

(b) *Iontophoresis device intended for any other purposes*—(1) *Identification*.

An iontophoresis device intended for any other purposes is a prescription device that is intended to use a current to introduce ions of drugs or non-drug solutions into the body for medical purposes other than those specified in paragraph (a) of this section, meaning that the device is not intended for use in diagnosis of cystic fibrosis, or a specific drug is not specified in the labeling of the iontophoresis device.

(2) *Classification*. Class II (special controls). The device is classified as class II. The special controls for this device are:

(i) The following performance testing must be conducted:

(A) Testing using a drug approved for iontophoretic delivery, or a solution, if identified in the labeling, to demonstrate safe use of the device as intended;

(B) Testing of the ability of the device to maintain a safe pH level; and

(C) If used in the ear, testing of the device to demonstrate mechanical safety.

(ii) Labeling must include adequate instructions for use, including sufficient information for the health care provider to determine the device characteristics that affect delivery of the drug or solution and to select appropriate drug or solution dosing information for administration by iontophoresis. This includes the following:

(A) A description and/or graphical representation of the electrical output;

(B) A description of the electrode materials and pH buffer;

(C) When intended for general drug delivery, language referring the user to drug labeling approved for iontophoretic delivery to determine if the drug they intend to deliver is specifically approved for use with that type of device and to obtain relevant dosing information; and

(D) A detailed summary of the device-related and procedure-related complications pertinent to use of the device, and appropriate warnings and contraindications, including the following warning:

Warning: Potential systemic adverse effects may result from use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labeling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action.

(iii) Appropriate analysis/testing must demonstrate electromagnetic compatibility, electrical safety, thermal safety, and mechanical safety.

(iv) Appropriate software verification, validation, and hazard analysis must be performed.

(v) The elements of the device that may contact the patient must be demonstrated to be biocompatible.

(vi) The elements of the device that may contact the patient must be assessed for sterility, for devices labeled as sterile.

(vii) Performance data must support the shelf life of the elements of the device that may be affected by aging by demonstrating continued package integrity and device functionality over the stated shelf life.

Dated: July 20, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9779]

RIN 1545-BM63

Property Transferred in Connection With the Performance of Services

AGENCY: Internal Revenue Service, Department of Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to property transferred in connection with the performance of services. These final regulations affect certain taxpayers who receive property transferred in connection with the performance of services and make an election to include the value of substantially nonvested property in income in the year of transfer.

DATES: *Effective Date:* These regulations are effective on July 26, 2016.

Applicability Date: For dates of applicability, see § 1.83-2(g).

FOR FURTHER INFORMATION CONTACT:

Thomas Scholz or Michael Hughes at (202) 317-5600 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 83 of the Internal Revenue Code (Code) addresses the tax consequences of a transfer of property in connection with the performance of

services. Section 83(a) of the Code provides generally that the excess of the fair market value of the transferred property (determined without regard to any restriction other than a restriction which by its terms will never lapse) as of the first time that the transferee's rights in the property are transferable or are not subject to a substantial risk of forfeiture, whichever occurs earlier, over the amount (if any) paid for the property is included in the service provider's gross income for the taxable year which includes such time. Section 83(b) and § 1.83-2(a) permit the service provider to elect to include in gross income, as compensation for services, the excess (if any) of the fair market value of the property at the time of transfer over the amount (if any) paid for the property. Under section 83(b)(2), an election under section 83(b) must be made in accordance with the regulations thereunder. Under § 1.83-2(c), the election must be filed with the IRS no later than 30 days after the date on which the property is transferred, and a copy of the election must be submitted with the taxpayer's income tax return for the taxable year in which the property is transferred.

On July 17, 2015, the Department of the Treasury (Treasury) and the Internal Revenue Service (IRS) published a notice of proposed rulemaking (REG-135524-14) in the **Federal Register** (137 FR 42439) under section 83 of the Code eliminating the requirement that a copy of a section 83(b) election be submitted with the taxpayer's income tax return for the taxable year in which the property is transferred. Treasury and the IRS received no comments responding to the notice of proposed rulemaking. No public hearing was requested and no public hearing was held. Treasury and the IRS now adopt the proposed regulations as final regulations without modification.

