

U.S. Federal Register Update: December 19 – 23, 2016

The U.S. Federal Register Update contains summaries of entries in the U.S. Federal Register that may be of particular interest to the standards and conformity assessment community. This update is provided on a weekly basis by ANSI as a service to its members as part of the Institute's e-newsletter, *What's New?*

[Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 046](#)

Published 12/23/2016

Reference ANSI, AAMI, ASTM, IEC, ISO

The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 046" (Recognition List Number: 046), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices. **Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective December 23, 2016.**

[Restart of a Nuclear Power Plant Shut Down by a Seismic Event](#)

Published 12/23/2016

Reference ANSI

On November 3, 2016, the U.S. Nuclear Regulatory Commission (NRC) issued for public comment draft regulatory guide (DG) DG-1337, "Restart of a Nuclear Power Plant Shut Down by a Seismic Event," in the Federal Register for a 60-day public comment period which ends on January 3, 2017. The NRC is extending the public comment period to February 28, 2017, recognizing the potential for unavailability of people during the holiday period. The guide describes methods acceptable to the NRC staff that can be used to demonstrate that a nuclear power plant is safe for restarting after a shutdown caused by a seismic event. **Submit comments by February 28, 2017. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.**

[Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions-Fall 2016](#)

Published 12/23/2016

Reference ANSI, AAMI, ASHRAE, ASTM, ISO, NFPA

Publication of the Unified Agenda of Regulatory and Deregulatory Actions and the Regulatory Plan represent key components of the regulatory planning mechanism prescribed in Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735) and incorporated in Executive Order 13563, "Improving Regulation and Regulatory Review" issued on January 18, 2011 (76 FR 3821). The fall editions of the Unified Agenda include the agency regulatory plans required by E.O. 12866, which identify regulatory priorities and provide additional detail about the most important significant regulatory actions that agencies expect to take in the coming year.

In addition, the Regulatory Flexibility Act requires that agencies publish semiannual "regulatory flexibility agendas" describing regulatory actions they are developing that will have significant effects on small businesses and other small entities (5 U.S.C. 602).

The Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda), published in the fall and spring, helps agencies fulfill all of these requirements. All federal regulatory agencies have chosen to publish their regulatory agendas as part of this publication. The complete Unified Agenda and Regulatory Plan can be found online at <http://www.reginfo.gov> and a reduced print version can be found in the Federal Register. Information regarding obtaining printed copies can also be found on the Reginfo.gov Web site (or below, VI. How can users get copies of the Plan and the Agenda?).

The fall 2016 Unified Agenda publication appearing in the Federal Register consists of The Regulatory Plan and agency regulatory flexibility agendas, in accordance with the publication requirements of the Regulatory Flexibility Act. Agency regulatory flexibility agendas contain only those Agenda entries for rules that are likely to have a significant economic

impact on a substantial number of small entities and entries that have been selected for periodic review under section 610 of the Regulatory Flexibility Act.

The complete fall 2016 Unified Agenda contains the Regulatory Plans of 30 Federal agencies and 60 Federal agency regulatory agendas. **This action may affect State, local or tribal governments.**

[Circular Welded Carbon-Quality Steel Pipe From the Sultanate of Oman, Pakistan, and the United Arab Emirates: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Orders](#)

Published 12/19/2016

Reference ANSI

Based on affirmative final determinations by the Department of Commerce (the Department) and the International Trade Commission (the ITC), the Department is issuing antidumping duty orders on circular welded carbon-quality steel pipe from the Sultanate of Oman (Oman), Pakistan, and the United Arab Emirates (UAE). In addition, as explained in this notice, the Department is amending its final affirmative determination with respect to Oman as a result of a ministerial error. **Effective December 19, 2016.**

[Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations](#)

Published 12/20/2016

Reference ANSI, ASME

Pursuant to Section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued, from November 22, 2016, to December 5, 2016. The last biweekly notice was published on December 6, 2016. **Comments must be filed by January 19, 2017. A request for a hearing must be filed by February 21, 2017.**

