

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this rule will have on small entities, including small businesses, and has determined that no significant economic impact on a substantial number of small entities will derive from this action.

IV. Paperwork Reduction Act of 1995

The direct final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Request for Comments

Interested persons may, on or before August 31, 1998, submit to the Dockets Management Branch (address above) written comments regarding this rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be considered as comments regarding this direct final rule. Likewise, any comment submitted under the direct final rule will be considered as comments to the companion proposed rule in the event the direct final rule is withdrawn.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR part 10 is amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 is revised to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 10.75 is amended by adding a sentence at the end of paragraph (b) to read as follows:

§ 10.75 Internal agency review of decisions.

* * * * *

(b) * * * A sponsor, applicant, or manufacturer of a drug or device

regulated under the act or the Public Health Service Act (42 U.S.C. 262), may request review of a scientific controversy by an appropriate scientific advisory panel as described in section 505(n) of the act, or an advisory committee as described in section 515(g)(2)(B) of the act.

* * * * *

Dated: June 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15815 Filed 6–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 8771]

RIN 1545–AW29

Federal Employment Tax Deposits—De Minimis Rule

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary and final regulations.

SUMMARY: This document contains temporary and final regulations relating to the deposit of Federal employment taxes. The regulations change the de minimis deposit rule for quarterly and annual return periods. The regulations affect taxpayers required to make deposits of Federal employment taxes. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective date:* These regulations are effective June 16, 1998.

Applicability date: For dates of applicability, see § 31.6302–1T(f)(4).

FOR FURTHER INFORMATION CONTACT: Vincent Surabian (202) 622–4940 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

This document contains amendments to 26 CFR part 31, Employment Taxes and Collection of Income Tax at Source. Section 31.6302–1(f)(4) provides that if the total amount of accumulated employment taxes for the quarter is less than \$500 and the amount is fully deposited or remitted with a timely filed return for the quarter, the amount

deposited or remitted will be deemed to be timely deposited.

The temporary regulations change the \$500 threshold to \$1,000. In addition, the regulations replace the term “quarter” with the term “return period” since some employment taxes are reported on an annual basis (Forms 943, 945, and CT–1) rather than quarterly (Form 941). Thus, a taxpayer that has accumulated employment taxes of less than \$1,000 for a return period (quarterly or annual, as the case may be) does not have to make deposits but may remit its full liability with a timely filed return for the return period.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information: The principal author of these regulations is Vincent Surabian, Office of Assistant Chief Counsel (Income Tax & Accounting). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 31 is amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

Paragraph 1. The authority citation for part 31 is amended by adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805. * * *

§ 31.6302–1T also issued under 26 U.S.C. 6302 (a) and (c). * * *

Par. 2. In § 31.6302-1, a new sentence is added at the end of paragraph (f)(4) to read as follows:

§ 31.6302-1 Federal tax deposit rules for withheld income taxes and taxes under the Federal Insurance Contributions Act (FICA) attributable to payments made after December 31, 1992.

* * * * *

(f) * * *

(4) *De Minimis rule.* * * * For guidance regarding de minimis amounts for quarterly return periods beginning on or after July 1, 1998, and annual return periods beginning on or after January 1, 1999, see § 31.6302-1T(f)(4).

* * * * *

Par. 3. Section 31.6302-1T is added to read as follows:

§ 31.6302-1T Federal tax deposit rules for withheld income taxes and taxes under the Federal Insurance Contributions Act (FICA) attributable to payments made after December 31, 1992 (temporary).

(a) through (f)(3). [Reserved] For further guidance, see § 31.6302-1(a) through (f)(3).

(f)(4) *De Minimis rule.* For quarterly return periods beginning on or after July 1, 1998, and annual return periods beginning on or after January 1, 1999, if the total amount of accumulated employment taxes for the return period is less than \$1,000 and the amount is fully deposited or remitted with a timely filed return for the return period, the amount deposited or remitted will be deemed to have been timely deposited.

