# U.S. Federal Register Update: January 15 – January 19, 2018

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?* 

# Approval of American Society of Mechanical Engineers' Code Cases

#### Published 1/17/2018

#### Reference ANSI, ASME, ASTM

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to incorporate by reference (IBR) the latest revisions of three regulatory guides (RGs) approving new, revised, and reaffirmed Code Cases published by the American Society of Mechanical Engineers (ASME). This action allows nuclear power plant licensees and applicants for construction permits, operating licenses, combined licenses, standard design certifications, standard design approvals and manufacturing licenses to voluntarily use the Code Cases listed in these RGs as alternatives to engineering standards for the construction, inservice inspection (ISI), and inservice testing (IST) of nuclear power plant components. These engineering standards are set forth in the ASME's Boiler and Pressure Vessel (BPV) Codes and ASME Operation and Maintenance (OM) Codes, which are currently incorporated by reference into the NRC's regulations. This final rule announces the availability of a related RG, not incorporated by reference into the NRC's regulations that lists Code Cases that the NRC has not approved for use. **This final rule is effective on February 16, 2018.** The incorporation by reference of certain **publications listed in the regulation is approved by the Director of the Federal Register as of February 16, 2018.** 

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension With Change, of a Previously Approved Collection Customer Satisfaction Assessment Survey

#### Published 1/19/2018

#### Reference ANSI

The Department of Justice (DOJ), Federal Bureau of Investigation, Laboratory Division (LD), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. **Comments are encouraged and will be accepted for 60 days until March 20, 2018**.

# Energy Conservation Program: Test Procedure for Microwave Ovens

# Published 1/18/2018

# Reference AHAM, IEC

The U.S. Department of Energy ("DOE") is initiating a data collection process through this request for information to consider whether to amend DOE's test procedures for microwave ovens. To inform interested parties and to facilitate this process, DOE has gathered data, identifying several issues associated with the currently applicable test procedures on which DOE is interested in receiving comment. The issues outlined in this document mainly concern the measurement of active mode, standby mode, and off mode energy use, and an integrated annual energy use metric for microwave ovens; and any additional topics that may inform DOE's decisions in a future test procedure rulemaking, including methods to reduce regulatory burden while ensuring the procedures' accuracy. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this RFI). Written comments and information are requested and will be accepted on or before February 20, 2018.

Incorporation by Reference of American Society of Mechanical Engineers Codes and Code Cases; Correction

# Published 1/18/2018

# Reference ASME

The U.S. Nuclear Regulatory Commission (NRC) published a final rule in the Federal Register on July 18, 2017, to incorporate by reference recent editions of and addenda to the American Society of Mechanical Engineers (ASME) Codes for nuclear power plants. The final rule contained a minor error when referring to a table related to certification requirements for non-destructive examination personnel. In addition, the final rule contained a minor error in a requirement for check valve monitoring. This document corrects the final rule by revising the section that contains these errors. **This correction is effective January 18, 2018.** 

# <u>Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No</u> Significant Hazards Considerations

#### Published 1/16/2018

#### Reference 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 December 19, 2017 to December 29, 2017. The last biweekly notice was published on January 2, 2018. **Comments must be filed by February 15, 2018. A request for a hearing must be filed by March 19, 2018.** 

Laser Products-Conformance With IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56); Draft Guidance for Industry and Food and Drug Administration Staff; Availability

#### Published 1/19/2018

#### Reference ASTM

The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56)." This draft guidance describes the Agency's proposed approach regarding compliance with FDA's performance standards for laser products. FDA believes that under the circumstances described in this guidance, conformance with certain International Electrotechnical Commission (IEC) standards would provide adequate protection of the public health and safety for laser products similar to performance standards in FDA's regulations. Accordingly, FDA does not intend to consider whether firms that comply with the comparable IEC standards discussed in this guidance document also comply with performance standards in FDA's regulations. This draft guidance is not final nor is it in effect at this time. **Submit either electronic or written comments on the draft guidance by March 20, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.** 

Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards; Public Workshop; Request for Comments

# Published 1/16/2018

#### Reference ASTM, ISO

The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Accreditation Scheme for Conformity Assessment of Medical Devices to FDA-Recognized Standards." The purpose of the workshop is to present a draft design of the Accreditation Scheme for Conformity Assessment (ASCA) pilot program. The workshop is intended to discuss and obtain input and recommendations from stakeholders on the draft accreditation scheme, including its goals and scope, a suitable framework and procedures, and requirements to facilitate implementation of an eventual pilot program. The overarching objectives of the ASCA pilot program are to streamline the standards conformity assessment of medical devices and to improve consistency and predictability in the premarket review process where certain FDA recognized standards are used. **The public workshop will be held on May 22 and 23, 2018, from 9 a.m.** to **5 p.m. Submit either electronic or written comments on this public workshop by June 29, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.** 

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Add a New Rule 6200 To Codify Participant Risk Settings in the Exchange's Trading System (as Set Forth in a Proposed IM-6200-1) and To Authorize the Exchange To Share Those Settings With the Clearing Member That Clears Transactions on Behalf of the Participant

# Published 1/17/2018

#### Reference ISO

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), and Rule 19b-4 thereunder, notice is hereby given that on January 3, 2018, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have

been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

Submission for OMB Review; OMB Circular A-119

# Published 1/18/2018

#### Reference ISO

Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division (MVCB) will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning OMB Circular A-119. **Submit comments on or before February 20, 2018.** 

# **Removing Barriers to Transit Bus Automation**

# Published 1/16/2018

#### Reference SAE

The Federal Transit Administration (FTA) seeks public comment regarding current or potential regulatory or other policy barriers to the development, demonstration, deployment, and evaluation of automated transit buses and related technologies for Society of Automotive Engineers (SAE) automation levels 3 through 5. For purposes of this notice, "bus" is defined broadly to consider a range of sizes, vehicle platforms and configurations, and passenger capacities, and could include both traditional and novel vehicle designs (e.g., full-size city buses, articulated buses, small shuttles, etc.). "Bus" includes bus rapid transit. **Comments must be submitted by March 2, 2018. FTA will consider late-filed comments to the extent practicable.** 

#### **Research Program: Automated Transit Buses**

# Published 1/16/2018

#### Reference SAE

The Federal Transit Administration (FTA) seeks public comment regarding the current and near-future status of automated transit buses and related technologies. FTA seeks comments in particular from parties involved in the development, demonstration, deployment, and evaluation of currently available or near-market ready automated buses; systems and components that support bus automation; and ancillary systems that support non-driving bus operator functions (e.g., wheelchair securement, occupant detection, passenger information assistance, fare payment, etc.). For purposes of this notice, "bus" is defined broadly to consider a range of sizes, vehicle platforms and configurations, and passenger capacities, and could include both traditional and novel vehicle designs (e.g., full-size city buses, articulated buses, small shuttles, etc.). "Bus" includes bus rapid transit. **Comments must be submitted by March 2, 2018. FTA will consider late-filed comments to the extent practicable.**