

devices. This reexamination of device remarketing issues is being undertaken, in part, because of competing interests and equity concerns raised by manufacturers, device remarketers, and others, during the rulemaking process for the agency's Quality System (Q/S) regulation part 820 (21 CFR part 820). It provides a method of addressing whether, and to what degree, current good manufacturing practice requirements in the Q/S regulation should be applied by the agency to firms, other than manufacturers and remanufacturers, which process and/or remarket previously used devices outside the control of the device's original manufacturer.

The agency's reassessment is also being undertaken, in part, because of FDA's experience in implementing CPG's 7133.20 and 7124.28. These guides identify what statutory and regulatory requirements, which control the activities of manufacturers, are applicable to the activities of firms considered to be x-ray tube reloaders, or device reconditioners or rebuilders. Agency experience indicates that many firms are unaware of these compliance guides or their own compliance responsibilities, or use other terms to describe their activities. The reassessment is also warranted on the basis of FDA's knowledge of changes in industry practices in the remarketing of used devices.

As a consequence of the previous factors, and for purposes of discussion and public comment during the agency's reevaluation of device remarketing compliance issues, FDA is proposing to define the activities of device refurbishers, servicers, and "as is" remarketers on the basis that their various activities, in contrast to the activities of device remanufacturers defined in 21 CFR 820.3(w), do not significantly change a finished device's performance or safety specifications, or intended use(s). Having proposed to characterize such device processing and remarketing activities in this fashion,

the agency is also considering alternative schemes or methods for applying certain regulatory controls to these activities on a voluntary or partial basis, or not at all. Comments, proposals for alternative regulatory schemes, and information were solicited by FDA from the public, the affected industry and other interested parties, in response to the ANPRM.

FDA received two requests to extend the comment period. One requested 30 additional days to focus resources on the referenced matter. The other requested an extension of 180 days so that issues may be discussed further at the multi-day conference of a device industry association, scheduled for September 1998.

FDA believes there is good cause to extend the comment period. However, FDA believes that a 180-extension period would unduly delay the process. Therefore, FDA is extending the comment period for 90 additional days.

Interested persons may, on or before June 29, 1998, submit to the Dockets Management Branch (address above) written comments regarding the December 23, 1997, ANPRM described above. 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.

Dated: March 4, 1998.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-209463-82]

RIN 1545-AV82

Required Distributions From Qualified Plans and Individual Retirement Plans; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains corrections to REG-209463-82, which was published in the **Federal Register** on Tuesday, December 30, 1997 (62 FR 67780). The amendments to existing proposed regulations make changes to the rules that apply if a trust is named as a beneficiary of an employees benefit under a retirement plan.

FOR FURTHER INFORMATION CONTACT: Thomas Foley, (202) 622-6030 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking that is the subject of these corrections is under section 401(a)(9) of the Internal Revenue Code.

Need for Correction

As published, REG-209463-82 contains errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (REG-209463-82), which is the subject of FR Doc. 97-33393, is corrected as follows:

§ 1.409(a)(9)-1 [Corrected]

1. On page 67783, § 1.409(a)(9)-1 is corrected as set out in the following table:

Section	Location	Incorrect language	Corrected language
1.409(a)(9)-1	Q&A D-5, column 2, paragraph (a) of A, line 10.	"paragraph (b) of this D-5A are met,"	"paragraph (b) of this D-5 are met,"
1.409(a)(9)-1	Q&A D-5, column 2, paragraph (a) of A., line 24.	"paragraph (b) of this D-5A are not met,"	"paragraph (b) of this D-5 are not met,"
1.409(a)(9)-1	Q&A D-5, column 3, paragraph (c) of A., line 10 from the top of the column.	"5A are satisfied with respect to such".	"5 are satisfied with respect to such"
1.409(a)(9)-1	Q&A D-6, column 3, paragraph (a) of A., line 3.	"requirements of paragraph (b) of D-5A".	"requirements of paragraph (b) of D-5"
1.409(a)(9)-1	Q&A D-6, column 3, paragraph (a) of A., line 13 from the bottom of the paragraph.	"5A of this section are satisfied with".	"5 of this section are satisfied with"
1.409(a)(9)-1	Q&A D-6, column 3, paragraph (a) of A., line 8 from the bottom of the paragraph.	"paragraph (b) of D-5A of this section are".	"paragraph (b) of D-5 of this section are"