[Energy Conservation Standards for Commercial Water Heating Equipment: Availability of Updated Analysis Results](#)

Published 12/23/2016

Reference ASHRAE

In this NODA, the U.S. Department of Energy (DOE) presents its updated analysis used to convert the potential energy conservation standard levels the Department has considered for residential-duty commercial gas-fired storage water heaters from thermal efficiency and standby loss metrics to the uniform energy factor (UEF) metric, as required by a recent change in law. In a notice of proposed rulemaking (NPR) for energy conservation standards for commercial water heating equipment published on May 30, 2016 ("May 2016 CWH ECS NPR"), DOE analyzed these potential standard levels for residential-duty commercial gas-fired storage waters in terms of thermal efficiency and standby loss, and converted the levels to UEF using conversion factors that were proposed in a separate NPR published on April 15, 2015 ("April 2015 conversion factor NPR"). However, DOE subsequently published a supplemental NPR ("August 2016 conversion factor SNOPR") in the conversion factor rulemaking in response to new data on August 30, 2016, and recently issued a conversion factor final rule ("December Start Printed Page 942356, 2016 conversion factor final rule") based upon the August 2016 conversion factor SNOPR, which finalized updated conversion factor equations. (See Docket EERE-2015-BT-TP-0007). This NODA presents the thermal efficiency and standby loss levels analyzed in the May 2016 CWH ECS NPR for residential-duty gas-fired storage water heaters in terms of UEF, using the recently updated conversion factors adopted in the December 6, 2016 conversion factor final rule. **DOE will accept comments, data, and information regarding this notice of data availability (NODA) no later than January 9, 2017.**

[Announcement of Requirements and Registration for National Institute of Standards and Technology Prize Competition-Reusable Abstractions of Manufacturing Processes \(RAMP\) Challenge](#)

Published 12/19/2016

Reference ASME, ASTM

In March 2016, National Institute of Standards and Technology (NIST) and ASTM International announced a new international standard that can “map” the critically important environmental aspects of manufacturing processes, leading to significant improvements in sustainability while keeping a product's life cycle low cost and efficient. Sustainability for manufacturing is beginning to be addressed through the recently approved ASTM Standard Guide for Characterizing Environmental Aspects of Manufacturing Processes (ASTM E60.13 E3012-16). The standard provides a science-based, systematic approach to capture and describe information about the environmental aspects for any manufacturing production process or group of processes, and then use that data to make informed decisions on improvements.

NIST is announcing the Reusable Abstractions of Manufacturing Processes (RAMP) Challenge, with support from ASTM International, the National Science Foundation (NSF), and the American Society of Mechanical Engineers (ASME) Manufacturing Science and Engineering Conference (MSEC) Organizing Committee, to familiarize the community with a recent standard for modeling manufacturing processes that was developed under the ASTM's E60.13 Subcommittee on Sustainable Manufacturing. The RAMP Challenge calls on participants (either as an individual or as a team) to model any manufacturing process and demonstrate application of the ASTM E3012-16 Unit Manufacturing Process (UMP) representation for purposes of information sharing and sustainability assessment. The RAMP Challenge will provide an opportunity for participants to put this standard into practice in modeling a process of their own interest, and to share experiences in applying the standard across a variety of processes. Formal methods for acquiring and exchanging information about manufacturing processes will lead to consistent characterizations and help establish a collection for reuse of these models. Standard methods will ensure effective communication of computational analytics and sharing of sustainability performance data. Results of the competition will assist in demonstrating the use of a reusable standard format leading to models suitable for automated inclusion in a system analysis, such as a system simulation model or an optimization program. **Submission Period: December 19, 2016 to March 20, 2017**

[Hazardous Materials: Notice of Applications for Special Permits](#)

Published 12/22/2016

Reference ASME

In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the “Nature of Application” portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Comments must be received on or before January 23, 2017.

