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**From:** Bloomberg BNA  
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## **EHS Federal Regulatory Alert**

July 25, 2017 - Number 141

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### Summaries

*AIR*

#### **Commercial Package Air Conditioning and Heating Equipment Test Procedures** **AIR**

Notice of the Energy Department requests information to inform regarding potential revisions to the test procedures for commercial package air conditioning and heating equipment. The agency seeks comments on the testing of products with newly available features, including evaporatively cooled commercial unitary air conditioners (ECUACs), water-cooled commercial unitary air conditioners (WCUACs), and air-cooled commercial unitary air conditioners with a rated cooling capacity greater than or equal to 65,000 British thermal units per hour (Btu/h) and less than 760,000 Btu/h. The agency also seeks comments on the testing of ECUACs and WCUACs with a rated cooling capacity less than 65,000 Btu/h, all classes of variable refrigerant flow multisplit air conditioners and heat pumps, and all classes of computer room air conditioners. In addition, the agency seeks comments on a potential new test procedure for dedicated outdoor air systems. Comments are due Aug. 24, 2017. Contact: Catherine Rivest; DOE, Office of Energy Efficiency and Renewable Energy; 202-586-7335; [ApplianceStandardsQuestions@ee.doe.gov](mailto:ApplianceStandardsQuestions@ee.doe.gov). Citations: 10 CFR 429, 431

82 FR 34427 (07/25/2017)

#### **Regulatory Update**

*AIR*

#### **Energy Standard for Buildings Preliminary Analysis** **AIR**

Notice of the Energy Department, Office of Energy Efficiency and Renewable Energy, announces the availability of a preliminary energy savings analysis of the October 2016 energy standard for buildings, except for low-rise residential buildings. The preliminary analysis quantifies the expected energy savings associated with the current standard as compared to the 2013 version of the standard. Comments are due Sept. 8, 2017. Contact: Jeremiah Williams; DOE, Office of Energy Efficiency and Renewable Energy; 202-441-1288; [Jeremiah.Williams@ee.doe.gov](mailto:Jeremiah.Williams@ee.doe.gov)

82 FR 34513 (07/25/2017)

Regulatory Update

**AIR**

Indiana/Clean Air Act Consent Decree Modification

**AIR**

Notice of the Justice Department announces a proposed third modification to a 2012 consent decree in *United States v. Essroc Cement Co.* (Civil Action No. 2:11-cv-01650-DSC), lodged on July 19, 2017, with the U.S. District Court for the Western District of Pennsylvania. The original consent decree (77 FR 517; 01/05/2012) addressed alleged violations under the Clean Air Act against six Essroc cement facilities in three states and in Puerto Rico. The proposed modification, which affects Essroc's facility in Logansport, Ind., revises nitrogen oxides (NOx) emissions control requirements to no longer require installation of the selective noncatalytic reduction NOx control technology at Kiln 2 and to instead require installation of water injection technology at both kilns. The proposed modification also reduces the allowable NOx emissions rate at both kilns and specifies that the company is now known as Lehigh Hanson ECC. Comments are due Aug. 24, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 34553 (07/25/2017)

Regulatory Update

**ENDANGERED SPECIES**

Washington State/Marine Mammals Incidental Take

**ENDANGERED SPECIES**

Notice of the National Marine Fisheries Service announces the receipt of a request for authorization to take 11 species of marine mammals incidental to pile driving activities for pier restoration located on Elliot Bay in Seattle. The proposed project will make limited modifications to Pier 63 and demolish and reconstruct Pier 62 between September 2017 and February 2018. The authorization allows take in the form of Level A and Level B harassment. A separate incidental take authorization application will be prepared for an expected second season of work at the site. Comments are due Aug. 24, 2017. Contact: Stephanie Egger; NMFS, Office of Protected Resources; 301-427-8401; ITP.egger@noaa.gov

