conducted a public hearing on the issue of research involving prisoners and considered papers on the ethical issues involved in research with prisoners that were prepared for it. The National Commission used all of this information in its final report. FDA has not found any reason to alter its decision to adopt the findings and recommendations contained in that report.

8. One comment received by the Secretary after publication of the recommendations of the National Commission stated that the discontinuation of research currently in progress within one year following issuance of the regulations, might cause valid data to be lost or new studies to be jeopardized by sudden termination of the therapeutic regimen afforded by the study. The Secretary stated in response that the Commissioner would consider the effect of this matter on non-HHS supported research (43 FR 1052).

FDA believes that the one year interval strikes an appropriate balance between the need for prompt implementation of these protections for prisoners and the need of sponsors of ongoing clinical investigations involving prisoners as subjects to complete or discontinue the investigations or to bring them into compliance with these regulations without unduly jeopardizing valid data.

9. One comment suggested that regulations of HHS and FDA concerning use of prisoners in clinical investigations be uniform.

FDA agrees that, wherever possible, its regulations should be compatible with, if not identical to, those of the Department. A multiplicity of dissimilar and inconsistent Federal requirements is burdensome to institutions, institutional review boards, and the process of clinical investigation. These regulations closely follow and apply the principles set forth in the HHS regulations on prisoner research.

10. Several comments pointed out that FDA's regulations would prohibit prisoner participation in any research subject to FDA jurisdiction that is not related to the health or well-being of the subjects or is not on conditions particularly affecting prisoners as a class. These comments noted that under the National Commission's recommendations, reports on such research involving prisoners could be accepted in fulfillment of regulatory requirements, if certain conditions were met in the particular study. These comments argue that FDA's regulations consequently exceed the National Commission's recommendations.

FDA acknowledges that the National Commission did not explicitly recommend a prohibition on the use of prisoners in all research that is not related to the health or well-being of subjects or is not on conditions particularly affecting prisoners as a class. However, FDA believes that these regulations are authorized by the act and implement the thrust of the National Commission's recommendations.

The National Commission recommended that reports on research involving prisoners should be accepted in fulfillment of regulatory requirements only if three requirements are satisfied:

a. The type of research fulfills an important social or scientific need, and the reasons for involving prisoners in the type of research are compelling;

b. The involvement of prisoners in research satisfied "conditions of equity"; and

c. A high degree of voluntariness on the part of research subjects and openness on the part of the institutions characterized the conduct of the research (see 42 FR 3080; January 14, 1977).

FDA has reviewed all research subject to its jurisdiction that would not be permitted under § 50.44. Based on the act's requirements that subjects of clinical investigations be protected (see paragraph 2), on the National Commission's finding that the environment in prisons is inherently

coercive, and on the findings of the Secretary, FDA has concluded that there are no compelling reasons for involving prisoners in this research, and, consequently, that the first of the National Commission's requirements for the acceptance of reports on investigations cannot be satisfied for such research.

None of the comments submitted in response to the proposal suggested that a compelling reason for the agency to accept reports on this research could be asserted. For example, several comments pointed to problems that might develop in Phase I testing if prisoners could not be used, but no comment suggested that alternate subjects for Phase I testing could not be found. Significantly, other nations active in biomedical research have been able to conduct investigations without involving prisoners.

In addition, FDA has incorporated the reasoning of HHS for restricting the use of prisoners as subjects, which is set forth in the preambles to the proposed and final rulemaking of the Department (see 43 FR 1050–1051 and 43 FR 53652, 53654).

Aside from these substantive factors, FDA decided to prohibit the use of prisoners in research subject to its jurisdiction that is not related to the health or well-being of the subjects or to conditions particularly affecting prisoners as a class because this prohibition is consistent with the regulations adopted by HHS. As discussed in paragraph 9 of this preamble, the agency believes that, when appropriate, there is significant value in FDA adopting regulations compatible with, if not identical to, those of HHS.