2. On page 67784, § 1.409(a)(9)–1 is corrected as set out in the following table:

Section	Location	Incorrect language	Corrected language
1.409(a)(9)–1	Q&A D–7, column 1, paragraph (a) of A., line 4.	“(b)(4) of D–5A of this section for”.	“(b)(4) of D–5 of this section for”
1.409(a)(9)–1	Q&A D–7, column 1, paragraph (a) introductory text of A., last line of the paragraph.	“(2) of this D–7A:”	“(2) of this D–7:”
1.409(a)(9)–1	Q&A D–7, column 1, paragraph (a)(2)(ii) of A., line 5.	“and (3) of D–5A of this section are”.	“and (3) of D–5 of this section are”
1.409(a)(9)–1	Q&A D–7, column 1, paragraph (b)(1) of A., second line from the bottom of the column.	“paragraph (b)(1), (2), and (3) of D–5A of”.	“paragraph (b)(1), (2) and (3) of D–5 of”
1.409(a)(9)–1	Q&A D–7, column 2, paragraph (c)(1) of A., line 6.	“(a)(1), (a)(2), or (b) of this D–7A, a plan”.	“(a)(1), (a)(2), or (b) of this D–7, a plan”
1.409(a)(9)–1	Q&A D–7, column 2, paragraph (c)(1) of A., line 10 from the bottom of the paragraph.	“requirements of paragraph (b) of D–5A”.	“requirements of paragraph (b) of D–5”

Cynthia E. Grigsby,
 Chief, Regulations Unit, Assistant Chief Counsel (Corporate).
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[FRL–5985–5]

Operating Permits Program; Notice of Availability of Draft Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability.

SUMMARY: The EPA is allowing public review and comment on the draft preamble and sections of the draft revisions to the operating permits regulations in 40 CFR part 70. The regulatory sections available for comment include those dealing with definitions, applicability, permit programs, permit applications, and permit content, among others, but do not include those associated with permit revisions or permit review by EPA, affected States, and the public. The draft revised sections being made available for review are the same as those contained in the May 14, 1997 draft preamble and regulatory revisions, which were announced as available for review in a June 3, 1997 **Federal Register** notice. The EPA is making these sections available for comment now so that any public comments may be considered before the close of stakeholder discussions. Draft revisions to the sections on permit revisions and permit review by EPA, affected States, and the public will be made available in the future.

DATES: Comments on the draft preamble and regulatory revisions must be received by April 24, 1998.

ADDRESSES: The draft preamble and regulatory revisions are available in EPA’s Air Docket number A–93–50 as

items VI–A–4 and VI–A–5, respectively. This docket is available for public inspection and copying between 8:30 a.m. and 3:30 p.m., Monday through Friday, at the address listed below. A reasonable fee may be charged for copying. The address of the EPA air docket is: EPA Air Docket (6102), Attention: Docket Number A–93–50, Room M–1500, Waterside Mall, 401 M Street SW, Washington, DC, 20460.

The drafts may also be downloaded from the Internet at: <http://www.epa.gov/ttn/oarpg/t5pgm.html>.

Comments on the materials referenced in today’s notice must be mailed (in duplicate if possible) to: EPA Air Docket (6102), Attention: Docket No. A–93–50, at the above address. Please identify comments as concerning today’s notice of availability of items VI–A–4 and VI–A–5.

FOR FURTHER INFORMATION CONTACT: Ray Vogel (telephone 919–541–3153) or Roger Powell (telephone 919–541–5331), Mail Drop 12, EPA, Information Transfer and Program Integration Division, Research Triangle Park, North Carolina, 27711. Internet addresses are: vogel.ray@epa.gov and powell.roger@epa.gov.

SUPPLEMENTARY INFORMATION: The part 70 operating permits regulations were originally promulgated on July 21, 1992 (57 FR 32250). Revisions to part 70 were proposed on August 29, 1994 (59 FR 44460) and August 31, 1995 (60 FR 45530). On May 13, 1997, the Agency released a draft of the final preamble and regulatory revision rulemaking that would revise part 70 for purposes of considering any final comments from interested parties before final action. The draft rulemaking reflected EPA’s consideration of comments on the 1994 and 1995 proposals, and included additional regulatory changes that EPA

believed appropriate based on comments. Availability of the May 13, 1997 draft and a 30-day public comment period was announced in a June 3, 1997 **Federal Register** notice (62 FR 30289).

Subsequently, after discussing the draft rulemaking with industry, environmental, and State/local permitting agency representatives (“stakeholders”), EPA decided that additional changes were necessary, particularly to the section on permit revision procedures. Consequently, EPA announced in a July 3, 1997 notice (62 FR 36039) that the public should withhold comment on the May 1997 draft until a new draft was prepared.

Since May 1997, EPA has discussed with stakeholders alternative approaches to the permit revision system contained in the May draft. While the discussions with stakeholders to date have involved the provisions of §§ 70.7 and 70.8, EPA also wants to discuss with the stakeholders any concerns with the remaining sections. To prepare for those discussions, it is important to be aware of concerns from the public at large on the remaining sections. Therefore, this notice announces availability of the remaining sections of part 70 for public review. The preamble and regulatory revisions related to §§ 70.7 and 70.8 will be made available in a future **Federal Register** notice of availability.

Items VI–A–4 and VI–A–5 in docket A–93–50 contain the portions of the preamble and regulations for the revisions that may be made to §§ 70.2 through 70.6 and §§ 70.9 through 70.11 of the part 70 regulations. That material is also available on the Internet at the address noted above. As in the June 3, 1997 notice, EPA seeks comment only on regulatory revisions that have changed since the August 1994 and