82 FR 34486 (07/25/2017)

Regulatory Update

**FOOD SAFETY**

Animal Drug User Fees, Fee Waivers and Reductions

**FOOD SAFETY**

Notice of the FDA announces the availability of a final guidance for industry regarding animal drug user fees, fee waivers and reductions. The guidance describes the types of fees the FDA is authorized to collect under the Animal Drug User Fee Act and how to request waivers and reductions from such fees. The revisions clarify several provisions, including the criteria for

Barrier to Innovation waivers and small business waivers. Comments may be submitted at any time. Contact: Diane Heinz; FDA, Center for Veterinary Medicine; 240-402-5692; [diane.heinz@fda.hhs.gov](mailto:diane.heinz@fda.hhs.gov)

82 FR 34534 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

FDA Civil Monetary Penalties

**GENERAL ENVIRONMENT AND SAFETY**

Final rule of the FDA amends regulations regarding the agency's maximum civil monetary penalties to correct a statutory reference. The rule is effective July 25, 2017. Contact: Jarilyn Dupont; FDA, Office of Policy; 301-796-4830. Citations: 21 CFR 17.3

82 FR 34402 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Institutional Review Board Waiver or Alteration of Informed Consent for Clinical Investigations

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the FDA announces the availability of a guidance for sponsors, investigators, and institutional review boards (IRBs) concerning IRB waiver or alteration of informed consent for clinical investigations involving no more than minimal risk to human subjects. The guidance provides that the FDA does not intend to object to an IRB waiving or altering informed consent requirements for certain minimal risk clinical investigations. The guidance also specifies that the FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described in the guidance. Comments may be submitted at any time. Contact: Janet Norden; FDA, Office of Good Clinical Practice; 301-796-1127

82 FR 34535 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

M4E(R2) Common Technical Document Guidance

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the FDA announces the availability of a final guidance for industry on preparing efficacy components of an application file for registration of human pharmaceuticals in the common technical document format. The guidance, M4E(R2): The Common Technical Document–Efficacy, revises the 2001 M4E guidance to standardize the presentation of benefit-risk information in regulatory submissions of pharmaceutical products. The guidance was prepared under the auspices of the International Council for Harmonisation, which addresses the harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators worldwide. Comments may be submitted at any time. Contact: Pujita Vaidya; FDA,

Center for Drug Evaluation and Research; 301-796-0684

82 FR 34538 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Nevada/Paiute Pipeline 2018 Expansion Project

**GENERAL ENVIRONMENT AND SAFETY**

Notice of FERC announces the receipt of an application for the 2018 Expansion Project, proposed by Paiute Pipeline Co. of Las Vegas. The project involves the installation of 4.61 miles of pipeline and the replacement of 3.85 miles of pipeline in Douglas and Lyon counties and Carson City, Nev. The project will provide incremental firm transportation services of 5,635 dekatherms per day on Paiute's system. The agency will complete an environmental assessment or issue a notice of schedule of environmental review by Oct. 17, 2017. Comments are due Aug. 9, 2017. Contact: FERC, Office of External Affairs; 866-208-3676; FERCOOnlineSupport@ferc.gov

82 FR 34515 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

New York/Colden Storage Field

**GENERAL ENVIRONMENT AND SAFETY**

Notice of FERC announces the filing of a prior notice request by National Fuel Gas Supply Corp., of Williamsville, N.Y., to plug and abandon one injection/withdrawal storage well and abandon in place the associated well line in the Colden Storage Field in Aurora, N.Y. The agency plans to complete an environmental assessment or issue a notice of schedule of environmental review by Oct. 17, 2017. Protests and motions to intervene are due Sept. 18, 2017. Contact: FERC; 866-208-3676; FERCOOnlineSupport@ferc.gov

82 FR 34516 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Nutrition Labeling for Restaurants/Retail Establishments