11. One comment suggested that a prisoner population is needed to maintain a well-controlled testing atmosphere. The comment pointed out that many activities of prisoners are monitored, and that there is less control over those same activities in nonprisoner populations. Therefore, the comment asserted, drug studies can be more effectively done in prisons.

While it is true that many activities of prisoners are monitored that are not monitored in nonprisoner populations, FDA disagrees with the conclusion and rejects the comment. No data showing that prisoners are necessary to conduct well-controlled research, and that no reasonable alternative is available, have ever been presented to FDA, nor is the existence of such data indicated in the National Commission's report. In addition, FDA has found that in certain circumstances, prisoners are actually an unsuitable population for drug testing. See, e.g., Warner-Lambert/Parke-Davis & Co.; Benylin; Final Decision (44 FR 51512, 51524, August 31, 1979).

12. Several comments stated that research was a good way for prisoners to earn money while incarcerated. Comments also suggested that prisoners receive other benefits from participation in the studies and are motivated by a desire to help the public.

In its report, the National Commission stated that in its interviews with prisoners involved in Phase I drug studies, participants gave many reasons for volunteering for research, "but it was clear that the overriding motivation was the money they received for participating. In fact, their strongest objection was that the pay for participation in research was held down to levels comparable to prison industries" (42 FR 3083). The National Commission found, however, that "although prisoners who participate in research affirm that they do so freely, the conditions of social and economic deprivation in which they live compromise their freedom" (42 FR 3078). The National Commission believed that the availability of a population living in conditions of social and economic deprivation makes it possible for researchers to bring to this population types of research which persons better situated would ordinarily refuse. The National Commission concluded that "prisoners are, as a consequence of being prisoners, more subject to coerced choice and more readily available for the imposition of burdens which others will not willingly bear" (42 FR 3078). FDA adopts these findings by the National Commission.

13. Several comments stated that research involving prisoners is safe, and that prisoners do not need special protections. These comments asserted that prisoners are now free from any outside influence in choosing to participate in studies, and therefore, these regulations are unnecessary.

FDA rejects these comments for the reasons that are set forth in paragraph 12 of this preamble.

14. One comment suggested that FDA prohibit the use of prisoners in any research that is subject to FDA jurisdiction.

FDA rejects this comment. One of the specific recommendations of the National Commission was that "[r]esearch on practices both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the individual prisoner may be conducted or supported * * *." (42 FR 3080). The National Commission believed, and FDA agrees, that a research subject should not be deprived of health benefits (even experimental ones) simply because the subject is a prisoner. Section 50.44(b)(2) and (3) (21 CFR 50.44 (b)(2) and (3)) allows submission of research that will benefit the prisoner subjects involved.

15. One comment suggested that psychiatric patients should not be used in drug studies that will not directly benefit their health. The comment stated that because of the nature of their illness, they may not be able to give effective informed consent to participate in a drug study.

FDA agrees with this comment, and except in limited circumstances, psychiatric patients in prisons, like other prisoners, cannot be used as subjects in studies subject to FDA's jurisdiction. The National Commission issued its report concerning the institutionalized mentally disabled patients in the **Federal Register** of March 17, 1978 (43 FR 11328). HHS has issued proposed regulations governing the use of mentally disabled patients as subjects in clinical investigations, and FDA is considering the need to publish similar regulations.

16. One comment questioned the scope of these regulations. The comment stated that it was unclear whether all clinical investigations, including those involving cosmetics, OTC drugs, and low-risk medical devices were covered by these regulations.

The scope of these regulations pertains to those clincial investigations regulated by FDA under sections 505(i), 507(d), or 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the agency. Therefore, the regulations would be applicable to clinical investigations involving OTC drug products and any medical devices, whether or not the devices are significant risk devices as defined in 21 CFR Part 812, if reports of those investigations are to be submitted to FDA. Cosmetic products are not included among the types of products to which the regulation applies.

