

TABLE 1—INTRAVENOUS CATHETER FORCE-ACTIVATED SEPARATION DEVICE RISKS AND MITIGATION MEASURES—Continued

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation, Pyrogenicity testing, and Non-clinical performance testing.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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 assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 880.5220 to read as follows:

§ 880.5220 Intravenous catheter force-activated separation device.

(a) *Identification.* An intravenous catheter force-activated separation device is placed in-line with an intravenous (IV) catheter and an intravascular administration set, including any administration set accessories. It separates into two parts when a specified force is applied. The device is intended to reduce the risk of IV catheter failure(s) requiring IV catheter replacement.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Performance data must be provided to demonstrate clinically acceptable performance for the intended use of the device.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

- (i) Separation force testing;
 - (ii) Validation of anti-reconnect features;
 - (iii) Air and liquid leakage testing, both before and after separation;
 - (iv) Luer connection testing;
 - (v) Flow rate testing;
 - (vi) Particulate testing; and
 - (vii) Microbial ingress testing.
- (3) The device must be demonstrated to be biocompatible.

(4) Performance testing must demonstrate that the device is sterile and non-pyrogenic.

(5) Performance testing must support the shelf life of the device by demonstrating continued sterility and device functionality over the identified shelf life.

(6) Device labeling must include:
 (i) Instructions for use; and
 (ii) A discussion of catheter dressings intended to be used with the device.

Dated: August 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9998]

RIN 1545–BQ62

Increased Amounts of Credit or Deduction for Satisfying Certain Prevailing Wage and Registered Apprenticeship Requirements; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule; correction.

SUMMARY: This document contains corrections to Treasury Decision 9998 published in the **Federal Register** on Tuesday, June 25, 2024. Treasury Decision 9998 sets forth final regulations regarding the increased credit amounts or the increased deduction amount available for taxpayers satisfying prevailing wage and registered apprenticeship (collectively, PWA) requirements established by the Inflation Reduction Act of 2022.

DATES:

Effective date: These corrections are effective on August 26, 2024.

Applicability date: For date of applicability, see §§ 1.30C–3(c), 1.45–6(d), 1.45–7(e), 1.45–8(h), 1.45–12(f), 1.45L–3(c), 1.45Q–6(c), 1.45U–3(c), 1.45V–3(c), 1.45Y–3(c), 1.45Z–3(c), 1.48C–3(b), 1.179D–3(c).

FOR FURTHER INFORMATION CONTACT:

Concerning these final regulations, Barbara Campbell or Nicole Cimino of the Office of the Associate Chief Counsel (Passthroughs & Special Industries) at (202) 317–6853 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9998) subject to these corrections are issued under sections 30C, 45, 45L, 45Q, 45U, 45V, 45Y, 45Z, 48C, and 179D of the Internal Revenue Code.

Correction of Publication

Accordingly, the final regulations (TD 9998) that are the subject of FR Doc. 2024–13331, published on Tuesday, June 25, 2024, at 89 FR 53184 are corrected as follows:

1. On page 53184, in the second column, in the third line of the second full paragraph, the language “credits” is corrected to read “credit”.
2. On page 53187, in the first column, under the heading “*IV. Prior Guidance*”, in the fifth line from the top of the paragraph, the language “credits” is corrected to read “credit”.
3. On page 53188, in the first column, in the second line from the bottom of the column, the language “grammatical or stylistic” is corrected to read “grammatical and stylistic”.
4. On page 53193, in the second column, in the eleventh line from the top of the column, the language “applicable” is corrected to read “applicable”.
5. On page 53196, in the first column, the sixth line from the top of the column is corrected to read “equivalent under the DBA, looks solely at”.
6. On page 53196, in the third column, the sixth line from the bottom of the column is corrected to read “definition of a qualified facility under”.
7. On page 53199, in the third column, the thirteenth line from the bottom of the column is corrected to read “laborer or mechanic”.
8. On page 53200, in the first column, the fourteenth line from the bottom of the column is corrected to read “but not all of the requests for qualified”.
9. On page 53204, in the first column, in the nineteenth line from the bottom of the column, the language “a” is removed.
10. On page 53204, in the first column, the third line from the bottom of the column is corrected to read “prevailing rates in accordance with”.
11. On page 53205, in the third column, the last line of the footnote is corrected to read “of section 179D(f); and in each case including any”.
12. On page 53209, in the first column, the tenth line from the top of the column is corrected to read “determinations is <https://www.sam.gov>”.
13. On page 53210, in the third column, the fifth line of the first full

paragraph is corrected to read “the greatest number of laborers or”.

14. On page 53213, in the third column, in the fifth line of the first full paragraph, the language “apprenticeships” is corrected to read “apprentices”.

