U.S. Federal Register Update: November 25 – November 29, 2019

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*?

Takes of Marine Mammals Incidental To Specified Activities; Taking Marine Mammals Incidental to Alaska Marine Lines Lutak Dock Project, Haines, Alaska

Published: 11/26/2019

Reference: ANSI

NMFS has received a request from Alaska Marine Lines, Inc. (AML) for authorization to take marine mammals incidental to Lutak Dock project in Haines, Alaska. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision. Comments and information must be received no later than **December 26, 2019**.

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Erickson Residence Marine Access Project in Juneau, Alaska

Published: 11/27/2019

Reference: ANSI

In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an IHA to Jim Erickson to incidentally harass, by Level A and Level B harassment, marine mammals during pile driving activities associated with the Erickson Residence Marine Access Project in Juneau, Alaska. This Authorization is effective from **January 1, 2020 through December 31, 2020**.

<u>Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Parallel</u> <u>Thimble Shoal Tunnel Project in Virginia Beach, Virginia</u>

Published: 11/25/2019

Reference: ANSI

NMFS has received a request from the Chesapeake Tunnel Joint Venture (CTJV) for authorization to take marine mammals incidental to Parallel Thimble Shoal Tunnel Project (PTST) in Virginia Beach, Virginia. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorizations and agency responses will be summarized in the final notice of our decision. Comments and information must be received no later than **December 26, 2019**.

<u>Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products; Guidance for Industry;</u> <u>Availability</u>

Published: 11/26/2019 Reference: ANSI,UL The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry entitled "Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products." This guidance describes FDA's compliance policy for premarket review requirements for two types of limited modifications to new tobacco products that were on the market as of August 8, 2016, specifically, modifications to battery-operated tobacco products solely to comply with UL 8139 and modifications to liquid nicotine products solely to comply with UL 8139 and modifications to liquid nicotine products solely to comply with UL 8139 and modifications to liquid nicotine products solely to comply with UL 8139. It will enable tobacco manufacturers to upgrade their battery-operated tobacco products to UL 8139. It will also enable manufacturers to comply with the CNPPA requirements for flow restrictors for liquid nicotine containers. FDA is issuing this guidance to address battery safety concerns and youth exposure to liquid nicotine toxicity. The announcement of the guidance is published in the Federal Register on **November 26, 2019**.

Protection of Stratospheric Ozone: Determination 35 for Significant New Alternatives Policy Program

Published: 11/25/2019

Reference: ASHRAE

This determination of acceptability expands the list of acceptable substitutes pursuant to the U.S. Environmental Protection Agency's (EPA) Significant New Alternatives Policy (SNAP) program. This action lists as acceptable additional substitutes for use in the refrigeration and air conditioning sector. This determination is applicable on November 25, 2019.

Improved Identification Techniques Against Alkali-Silica Reaction (ASR) Concrete Degradation at Nuclear Power Plants

Published: 11/26/2019

Reference: ASME, ASTM

The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM), PRM-50-109, dated September 25, 2014, submitted by the C-10 Research and Education Foundation (C-10 or the petitioner). The petitioner requests that the NRC amend its regulations to provide improved identification techniques for better protection against concrete degradation due to alkali-silica reaction (ASR) at U.S. nuclear power plants. The petitioner asserts that reliance on visual inspection will not adequately identify ASR, confirm ASR, or provide the current state of ASR damage without petrographic examination. The NRC is denying the petition because existing NRC regulations and NRC oversight activities provide reasonable assurance of adequate protection of public health and safety. Specifically, existing NRC regulations are sufficient to ensure that concrete degradation due to ASR will not result in unacceptable reductions in the structural capacity of safety-related structures at nuclear power plants. The docket for the petition for rulemaking PRM-50-109 is closed on **November 26, 2019.**

Magnesium From Israel: Final Affirmative Determination of Sales at Less Than Fair Value

Published: 11/29/2019

Reference: ASTM

The Department of Commerce (Commerce) determines that magnesium from Israel is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2017 through September 30, 2018. The final estimated dumping margins of sales at LTFV are shown in the Final Determination section of this notice. **Applicable November 29, 2019**.

