

control number 0910–0437. The collections of information in the UDI rule have been approved under OMB control number 0910–0720.

The information collection provisions in the eMDR rule have been submitted to OMB for review as required by section 3507(d) of the PRA (44 U.S.C. 3507(d)). Before the effective date of the final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 803 as amended by the Medical Device Reporting: Electronic Submission Requirements final rule of February 14, 2014, 79 FR 8832, is further amended as follows:

PART 803—MEDICAL DEVICE REPORTING

■ 1. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 2. Amend § 803.3 by adding paragraphs (aa) and (bb) to read as follows:

§ 803.3 How does FDA define the terms used in this part?

* * * * *

(aa) *Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device* means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

(bb) *Unique device identifier (UDI)* means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A *unique device identifier* is composed of:

(1) A *device identifier*—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and

(2) A *production identifier*—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(i) The lot or batch within which a device was manufactured;

(ii) The serial number of a specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

* * * * *

■ 3. Amend § 803.11 by revising paragraph (d) to read as follows:

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

* * * * *

(d) Form FDA 3500A is available on the Internet at <http://www.fda.gov/medwatch/getforms.htm> or from Division of International and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, Silver Spring, MD 20993–0002, by email: DICE@fda.hhs.gov, FAX: 301–847–8149, or telephone: 800–638–2041.

■ 4. Amend § 803.32 by revising paragraph (c)(4) to read as follows:

§ 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?

* * * * *

(c) * * *

(4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

■ 5. Amend § 803.33 by revising paragraphs (a)(2) and (b)(7)(iv) to read as follows:

§ 803.33 If I am a user facility, what must I include when I submit an annual report?

* * * * *

(a) * * *

(2) Division of International and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, Silver Spring, MD 20993–0002, by email: DICE@fda.hhs.gov, FAX: 301–847–8149, or telephone: 800–638–2041.

* * * * *

(b) * * *

(7) * * *

(iv) Product model, catalog, serial, and lot number and unique device

identifier (UDI) that appears on the device label or on the device package;

* * * * *

■ 6. Amend § 803.42 by revising paragraph (c)(4) to read as follows:

§ 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

* * * * *

(c) * * *

(4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

■ 7. Amend § 803.52 by revising paragraph (c)(4) to read as follows:

§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

* * * * *

(c) * * *

(4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

Dated: February 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03943 Filed 2–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9712]

RIN 1545–BL78

Alternative Simplified Credit Election

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations relating to the election of the alternative simplified credit under section 41(c)(5) of the Internal Revenue Code (Code). The final regulations affect certain taxpayers claiming the credit under section 41.

DATES: *Effective Date:* These regulations are effective on February 27, 2015.

Applicability Date: For dates of applicability, see § 1.41–9(d).

FOR FURTHER INFORMATION CONTACT: David Selig (202) 317-4137 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends 26 CFR part 1 to provide rules relating to the time and manner of electing the alternative simplified credit (ASC) under section 41(c)(5) of the Internal Revenue Code (Code).

Section 41(a) provides an incremental tax credit for increasing research activities (research credit) based on a percentage of a taxpayer's qualified research expenses above a base amount. A taxpayer can apply the rules and credit rate percentages under section 41(a)(1) to calculate the credit (commonly referred to as the regular credit) or a taxpayer can make an election to apply the ASC rules and credit rate percentages under section 41(c)(5) to calculate the credit. Section 41(c)(5)(C) provides that an ASC election under section 41(c)(5) applies to the taxable year for which it is made and all succeeding taxable years unless revoked with the consent of the Secretary.

On June 10, 2011, the Treasury Department and the IRS published final regulations (TD 9528) (2011 Final Regulations) in the **Federal Register** (76 FR 33994) relating to the election and calculation of the ASC. Section 1.41-9(b)(2) provides that a taxpayer makes an election under section 41(c)(5) by completing the portion of Form 6765, "Credit for Increasing Research Activities," (or successor form) relating to the ASC election, and attaching the completed form to the taxpayer's timely filed (including extensions) original return for the taxable year to which the election applies. Section 1.41-9(b)(2) also provides that a taxpayer may not make an election under section 41(c)(5) on an amended return and that an extension of time to make an election under section 41(c)(5) will not be granted under § 301.9100-3.

