

U.S. Federal Register Update: June 13 – June 17, 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?*

[Notice of Petition for Waiver from Johnston Boiler Company from the Department of Energy Commercial Packaged Boiler Test Procedure](#)

Published 6/13/2016

Reference ANSI, ASHRAE, ASME, NFPA

This notice announces receipt of a petition for waiver from Johnston Boiler Company (Johnston) seeking an exemption from specified portions of the U.S. Department of Energy (DOE) test procedure applicable to commercial packaged boilers. Johnston contends that some of their commercial packaged boilers cannot be accurately tested using the currently applicable DOE test procedure and, as a result, seeks to use an alternate test procedure to test these basic models. DOE solicits comments, data, and information concerning Johnston's petition and the suggested alternate test procedure. **DOE will accept comments, data, and information with respect to the Johnston petition until July 13, 2016.**

[Use of Symbols in Labeling](#)

Published 6/15/2016

Reference ANSI, AAMI, IEC, ISO

The Food and Drug Administration (FDA or the Agency) is issuing this final rule revising its medical device and certain biological product labeling regulations to explicitly allow for the optional inclusion of graphical representations of information, or symbols, in labeling (including labels) without adjacent explanatory text (referred to in this document as "stand-alone symbols") if certain requirements are met. The final rule also specifies that the use of symbols, accompanied by adjacent explanatory text continues to be permitted. FDA is also revising its prescription device labeling regulations to allow the use of the symbol statement "Rx only" or "R only" in the labeling for prescription devices. **This rule is effective September 13, 2016.**

[Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 042](#)

Published 6/15/2016

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: 042" (Recognition List Number: 042), 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 June 15, 2016.**

[Xcel Energy, Monticello Nuclear Generating Plant Independent Spent Fuel Storage Installation](#)

Published 6/15/2016

Reference ANSI, ASME

The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a request submitted by Xcel Energy on September 29, 2015, from meeting Technical Specification (TS) 1.2.5 of Attachment A of Certificate of Compliance (CoC) No. 1004, Amendment No. 10, which requires that all dry shielded canister (DSC) closure welds, except those subjected to full volumetric inspection, shall be dye penetrant tested in accordance with the requirements of American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code Section III, Division 1, Article NB-5000. This exemption applies to one loaded Standardized NUHOMS® 61BTH, DSC 16 (DSC 16), at the Monticello Nuclear Generating Plant (MNGP) Independent Spent Fuel Storage Installation (ISFSI).

[Energy Conservation Program: Energy Conservation Standards for Dehumidifiers](#)

Published 6/13/2016

Reference ANSI, AHAM, CSA, UL

The Energy Policy and Conservation Act of 1975 (EPCA), as amended, prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including dehumidifiers. EPCA also requires the U.S. Department of Energy (DOE) to periodically determine whether more-stringent standards would be technologically feasible and economically justified, and would save a significant amount of energy. In this final rule, DOE is adopting more-stringent energy conservation standards for dehumidifiers. It has determined that the amended energy conservation standards for these products would result in significant conservation of energy, and are technologically feasible and economically justified. **The effective date of this rule is August 12, 2016. Compliance with the amended standards established for dehumidifiers in this final rule is required on and after June 13, 2019.**

[Tree Care Operations](#)

Published 6/13/2016

Reference ANSI

OSHA invites interested parties to participate in an informal stakeholder meeting concerning tree care operations on July 13, 2016, in Washington, DC. This meeting is a continuation of OSHA's information collection on tree care operations. OSHA plans to use the information gathered at this meeting, together with other information in the record, to explore the possible development of a proposed standard to protect workers from hazards, fatalities, and injuries in tree care operations. **The stakeholder meeting will be from 9 a.m. to 5 p.m., Tuesday, July 13, 2016.**

[Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Northwest Fisheries Science Center Fisheries Research](#)

Published 6/13/2016

Reference ANSI, ISO

NMFS' Office of Protected Resources has received a request from NMFS' Northwest Fisheries Science Center (NWFSC) for authorization to take marine mammals incidental to fisheries research conducted in the Pacific Ocean off the northwest United States, over the course of five years from the date of issuance. As required by the Marine Mammal Protection Act (MMPA), NMFS is proposing regulations to govern that take, and requests comments on the proposed regulations.

Comments and information must be received no later than July 13, 2016.