Magnesium From Israel: Final Affirmative Countervailing Duty Determination

Published: 11/29/2019

Reference: ASTM

The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of magnesium from Israel. For information on the estimated subsidy rates, see the "Final Determination" section of this notice. **Applicable November 29, 2019.**

Improved Identification Techniques Against Alkali-Silica Reaction (ASR) Concrete Degradation at Nuclear Power Plants

Published: 11/26/2019 Reference: CSA

The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM), PRM-50-109, dated September 25, 2014, submitted by the C-10 Research and Education Foundation (C-10 or the petitioner). The petitioner requests that the NRC amend its regulations to provide improved identification techniques for better protection against concrete degradation due to alkali-silica reaction (ASR) at U.S. nuclear power plants. The petitioner asserts that reliance on visual inspection will not adequately identify ASR, confirm ASR, or provide the current state of ASR damage without petrographic examination. The NRC is denying the petition because existing NRC regulations and NRC oversight activities provide reasonable assurance of adequate protection of public health and safety. Specifically, existing NRC regulations are sufficient to ensure that concrete degradation due to ASR will not result in unacceptable reductions in the structural capacity of safety-related structures at nuclear power plants. **The docket for the petition for rulemaking PRM-50-109 is closed on November 26, 2019.**

Center for Devices and Radiological Health Ethylene Oxide Sterilization Master File Pilot Program

Published: 11/26/2019

Reference: ISO

The Food and Drug Administration's (FDA or Agency or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its Ethylene Oxide Sterilization Master File Pilot Program ("EtO Pilot Program"). The EtO Pilot Program is voluntary and intends to allow companies ("sterilization providers") that sterilize single-use medical devices using fixed chamber ethylene oxide (EtO) to submit a Master File when making certain changes between sterilization sites or when making certain changes to sterilization processes that utilize reduced EtO concentrations. Under this voluntary program, manufacturers ("PreMarket Application (PMA) holders") of Class III devices subject to premarket approval that are affected by such changes may, upon FDA's permission, reference the Master File submitted by their sterilization provider in a postapproval report in lieu of submission of a premarket approval application (PMA) supplement. The EtO Pilot Program seeks to help ensure patient access to safe medical devices while encouraging new, innovative ways to sterilize medical devices that reduce the potential impact of EtO on the environment and on the public health while providing a regulatory approach that would address potential device shortages.

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Long Beach Cruise Terminal Improvement Project in the Port of Long Beach, California

Published: 11/25/2019

Reference: ISO

In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to Carnival Corporation & PLC (Carnival) to incidentally take, by Level A harassment and Level B harassment, five species of marine mammals during the Port of Long Beach Cruise Terminal Improvement Project in Port of Long Beach, California. **This Authorization is effective from November 19, 2019 through November 18, 2020.**

Medicare and Medicaid Programs; Continued Approval of the Accreditation Commission for Health Care Accreditation Program

Published: 11/25/2019

Reference: NFPA

This final notice announces our decision to approve the Accreditation Commission for Health Care (ACHC) for continued recognition as a national accrediting organization for hospices that wish to participate in the Medicare or Medicaid programs. A hospice that participates in Medicaid must also meet the Medicare conditions for participation. This final notice is effective **November 27, 2019** through **November 27, 2025**.

Odometer Disclosure Requirements

Published: 11/26/2019

Reference: SAE

This document responds to petitions for reconsideration regarding NHTSA's October 2, 2019, final rule amending NHTSA's odometer disclosure requirements to allow States to adopt electronic odometer disclosure systems and changing the time when vehicles become exempt from federal odometer disclosure requirements from ten years to twenty years. NHTSA received petitions for reconsideration from the America Association of Motor Vehicle Administrators (AAMVA) and the State of Delaware Department of Transportation requesting that the agency delay the effective date of the changes to the exemption from odometer disclosure requirements for one year. After consideration of the petitions, NHTSA has decided to grant the petition. The change to the exemption from the odometer disclosure requirements will take effect on January 1, 2021 and will apply to model year 2011 and newer vehicles. The amendments in the October 2, 2019, final rule allowing States to adopt electronic odometer disclosure systems will still take effect as scheduled on **December 31, 2019**.

Medicare and Medicaid Programs; Continued Approval of the Accreditation Commission for Health Care Accreditation Program

Published: 11/25/2019

Reference: NFPA

This final notice announces our decision to approve the Accreditation Commission for Health Care (ACHC) for continued recognition as a national accrediting organization for hospices that wish to participate in the Medicare or Medicaid programs. A hospice that participates in Medicaid must also meet the Medicare conditions for participation. This final notice is effective **November 27, 2019** through **November 27, 2025**.

Notice of Product Exclusions: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

Published: 11/29/2019

Reference: UL

In September 2018, the U.S. Trade Representative imposed additional duties on goods of China with an annual trade value of approximately \$200 billion as part of the action in the Section 301 investigation of China's acts, policies, and practices related to technology transfer, intellectual property, and innovation. The U.S. Trade Representative initiated a product exclusion process in June 2019, and interested persons have submitted requests for the exclusion of specific Start Printed Page 65883products. This notice announces the U.S. Trade Representative's determination to grant certain exclusion requests specified in the Annex to this notice. The product exclusions announced in this notice will apply as of the September 24, 2018, effective date of the \$200 billion action, to August 7, 2020.