

U.S. Federal Register Update: September 23 – September 27, 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?*

[Additional Ambient Aerosol CNC Quantitative Fit Testing Protocols: Respiratory Protection Standard](#)

Published 9/26/2019

Reference ANSI, NFPA

OSHA is approving two additional quantitative fit testing protocols for inclusion in appendix A of the Respiratory Protection Standard. These protocols are: The modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for full-facepiece and half-mask elastomeric respirators and the modified ambient aerosol CNC quantitative fit testing protocol for filtering facepiece respirators. The protocols apply to employers in general industry, shipyard employment, and the construction industry. Both protocols are abbreviated variations of the original OSHA-approved ambient aerosol CNC quantitative fit testing protocol (often referred to as the PortaCount® protocol), but differ from the test by the exercise sets, exercise duration, and sampling sequence. These protocols will serve as alternatives to the four existing quantitative fit testing protocols already listed in appendix A of the Respiratory Protection Standard and will maintain safety and health protections for workers while providing additional flexibility and reducing compliance burdens.

The final rule becomes effective on September 26, 2019.

[Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Site Characterization Surveys Off of Delaware and Maryland](#)

Published 9/27/2019

Reference ANSI, ISO

NMFS has received a request from Skipjack Offshore Energy, LLC (Skipjack) for authorization to take marine mammals incidental to marine site characterization surveys offshore of Delaware in the area of the Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS-A 0519) and along potential submarine cable routes to a landfall location in Delaware or Maryland. 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 October 28, 2019.**

[National Emission Standards for Hazardous Air Pollutants: Taconite Iron Ore Processing Residual Risk and Technology Review](#)

Published 9/25/2019

Reference ANSI, ASME

This proposal presents the results of the U.S. Environmental Protection Agency's (EPA's) residual risk and technology reviews (RTRs) for the National Emission Standards for the Hazardous Air Pollutants (NESHAP) for Taconite Iron Ore Processing, as required under the Clean Air Act (CAA). Based on the results of the risk review, the EPA is proposing that risks from emissions of air toxics from this source category are acceptable and that the existing standards provide an ample margin of safety. Furthermore, under the technology review, the EPA identified no cost-effective developments in controls, practices, or processes to achieve further emissions reductions. Therefore, the EPA is proposing no revisions to the existing standards based on the RTRs. However, in this action the EPA is proposing: The removal of exemptions for periods of startup, shutdown, and malfunction (SSM) and clarifying that the emissions standards apply at all times; the addition of electronic reporting of performance test results and compliance reports; minor technical corrections and amendments to monitoring and testing requirements that would reduce the compliance burden on industry while continuing to be protective of the environment; and that regulation of a certain type compound emitted by one of the facilities, known as elongated mineral particulate, is not required under CAA section 112 because this compound is not a hazardous air pollutant (HAP) pursuant to the CAA. This action, if finalized, would result in improved monitoring, compliance, and implementation of the existing standards. Comments must be received on or before November 12, 2019. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before October 25, 2019.

[Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Erickson Residence Marine Access Project in Juneau, Alaska](#)

Published 9/25/2019

Reference ANSI

NMFS has received a request from Jim Erickson for authorization to take marine mammals incidental to the Erickson Residence Marine Access Project in Juneau, 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 October 25, 2019.**

[Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Office of Naval Research Arctic Research Activities](#)

Published 9/24/2019

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 incidental harassment authorization (IHA) to the Office of Naval Research (ONR) to incidentally harass, by Level B harassment only, marine mammals during Arctic Research Activities in the Beaufort and Chukchi Seas. ONR's activities are considered military readiness activities pursuant to the MMPA, as amended by the National Defense Authorization Act for Fiscal Year 2004 (NDAA). **This Authorization is effective from September 10, 2019 through September 9, 2020.**

[Carbon and Alloy Steel Threaded Rod From India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures](#)

Published 9/25/2019

Reference ASME, ASTM

The Department of Commerce (Commerce) preliminarily determines that carbon and alloy steel threaded rod (CASTR) from India is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2018 through December 31, 2018. Interested parties are invited to comment on this preliminary determination. **Applicable September 25, 2019.**

[Carbon and Alloy Steel Threaded Rod From Taiwan: Preliminary Affirmative Determination of Sales at Less Than Fair Value](#)

Published 9/25/2019

Reference ASME, ASTM

The Department of Commerce (Commerce) preliminarily determines that Carbon and Alloy Steel Threaded Rod (CASTR) from Taiwan is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2018 through December 31, 2018. Interested parties are invited to comment on this preliminary determination. **Applicable September 25, 2019.**

[Alloy and Certain Carbon Steel Threaded Rod From the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Extension of Provisional Measures](#)

Published 9/25/2019

Reference ASTM, ISO, SAE

The Department of Commerce (Commerce) preliminarily determines that Alloy and Certain Carbon Steel Threaded Rod (ACSTR) from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is July 1, 2018 through December 31, 2018. Interested parties are invited to comment on this preliminary determination. **Applicable September 25, 2019.**

[Amendment to Requirements for Consumer Registration of Durable Infant or Toddler Products](#)

Published 9/24/2019

Reference ASTM

In 2009, the Consumer Product Safety Commission (CPSC) fulfilled a statutory requirement in the Consumer Product Safety Improvement Act of 2008 (CPSIA) to issue a rule requiring manufacturers of durable infant or toddler products to establish a consumer registration program. The Commission is now finalizing an amendment to the definition of “durable infant or toddler product” in the rule to include the full statutory definition; clarify that the scope of each listed product category is further defined in the applicable mandatory standard; clarify listed product categories using the product name in the applicable mandatory standard; and clarify the scope of the infant carriers and bassinets and cradles product categories. **The rule will become effective on October 24, 2019.**