Following the publication of the 2011 Final Regulations, the Treasury Department and the IRS received requests to amend the regulations to allow taxpayers to make an ASC election on an amended return. The requests explained that the burden of substantiating expenditures and costs for the base period under the regular credit can be costly, time-consuming, and difficult, and suggested that taxpayers often need additional time to determine whether to claim the regular credit or the ASC.

On June 3, 2014, the Treasury Department and the IRS published a

notice of proposed rulemaking by cross-reference to temporary regulations (REG-133495-13) in the **Federal Register** (79 FR 31892), and final and temporary regulations (TD 9666) (the Temporary Regulations) in the **Federal Register** (79 FR 31863). The final regulations removed the rule in § 1.41-9(b)(2) that prohibited a taxpayer from making an ASC election for a tax year on an amended return. In its place, the Temporary Regulations provided a rule allowing a taxpayer to make an ASC election for a tax year on an amended return if the taxpayer had not previously claimed a section 41 credit for that tax year on an original or amended return. In addition, the Temporary Regulations provided that a taxpayer that is a member of a controlled group in a tax year may not make an election under section 41(c)(5) for that tax year on an amended return if any member of the controlled group for that year claimed the research credit using a method other than the ASC on an original or amended return.

Written and electronic comments responding to the proposed regulations were received. No requests for a public hearing were made and no public hearing was held. After consideration of all the comments, the proposed regulations are adopted as revised by this Treasury decision.

Summary of Comments and Explanation of Provisions

Interaction With Section 280C Elections

A commenter requested clarification regarding whether a section 280C(c)(3) election made for a taxable year on line 17 of Form 6765, Credit For Increasing Research Activities, where no amount of regular credit is claimed, will be viewed by the IRS as a claim of the section 41(a)(1) credit and preclude an ASC election from being made on an amended return for that taxable year. Section 280(c)(3) allows a taxpayer to make an annual irrevocable election to claim a reduced research credit rather than reducing the section 174 deduction, as required by section 280(c)(1). A section 280C(c)(3) election must be made on an original return. If a taxpayer is undecided whether to claim the regular credit for a taxable year but wants to preserve the operative effect of the section 280C(c)(3) election for that taxable year, then the taxpayer will make the section 280C(c)(3) election on line 17 of Form 6765, but leave the remaining section of the form blank. A section 280C(c)(3) election on line 17 of Form 6765 made in a taxable year does not, in and of itself, constitute a credit claim under section 41(a)(1),

and accordingly does not preclude a taxpayer from making an ASC election on an amended return for that taxable year.

Section 9100 Relief

One commenter requested that the final regulations allow an extension of time to make an election under section 41(c)(5) under § 301.9100-3. Under § 301.9100-3(c), the Commissioner will grant a reasonable extension of time to make a regulatory election only when the interests of the Government will not be prejudiced by the granting of relief. Under § 301.9100-3(c)(1)(ii), the interests of the Government are ordinarily prejudiced if the taxable year in which the regulatory election should have been made or any taxable years that would have been affected by the election had it been timely made are closed by the period of limitations on assessment under section 6501(a) before the taxpayer's receipt of a ruling granting relief under this section. Because the final regulations allow a taxpayer to amend its return to make the ASC election in a taxable year that is not closed by the period of limitations for assessment under section 6501(a) if no credit under section 41(a)(1) was claimed in the prior taxable year on an original or amended return, an extension of time under § 301.9100-3 to make the ASC election is not necessary during this period. An extension of time to make an ASC election in a taxable year closed by the period of limitations on assessment under section 6501(a) ordinarily prejudices the interests of the government. See section 301.9100-3(c)(1)(ii). Accordingly, the final regulations retain the rule that an extension of time to make an election under section 41(c)(5) will not be granted under § 301.9100-3.

