U.S. Federal Register Update: March 13 – March 17, 2017

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?*

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Request for Comments

Published 3/14/2017 Reference ANSI

The Food and Drug Administration (FDA or Agency) has identified a list of class II devices that, when finalized, will be exempt from premarket notification requirements, subject to certain limitations. FDA is publishing this notice of that determination and requesting public comment in accordance with procedures established by the 21st Century Cures Act. This notice does not represent FDA's final determination with respect to the class II devices included in this document. FDA will review any comments submitted within the 60-day comment period and will consider whether the list of class II devices should be modified prior to publication of its final determination in the Federal Register. Submit either electronic or written comments on the notice by May 15, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 15, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of May 15, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Assessment of Abnormal Radioactive Discharges in Ground Water to the Unrestricted Area at Nuclear Power Plant Sites

Published 3/15/2017

Reference ANSI

The U.S. Nuclear Regulatory Commission (NRC) is issuing Regulatory Guide (RG) 4.25, "Assessment of Abnormal Radioactive Discharges in Ground Water to the Unrestricted Area at Nuclear Power Plant Sites," as a new guide (Revision 0). The guide describes an approach that the NRC staff considers acceptable for use in assessing abnormal discharges of radionuclides in ground water from the subsurface to the unrestricted area at commercial nuclear power plant sites. **Revision 0 to RG 4.25** is available on March 15, 2017.

<u>Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Commercial Fireworks Displays at Monterey Bay National Marine Sanctuary</u>

Published 3/17/2017

Reference ANSI

NMFS has received a request from the Monterey Bay National Marine Sanctuary (MBNMS or Sanctuary) for authorization to take marine mammals incidental to commercial fireworks displays permitted by the Sanctuary in California, over the course of five years (2017-2022). 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 April 17, 2017.**

Pipeline Safety: Deactivation of Threats

Published 3/16/2017

Reference ASME

PHMSA is issuing this Advisory Bulletin to inform owners and operators of gas transmission pipelines that PHMSA has developed guidance on threat identification and the minimum criteria for deactivation of threats, as established by a previously issued rule. This Advisory Bulletin also provides guidance to gas transmission pipeline operators regarding documenting their rationale of analyses, justifications, determinations, and decisions related to threat deactivation.

Airworthiness Directives; Airbus Airplanes

Published 3/13/2017 Reference ASME

We are superseding Airworthiness Directive (AD) 2015-16-02 for all Airbus Model A330 series airplanes. AD 2015-16-02 required revising the maintenance or inspection program to incorporate certain maintenance requirements and airworthiness limitations. This new AD requires revising the maintenance or inspection program to incorporate new

maintenance requirements and airworthiness limitations. This AD was prompted by a revision of the airworthiness limitations items (ALI) document, which provides new and more restrictive maintenance requirements and airworthiness limitations for airplane structures and systems. We are issuing this AD to address the unsafe condition on these products. This AD is effective April 17, 2017.

Notice of Scope Rulings

Published 3/15/2017

Reference ASME, ASTM, UL

The Department of Commerce ("Department") hereby publishes a list of scope rulings and anticircumvention determinations made between January 1, 2016, and March 31, 2016, inclusive. We intend to publish future lists after the close of the next calendar quarter. **Effective Date: March 15, 2017**

International Association of Plumbing and Mechanical Officials EGS: Application for Expansion of Recognition

Published 3/15/2017 Reference IAPMO, UL

In this notice, OSHA announces the application of International Association of Plumbing and Mechanical Officials EGS (IAPMO) for expansion of its recognition as a Nationally Recognized Testing Laboratory (NRTL) and presents the Agency's preliminary finding to grant the application. Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before March 30, 2017.

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

Published 3/14/2017 Reference IEEE

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 February 14 to February 27, 2017. The last biweekly notice was published on February 28, 2017. **Comments must be filed by April 13, 2017. A request for a hearing must be filed by May 15, 2017.**

<u>Self-Regulatory Organizations; International Securities Exchange, LLC; Order Approving Proposed Rule Change, as</u>
Modified by Amendment No. 1, To Amend the Exchange Opening Process

Published 3/17/2017

Reference ISO

On January 13, 2017, the International Securities Exchange, LLC ("ISE" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b-4 thereunder,[2] a proposed rule change to amend the Exchange's opening process. The proposed rule change was published for comment in the Federal Register on January 27, 2017.[3] On March 3, 2017, the Exchange filed Amendment No. 1 to the proposed rule change.[4] The Commission received no comment letters on the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

Special Conditions: Robinson Helicopter Company Model R22 BETA Helicopter; Installation of Helitrak Autopilot System

Published 3/16/2017

Reference SAE

These special conditions are issued for the Robinson Helicopter Company (Robinson) Model R22 BETA helicopter. This helicopter as modified by Helitrak, Incorporated (Helitrak) will have a novel or unusual design feature associated with an autopilot (AP) system. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards the Administrator considers necessary

to establish a level of safety equivalent to that ensured by the existing airworthiness standards. The effective date of these special conditions is March 16, 2017. We must receive your comments by May 15, 2017.

SGS North America, Inc.: Application for Expansion of Recognition

Published 3/15/2017

Reference UL

In this notice, OSHA announces the application of SGS North America, Inc., for expansion of its recognition as a Nationally Recognized Testing Laboratory (NRTL) and presents the Agency's preliminary finding to grant the application. **Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before March 30, 2017.**