U.S. Federal Register Update: September 5 – September 9, 2016

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?*

Oil and Gas and Sulfur Operations on the Outer Continental Shelf-Oil and Gas Production Safety Systems

Published 9/7/2016

Reference ANSI, ASME, ISO, UL

The Bureau of Safety and Environmental Enforcement (BSEE) is amending and updating the regulations regarding oil and natural gas production safety on the Outer Continental Shelf (OCS) by addressing issues such as: Safety and pollution prevention equipment design and maintenance, production safety systems, subsurface safety devices, and safety device testing. The rule differentiates the requirements for operating dry tree and subsea tree production systems and divides the current BSEE regulations regarding oil and gas production safety systems into multiple sections to make the regulations easier to read and understand. The changes in this rule are necessary to improve human safety, environmental protection, and regulatory oversight of critical equipment involving production safety systems. This rule becomes effective on November 7, 2016. Compliance with certain provisions of the final rule, however, will be deferred until the times specified in those provisions and as described in part II.E of this document.

Fall Protection in Shipyard Employment

Published 9/8/2016 Reference ANSI, ASSE

OSHA is considering revising and updating its safety standards that address access and egress (including stairways and ladders), fall and falling object protection, and scaffolds in shipbuilding, ship repair, shipbreaking, and other shipyard related employment (collectively referred to as "shipyard employment" in this document). The Agency has not updated these standards since adopting them in 1971. To assist with this determination, OSHA requests comment, information and data on a number of issues, including: The workplace hazards these standards address, particularly fall hazards; the current practices employers in shipyard employment use to protect workers from those hazards; any advances in technology since OSHA adopted the standards in subpart E; and the revisions and updates to subpart E that stakeholders recommend. OSHA will use the information received in response to this RFI to determine what action, if any, it may take. **Submit comments and additional material on or before December 7, 2016.**

Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use

Published 9/6/2016

Reference ASME, ASTM

The Food and Drug Administration (FDA, we, or the Agency) is issuing this final rule establishing that certain active ingredients used in over-the-counter (OTC) consumer antiseptic products intended for use with water (referred to throughout this document as consumer antiseptic washes) are not generally recognized as safe and effective (GRAS/GRAE) and are misbranded. FDA is issuing this final rule after considering the recommendations of the Nonprescription Drugs Advisory Committee (NDAC); public comments on the Agency's notices of proposed rulemaking; and all data and information on OTC consumer antiseptic wash products that have come to the Agency's attention. This final rule amends the 1994 tentative final monograph (TFM) for OTC antiseptic drug products that published in the Federal Register of June 17, 1994 (the 1994 TFM). The final rule is part of the ongoing review of OTC drug products conducted by FDA. **This rule is effective September 6, 2017.**

Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients

Published 9/7/2016

Reference ASSE

This document seeks comment on the proposed amendment of Title X regulations specifying the requirements Title X projects must meet to be eligible for awards. The amendment precludes project recipients from using criteria in their selection of subrecipients that are unrelated to the ability to deliver services to program beneficiaries in an effective manner. To be considered, comments should be submitted by October 7, 2016. Subject to consideration of the comments submitted, the Department will publish final regulations.

Rail Transportation of Grain, Rate Regulation Review; Expanding Access to Rate Relief

Published 9/7/2016

Reference ASSE

The Surface Transportation Board (Board) is seeking comments and suggestions through this Advance Notice of Proposed Rulemaking (ANPR) regarding the Board's effort to develop a new rate reasonableness methodology for use in very small disputes, which would be available to shippers of all commodities. **Comments are due by November 14, 2016. Reply comments are due by December 19, 2016.**

<u>Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products From the Russian Federation: Final Results of the Expedited</u>
<u>Sunset Review of the Antidumping Duty Order</u>

Published 9/8/2016 Reference ASTM, SAE

As a result of this sunset review, the Department of Commerce (the Department) finds that revocation of the antidumping duty order on certain hot-rolled flat-rolled carbon-quality steel products (hot-rolled steel) from the Russian Federation (Russia) would be likely to lead to continuation or recurrence of dumping at the rates identified in the "Final Results of Review" section of this notice. **Effective September 8, 2016.**

Head Start Performance Standards

Published 9/6/2016 Reference ASTM

This final rule modernizes the Head Start Program Performance Standards, last revised in 1998. In the Improving Head Start for School Readiness Act of 2007, Congress instructed the Office of Head Start to update its performance standards and to ensure any such revisions to the standards do not eliminate or reduce quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services programs provide. This rule responds to public comment, incorporates extensive findings from research and from consultation with experts, reflects best practices, lessons from program input and innovation, integrates recommendations from the Secretary's Advisory Committee Final Report on Head Start Research and Evaluation, and reflects the Obama Administration's deep commitment to improve the school readiness of young children. These performance standards will improve program quality, reduce burden on programs, and improve regulatory clarity and transparency. They provide a clear road map for current and prospective grantees to support high-quality Head Start services and to strengthen the outcomes of the children and families Head Start serves.