Period for Making an ASC Election

One commenter requested that the final regulations provide that a taxpayer may make an ASC election for an earlier, closed tax year on a later year's return in which a research credit from that closed year is reported on a carryforward schedule, or actually used as a credit against tax, so long as no intervening amended return claiming a research credit for that tax year using a different method has been claimed. The Temporary Regulations only permitted a taxpayer to elect the ASC on an amended return for taxable years ending before June 3, 2014, (the effective/applicability date of those regulations) if the taxpayer makes the election before the period of limitations for assessment of tax has expired for that year. The rule in the Temporary Regulations provided

a reasonable time period for taxpayers to determine whether or not to make an ASC election with respect to a prior, open tax year. To permit a taxpayer to make an ASC election for a tax year in which the period of limitations for assessment of tax has expired has the practical effect of permitting the taxpayer to make an ASC election on a return that cannot be amended. Therefore, these final regulations do not adopt this suggested modification.

One commenter requested that these final regulations provide that an ASC election can be made on an amended return for a tax year so long as the period for making a refund claim under section 6511 has not expired for that tax year, even in cases where the statute of limitations on assessment under section 6501 is closed. These final regulations retain the rule of the Temporary Regulations that a taxpayer must make an ASC election on an amended return before the statute of limitations on assessment under section 6501(a) is closed. The general period under the statute of limitations on assessment under section 6501(a), which is three years after the tax return is filed, provides a reasonable time for taxpayers to file an ASC election on an amended return, and a reasonable time for the IRS to examine the amended return. This rule also preserves the integrity of the rule in the final regulations providing that an extension of time to make an election under section 41(c)(5) will not be granted under § 301.9100-3. Under § 301.9100-3, the interests of the government are ordinarily prejudiced if the taxable year in which a regulatory election should have been made or any taxable years that would have been affected by the election had it been timely made are closed by the period of limitations on assessment under section 6501(a) before the taxpayer's receipt of a ruling granting relief under § 301.9100. This requirement is mitigated by the fact that the period of limitations on assessment may be extended by agreement of the IRS and the taxpayer. For clarity, the language found in the effective date of the Temporary Regulations referencing the period of limitations for assessment of tax is added to the text of the final regulations under § 1.41-9(b)(2) relating to the time and manner of making the ASC election.

Controlled Group ASC Elections

One commenter requested that the final regulations modify the rules for controlled group ASC elections under § 1.41-9(b)(4), under which only the designated member of a controlled group may make or revoke an ASC

election. Revising those rules is beyond the scope of these regulations. Therefore, the final regulations do not amend § 1.41-9(b)(4).

Modification of the Election Rule

One commenter requested that these final regulations amend the rule in the Temporary Regulations that allows a taxpayer to make an ASC election for a tax year on an amended return only if the taxpayer has not previously claimed the section 41 credit on its original return or an amended return for that tax year to clarify that the previously claimed section 41 credit is determined under section 41(a)(1), and not under sections 41(a)(2) or (3). The commenter stated that the ASC is an alternative method to the regular credit under section 41(a)(1), and whether a taxpayer elects the ASC or claims the regular credit does not impact the determination of the credits allowable under sections 41(a)(2) and 41(a)(3). This approach is consistent with the language of section 41(c)(5)(A) and § 1.41-9(a), which specifically reference section 41(a)(1). Accordingly, the final regulations provide that a taxpayer may make an ASC election for a tax year on an amended return only if the taxpayer has not previously claimed the section 41(a)(1) credit on its original return or an amended return for that tax year.

Effect on Other Documents

The Temporary Regulations are obsolete for taxable years beginning on or after February 27, 2015.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. 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. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. Although a substantial number of small entities may make an ASC election on an amended return pursuant to these regulations, the economic impact of any collection burden on these entities relating to this election is minimal because the regulations will result in a benefit to taxpayers by providing additional time for taxpayer to calculate and elect the ASC. Accordingly, a regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is

not required. Pursuant to section 7805(f) of the Code, these regulations have been 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 David Selig, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

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

Section 1.41-9 also issued under 26 U.S.C. 41(c)(5)(C). * * *

■ **Par. 2.** Section 1.41-9 is amended by:
 ■ 1. Revising paragraph (b)(2).
 ■ 2. Adding a third and fourth sentence to paragraph (d).

The revision and addition read as follows:

§ 1.41-9 Alternative simplified credit.