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the FDA announces a correction to a July 3, 2017, extension (82 FR 30730) of the comment period for a May 4, 2017, interim final rule (82 FR 20825) that delays the compliance date for a 2014 final rule that established requirements for nutrition labeling of standard menu items in restaurants and retail food establishments (79 FR 71155; 12/01/2014). The correction revises the RIN number, which was published incorrectly. The correct RIN number is 0910-ZA48. The correction is effective July 25, 2017. Contact: Lisa Granger; FDA, Office of Policy; 301-796-9115. Citations: 21 CFR 11.1, 101.9, 101.10, 101.11

82 FR 34401 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Permitted Daily Exposures/Residual Solvents

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the FDA announces the availability of recommendations for the permitted daily exposures (PDEs) for the residual solvents triethylamine and methylisobutylketone in pharmaceuticals. The guidance provides for a new PDE for trimethylamine, a revised PDE to 45 milligrams per day for the solvent methylisobutylketone, and placement of methylisobutylketone into class 2. The revision is based on reconsideration of the severity of effects identified in rat studies and the human relevance of effects identified in mouse carcinogenicity study. The recommendations were developed under the methods for establishing exposure limits in the guidance for industry, Q3C Impurities: Residual Solvents, and under the auspices of the International Council for Harmonisation. Comments may be submitted at any time. Contact: Timothy McGovern; FDA, Center for Drug Evaluation and Research; 240-402-0477

82 FR 34537 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Presidential Advisory Council on Infrastructure Executive Order

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Executive Office of the President announces the issuance of Executive Order 13805 concerning the establishment of the Presidential Advisory Council on Infrastructure. The order provides that it will be the policy of the executive branch to advance infrastructure projects that create high-quality jobs for American workers, enhance productivity, improve quality of life, protect the environment, and strengthen economic growth. The order also provides that the council, established under the Commerce Department, will consist of not more than 15 members, including two co-chairs. Members will be drawn from the public and will have subject-matter expertise in real estate, finance, construction, communications and technology, transportation and logistics, labor, environmental policy, regional and economic development, and other appropriate sectors. The council will make recommendations concerning infrastructure priorities, acceleration of the preconstruction and approval processes, development of financing options to generate new investment over the next 10 years, and additional methods to increase public-private partnerships. The council also will make recommendations concerning best practices to improve procurement methods, grant procedures, and delivery systems and the promotion of advanced manufacturing and technological innovation. In addition, the council will submit a report to the president summarizing its findings and recommendations. The council will terminate on Dec. 31, 2018, unless extended by the president, or within 60 days of submitting the report, whichever occurs first. The order is dated July 19, 2017.

82 FR 34383 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Voluntary Medical Device Manufacturing and Product Quality Program Workshop

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the FDA announces a workshop concerning the Voluntary Medical Device Manufacturing and Product Quality Pilot Program. The workshop will announce the proposed framework and preliminary outline of the program that recognizes an independent assessment of manufacturing and product quality. The agenda includes discussions concerning the independent assessment, details of participation, rules of engagement, monitoring and performance expectations, and potential modifications of FDA oversight actions in response to demonstrated manufacturing quality performance. The workshop is scheduled for Oct. 10, 2017, in Silver Spring, Md., and via webcast. Comments are due Oct. 18, 2017. Contact: Francisco Vicenty; FDA, Center for Devices and Radiological Health; 301-796-5577; [Francisco.Vicenty@fda.hhs.gov](mailto:Francisco.Vicenty@fda.hhs.gov)

82 FR 34531 (07/25/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Washington State/North Fork Nooksack Line Lowering Project

**GENERAL ENVIRONMENT AND SAFETY**

Notice of FERC announces the availability of the schedule of environmental review for the North Fork Nooksack Line Lowering Project in Whatcom County, Wash. The project, proposed by Northwest Pipeline LLC, of Salt Lake City, consists of the removal and replacement of pipeline and removal of previously abandoned-in-place pipeline to reduce exposure due to river channel migration. The issuance of the environmental assessment is scheduled for Nov. 13, 2017, and the 90-day federal authorization decision is due Feb. 11, 2018. Contact: FERC, Office of External Affairs; 866-208-3676; [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov)