[Notice of Scope Rulings](#)

Published 9/25/2019

Reference ASTM

The Department of Commerce (Commerce) hereby publishes a list of scope rulings and anti-circumvention determinations made during the period October 1, 2018 through December 31, 2018. We intend to publish future lists after the close of the next calendar quarter. **Applicable September 25, 2019.**

[The Accreditation Scheme for Conformity Assessment Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff; Availability](#)

Published 9/23/2019

Reference IEC, ISO

The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.” The Pilot Accreditation Scheme for Conformity Assessment Program (hereafter referred to as the ASCA Pilot) is authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act). In accordance with amendments made to the FD&C Act by the FDA Reauthorization Act of 2017 (FDARA) and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV), FDA was directed to issue a draft guidance regarding the goals and implementation of the ASCA Pilot. The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Pilot supports the Agency’s continued efforts to use its scientific resources effectively to protect and promote public health by simplifying certain aspects of premarket review, thereby reducing burdens on the Agency for individual submissions. FDA believes the voluntary ASCA Pilot may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (e.g., ISO/IEC 17000 series). The voluntary ASCA Pilot does not supplant or alter any other existing statutory or regulatory requirements governing the decision-making process for premarket submissions. 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 December 23, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.**

[Music Modernization Act Implementing Regulations for the Blanket License for Digital Uses and Mechanical Licensing Collective](#)

Published 9/24/2019

Reference IEC, ISO

The U.S. Copyright Office is issuing a notification of inquiry regarding the Musical Works Modernization Act, title I of the Orrin G. Hatch-Bob Goodlatte Music Modernization Act. Title I establishes a blanket compulsory license, which digital music providers may obtain to make and deliver digital phonorecords of musical works. The blanket license, which will be administered by a mechanical licensing collective, will become available on January 1, 2021. The MMA specifically directs the Copyright Office to adopt a number of regulations to govern the new blanket licensing regime, including regulations regarding notices of license, notices of nonblanket activity, usage reports and adjustments, information to be included in the mechanical licensing collective's database, database usability, interoperability, and usage restrictions, and the handling of confidential information. The statute also vests the Office with general authority to adopt such regulations as may be necessary or appropriate to effectuate this new blanket licensing structure. To promulgate these regulations, the Office seeks public comment regarding the subjects of inquiry discussed in this notification. **Initial written comments must be received no later than 11:59 p.m. Eastern Time on November 8, 2019. Written reply comments must be received no later than 11:59 p.m. Eastern Time on December 9, 2019.**

[Premarket Tobacco Product Applications and Recordkeeping Requirements](#)

Published 9/25/2019

Reference ISO

The Food and Drug Administration (FDA) is issuing a proposed rule that would set forth requirements for premarket tobacco product applications (PMTAs) and would require manufacturers to maintain records establishing that their tobacco products are legally marketed. The proposed rule would help to ensure that PMTAs contain sufficient information for FDA to determine whether a marketing order should be issued for a new tobacco product, including detailed information regarding the physical aspects of a tobacco product, as well as full reports of information to demonstrate the scope of, and details regarding, investigations that may show the potential health risks of the product. The proposed rule would codify the general procedures FDA would follow when evaluating PMTAs, including application acceptance, application filing, and inspections, and would also create postmarket reporting requirements for applicants that receive marketing orders. The proposed rule would allow for the submission of PMTAs in alternative formats in certain instances to reduce the burden of submitting a PMTA for modifications to a product that previously received a PMTA marketing order or resubmitting a PMTA to address deficiencies specified in a no marketing order. The proposed rule would also require tobacco product manufacturers to keep records regarding the legal marketing of certain tobacco products without a PMTA, such as documents showing that a tobacco product is not required to undergo premarket review or has received premarket authorization. **Submit either electronic or written comments on the proposed rule by November 25, 2019.**

[Energy Conservation Program: Energy Conservation Standards for General Service Incandescent Lamps; Correction](#)

Published 9/24/2019

Reference NEMA

On September 5, 2019, the U.S. Department of Energy (“DOE”) published a notice of proposed determination (“NOPD”) initially determining that energy conservation standards for general service incandescent lamps (“GSILs”) do not need to be amended (hereafter the “September 2019 NOPD”). This correction addresses typographical errors that appear in the September 2019 NOPD. This document corrects values listed in Tables V.4, V.7, V.9, and V.10, and corrects duplicative numbering of tables and reference to those tables. Neither the errors nor the corrections in this document affect the substance of the rulemaking or any initial conclusions reached in support of the NOPD. **This document is published on September 24, 2019.**

[Federal Motor Vehicle Safety Standards; Occupant Crash Protection](#)

Published 9/27/2019

Reference SAE

The Moving Ahead for Progress in the 21st Century Act of 2012 directs NHTSA to initiate a rulemaking proceeding to amend Federal Motor Vehicle Safety Standard No. 208, “Occupant crash protection,” to require a seat belt use warning system for rear seats. NHTSA initiated a rulemaking proceeding in 2013, and as it continues with this proceeding NHTSA is seeking public comment on a variety of issues related to a requirement for a rear seat belt warning system. NHTSA seeks comment on, among other things, potential requirements for such systems, the vehicles to which they should apply, their effectiveness, the likely consumer acceptance, and the associated costs and benefits. **You should submit your comments early enough to be received not later than November 26, 2019.**