Energy Conservation Program: Test Procedures for Integrated Light-Emitting Diode Lamps; Correction

Published 9/8/2016

Reference IEC

On July 1, 2016, the U.S. Department of Energy (DOE) published a final rule adopting a test procedure for integrated light-emitting diode (LED) lamps (hereafter referred to as "LED lamps") to support the implementation of labeling provisions by the Federal Trade Commission, as well as the ongoing general service lamps rulemaking, which includes LED lamps (hereafter the "July 2016 final rule"). This correction addresses an error in the July 2016 final rule to add appendix BB to 10 CFR 430.3(p)(5). Neither the error nor the correction in this document affect the substance of the test procedure rulemaking or any of the conclusions reached in support of the final rule.

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for Guadalupe Fescue

Published 9/9/2016

Reference IEC

We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for Festuca ligulata (Guadalupe fescue) under the Endangered Species Act of 1973, as amended (Act). In total, approximately 7,815 acres (3,163 hectares) in Brewster County, Texas, located entirely in Big Bend National Park, fall within the boundaries of the proposed critical habitat designation. If we finalize this rule as proposed, it would extend the Act's protections to this species' critical habitat. We also announce the availability of a draft economic analysis (DEA) of the proposed designation of critical habitat for Guadalupe fescue.

Hazardous Materials: Harmonization With International Standards (RRR)

Published 9/7/2016 Reference ISO The Pipeline and Hazardous Materials Safety Administration (PHMSA) proposes to amend the Hazardous Materials Regulations (HMR) to maintain consistency with international regulations and standards by incorporating various amendments, including changes to proper shipping names, hazard classes, packing groups, special provisions, packaging authorizations, air transport quantity limitations, and vessel stowage requirements. These revisions are necessary to harmonize the HMR with recent changes made to the International Maritime Dangerous Goods Code, the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air, and the United Nations Recommendations on the Transport of Dangerous Goods—Model Regulations. Additionally, PHMSA proposes several amendments to the HMR that result from coordination with Canada under the U.S.-Canada Regulatory Cooperation Council. Comments must be received by November 7, 2016.

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device: Current Good Manufacturing Practice Quality System Regulations

Published 9/8/2016 Reference ISO

The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recordkeeping requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation (CGMP/QS regulation). Submit either electronic or written comments on the collection of information by November 7, 2016.

<u>Federal Motor Vehicle Safety Standards; Federal Motor Carrier Safety Regulations; Parts and Accessories Necessary for Safe Operation; Speed Limiting Devices</u>

Published 9/7/2016

Reference SAE

NHTSA and FMCSA are proposing regulations that would require vehicles with a gross vehicle weight rating of more than 11,793.4 kilograms (26,000 pounds) to be equipped with a speed limiting device initially set to a speed no greater than a speed to be specified in a final rule and would require motor carriers operating such vehicles in interstate commerce to maintain functional speed limiting devices set to a speed no greater than a speed to be specified in the final rule for the service life of the vehicle.

Specifically, NHTSA is proposing to establish a new Federal motor vehicle safety standard (FMVSS) requiring that each new multipurpose passenger vehicle, truck, bus and school bus with a gross vehicle weight rating (GVWR) of more than 11,793.4 kilograms (26,000 pounds) be equipped with a speed limiting device. The proposed FMVSS would also require each vehicle, as manufactured and sold, to have its device set to a speed not greater than a specified speed and to be equipped with means of reading the vehicle's current speed setting and the two previous speed settings (including the time and date the settings were changed) through its On-Board Diagnostic connection.

FMCSA is proposing a complementary Federal motor carrier safety regulation (FMCSR) requiring each commercial motor vehicle (CMV) with a GVWR of more than 11,793.4 kilograms (26,000 pounds) to be equipped with a speed limiting device meeting the requirements of the proposed FMVSS applicable to the vehicle at the time of manufacture, including the requirement that the device be set to a speed not greater than a specified speed. Motor carriers operating such vehicles in interstate commerce would be required to maintain the speed limiting devices for the service life of the vehicle.

Based on the agencies' review of the available data, limiting the speed of these heavy vehicles would reduce the severity of crashes involving these vehicles and reduce the resulting fatalities and injuries. We expect that, as a result of this joint rulemaking, virtually all of these vehicles would be limited to that speed. You should submit your comments early enough to ensure that the docket receives them not later than November 7, 2016.