17. Several comments raised questions about specific definitions in proposed § 50.3 (21 CFR 50.3). Other comments suggested alternative definitions to those contained in that section.

With one exception, proposed § 50.3 has been reproposed by the agency in its proposed standards for informed consent, published in the **Federal Register** of August 14, 1979 (44 FR 47713). Comments on the proposed standards for informed consent, including reproposed § 50.3, are on file in the Hearing Clerk's office (HFA–305), Rm. 4–62, 5600 Fishers Lane, Rockville,

MD 20857, under Docket No. 78N-0400. Those comments on the prisoner research regulations that contained questions or suggestions about definitions in proposed § 50.3 have been included in Docket No. 78N-0400 and will be addressed when the final regulations governing informed consent are published.

FDA is adopting at this time the definition of the term "Application for research or marketing permit," § 50.3(b) (21 CFR 50.3(b)). The agency has decided to do so to ensure that the meaning of this phrase, which is used to define the scope of these regulations, is clear.

18. Several comments urged that the regulations should permit prisoners to receive placebos as a control group. A few comments stated that the validity of any research done would be questionable unless there was a placebo control group. One comment suggested that the regulationd does not clearly state whether prisoners would be able to act as placebo controls in otherwise permissible prisoner research.

To be consistent with the HHS regulations, FDA has revised § 50.44 (21 CFR 50.44) to permit certain research on conditions particularly affecting prisoners as a class, in addition to research on practices that have the intent and reasonable probability of improving the health and well-being of the subjects. FDA has also decided to permit prisoners to participate in these types of research as members of a control group, including a placebo control group, even though as members of a control group they may not benefit directly from the research. These changes were based on comments received by FDA and the Department. However, to be consistent with the recommendations of the National Commission, FDA has required that prisoner participation in research on conditions affecting prisoners as a class and in research as control subjects be approved by the agency on a study by study basis.

19. One comment noted that the preamble to the proposal stated that the agency has concluded that an environmental impact statement is not required for this regulation, but that an environmental impact assessment was on file with the FDA Hearing Clerk. The comment pointed out that, in fact, no environmental impact assessment had been filed.

The notice of proposed rulemaking did inadvertently refer to an environmental impact assessment (43 FR 19419). However, this proposed action did not require the preparation of an environmental impact assessment under 21 CFR 25.1(b) and (h). An environmental impact assessment also is not required under FDA's proposed new environmental regulations (44 FR 71742; December 11, 1979). The agency has determined pursuant to proposed 21 CFR 25.24(b)(12) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental impact assessment nor an environmental impact statement is required.

20. One comment asserted that a proper economic assessment of the impact of this regulation had not been prepared by FDA. The comment stated that the document FDA prepared did not adequately describe the proposed regulations and was not prepared under the appropriate Executive Order.

FDA agrees with the comment concerning the reference to the appropriate Executive Order. The original economic impact assessment concluded that the proposed regulations would not have a major economic impact as defined by Executive Order 11821, as amended by Executive Order 11949. During the period from January 1, 1978 to March 22, 1978, when Executive Order 12044 was issued, no Executive Order was in effect, although FDA continued to prepare economic impact assessments under the expired order. This process continued until August, 1978, when FDA prepared "Interim Regulatory Analysis Guidelines" for use by the agency in implementing Executive Order 12044. Because the proposed regulations were published during the period of transition from the standards of Executive Order 11821, as amended, to those of Executive Order 12044, the technically appropriate reference was not made. However, the specific relevant standard for assessing whether the action would have a major economic impact was the same.

FDA also agrees in part with the comment that the original economic impact assessment did not adequately describe the proposed regulations. FDA therefore has reassessed the economic impact of this regulation under the standards established in Executive Order 12044. This assessment has confirmed that the regulation will not have a major economic impact as defined by that order.

