

U.S. Federal Register Update: December 3 – December 7, 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?*

[Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Geophysical Surveys in the Atlantic Ocean](#)

Published 12/7/2018

Reference ANSI, ISO

In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that we have issued incidental harassment authorizations (IHA) to five separate applicants to incidentally harass marine mammals during geophysical survey activities in the Atlantic Ocean. **These authorizations are effective for one year from the date of effectiveness.**

[Certain Steel Racks From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination](#)

Published 12/3/2018

Reference ANSI

The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain steel racks (steel racks) from the People's Republic of China (China) for the period of investigation (POI) January 1, 2017 through December 31, 2017. Interested parties are invited to comment on this preliminary determination. **Applicable December 3, 2018.**

[Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information](#)

Published 12/7/2018

Reference ASTM

The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to obtain data, information, and comments that will assist the Agency in assessing the safety and effectiveness of food handler antiseptic drug products (i.e., antiseptic hand washes or rubs intended for use in food handling settings) for over-the-counter (OTC) human use. We are asking manufacturers of food handler antiseptics and other interested parties to submit safety and effectiveness data on OTC food handler antiseptics marketed for use by food handlers in commercial or regulated environments where growth, harvest, production, manufacturing, processing, packaging, transportation, storage, preparation, service, or consumption of food occurs. We also are inviting comments and requesting data on definitions, eligibility, current conditions of use of food handler antiseptics; safety and effectiveness criteria; as well as test methods to demonstrate the effectiveness of food handler antiseptics. In general, we are seeking input on current use conditions of antiseptics used in the food handler setting and recommended testing to establish the effectiveness of OTC food handler antiseptics. This information and data will inform FDA's ongoing review of OTC antiseptic drug products and will specifically inform our review of food handler antiseptic products. **Submit either electronic or written comments, data, or information by February 5, 2019.**

[Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review](#)

Published 12/3/2018

Reference ASTM

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (Commerce) conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

[Exempt Chemical Preparations Under the Controlled Substances Act](#)

Published 12/3/2018

Reference ISO

The applications for exempt chemical preparations received by the Drug Enforcement Administration (DEA) between January 1, 2017, and June 30, 2018, as listed below, were accepted for filing and have been approved or denied as indicated. **Interested persons may file written comments on this order in accordance with 21 CFR 1308.23(e). Electronic comments must be submitted, and written comments must be postmarked, on or before February 1, 2019. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.**

[Medical Device De Novo Classification Process](#)

Published 12/7/2018

Reference ISO

The Food and Drug Administration (FDA) proposes to establish requirements for the medical device De Novo classification process under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The proposed requirements establish procedures and criteria related to requests for De Novo classification ("De Novo request"). These requirements are intended to ensure the most appropriate classification of devices consistent with the protection of the public health and the statutory scheme for device regulation, as well as to limit the unnecessary expenditure of FDA and industry resources that may occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness are subject to premarket approval. The proposed rule, if finalized, would implement the De Novo classification process under the FD&C Act, as enacted by the Food and Drug Administration Modernization Act of 1997 and modified by the Food and Drug Administration Safety and Innovation Act and the 21st Century Cures Act. **Submit either electronic or written comments on the proposed rule by March 7, 2019. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by January 7, 2019.**

[Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information](#)

Published 12/4/2018

Reference NFPA

The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of four amendment requests. The amendment requests are for North Anna Power Station, Unit Nos. 1 and 2; Shearon Harris Nuclear Power Plant, Unit 1; H. B. Robinson Steam Electric Plant Unit No. 2; and Virgil C. Summer Nuclear Station, Unit No. 1. For each amendment request, the NRC proposes to determine that they involve no significant hazards consideration. Because each amendment request contains sensitive unclassified non-safeguards information (SUNSI) an order imposes procedures to obtain access to SUNSI for contention preparation. **Comments must be filed by January 3, 2019. A request for a hearing must be filed by February 4, 2019. Any potential party as defined in section 2.4 of title 10 of the Code of Federal Regulations (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by December 14, 2018.**
