Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9F dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies Class E airspace at Sault Ste Marie, ON, to correctly identify the northwest extension of the existing controlled airspace. The area will be depicted on appropriate aeronautical charts.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporations by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 95665, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL ON E4 Sault Ste Marie, ON [Revised]

Sault Ste Marie Airport, ON, Canada
(Lat. 46°29′06″N., long. 84°30′34″W.)

That airspace in the United States extending upward from the surface within 1.6 miles north of the 108° bearing from the airport extending from the 4.4-mile radius of Sault Ste Marie Airport to 4.8 miles southeast of the airport, and within 1.6 miles each side of the 118° bearing from the airport extending from the 4.4-mile radius to 9.6 miles southeast of the airport, and within 1.6 miles each side of the 293° bearing from the airport extending from the 4.4-mile radius to 4.8 miles northwest of the airport.

* * * * *

Issued in Des Plaines, Illinois on March 18, 1999.

John A. Clayborn,

Acting Manager, Air Traffic Division.

[FR Doc. 99–8244 Filed 4–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 10, 18, 113 and 178

[T.D. 99–33]

RIN 1515–AB67

Warehouse Withdrawals; Aircraft Fuel Supplies; Pipeline Transportation of Merchandise in Bond

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule, with some changes, the interim rule amending the Customs Regulations that was published in the **Federal Register** on February 22, 1996, as T.D. 96–18. The interim rule implemented certain statutory changes to the Customs laws contained in the Customs modernization portion of the North American Free Trade Agreement Implementation Act regarding recordkeeping for merchandise transported by pipeline and duty-free withdrawals from Customs bonded warehouses of aircraft turbine fuel. The interim rule also clarified the procedures applicable to aircraft turbine fuel withdrawn from a bonded warehouse for certain duty-free use and then commingled with other lots of fuel before being so used.

EFFECTIVE DATE: April 5, 1999.

FOR FURTHER INFORMATION CONTACT: Jerry C. Laderberg, Office of Regulations and Rulings, 202–927–2320.

SUPPLEMENTARY INFORMATION:

Background

Title VI of the North American Free Trade Agreement Implementation Act, Pub. L. 103–182 (December 8, 1993), popularly known as the Customs Modernization Act (Mod Act), significantly amended certain Customs laws. This document concerns sections 664 and 665 of the Mod Act. Section 664 added a new section 553a to the Tariff Act of 1930 (19 U.S.C. 1553a), to account for bonded merchandise transported by pipeline. Section 665 amended section 557(a) of the Tariff Act of 1930 (19 U.S.C. 1557(a)), to provide for the duty-free withdrawal of turbine fuel from a Customs bonded warehouse under a 30-day accounting period.

Under section 553a, bonded merchandise transported by pipeline may be accounted for on a quantitative basis. For this purpose, the bill of lading or equivalent document of receipt, issued by the pipeline carrier to the shipper and accepted by the consignee, may be used to account for the quantity of merchandise so transported and to maintain the identity of that merchandise. This facilitates the commingling of bonded merchandise with non-bonded merchandise being transported by pipeline. Commingling previously was not permitted under Customs law, which required that the physical identity of the bonded merchandise be maintained. However, since most merchandise transported by pipeline is commingled and is susceptible to quantitative accounting, section 553a is intended both to enable the effective use of modern fuel transportation systems and to reduce the administrative costs and paperwork for the industry and the Government.

Under amended section 1557(a), aircraft turbine fuel may be withdrawn from a Customs bonded warehouse for use as provided under section 309 of the Tariff Act of 1930 (19 U.S.C. 1309) without the payment of duty if an amount equal to the quantity of fuel withdrawn is shown to be used as provided for in section 1309 within 30 days of its withdrawal. Duties must be deposited on turbine fuel that was withdrawn in excess of the quantity

shown to have been used under section 1309 during the 30-day period following withdrawal of the fuel. Previously, Customs required daily accounting for such fuel, which resulted in great administrative expense and excessive paperwork for industry. The amended procedure allows for the commingling of different lots of fuel, whether bonded, imported, or domestic, in a modern hydrant system, with accounting for the bonded fuel in a manner which is cost-effective and which substantially reduces paperwork.

Accordingly, by a document published in the **Federal Register** (61 FR 6772) on February 22, 1996, as T.D. 96–18, Customs issued interim regulations to implement the foregoing statutory enactments.