(f)(5) through (m). [Reserved] For further guidance, see § 31.6302-1(g) through (m).

Michael P. Dolan,

Deputy Commissioner of Internal Revenue.

Approved: June 1, 1998.

Donald C. Lubick,

Assistant Secretary of the Treasury.

[FR Doc. 98-15984 Filed 6-15-98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05-98-040]

RIN 2115-AE46

Special Local Regulations for Marine Events; Patapsco River, Baltimore, MD

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements the special local regulations at 33 CFR

100.515 during the fireworks display to be held July 4, 1998, on the Patapsco River at Baltimore, Maryland. These special local regulations are necessary to control vessel traffic due to the confined nature of the waterway and expected vessel congestion during the fireworks display. The effect will be to restrict general navigation in the regulated area for the safety of spectators and vessels transiting the event area.

DATES: 33 CFR 100.515 is effective from 9 p.m. to 10 p.m. on July 4, 1998.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer R.L. Houck, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore, MD 21226-1971, (410) 576-2674.

SUPPLEMENTARY INFORMATION: The City of Baltimore will sponsor a fireworks display on July 4, 1998 on the Patapsco River, Baltimore, Maryland. The fireworks display will be launched from a barge positioned within the regulated area. In order to ensure the safety of participants and transiting vessels, 33 CFR 100.515 will be in effect for the duration of the event. Under provisions of 33 CFR 100.515, a vessel may not enter the regulated area unless it receives permission from the Coast Guard Patrol Commander. Spectator vessels may anchor outside the regulated area but may not block a navigable channel. Because these restrictions will be in effect for a limited period, they should not result in a significant disruption of maritime traffic.

Dated: May 29, 1998.

P.M. Stillman,

Captain, U.S. Coast Guard, Acting Commander, Fifth Coast Guard District.

[FR Doc. 98-15900 Filed 6-15-98; 8:45 am]

BILLING CODE 4910-15-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05-98-039]

RIN 2115-AE46

Special Local Regulations for Marine Events; Severn River, College Creek, and Weems Creek, Annapolis, MD

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements the special local regulations at 33 CFR 100.518 during the fireworks display to be held July 4, 1998, on the Severn

River at Annapolis, Maryland. These special local regulations are necessary to control vessel traffic due to the confined nature of the waterway and expected vessel congestion during the fireworks display. The effect will be to restrict general navigation in the regulated area for the safety of spectators and vessels transiting the event area.

DATES: 33 CFR 100.518 is effective from 8 p.m. to 11 p.m. on July 4, 1998.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer R. L. Houck, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore, MD 21226-1971, (410) 576-2674.

SUPPLEMENTARY INFORMATION: The City of Annapolis will sponsor a fireworks display on July 4, 1998 on the Severn River, Annapolis, Maryland. The fireworks display will be launched from a barge positioned within the regulated area. In order to ensure the safety of spectators and transiting vessels, 33 CFR 100.518 will be in effect for the duration of the event. Under provisions of 33 CFR 100.518, a vessel may not enter the regulated area unless it receives permission from the Coast Guard Patrol Commander. Spectator vessels may anchor outside the regulated area but may not block a navigable channel. Because these restrictions will be in effect for a limited period, they should not result in a significant disruption of maritime traffic.

Dated: May 29, 1998.

P.M. Stillman,

Captain, U.S. Coast Guard, Acting Commander, Fifth Coast Guard District.

[FR Doc. 98-15899 Filed 6-15-98; 8:45 am]

BILLING CODE 4910-15-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD01-98-065]

RIN 2115-AE46

Special Local Regulation: Fireworks Displays Within the First Coast Guard District

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This document provides notice of the dates and times of the special local regulations contained in 33 CFR 100.114, Fireworks Displays within the First Coast Guard District. All vessels will be restricted from entering the area of navigable water within a 500-