82 FR 34517 (07/25/2017)

Regulatory Update

**HAZARDOUS MATERIALS TRANSPORTATION**

Railroad Workforce Development Survey

**HAZARDOUS MATERIALS TRANSPORTATION**

Notice of the Federal Railroad Administration announces the submission of a new information collection request to the OMB regarding the railroad industry workforce development survey (Form FRA 240). The survey will collect information regarding current workforce development strategies and challenges from class I freight and passenger railroads, short line and regional railroads, labor unions, major associations, academia and specialty experts. Comments are due Aug. 24, 2017. Contact: Kim Toone; FRA, Office of Information Technology; 202-493-6132

82 FR 34569 (07/25/2017)

Regulatory Update

**OCCUPATIONAL SAFETY AND HEALTH**

Commerce Department Health Units, Health and Safety Related Records

**OCCUPATIONAL SAFETY AND HEALTH**

Notice announces the intention of the National Institute of Standards and Technology to seek OMB approval for a new information collection request regarding routine information from volunteers, associates, and visitors who utilize Commerce Department health units and other health and safety related records. The information will be collected in paper format, electronically via web applications, and through interviews. Comments are due Sept. 25, 2017. Contact: Stephen Banovic; National Institute of Standards and Technology; 301-975-8822; stephen.banovic@nist.gov

82 FR 34484 (07/25/2017)

Regulatory Update

***OIL AND GAS INDUSTRY***

Hydraulic Fracturing on Federal and Indian Lands

**OIL AND GAS INDUSTRY**

Proposed rule of the Bureau of Land Management would rescind a March 26, 2015, final rule (80 FR 16128) regarding hydraulic fracturing on federal and Indian lands. The 2015 rule addressed well construction requirements and management of fluids that flow back to the surface as a result of hydraulic fracturing operations and required public disclosure of the chemicals used in hydraulic fracturing fluid. The current proposed rule would return affected CFR sections to the language that existed immediately before the effective date of the 2015 final rule. The action is being taken under Executive Order 13783 (82 FR 16093, 03/31/2017), which required the secretary of the Interior Department to review and revise or rescind certain rules that potentially burden the development and use of domestically produced energy resources. Comments on the proposed rule and the supporting environmental assessment are due Sept. 25, 2017. Contact: Steven Wells; BLM, Fluid Minerals Division; 202-912-7143. Citations: 43 CFR 3160.0-3, 3160.0-5, 3162.3-2, 3162.3-3, 3162.5-2

82 FR 34464 (07/25/2017)

Regulatory Update

***RADIATION***

List of Approved Spent Fuel Storage Casks

**RADIATION**

Final rule of the NRC corrects the certification expiration date specified in a March 24, 2017, direct final rule (82 FR 14987) that added the TN Americas LLC NUHOMS® Extended Optimized Storage (EOS) Dry Spent Fuel Storage System to the list of approved spent fuel storage casks as Certificate of Compliance (CoC) No. 1042. The correct expiration date for the CoC is June 7, 2037. The rule is effective July 25, 2017. Contact: Edward Lohr; NRC, Office of Nuclear Material Safety and Safeguards; 301-415-0253; Edward.Lohr@nrc.gov. Citations: 10 CFR 72.214

82 FR 34387 (07/25/2017)

Regulatory Update

***RADIATION***

U.S./IAEA Agreement on Safeguards on Nuclear Material

**RADIATION**

Notice of the NRC announces the submission of a continuing information collection request to the OMB regarding implementation of the U.S./International Atomic Energy Agency (IAEA) agreement concerning safeguards on nuclear material. The collection addresses required licensee reporting on nuclear material inventory and flow for selected facilities, inspections, immediate notification of the loss of nuclear material, and notification for import and export of specified amounts of nuclear material. Comments are due Aug. 24, 2017. Contact: David Cullison; NRC, Office of the Chief Information Officer; 301-415-2084; INFOCOLLECTS.Resource@NRC.GOV. Citations: 10 CFR 75

82 FR 34556 (07/25/2017)

Regulatory Update

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