The interim regulations added a new § 18.31 to its regulations (19 CFR 18.31) to allow bonded merchandise being transported by pipeline to be accounted for on a quantitative basis, and a new § 10.62b to permit accounting on a monthly basis for the duty-free withdrawal of aircraft turbine fuel from a bonded warehouse for use as provided in 19 U.S.C. 1309. In connection with new §§ 10.62b and 18.31, the interim regulations also made conforming changes to existing §§ 10.60(d), 10.62(a), 18.1(a)(1), and 113.62(b) of the Customs Regulations (19 CFR 10.60(d), 10.62(a), 18.1(a)(1), and 113.62(b)).

Discussion of Comments

One commenter responded to the request for comments on the interim regulations contained in T.D. 96–18. This commenter agreed with the substance of the interim regulations, but made a number of suggestions in an effort to clarify the meaning of the regulations or to further simplify their administration. The suggestions made by the commenter, together with the responses by Customs, are set forth below.

Comment: The reference in § 10.62(a) to Customs Form (CF) 7506 should be changed to Customs Form 7501 because Customs has since adopted the use of CF 7501 in place of CF 7506.

Customs Response: Customs agrees. Section 10.62(a) is changed accordingly.

Comment: The last sentence in § 10.62b(b) should be changed to require that the withdrawal of turbine fuel be made using CF 7512 unless the blanket withdrawal procedure is used.

Customs Response: Customs disagrees. Under § 144.37, Customs Regulations (19 CFR 144.37), either a CF 7512 or a CF 7501 may be used to document the withdrawal.

Comment: The commenter stated that the use of the phrase, ''the fuel withdrawn which is not entered and upon which duties have not been paid'', in § 10.62b(c)(1) and its subordinate paragraphs, is superfluous and should be deleted from these provisions. The commenter asserts that, as used in paragraph (c)(1)(ii)(C) of § 10.62b, the phrase appears misplaced because this paragraph deals with fuel being loaded onto an aircraft, as opposed to being withdrawn without entry or payment of duty from a bonded warehouse.

Customs Response: Customs disagrees that the phrase should be entirely deleted from § 10.62b(c). It serves to remind Customs and the party withdrawing the fuel that the fuel must be entered if not timely laden under 19 U.S.C. 1309. Customs agrees, however, that the phrase is inappropriate as used in § 10.62b(c)(1)(ii)(C). Section 10.62b(c)(1)(ii)(C) is revised consistent with the request made by the commenter.

Comment: The commenter believes that it would be helpful to both Customs and importers to indicate in § 10.62b(c)(1) that the referenced documents should be submitted to Customs at the port where the bonded entry was filed.

Customs Response: Customs agrees and the provision is modified.

Comment: The commenter states, with reference to § 10.62b(g)(5), that blanket withdrawals of fuel from a bonded warehouse eliminate the need to file a CF 7512. The commenter advocates that the provision be revised to provide that a withdrawal document meeting the requirements of § 10.62b can be submitted instead of CF 7512. The commenter also suggests that the withdrawal document, which is issued by the warehouse proprietor under § 10.62b(g)(5), could also be issued by a pipeline operator, barge or vessel operator, or other party acceptable to Customs.

In addition, the commenter wants to delete the requirement in § 10.62b(g)(5)(ii) that the withdrawal document identify the specific tank from which the bonded fuel is withdrawn. The commenter is of the opinion that because fuel may be withdrawn from several tanks in frequent batches at multi-tank terminals, the precise tank or tanks from which a particular batch of fuel is withdrawn cannot readily be known. Moreover, the commenter declares that precise tank identification is not currently maintained for commercial or Customs purposes.

Customs Response: Customs disagrees with the suggested changes. As already mentioned, under § 144.37, Customs Regulations (19 CFR 144.37), a CF 7512, or a CF 7501, may be used to document withdrawals for export.

Because the warehouse proprietor is the party obligated under bond for the proper withdrawal of fuel supplies from the warehouse, the proprietor is the appropriate party to issue the withdrawal document. Customs believes that permitting another party, such as a pipeline, vessel, or barge operator, to issue a withdrawal document would impose an administrative burden on the agency as well as on the trade.

Furthermore, Customs believes that the withdrawal document must include the specific tank from which fuel is withdrawn in order to enable the agency to audit the withdrawal of the fuel accurately and effectively.

