

U.S. Federal Register Update: July 11 – 15, 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?*

[Records Management](#)

Published 7/13/2016

Reference ANSI, ISO, NFPA

NARA proposes to revise its records management regulations to reflect executive actions, statutory changes, advances in technology, and organizational changes. This is phase II of the revisions and includes changes to provisions in transferring records to the National Archives of the United States, managing electronic records, and managing audiovisual, cartographic, and related records. **Submit comments on or before September 12, 2016.**

[Oil and Gas and Sulfur Operations on the Outer Continental Shelf-Requirements for Exploratory Drilling on the Arctic Outer Continental Shelf](#)

Published 7/15/2016

Reference ANSI, IEC, ISO

The Department of the Interior (DOI or the Department), acting through BOEM and BSEE, is revising and adding new requirements to regulations for exploratory drilling and related operations on the Outer Continental Shelf (OCS) seaward of the State of Alaska. This final rule focuses solely on the OCS within the Beaufort Sea and Chukchi Sea Planning Areas (Arctic OCS). The Arctic region is characterized by extreme environmental conditions, geographic remoteness, and a relative lack of fixed infrastructure and existing operations. This final rule is designed to help ensure the safe, effective, and responsible exploration of Arctic OCS oil and gas resources, while protecting the marine, coastal, and human environments, and Alaska Natives' cultural traditions and access to subsistence resources. **This rule becomes effective on September 13, 2016.**

[Electronic Filing of Certain Import/Export Data Relating to Controlled Substances and Listed Chemicals: Announcement of the Partner Government Agency Message Set/Document Image System Test and Request for Participants](#)

Published 7/15/2016

Reference ANSI

The Drug Enforcement Administration (DEA) announces, in coordination with U.S. Customs and Border Protection (CBP), a pilot test of the International Trade Data System (ITDS) involving the electronic submission of data related to the importation and exportation of controlled substances and listed chemicals. The pilot program will test the electronic transmission through the CBP's Automated Commercial Environment (ACE) system, of data, forms and documents required by the DEA using the Partner Government Agency (PGA) Message Set and the Document Image System (DIS). The data, forms and documents will be transmitted for review by the DEA. CBP's PGA Message Set and DIS enable importers, exporters, and brokers to electronically transmit data required by the DEA directly to ACE. This electronic process will replace certain paper-based processes currently used during the pilot program for pilot participants. **The test will commence no earlier than August 1, 2016, and will continue until concluded by publication of a notice in the Federal Register ending the test. Applications to participate may be submitted throughout the duration of this test.**

[Information To Support a Claim of Electromagnetic Compatibility of Electrically-Powered Medical Device; Guidance for Industry and Food and Drug Administration Staff; Availability](#)

Published 7/11/2016

Reference ANSI, AAMI, IEC

The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Device." This guidance describes the types of information that should be provided to support a claim of EMC in a premarket submission for an electrically powered medical device. Electromagnetic disturbance is electronic product radiation that may interfere with the performance of an electrically powered medical device in its intended environment (i.e., cause an electromagnetic interference (EMI)). EMC assessment helps to ensure that a device is able to function in its intended environment without introducing excessive electromagnetic disturbances that might interfere with other devices. **Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.**

National Emission Standards for Hazardous Air Pollutants: Ferroalloys Production

Published 7/12/2016

Reference ASTM

On June 30, 2015, the Environmental Protection Agency (EPA) published the residual risk and technology review (RTR) final rule, establishing national emission standards for hazardous air pollutants (NESHAP) for the Ferroalloys Production source category. Subsequently, the EPA received two petitions for reconsideration of certain aspects of the final rule. The EPA is announcing reconsideration of and requesting public comment on three issues raised in the petitions for reconsideration, as detailed in the SUPPLEMENTARY INFORMATION section of this action. The three issues the EPA is reconsidering and seeking public comment on are the following: the polycyclic aromatic hydrocarbons (PAH) compliance testing frequency for furnaces that produce ferromanganese (FeMn); the use of the digital camera opacity technique (DCOT) for determining compliance with the shop building opacity standards; and the use of bag leak detection systems (BLDS) on positive pressure baghouses. The EPA is seeking comment only on these three issues and will not respond to comments addressing other issues or other provisions of the final rule. The EPA is not proposing any changes to the NESHAP in this document.

Comments must be received on or before August 26, 2016.

Special Conditions: Cirrus Design Corporation, Model SF50; Whole Airplane Parachute Recovery System

Published 7/15/2016

Reference ASTM

These special conditions are issued for the Cirrus Design Corporation (Cirrus), model SF50 airplane. This airplane will have a novel or unusual design feature(s) associated with a whole airplane parachute recovery system. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards. **These special conditions are effective August 15, 2016 and are applicable on July 6, 2016.**

Tankers-Automatic Pilot Systems in Waters

Published 7/11/2016

Reference IEC

The Coast Guard proposes to permit tankers with automatic pilot systems that meet certain international standards to operate using those systems in waters subject to the shipping safety fairway or traffic separation scheme controls specified in our regulations. The proposed amendments would remove an unnecessary regulatory restriction, update the technical requirements for automatic pilot systems, and promote the Coast Guard's maritime safety and stewardship (environmental protection) missions by enhancing maritime safety. **Comments and related material must be submitted to the online docket via <http://www.regulations.gov>, or reach the Docket Management Facility, on or before October 11, 2016.**

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program

Published 7/14/2016

Reference NEMA

This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2017 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Further, in this proposed rule, we are proposing to make changes to tolerance thresholds for clinical outcomes for solid organ transplant programs; to Organ Procurement Organizations (OPOs) definitions, outcome measures, and organ transport documentation; and to the Medicare and Medicaid Electronic Health Record Incentive Programs. We also are proposing to remove the HCAHPS Pain Management dimension from the Hospital Value-Based Purchasing (VBP) Program. In addition, we are proposing to implement section 603 of the Bipartisan Budget Act of 2015 relating to payment for certain

items and services furnished by certain off-campus outpatient departments of a provider. **To be assured consideration, comments on all sections of this proposed rule must be received at one of the addresses provided in the ADDRESSES section no later than 5 p.m. EST on September 6, 2016.**

[Special Conditions: American Airlines, Boeing 777-200 Series Airplanes; Dynamic Test Requirements for Single-Occupant Oblique \(Side-Facing\) Seats Equipped With Inflatable Lapbelts](#)

Published 7/14/2016

Reference SAE

These special conditions are issued for the Boeing 777-200 series airplane. This airplane, as modified by American Airlines, will have novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. These airplanes will include single-occupant oblique seats with inflatable lapbelts requiring dynamic testing. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for these design features. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards. **This action is effective on American Airlines on July 14, 2016. We must receive your comments by August 29, 2016.**
