(G) Mechanical hemolysis testing must be conducted.

(H) Chemical tolerance of the catheter to repeated exposure to commonly used disinfection agents must be established.

(iii) Performance data must demonstrate the sterility of the device.

(iv) Performance data must support the shelf life of the device for continued sterility, package integrity, and functionality over the requested shelf life that must include tensile, repeated clamping, and leakage testing.

(v) Labeling must bear all information required for the safe and effective use of implanted blood access devices for hemodialysis including the following:

(A) Labeling must provide arterial and venous pressure versus flow rates, either in tabular or graphical format.

(B) Labeling must provide the arterial and venous priming volumes.

(C) Labeling must specify the forward and reverse recirculation rates.

(D) Labeling must specify an expiration date.

(E) Labeling must identify any disinfecting agents that cannot be used to clean any components of the device.

(F) Any contraindicated disinfecting agents due to material incompatibility must be identified by printing a warning on the catheter. Alternatively a label can be provided that can be affixed to the patient's medical record with this information.

(G) The labeling must contain the following information: Comprehensive instructions for the preparation and insertion of the hemodialysis catheter, including recommended site of insertion, method of insertion, a reference on the proper location for tip placement, a method for removal of the catheter, anticoagulation, guidance for management of obstruction and thrombus formation, and site care.

(H) The labeling must identify any coatings or additives and summarize the results of performance testing for any coating or material with special characteristics, such as decreased thrombus formation or antimicrobial properties.

(vi) For subcutaneous devices, the recommended type of needle for access must be described, stated in the labeling, and test results on repeated use of the ports must be provided.

(vii) Coated devices must include a description of the coating or additive material, duration of effectiveness, how the coating is applied, and testing to adequately demonstrate the performance of the coating.

* * * * *

Dated: June 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15504 Filed 6–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–160873–04]

RIN 1545–BF39

American Jobs Creation Act Modifications to Section 6708, Failure To Maintain List of Advisees With Respect to Reportable Transactions; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations relating to the penalty under section 6708 of the Internal Revenue Code for failing to make available lists of advisees with respect to reportable transactions.

DATES: The public hearing originally scheduled for July 2, 2013 at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Oluwafunmilayo Taylor of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and a notice of public hearing that appeared in the **Federal Register** on Friday, March 8, 2013 (78 FR 14939) announced that a public hearing was scheduled for July 2, 2013, at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC. The subject of the public hearing is under section 6708 of the Internal Revenue Code.

The public comment period for these regulations expired on June 6, 2013. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed by June 10, 2013. As of Monday, June 24, 2013, no one has requested to speak. Therefore, the public hearing scheduled for July 2, 2013, is cancelled.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2013–15471 Filed 6–27–13; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2012–0581; A–1–FRL–9827–7]

Approval and Promulgation of Air Quality Implementation Plans; Idaho Amalgamated Sugar Company Nampa BART Alternative

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revised BART determination and an alternate control measure for The Amalgamated Sugar Company, LLC. (TASCO) plant located in Nampa, Canyon County, Idaho, to meet the requirements of Best Available Retrofit Technology (BART) for regional haze. The EPA previously approved the State's BART determination for TASCO as meeting the requirements for the regional haze provisions in the Clean Air Act (CAA) on June 22, 2011. On June 29, 2012, the State of Idaho submitted revisions to its Regional Haze State Implementation Plan that included a revised BART determination for the TASCO facility, a revised emission limitation for particulate matter (PM), and an alternative control measure for TASCO to replace the Federally approved sulfur dioxide (SO_2) BART determination. The EPA proposes to vacate the previously approved SO_2 BART determination for TASCO, approve the revised BART determination, the revised emission limitation, and the alternative control measure at TASCO.

DATES: Written comments must be received on or before July 29, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2012–0581, by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Mail:* Steve Body, EPA, Office of Air, Waste, and Toxics, AWT–107, 1200