[Seamless Refined Copper Pipe and Tube from the People's Republic of China and Mexico: Continuation of Antidumping Duty Orders](#)

Published 12/21/2016

Reference ASTM

As a result of the determinations by the Department of Commerce (the “Department”) and the International Trade Commission (the “ITC”) that revocation of the antidumping duty (“AD”) orders on seamless refined copper pipe and tube (“copper pipe and tube”) from the People's Republic of China (“PRC”) and Mexico would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing this notice of continuation of the AD orders. **Effective December 21, 2016.**

[Revisions to the Unregulated Contaminant Monitoring Rule \(UCMR 4\) for Public Water Systems and Announcement of Public Meeting](#)

Published 12/20/2016

Reference ASTM

The U.S. Environmental Protection Agency (EPA) is finalizing a Safe Drinking Water Act (SDWA) rule that requires public water systems to collect occurrence data for contaminants that may be present in drinking water but are not yet subject to EPA's drinking water standards set under the SDWA. This rule identifies eleven analytical methods to support water system monitoring for a total of 30 chemical contaminants, consisting of nine cyanotoxins and one cyanotoxin group; two metals; eight pesticides plus one pesticide manufacturing byproduct (hereinafter collectively referred to as “pesticides”); three brominated haloacetic acid disinfection byproduct groups; three alcohols; and three semivolatile organic chemicals. EPA is also announcing a public meeting and webinar to discuss the implementation of the fourth Unregulated Contaminant Monitoring Rule. **This final rule is effective on January 19, 2017, 30 days after publication in the Federal Register. The**

incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 19, 2017.

[Semiannual Regulatory Agenda](#)

Published 12/23/2016

Reference ASTM

In this document, the Commission publishes its semiannual regulatory flexibility agenda. In addition, this document includes an agenda of regulatory actions that the Commission expects to be under development or review by the agency during the next year. This document meets the requirements of the Regulatory Flexibility Act and Executive Order 12866. The Commission welcomes comments on the agenda and on the individual agenda entries. **Comments should be received in the Office of the Secretary on or before December 14, 2016.**

[Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove](#)

Published 12/19/2016

Reference ASTM

The Food and Drug Administration (FDA or Agency) has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. Consequently, FDA is banning these devices. **This rule is effective on January 18, 2017.**

[Circular Welded Carbon-Quality Steel Pipe From the Sultanate of Oman, Pakistan, and the United Arab Emirates: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Orders](#)

Published 12/19/2016

Reference ASTM, UL

Based on affirmative final determinations by the Department of Commerce (the Department) and the International Trade Commission (the ITC), the Department is issuing antidumping duty orders on circular welded carbon-quality steel pipe from the Sultanate of Oman (Oman), Pakistan, and the United Arab Emirates (UAE). In addition, as explained in this notice, the Department is amending its final affirmative determination with respect to Oman as a result of a ministerial error. **Effective December 19, 2016.**

[Stream Protection Rule](#)

Published 12/20/2016

Reference ASTM

We, the Office of Surface Mining Reclamation and Enforcement (OSMRE or OSM), are revising our regulations, based on, among other things, advances in science, to improve the balance between environmental protection and the Nation's need for coal as a source of energy. This final rule will better protect water supplies, surface water and groundwater quality, streams, fish, wildlife, and related environmental values from the adverse impacts of surface coal mining operations and provide mine operators with a regulatory framework to avoid water pollution and the long-term costs associated with water treatment. We have revised our regulations to define "material damage to the hydrologic balance outside the permit area" and require that each permit specify the point at which adverse mining-related impacts on groundwater and surface water would reach that level of damage; collect adequate premining data about the site of the proposed mining operation and adjacent areas to establish an adequate baseline for evaluation of the impacts of mining and the effectiveness of reclamation; adjust monitoring requirements to enable timely detection and correction of any adverse trends in the quality or quantity of surface water and groundwater or the biological condition of streams; ensure protection or restoration of perennial and intermittent streams and related resources; ensure that permittees and regulatory authorities make use of advances in science and technology; ensure that land disturbed by mining operations is restored to a condition capable of supporting the uses that it was capable of supporting before mining; and update and codify the requirements and procedures for protection of threatened or endangered species and designated critical habitat. Approximately thirty percent of the final rule consists of editorial revisions and organizational changes intended to improve consistency, clarity, accuracy, and ease of use. **This rule is effective January 19, 2017.**