A copy of the amended regulatory analysis assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 406, 409, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701(a), 706, and 801, 52 Stat. 1049–1054 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–407 as amended, 76 Stat. 794–795 as amended, 90 Stat. 540–560, 562–574 (21 U.S.C. 346, 348, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371(a), 376, and 381)) and the Public Health Service Act (secs. 215, 351, 354–360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 262, 263b–263n)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Subchapter A of Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 50, to read as follows:

PART 50—PROTECTION OF HUMAN SUBJECTS

Subpart A—General Provisions

Sec.
50.1 Scope.
50.3 Definitions.

Subpart B—[Reserved]

Subpart C—Protections Pertaining to Clinical Investigations Involving Prisoners as Subjects

50.40 Applicability.
50.42 Purpose.
50.44 Restrictions on clinical investigations involving prisoners.
50.46 Composition of institutional review boards where prisoners are involved.
50.48 Additional duties of the institutional review boards where prisoners are involved.

Authority: Secs. 406, 409, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701(a), 706, and 801, Pub. L. 717, 52 Stat. 1049–1054 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–407 as amended, 76 Stat. 794–795 as amended, 90 Stat. 540–560, 562–574 (21 U.S.C. 346, 348, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371(a), 376, and 381); secs. 215, 351, 354–360F, Pub. L. 410, 58 Stat. 690, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 262, 263b–263n)

Subpart A—General Provisions

§ 50.1 Scope.

(a) This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or

monitor clinical investigations involving particular test articles may also be found in other parts (e.g., Parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of prisoner subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 406, 409, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 706, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 50.3 Definitions.

As used in this part:

(a) [Reserved]

(b) "Application for research or marketing permit" includes:

(1) A color additive petition, described in Part 71.

(2) A food additive petition, described in Parts 171 and 571.

(3) Data and information about a substance submitted as part of the procedures for establishing that the substance is generally recognized as safe for use that results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§ 170.30 and 570.30.

(4) Data and information about a food additive submitted as part of the procedures for food additives permitted to be used on an interim basis pending additional study, described in § 180.1.

(5) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) A "Notice of Claimed Investigational Exemption for a New Drug," described in Part 312.

(7) A new drug application, described in Part 314.

(8) Data and information about the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in Part 320.

(9) Data and information about an over-the-counter drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in Part 330.

(10) Data and information about a prescription drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in this chapter.

(11) Data and information about an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for these drugs, described in Part 430.

(12) An application for a biological product license, described in Part 601.

(13) Data and information about a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, described in Part 601.

(14) Data and information about an in vitro diagnostic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in Part 809.

(15) An "Application for an Investigational Device Exemption," described in Part 812.

(16) Data and information about a medical device submitted as part of the procedures for classifying these devices, described in section 513.

(17) Data and information about a medical device submitted as part of the procedures for establishing, amending, or repealing a standard for these devices, described in section 514.

(18) An application for premarket approval of a medical device, described in section 515.

(19) A product development protocol for a medical device, described in section 515.

(20) Data and information about an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in section 358 of the Public Health Service Act.

(21) Data and information about an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in § 1010.4.

(22) Data and information about an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in § 1010.5.

Subpart B—[Reserved]

Subpart C—Protections Pertaining to Clinical Investigations Involving Prisoners as Subjects

§ 50.40 Applicability.

(a) The regulations in this subpart apply to all clinical investigations involving prisoners as subjects that are regulated by the Food and Drug Administration under sections 505(i), 507(d), or 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations involving prisoners that support applications for research or marketing permits for products regulated by the Food and Drug Administration.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects to the extent such research is limited or barred by applicable State or local law.

§ 50.42 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 50.44 Restrictions on clinical investigations involving prisoners.

(a) Except as provided in § 50.44(b), clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 505(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration may not involve prisoners as subjects.