15. On page 53222, in the first column, in the fifth line from the top of the first full paragraph, the language “and amount” is removed.

16. On page 53225, in the first column, in the first line of the column, the language “applies” is corrected to read “apply”.

17. On page 53228, in the third column, the fourth line from the bottom of the second full paragraph is corrected to read “apprenticeship agency pursuant to 29 CFR”.

18. On page 53233, in the third column, in the second line of the footnote, the language “an NPRM” is corrected to read “a notice of proposed rulemaking”.

19. On page 53235, in the first column, the fourth line of last partial paragraph is corrected to read “programs. Under section 45(b)(8)(D)(ii), to”.

20. On page 53238, in the first column, the fourth line from the bottom of the partial paragraph is corrected to read “Under section 30C(c)(g)(3), rules similar”.

21. On page 53242, in the third column, in the sixth line of the second full paragraph, the language “48C(c)(2)” is corrected to read “section 48C(c)(2)”.

22. On page 53243, in the first column, in third line from the bottom of the first partial paragraph, the language “179D(b)” is corrected to read “section 179D(b)”.

23. On page 53244, in the second column, the fourth line of the last partial paragraph is corrected to read “suggested that the final regulations”.

24. On page 53246, in the third column, the fifth line from the second full paragraph is corrected to read “as it applies to facilities, property, projects”.

25. On page 53247, in the third column, the sixth line of the second full paragraph is corrected to read “preamble to the notice of proposed rulemaking estimated these”.

26. On page 53248, in the second column, in the sixth line of the third paragraph, the language “paying” is removed.

27. On page 53248, in the second column, in the seventh line of the third paragraph, the language “qualified” is corrected to read “of qualified”.

28. On page 53248, in the third column, in the third line from the top of the column, the language “be” is removed.

29. On page 53249, in the second column, the ninth line of the second full paragraph is corrected to read “data includes approximately 18 million”.

30. On page 53249, in the second column, the eleventh line of the second full paragraph is corrected to read “the tax data includes more small”.

31. On page 53249, in the second column, the thirteenth line of the second full paragraph is corrected to read “one employee. Tax data provides a more”.

32. On page 53249, in the second column, the sixteenth line of the second full paragraph is corrected to read “tax data is an appropriate resource for”.

33. On page 53250, in the third column, the seventh line from the bottom of the first full paragraph is corrected to read “rates. Commenters suggested that the”.

34. On page 53251, in the first column, the fourth line from the bottom of the first full paragraph is corrected to read “processes for setting standards are”.

PART 1 [Corrected]

■ 35. On page 53251, in the third column, in amendatory instruction 1 for part 1, “§ 1.48C–3,” is removed.

§§ 1.45–9—1.45–12 [Corrected]

■ 36. On page 53252, in the first column, in amendatory instruction 3 for §§ 1.45–9 through 1.45–12, in the table of contents for the sections, the text “1.45–9—1.45.11 [Reserved]” is corrected to read “1.45–9—1.45–11 [Reserved]”.

§ 1.45–7 [Corrected]

- 37. In amendatory instruction 3, in § 1.45–7:
- i. On page 53255, in the first column, the fourteenth line from the bottom of paragraph (b)(5) is corrected to read “repair starts within 180 days of”.
 - ii. On page 53255, in the third column, the fifth line from the bottom of paragraph (b)(7)(i) is corrected to read “Wage Requirements by paying”.
 - iii. On page 53257, in the first column, the tenth line of paragraph (c)(1)(vi)(C) is corrected to read “facility for 22 weeks in 2023 and was paid”.
 - iv. On page 53257, in the second column, the seventh line of paragraph (c)(3)(i) introductory text is corrected to read “the requirements—”.
 - v. On page 53258, in the first column, the ninth line from the bottom of paragraph (c)(3)(i)(f) is corrected to read “action, and whether the taxpayer”.
 - vi. On page 53258, in the second column, the seventeenth line from the bottom of paragraph (c)(3)(iv)(A) is

corrected to read “wages paid to any laborers and”.

■ vii. On page 53260, in the third column, the sixth line from the bottom of paragraph (c)(6)(iv)(E) is corrected to read “period of August 1, 2023, to September”.

§ 1.45–8 [Corrected]

■ 38. In amendatory instruction 3, in § 1.45–8:

■ i. On page 53262, in the third column, the third line from the bottom of paragraph (b)(1) is corrected to read “dividing the total hours worked by all”.

■ ii. On page 53265, in the third column, the third line of paragraph (f)(2)(i)(A) is corrected to read “failures to meet the percentage of the total”.

■ iii. On page 53266, in the first column, last line of the partial paragraph (f)(2)(i)(A) is corrected to read “Exception.”.