* * * * *

(b) * * *

(2) *Time and manner of election.* A taxpayer makes an election under section 41(c)(5) by completing the portion of Form 6765, "Credit for Increasing Research Activities," (or successor form) relating to the election of the ASC, and attaching the completed form to the taxpayer's timely filed (including extensions) original return for the taxable year to which the election applies. A taxpayer may make an election under section 41(c)(5) for a tax year on an amended return, but only if the taxpayer has not previously claimed a section 41(a)(1) credit on its original return or an amended return for that tax year, and only if that tax year is not closed by the period of limitations on assessment under section 6501(a). An extension of time to make an election under section 41(c)(5) will not be granted under § 301.9100-3 of this chapter. A taxpayer that is a member of a controlled group in a tax year may not make an election under section 41(c)(5) for that tax year on an amended return

if any member of the controlled group for that tax year previously claimed the research credit under section 41(a)(1) using a method other than the ASC on an original or amended return for that tax year. See paragraph (b)(4) of this section for additional rules concerning controlled groups. See also § 1.41–6(b)(1) requiring that all members of the controlled group use the same method of computation.

* * * * *

(d) *Effective/applicability date.* * * * Paragraph (b)(2) of this section applies to elections with respect to taxable years ending on or after February 27, 2015. For taxable years ending before February 27, 2015, see § 1.41–9T as contained in 26 CFR part 1, revised April 1, 2015.

§ 1.41–9T [Removed]

■ **Par. 3.** Section 1.41–9T is removed.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: February 3, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2015–04111 Filed 2–26–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2014–1070]

RIN 1625–AA09

Drawbridge Operation Regulation; Passaic River, Rutherford, NJ

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the existing drawbridge operation regulation for the drawbridge across the Passaic River, mile 11.8, at Rutherford, New Jersey. The drawbridge was converted to a fixed bridge in October 2010, and the operating regulation is no longer applicable or necessary.

DATES: This rule is effective February 27, 2015.

ADDRESSES: The docket for this final rule, [USCG–2014–1070] is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this final rule. You may also visit the Docket Management Facility in

Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Joe Arca, Project Officer, First Coast Guard District Bridge Program, telephone 212–514–4336, email joe.m.arca@uscg.mil. If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

A. Regulatory History and Information

The Coast Guard is issuing this final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Route 3 Bridge, that once required draw operations in 33 CFR 117.739(n), was converted to a fixed bridge in October 2010. Therefore, the regulation is no longer applicable and shall be removed from publication. It is unnecessary to publish an NPRM because this regulatory action does not purport to place any restrictions on mariners but rather removes a restriction that has no further use or value.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. The bridge has been a fixed bridge for 4 years and this rule merely requires an administrative change to the **Federal Register**, in order to omit a regulatory requirement that is no longer applicable or necessary.

B. Basis and Purpose

The Route 3 Bridge across the Passaic River, mile 11.8, was converted to a fixed bridge in 2010. It has come to the attention of the Coast Guard that the governing regulation for this drawbridge was never removed subsequent to the conversion to a fixed bridge. The conversion of this drawbridge necessitates the removal of the drawbridge operation regulation, 33

CFR 117.739(n), pertaining to the former drawbridge.

The purpose of this rule is to remove paragraph 33 CFR 117.739(n), that refers to the Route 3 Bridge at mile 11.8, from the Code of Federal Regulations since it governs a bridge that is no longer able to be opened.

C. Discussion of Rule

The Coast Guard is changing the regulation in 33 CFR 117.739 by removing restrictions and the regulatory burden related to the draw operations for this bridge that is no longer a drawbridge. The change removes paragraph 117.739(n) of the regulation which governs the Route 3 Bridge and redesignates (o) through (t) as (n) through (s). This Final Rule seeks to update the Code of Federal Regulations by removing language that governs the operation of the Route 3 Bridge, which in fact no longer is a drawbridge. This change does not affect waterway or land traffic. This change does not affect nor does it alter the operating schedules in 33 CFR 117.739 that govern the remaining active drawbridges on the Passaic River except to redesignate these bridges.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The Coast Guard does not consider this rule to be “significant” under that Order because it is an administrative change and does not affect the way vessels operate on the waterway.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their