[Energy Conservation Program: Energy Conservation Standards for Portable Air Conditioners](#)

Published 6/13/2016

Reference ANSI, AHAM, ASHRAE, UL

The Energy Policy and Conservation Act of 1975 (EPCA), as amended, sets forth various provisions designed to improve energy efficiency for consumer products and certain commercial and industrial equipment. In addition to specifying a list of covered residential products and commercial equipment, EPCA contains provisions that enable the Secretary of Energy to classify additional types of consumer products as covered products. The U.S. Department of Energy (DOE) has previously published a proposed determination of coverage to classify portable air conditioners (ACs) as covered consumer products under the applicable provisions in EPCA. In this document, DOE proposes energy conservation standards for portable ACs following its notice of final determination of coverage. This document also announces a public meeting to receive comment on these proposed standards and associated analyses and results. **DOE will accept comments, data, and information regarding this NOPR before and after the public meeting, but no later than August 12, 2016. See section VIII, "Public Participation," for details.**

[Energy Conservation Program: Energy Conservation Standards for Battery Chargers](#)

Published 6/13/2016

Reference AHAM, IEC, NEMA

The Energy Policy and Conservation Act of 1975, as amended ("EPCA" or in context, "the Act"), prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including battery chargers. EPCA also requires the U.S. Department of Energy ("DOE" or, in context, "the Department") to determine whether Federal energy conservation standards for a particular type of product or equipment would be technologically feasible and economically justified, and would save a significant amount of energy. On March 27, 2012, DOE published a notice of proposed rulemaking ("NOPR") to establish energy conservation standards for battery chargers. Responding to stakeholder comments, DOE updated its analysis and revised its proposed approach, resulting in a supplemental notice of proposed rulemaking ("SNOPR") published on September 1, 2015. After considering all the stakeholder comments responding to the SNOPR, DOE is adopting the proposed energy conservation standards for battery chargers in this final rule. DOE has determined that these standards will result in the significant conservation of energy and are technologically feasible and

economically justified. **The effective date of this rule is August 12, 2016. Compliance with the adopted standards established for battery chargers in this final rule is required starting on June 13, 2018.**

[Energy Conservation Standards for Manufactured Housing](#)

Published 6/17/2016

Reference ASHRAE, NFPA

The U.S. Department of Energy (DOE) is publishing a proposed rule to implement the Energy Independence and Security Act of 2007, which directs DOE to establish energy conservation standards for manufactured housing. DOE proposes to establish energy conservation standards for manufactured housing based on the negotiated consensus recommendations of the manufactured housing working group (MH working group). The MH working group's recommendations were based on the 2015 edition of the International Energy Conservation Code (IECC), the impact of the IECC on the purchase price of manufactured housing, total lifecycle construction and operating costs, factory design and construction techniques unique to manufactured housing, and the current construction and safety standards set forth by U.S. Department of Housing and Urban Development. **DOE will accept comments, data, and information regarding this proposed rule before and after the public meeting, but no later than August 16, 2016 DOE will hold a public meeting on Wednesday, July 13, 2016 from 9:00 a.m. to 4:00 p.m. in Washington, DC.**

[Pure Magnesium from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2014-2015](#)

Published 6/14/2016

Reference ASTM

On February 8, 2016, the Department of Commerce ("Department") published in the Federal Register the preliminary results of the administrative review of the antidumping duty order on pure magnesium from the People's Republic of China ("PRC") covering the period May 1, 2014 through April 31, 2015. This review covers one PRC exporter, Tianjin Magnesium International, Co., Ltd. ("TMI") and Tianjin Magnesium Metal, Co., Ltd. ("TMM") (collectively "TMI/TMM"). The Department gave interested parties an opportunity to comment on the Preliminary Results, but we received no comments. Hence, these final results are unchanged from the Preliminary Results, and we continue to find that TMI/TMM did not have reviewable entries during the period of review ("POR").

[National Emission Standards for Hazardous Air Pollutants for Secondary Aluminum Production](#)

Published 6/13/2016

Reference ASTM

The Environmental Protection Agency (EPA) is taking direct final action to amend the National Emission Standards for Hazardous Air Pollutants for Secondary Aluminum Production (Secondary Aluminum NESHAP). This direct final rule amends the final rule that was published in the Federal Register on September 18, 2015, by correcting inadvertent errors, clarifying rule requirements for initial performance tests and submittal of malfunction reports, providing an additional option for new round top furnaces to account for unmeasured emissions during compliance testing, and clarifying what constitutes a change in furnace operating mode. The direct final rule also updates Web site addresses for the EPA's Electronic Reporting Tool (ERT) and the Compliance and Emissions Data Reporting Interface (CEDRI). These amendments will help to improve compliance and implementation of the rule. **This rule is effective on September 12, 2016 without further notice, unless the EPA receives adverse comment by July 28, 2016. If the EPA receives adverse comment, we will publish a timely withdrawal in the Federal Register informing the public that the rule will not take effect.**

[Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process'; Guidance for Industry and Food and Drug Administration Staff; Availability](#)

Published 6/16/2016

Reference ISO

The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.'" FDA has developed this guidance document to assist industry in preparing Premarket Applications (PMAs), Humanitarian Device Exceptions (HDEs), Investigational Device Applications (IDEs), Premarket Notifications (510(k)s), and de novo requests for medical devices that come into direct contact or indirect contact with the human body in order to determine the potential for an unacceptable adverse biological response resulting from contact of the component materials of the device with the body.

The purpose of this guidance is to provide further clarification and updated information on the use of International Standard ISO 10993-1, "Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process" to support applications to FDA. This guidance supersedes Office of Device Evaluation (ODE) Blue Book Memorandum #G95-1 (1995), entitled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing.'" **Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.**