(b) Clinical investigations that are regulated by the Food and Drug Administration under sections 505(i), 507(d), or 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, may involve prisoners as subjects only if the institution responsible for the conduct of the clinical investigation has certified to the Food and Drug Administration that the institutional review board has approved the clinical investigation under § 50.48; and

(1)(i) In the judgment of the Food and Drug Administration, the proposed clinical investigation involves solely research on practices both innovative and accepted, which have the intent and reasonable probability of improving, the health and well-being of the subjects;

(ii) In cases in which these studies require the assignment of prisoners in a manner consistent with protocols approved by the institutional review board to control groups that may not benefit from the research, the study may proceed only after the Food and Drug

Administration has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the **Federal Register** of its intent to approve such research; or

(2) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis, which is much more prevalent in prisons than elsewhere) provided that the Food and Drug Administration has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the **Federal Register** of its intent to approve such research; subject to the approval of the Food and Drug Administration, prisoners may participate in the research even though they are assigned, in a manner consistent with protocols approved by the institutional review board, to control groups that may not benefit from the research.

§ 50.46 Composition of institutional review boards where prisoners are involved.

In addition to satisfying any other requirements governing institutional review boards set forth in this chapter, an institutional review board, in carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the institutional review board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the institutional review board.

(b) At least one member of the institutional review board shall be a prisoner, or a prisoner advocate with appropriate background and experience to serve in that capacity, except that if a particular research project is reviewed by more than one institutional review board, only one institutional review board need satisfy this requirement.

§ 50.48 Additional duties of the institutional review boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for institutional review boards under this chapter, the institutional review board shall review clinical investigations covered by this subpart and approve such clinical investigations only if it finds that:

(1) The research under review represents one of the categories of research permitted under § 50.44(b) (1) and (2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the clinical investigation, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that his or her ability to weigh the risks of the clinical investigation against the value of such advantages in the limited-choice environment of the prison is impaired;

(3) The risks involved in the clinical investigation are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners; unless the principal investigator provides to the institutional review board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that research project;

(5) Any information given to subjects is presented in language which is appropriate for the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the clinical investigation in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the clinical investigation will have no effect on his or her parole; and

(7) Where the institutional review board finds there may be need for followup examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The institutional review board shall carry out such other duties as may be assigned by the Food and Drug Administration.

(c) The institution shall certify to the Food and Drug Administration, in such form and manner as the Food and Drug Administration may require, that the duties of the institutional review board under this section have been fulfilled.

Effective date. This regulation shall become effective June 1, 1981.

Dated: May 27, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80-16578 Filed 5-29-80; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 201

[Docket No. R-80-817]

Mortgage Insurance and Home Improvement Loans; Changes in Interest Rates

AGENCY: Department of Housing and Urban Development.

ACTION: Final rule.

SUMMARY: The change in the regulations decreases the HUD/FHA maximum allowable finance charge on Title I property improvement, mobile home loans, and combination and mobile home lot loans. This action by HUD is designed to bring the maximum interest rate and financing charges on HUD/FHA-insured loans into line with market rates and help assure an adequate supply of and demand for FHA financing.

EFFECTIVE DATE: May 19, 1980.

FOR FURTHER INFORMATION CONTACT: John N. Dickie, Director, Financial Analysis Division, Office of Financial Management, Department of Housing and Urban Development, 451 7th Street, S.W., Washington, D.C. 20410 (202–426–4667).

SUPPLEMENTARY INFORMATION: The following miscellaneous amendments have been made to this chapter to decrease the maximum interest rate which may be charged on loans insured by this Department. Maximum finance charges on mobile home loans and the property improvement loans have been lowered from 18.00 percent to 16.50 percent and the finance charges on combination loans for the purchase of a mobile home and a developed or undeveloped lot has been lowered from 17.50 percent to 16.00 percent.

The Secretary has determined that such changes are immediately necessary to meet the needs of the market and to prevent speculation in anticipation of a change, in accordance with his authority contained in 12 U.S.C. 1709–1, as amended. The Secretary has, therefore, determined that advance notice and public comment procedures are unnecessary and that good cause exists for making this amendment effective immediately.

A Finding of Inapplicability respecting the National Environmental Policy Act of 1969 has been made in accordance with HUD's environmental procedures.