

## U.S. Federal Register Update: October 18 – October 22, 2021

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; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids](#)

**Published** 10/20/2021

**Reference** ANSI, ISO

The Food and Drug Administration (FDA, we, or the Agency) is proposing to establish a regulatory category for over-the-counter (OTC) hearing aids and to make related amendments to update the regulatory framework for hearing aids. Specifically, we propose to define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with a new OTC category; repeal the conditions for sale applicable to hearing aids; amend the existing labeling requirements for hearing aids; and update regulations relating to decisions on applications for exemption from Federal preemption that would become obsolete as a result of changes to the hearing aid requirements. This action, if finalized, would more clearly define prescription hearing aids; however, it would not change the classification of existing device types. In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health. **Submit either electronic or written comments on the proposed rule by January 18, 2022. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by November 19, 2021.**

---

### [Updates to Marine Engineering Standards](#)

**Published** 10/19/2021

**Reference** ANSI, ASME, ASTM, ISO, NFPA, SAE, UL

The Coast Guard proposes to incorporate by reference updated marine engineering standards and eliminate outdated or unnecessarily prescriptive regulations in Title 46 of the Code of Federal Regulations (CFR) subchapter F. This proposed rule is part of a continuing effort for regulatory reform that increases compliance options for the regulated public while providing a cost savings to the regulated public and the U.S. government. **Comments and related material must be received by the Coast Guard on or before December 20, 2021.**

---

### [Alternate PCB Extraction Methods and Amendments to PCB Cleanup and Disposal Regulations](#)

**Published** 10/22/2021

**Reference** ASTM

The Environmental Protection Agency (EPA or the Agency) proposes to expand the available options for extraction and determinative methods used to characterize and verify the cleanup of polychlorinated biphenyls (PCBs) waste under the federal Toxic Substances Control Act (TSCA) regulations (also referred to as the PCB regulations). These proposed changes are expected to greatly reduce the amount of solvent used in PCB extraction processes, thereby conserving resources and reducing waste. In addition, the proposed changes are expected to result in quicker, more efficient, and less costly cleanups, due to greater flexibility in the cleanup and disposal of PCB waste, while still being equally protective of human health and the environment. EPA also proposes several other amendments to the PCB regulations, including the amendment of performance-based disposal option for PCB remediation waste; the removal of the provision allowing PCB bulk product waste to be disposed as roadbed material; the addition of more flexible provisions for cleanup and disposal of waste generated by spills that occur during emergency situations (e.g., hurricanes or floods); harmonizing the general disposal requirements for PCB remediation waste; and making other amendments to improve the implementation of the regulations, clarify ambiguity and correct technical errors. **Comments must be received on or before December 21, 2021. 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 November 22, 2021.**

---

### [Information Security Controls: Cybersecurity Items](#)

**Published** 10/21/2021

**Reference** IEC, IEEE, ISO

This interim final rule outlines the progress the United States has made in export controls pertaining to cybersecurity items, revised Commerce Control List (CCL) implementation, and requests from the public information about the impact of these revised controls on U.S. industry and the cybersecurity community. Specifically, this rule establishes a new control on these items for National Security (NS) and Anti-terrorism (AT) reasons, along with a new License Exception Authorized Cybersecurity Exports (ACE) that authorizes exports of these items to most destinations except in the circumstances described. These items warrant controls because these tools could be used for surveillance, espionage, or other actions that disrupt, deny or degrade the network or devices on it. **Effective date: This rule is effective January 19, 2022. Comments must be received by BIS no later than December 6, 2021.**

---

#### [Clarifications of Availability and Expansion of Restrictions on Availability of License Exception Strategic Trade Authorization Under the Export Administration Regulations](#)

**Published** 10/21/2021

**Reference** ISO, SAE

In this rule, the Bureau of Industry and Security (BIS) proposes to amend the Export Administration Regulations (EAR) to clarify and expand restrictions on the availability of License Exception Strategic Trade Authorization (License Exception STA or STA) for the export, reexport and transfer (in-country) of certain items controlled under the EAR. Specifically, BIS proposes to clarify the "Special Conditions for STA" paragraph in certain Category 9 Export Control Classification Numbers (ECCNs) on the Commerce Control List to refer exporters to the limitations set forth in the EAR. Also, continuing its efforts to improve export controls and refine License Exception STA, BIS proposes to further restrict the availability of License Exception STA for certain technology controlled under ECCNs 2E003.f and 1E001. This rule also proposes related conforming amendments in License Exception STA and in affected ECCNs. **Comments must be received by December 6, 2021.**

---

#### [Fire Protection for Recreational Vessels](#)

**Published** 10/22/2021

**Reference** NFPA, UL

The Coast Guard is amending fire extinguishing equipment regulations for recreational vessels that are propelled or controlled by propulsion machinery. This rule relieves owners of these recreational vessels from certain inspection, maintenance, and recordkeeping requirements that are more suited for commercial vessels. To make it easier to find these regulations, this rule also relocates the regulations to another part of the Code of Federal Regulations. **This final rule is effective April 20, 2022.**

---

#### [Draft of Promoting Access to Voting: Recommendations for Addressing Barriers to Private and Independent Voting for People With Disabilities](#)

**Published** 10/21/2021

**Reference** NIST

The National Institute of Standards and Technology (NIST) requests public comments on the Draft Promoting Access to Voting: Recommendations for Addressing Barriers to Private and Independent Voting for People with Disabilities Document (Draft). The Draft was developed by NIST using information collected through the Request for Information (RFI) that was published in the Federal Register on June 16, 2021; review of reports, papers and other literature; and engagement with stakeholder organizations and election officials. The Draft was developed in response to NIST responsibilities set forth in Executive Order (E.O.) 14019, Promoting Access to Voting. Under section 7 of the E.O., Ensuring Equal Access for Voters with Disabilities, NIST is directed to evaluate the steps needed to ensure that the online Federal Voter Registration Form is accessible to people with disabilities and to analyze barriers to private and independent voting for people with disabilities and make recommendations to remove these barriers. The Draft is posted on the Federal eRulemaking Portal at <https://www.regulations.gov> as well as the NIST website at: <https://www.nist.gov/itl/voting>. The use of the eRulemaking Portal does not imply that the Draft is a regulation, nor mandatory guidance for federal agencies. **Comments must be received by 5:00 p.m. Eastern time on November 22, 2021. Written comments in response to this request for public comment should be submitted according to the instructions in the ADDRESSES and SUPPLEMENTARY INFORMATION sections below. Submissions received after that date may not be considered.**

---

#### [Ride the Ducks International, LLC, Denial of Petition for Decision of Inconsequential Noncompliance](#)

**Published** 10/21/2021

**Reference** SAE

Ride the Ducks International, LLC (RTDI), has determined that certain model year (MY) 1996-2014 Ride the Ducks International Stretch Amphibious passenger vehicles (APVs) do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 104, Windshield Wiping and Washing Systems. RTDI filed a noncompliance information report dated March 15, 2017. RTDI also petitioned NHTSA on April 12, 2017, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety.

---

#### **Bay Area Compliance Laboratories Corp.: Application for Expansion of Recognition**

**Published** 10/21/2021

#### **Reference UL**

In this notice, OSHA announces the application of Bay Area Compliance Laboratories Corp., for expansion of 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 November 8, 2021.**

---