■ iv. On page 53266, in the third column, the sixth line from bottom of paragraph (f)(2)(i)(D)(2) is corrected to read “(5) on the construction of the”.

■ v. On page 53267, in the third column, the fourth line of paragraph (f)(2)(ii)(C)(13) is corrected to read “Apprenticeship Requirements for”.

■ vi. On page 53268, in the first column, the sixth line of paragraph (f)(2)(ii)(D)(1) is corrected to read “include contract provisions that require”.

§ 1.45U–3 [Corrected]

■ 39. On page 53271, in the second column, in amendatory instruction 6, in § 1.45U–3, the second line of paragraph (b)(1) is corrected to read “agreement with one or more labor”.

Regina L. Johnson, Federal Register Liaison, Publications and Regulations Section, Associate Chief Counsel, (Procedure and Administration). [FR Doc. 2024–17143 Filed 8–15–24; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 9988]

RIN 1545–BQ63

Elective Payment of Applicable Credits; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule; correction and correcting amendments.

SUMMARY: This document contains corrections to Treasury Decision 9988,

which was published in the Federal Register for Monday, March 11, 2024. Treasury Decision 9988 issued final regulations concerning the election under the Inflation Reduction Act of 2022 to treat the amount of certain tax credits as a payment of Federal income tax.

DATES: These corrections are effective on August 16, 2024 and for dates of applicability see §§ 1.6417–1(q), 1.6417–2(f), 1.6417–3(f), 1.6417–4(f), 1.6417–5(d), 1.6417–6(e), 301.6241–1(b)(1), and 301.6241–7(k)(3).

FOR FURTHER INFORMATION CONTACT: Concerning these final regulations, Jeremy Milton at (202) 317–5665 and James Holmes at (202) 317–5114 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9988) that are the subject of this correction are under section 6417 of the Code.

Corrections to Publication

Accordingly, the final regulations (TD 9988) that are the subject of FR Doc. 2024–04604, published on March 11, 2024, are corrected to read:

1. On page 17550, in the first column, in the fourth line from the top of the first full paragraph, the language “designed” is corrected to read “designated”.

2. On page 17552, in the third column, in the eighth line from the bottom of the first full paragraph, the language “cert denied” is corrected to read “cert. denied”.

3. On page 17559, in the third column, in the twelfth line from the top of the first partial paragraph, the language “[]” is corrected to read “...”.

4. On page 17560, in the first column, in the tenth line from the top of the first partial paragraph, the language “book” is corrected to read “books”.

5. On page 17561, in the second column, in the eighth line from the bottom of the last partial paragraph, the language “tax-exempt” is corrected to read, “tax exempt”.

6. On page 17561, in the third column, in the fifteenth line from the top of the first partial paragraph, the language “tax-exempt” is corrected to read “tax exempt”.

7. On page 17562, in the second column, the third line from the bottom of the second full paragraph is corrected to read, “so as not to incur an addition to tax due”.

8. On page 17575, in the first column, in the tenth line from the top of the first partial paragraph, the language “tax-exempt” is corrected to read “tax exempt”.

9. On page 17577, in the second column, in the tenth line from the top of the first full paragraph, the language “Section” is corrected to read “part”.

10. On page 17581, in the third column, the second line from the bottom of the last partial paragraph the language “Section” is corrected to read “section”.

11. On page 17582, in the third column, the last sentence of the first full paragraph is corrected to read, “Although there is uncertainty as to the exact number of small businesses within this group, the current estimated number of respondents to these final rules is 20,000 taxpayers.”.

12. On page 17583, in the first column, in the fourth line the from the bottom of the second full paragraph, the column is corrected to read, “verified or have received registration”.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Corrections to the Regulations

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ Paragraph 1. The authority citation for part 1 is amended by adding the entries for Sections 1.6417–0 through 1.6417–6 in numerical order and removing the entry for section 1.6417–5T to read in part as follows:

- Authority: 26 U.S.C. 7805 * * * * *
* * * * *
Section 1.6417–0 also issued under 26 U.S.C. 6417(h).
Section 1.6417–1 also issued under 26 U.S.C. 6417(h).
Section 1.6417–2 also issued under 26 U.S.C. 6417(h).
Section 1.6417–3 also issued under 26 U.S.C. 6417(h).
Section 1.6417–4 also issued under 26 U.S.C. 6417(h).
Section 1.6417–5 also issued under 26 U.S.C. 6417(h).
Section 1.6417–6 also issued under 26 U.S.C. 6417(h).
* * * * *

■ Par. 2. Section 1.6417–0 is amended by revising the entry for § 1.6417–1(b) to read as follows:

§ 1.6417–0 Table of contents.
* * * * *

§ 1.6417–1 Elective payment election of applicable credits.
* * * * *

(b) Annual tax return.
* * * * *