[Accreditation and Approval of Intertek USA, Inc. as a Commercial Gauger and Laboratory](#)

Published 12/21/2016

Reference ASTM

Notice is hereby given, pursuant to CBP regulations, that Intertek USA, Inc., has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of March 15, 2016. **The accreditation and approval of Intertek USA, Inc., as commercial gauger and laboratory became effective on March 15, 2016. The next triennial inspection date will be scheduled for March 2019.**

[General Hospital and Personal Use Devices: Renaming of Pediatric Hospital Bed Classification and Designation of Special Controls for Pediatric Medical Crib; Classification of Medical Bassinet](#)

Published 12/19/2016

Reference ASTM, IEC

The Food and Drug Administration (FDA) is issuing a final rule to rename pediatric hospital beds as pediatric medical cribs and establish special controls for these devices. FDA is also establishing a separate classification regulation for medical bassinets, previously under the pediatric hospital bed classification regulation, as a class II (special controls) device. In addition, this rule continues to allow both devices to be exempt from premarket notification and use of the device in traditional health care settings and permits prescription use of pediatric medical cribs and bassinets outside of traditional health care settings. **This order is effective on January 18, 2017.**

[Unfair Practices and Undue Preferences in Violation of the Packers and Stockyards Act](#)

Published 12/20/2016

Reference ASTM

The Department of Agriculture's (USDA) Grain Inspection, Packers and Stockyards Administration (GIPSA), Packers and Stockyards Program (P&SP) is proposing to amend the regulations issued under the Packers and Stockyards Act, 1921, as amended and supplemented (P&S Act). The proposed amendments will clarify the conduct or action by packers, swine contractors, or live poultry dealers that GIPSA considers unfair, unjustly discriminatory, or deceptive and a violation of section 202(a) of the P&S Act. The proposed amendments will also identify criteria that the Secretary will consider in determining whether conduct or action by packers, swine contractors, or live poultry dealers constitutes an undue or unreasonable preference or advantage and a violation of section 202(b) of the P&S Act.

This proposed rule identifies the conduct or action that is a per se violation of section 202(a) of the P&S Act, includes an illustrative list of conduct or action, absent demonstration of a legitimate business justification, GIPSA believes is unfair, unjustly discriminatory, or deceptive and a violation of section 202(a) of the P&S Act regardless of harm to competition, and clarifies that any conduct or action that harms or is likely to harm competition is a violation of section 202(a) of the P&S Act. The proposed rule also includes criteria the Secretary will consider in determining whether conduct or action constitutes an undue or unreasonable preference or advantage and a violation of section 202(b) of the P&S Act. **We will consider comments we receive by February 21, 2017.**

[Information Collections Being Submitted for Review and Approval to the Office of Management and Budget](#)

Published 12/23/2016

Reference IEC

As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communication Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number. **Written comments should be submitted on or before January 23, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.**

Regulatory Agenda

Published 12/23/2016

Reference IEC

The Regulatory Flexibility Act of 1980 and Executive Order (E.O.) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department, offering for public review summarized information about forthcoming regulatory actions.

Unified Agenda of Federal Regulatory and Deregulatory Actions-Fall 2016

Published 12/23/2016

Reference IEC, ISO, UL

Twice a year, in spring and fall, the Commission publishes in the Federal Register a list in the Unified Agenda of those major items and other significant proceedings under development or review that pertain to the Regulatory Flexibility Act (U.S.C. 602). The Unified Agenda also provides the Code of Federal Regulations citations and legal authorities that govern these proceedings. The complete Unified Agenda will be published on the Internet in a searchable format at www.reginfo.gov.

Proposed Information Collection Submitted to the Office of Management and Budget; Request for Comments

Published 12/19/2016

Reference ISO, SAE

In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comments. A Federal Register Notice with a 60-day comment period soliciting comments on the following information collection was published on September 20, 2016 (81 FR 65709). **Comments must be submitted on or before January 18, 2017.**