Conclusion

For these reasons, and after careful consideration of the comments and further review of the matter, Customs concludes that the interim rule published in the **Federal Register** (61 FR 6772) on February 22, 1996, as T.D. 96–18, should be adopted as a final rule with the changes explained above.

Regulatory Flexibility Act and Executive Order 12866

As discussed in the interim rule, since the amendments are not subject to the notice and public procedure requirements of the Administrative Procedure Act (5 U.S.C. 553), they are not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Nor do the amendments constitute a ''significant regulatory action'' under E.O. 12866.

Paperwork Reduction Act

The collection of information contained in this final regulation has been reviewed and approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1515–0209. Part 178, Customs Regulations (19 CFR part 178) is amended to make provision for this information collection. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

The collection of information in this final rule is in § 10.62b. This information is required and will be used to verify that turbine fuel withdrawn from a Customs bonded warehouse is used on aircraft qualifying for duty-free withdrawal of fuel supplies, in accordance with statutory law. The likely respondents are businesses.

The estimated average annual burden associated with the collection of information in this final rule is 12 hours per respondent/recordkeeper.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue, NW., 3rd Floor, Washington, DC 20229.

List of Subjects

19 CFR Part 10

Customs duties and inspection, Exports, Imports, Reporting and recordkeeping requirements, Shipments.

19 CFR Part 18

Bonded transportation, Common carriers, Customs duties and inspection, Exports, Imports.

19 CFR Part 113

Common carriers, Customs duties and inspection, Exports, Freight, Laboratories, Reporting and recordkeeping requirements, Surety bonds.

19 CFR Part 178

Administrative practice and procedure, Exports, Imports, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, the interim rule amending parts 10, 18 and 113, Customs Regulations (19 CFR parts 10, 18 and 113), which was published at 61 FR 6772 on February 22, 1996, is adopted as a final rule with the changes set forth below. In addition, part 178 is amended to add a new listing to Customs approved information collection requirements.

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

1. The general authority citation for part 10, and the relevant specific authority citations, continue to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1321, 1481, 1484, 1498, 1508, 1623, 1624, 3314.

* * * * *

Sections 10.61, 10.62, 10.63, 10.64, 10.64a also issued under 19 U.S.C. 1309;

* * * * *

Section 10.62b also issued under 19 U.S.C. 1557;

* * * * *

§ 10.62 [Amended]

2. In § 10.62(a), the first sentence is amended by removing the reference to ''Customs Form 7506'' and by adding, in its place, ''Customs Form 7501''.

3. Section 10.62b is amended by revising paragraphs (c)(1) and (c)(1)(ii)(C) to read as follows:

§ 10.62b Aircraft turbine fuel.

* * * * *

(c) *Establishment of use of fuel by qualifying aircraft.* * * *

(1) The person withdrawing aircraft turbine fuel under paragraph (b) of this section must establish that an aircraft qualifying for the privileges provided for in section 309, Tariff Act of 1930, as amended, used fuel in an amount equal to or exceeding the quantity of the fuel withdrawn that is not entered and upon which duties are not paid by submitting to Customs, at the port where the bonded warehouse entry was filed, within the time provided in paragraph (d) of this section, either—

* * * * *

(ii) * * *

(C) All of the aircraft into which fuel is loaded hereunder were used in a trade provided for in section 309; and

* * * * *

PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

1. The authority citation for part 178 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

2. Section 178.2 is amended by adding a new listing to the table in appropriate numerical order to read as follows:

§ 178.2 Listing of OMB control numbers.

19 CFR section	Description	OMB Control No.
*	*	*
§ 10.62b	Certificate of compliance for turbine fuel withdrawals	1515–0209
*	*	*

Approved: March 8, 1999.

Raymond W. Kelly,

Commissioner of Customs.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 99–8333 Filed 4–2–99; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 26

[Docket No. 98N–0185]

RIN 0910–ZA11

Mutual Recognition of Pharmaceutical Good Manufacturing Practice Inspection Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports Between the United States and the European Community; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of November 6, 1998 (63 FR 60122). The document amended FDA's regulations under an international agreement between the United States and the European Community. FDA took this action to enhance its ability to ensure the safety and effectiveness of pharmaceuticals and medical devices through more efficient utilization of its regulatory resources. The document was published with some inadvertent errors. This document corrects those errors.

EFFECTIVE DATE: March 31, 1999.

FOR FURTHER INFORMATION CONTACT: Merton V. Smith, Office of International