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

<u>Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the San Francisco</u>
<u>Ferry Terminal Expansion Project, South Basin Improvements Project</u>

Published 5/25/2016 Reference ANSI, ISO

NMFS has received a request from the San Francisco Bay Area Water Emergency Transportation Authority (WETA) for authorization to take marine mammals incidental to construction activities as part of a ferry terminal expansion and improvements project. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting public comment on its proposal to issue an incidental harassment authorization (IHA) to WETA to incidentally take marine mammals, by Level B harassment only, during the specified activity. **Comments and information must be received no later than June 24, 2016.**

Protection of Stratospheric Ozone: Determination 31 for Significant New Alternatives Policy Program

Published 5/23/2016 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 effective on May 23, 2016.**

Containment Shell or Liner Moisture Barrier Inspection

Published 5/23/2016

Reference ASME

The U.S. Nuclear Regulatory Commission (NRC) is issuing Regulatory Issue Summary (RIS) 2016-07, "Containment Shell or Liner Moisture Barrier Inspection." This RIS reiterates the NRC staff's position regarding American Society of Mechanical Engineers (ASME) code inservice inspection requirements for moisture barriers. The NRC's regulations require, in part, that licensees implement the inservice inspection program for pressure retaining components and their integral attachments of metal containments and metallic liners of concrete containments in accordance with the ASME Code. If a material prevents moisture from contacting inaccessible areas of the containment shell or liner, especially if the material is being relied upon in lieu of augmented examinations of a susceptible location, the material must be inspected as a moisture barrier. The applicable ASME Code sections require licensees to inspect 100 percent of accessible moisture barriers during each inspection period.

Air Plan Approval; Connecticut; Sulfur Content of Fuel Oil Burned in Stationary Sources

Published 5/25/2016

Reference ASTM

The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of Connecticut on April 22, 2014, with supplemental submittals on June 18, 2015 and September 25, 2015. This revision establishes sulfur in fuel oil content limits for use in stationary sources. In addition, the submittal includes a revision to the sampling and emission testing methods for the sulfur content in liquid fuels. The intended effect of this action is to approve these requirements into the Connecticut SIP. This action is being taken under the Clean Air Act. This direct final rule will be effective July 25, 2016, unless EPA receives adverse comments by June 24, 2016. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the Federal Register informing the public that the rule will not take effect.

Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft

Published 5/24/2016 Reference IEC, ISO

This final rule replaces the existing process by which the Federal Aviation Administration (Agency or FAA) approves portable oxygen concentrators (POC) for use on board aircraft in air carrier operations, commercial operations, and certain other operations using large aircraft. The FAA currently assesses each POC make and model on a case-by-case basis and if the FAA

determines that a particular POC is safe for use on board an aircraft, the FAA conducts rulemaking to identify the specific POC model in an FAA regulation. This final rule replaces the current process and allows passengers to use a POC on board an aircraft if the POC satisfies certain acceptance criteria and bears a label indicating conformance with the acceptance criteria. The labeling requirement only affects POCs intended for use on board aircraft that were not previously approved for use on aircraft by the FAA. Additionally, this rulemaking will eliminate redundant operational requirements and paperwork requirements related to the physician's statement. As a result, this rulemaking will reduce burdens for POC manufacturers, passengers who use POCs while traveling, and affected aircraft operators. This final rule also makes conforming amendments to the Department of Transportation's (Department or DOT) rule implementing the Air Carrier Access Act (ACAA) to require carriers to accept all POC models that meet FAA acceptance criteria as detailed in this rule. The amendments to 14 CFR 1.1, 1.2, 121.574, 125.219, and 135.91 are effective June 23, 2016. The amendments to 14 CFR 11.201, 121.306, 125.204, 135.144, 382,27, and 382.133, and the removal of Special Federal Aviation Regulation No. 106 are effective August 22, 2016.

Mitigation Strategies To Protect Food Against Intentional Adulteration

Published 5/27/2016

Reference ISO

The Food and Drug Administration (FDA or we) is issuing this final rule to require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to address hazards that may be introduced with the intention to cause wide scale public health harm. These food facilities are required to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA is issuing these requirements as part of our implementation of the FDA Food Safety Modernization Act (FSMA). This rule is effective July 26, 2016. See section VIII for compliance dates.

<u>Cardiovascular Devices; Reclassification of External Cardiac Compressor; Reclassification of Cardiopulmonary</u> Resuscitation Aids

Published 5/25/2016

Reference ISO

The Food and Drug Administration (FDA) is issuing a final order to reclassify external cardiac compressors (ECC) (under FDA product code DRM), a preamendments class III device, into class II (special controls). FDA is also creating a separate classification regulation for a subgroup of devices previously included within this classification regulation, to be called cardiopulmonary resuscitation (CPR) aids, and reclassifying these devices from class III to class II for CPR aids with feedback and to class I for CPR aids without feedback. **This order is effective on May 25, 2016.**