Explanation of Provisions

These final regulations remove the second sentence in § 1.83-2(c) of the existing regulations, which requires that a taxpayer submit a copy of a section 83(b) election with the taxpayer's tax return for the year in which the property subject to the election was transferred. Accordingly, under these final regulations, a taxpayer is no longer required to file a copy of a section 83(b) election with the taxpayer's income tax return.

Taxpayers are reminded of their general recordkeeping responsibilities pursuant to section 6001 of the Code, and more specifically of the need to keep records that show the basis of property owned by the taxpayer.

Taxpayers must maintain sufficient records to show the original cost of the property and to support the tax treatment of the property transfer reported on the taxpayers' returns. Taxpayers must keep these records as long as they may be needed for the administration of any provision of the Code. Generally, this means records that support items shown on a return must be retained until the period of limitations for that return expires. See section 6501 of the Code. A copy of any section 83(b) election made with respect to property must be kept until the period of limitations expires for any return with respect to which the income inclusion or basis of the property is relevant.

Applicability Date

These regulations apply to property transferred on or after January 1, 2016. For transfers of property on or after January 1, 2015 and prior to January 1, 2016, the preamble to the proposed regulations provides that taxpayers may rely on the guidance in the proposed regulations (which is identical to the guidance contained in these final regulations).

Effect on Other Documents

Rev. Proc. 2012–29 (IRB 2012–28, 49) states that a taxpayer making a section 83(b) election must submit a copy of the election with his or her tax return for the taxable year in which such property was transferred. Effective as of July 26, 2016, Rev. Proc. 2012–29 is revoked, in part, to the extent it requires, inconsistent with these final regulations, a taxpayer to submit a copy of a section 83(b) election with his or her income tax return.

Statement of Availability of IRS Documents

Rev. Proc. 2012–29 is published in the Internal Revenue Bulletin (or Cumulative Bulletin) and is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or by visiting the IRS Web site at <http://www.irs.gov>.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact 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 the 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 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 authors of these final regulations are Thomas Scholz and Michael Hughes, Office of the Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and the Treasury participated in their development.

List of Subjects 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 * * *

■ **Par. 2.** Section 1.83–2 is amended by revising paragraph (c) and adding paragraph (g) to read as follows:

§ 1.83–2 Election to include in gross income in year of transfer.

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(c) *Manner of making election.* The election referred to in paragraph (a) of this section is made by filing one copy of a written statement with the internal revenue office with which the person who performed the services files his return.

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(g) *Effective/applicability date.* Paragraph (c) of this section applies to property transferred on or after January 1, 2016.

John M. Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: April 20, 2016.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, and 1926

[Docket No. OSHA–2010–0034]

RIN 1218–AB70

Occupational Exposure to Respirable Crystalline Silica; Approval of Collections of Information

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule; Office of Management and Budget's (OMB) approval of collections of information.

SUMMARY: This rule is a technical amendment announcing that OMB has approved the collections of information contained in OSHA's standards for Occupational Exposure to Respirable Crystalline Silica and revising OSHA's regulations to reflect that approval. The OMB approval number is 1218–0266.

DATES: Effective July 26, 2016.

FOR FURTHER INFORMATION CONTACT: Todd Owen, OSHA, Directorate of Standards and Guidance, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION: OSHA published a final rule for the Occupational Exposure to Respirable Crystalline Silica standards on March 25, 2016 (81 FR 16286), after determining that employees exposed to respirable crystalline silica at the previous permissible exposure limits face a significant risk of material impairment to their health. The evidence in the record for this rulemaking indicates that workers exposed to respirable crystalline silica are at increased risk of developing silicosis and other nonmalignant respiratory diseases, lung cancer, and kidney disease. These requirements are necessary to provide protection from these hazards. The silica final rule becomes effective on June 23, 2016. Start-up dates for specific provisions are set in § 1910.1053(l) for general industry and maritime and in § 1926.1153(k) for construction.

Consistent with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520), the **Federal Register** notice for the Occupational Exposure to Respirable Crystalline Silica final rule states that employers do not have to comply with the collections of information until OMB approves those collections of information and the