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From: Bloomberg BNA
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EHS Federal Regulatory Alert

November 08, 2017 - Number 215

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Summaries

AIR
Carbon Pollution Emissions/Electric Generating Units
AIR

Notice of the EPA announces a hearing on and extension of the comment period for an Oct. 16, 2017, proposed rule (82 FR 48035) that would repeal the Clean Power Plan (CPP). The CPP established guidelines and approval criteria for state plans regarding carbon dioxide emission limits from electric generating units and stationary combustion turbines (80 FR 64662; 10/23/2015). The proposed repeal would be based on the EPA's determination that the second and third building blocks of the plan, which address the purchase of or investment in lower-emitting generation and purchase of emissions credits, exceed the agency's statutory authority. The agency is proposing to revise the legal interpretation under Section 111(d) of the Clean Air Act to interpret the phrase "best system of emission reduction" as considering only measures that can be applied to or at the source. The rule is issued in response to Executive Order 13783 (82 FR 16093; 03/31/2017) that requires the EPA to review and consider rescinding or withdrawing rules related to the CPP. The hearing is scheduled for Nov. 28-29, 2017, in Charleston, W.Va., and may be extended to Nov. 30, 2017, based on request volume. An additional hearing may be announced at a later date. Comments now are due Jan. 16, 2018. Contact: Peter Tsirigotis; EPA, Policies and Programs Division; 888-627-7764; airaction@epa.gov. Citations: 40 CFR 60, Subpart UUUU

82 FR 51787 (11/08/2017)

Regulatory Update

AIR
Colorado/Clean Air Act Consent Decree
AIR

Notice of the Justice Department announces a proposed consent decree in *United States v. PDC Energy Inc.* (Civil Action No. 1:17-cv-01552-MSK-MJW), lodged Oct. 31, 2017, with the U.S. District Court for the District of Colorado. The consent decree resolves claims concerning alleged

violations of the Clean Air Act, the Colorado SIP, and various state regulations relating to failures to adequately design, operate, and maintain vapor control systems at tank systems owned and operated by the defendant in a portion of the Denver-Julesburg eight-hour ozone nonattainment area. The consent decree requires the defendants to pay a \$2.5 million civil penalty, to perform injunctive relief, and to complete two environmental mitigation projects at a cost of \$1.7 million. Comments are due Dec. 8, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 51877 (11/08/2017)

Regulatory Update

AIR

Oil and Natural Gas Sector NSPS/Methane and VOC Emissions

AIR

Notice of the EPA announces the availability of new data relating to a proposed rule (82 FR 27641; 06/16/2017) that stayed until Sept. 14, 2017, portions of a final rule (81 FR 35824; 06/03/2016) that revises the NSPS for the oil and natural gas sector. The rule stayed the effectiveness of the fugitive emissions requirements, the standards for pneumatic pumps at well sites, and the certification by a professional engineer requirements. The agency previously stayed the provisions through Aug. 31, 2017 (82 FR 25730). The additional short-term stay is intended to provide the agency time to finalize a longer-term stay during which the agency plans to reconsider issues related to low-production well sites, technical infeasibility exemptions, new construction known as "greenfield," and alternative means of emission limitation. The data addresses several topics raised by stakeholders, including the legal authority to issue a stay; the technological, resource, and economic challenges with implementing the fugitive emissions requirements; and an updated cost savings and forgone benefit analysis for a two-year stay. A concurrent notice announces the availability of new data relating to a concurrent proposed two-year stay. Comments are due Dec. 8, 2017. Contact: Peter Tsirigotis; EPA, Sector Policies and Programs Division; 888-627-7764; airaction@epa.gov. Citations: 40 CFR 60.17; 60.5360 through 60.5430 (Subpart OOOO); 60.5360a through 60.5499a (Subpart OOOOa)

82 FR 51794 (11/08/2017)

Regulatory Update

AIR

Oil and Natural Gas Sector NSPS/Methane and VOC Emissions

AIR

Notice of the EPA announces the availability of new data relating to a proposed rule (82 FR 27645; 06/16/2017) that would stay until June 16, 2019, portions of a final rule (81 FR 35824; 06/03/2016) that revises the NSPS for the oil and natural gas sector. The rule stays the effectiveness of the fugitive emissions requirements, the standards for pneumatic pumps at well sites, and the certification by a professional engineer requirements. The stay is intended to provide the agency time to reconsider issues related to low-production well sites, technical infeasibility exemptions, new construction known as "greenfield," and alternative means of emission limitation. The data addresses several topics raised by stakeholders, including the legal authority to issue a stay; the technological, resource, and economic challenges with implementing the fugitive emissions requirements; and an updated cost savings and forgone benefit analysis for a two-year stay. A concurrent notice announces the availability of new data

relating to an existing short-term stay while the two-year stay is finalized. Comments are due Dec. 8, 2017. Contact: Peter Tsirigotis; EPA, Sector Policies and Programs Division; 888-627-7764; airaction@epa.gov. Citations: 40 CFR 60.17; 60.5360 through 60.5430 (Subpart OOOO); 60.5360a through 60.5499a (Subpart OOOOa)

82 FR 51788 (11/08/2017)

Regulatory Update

AIR

Ozone NAAQS State Implementation Plans

AIR

Notice of the EPA announces the reopening of the comment period for an Oct. 2, 2017, notice (82 FR 45843) regarding the submission of a continuing information collection request to the OMB regarding state implementation requirements of the 2008 ozone NAAQS adopted under a March 15, 2015, final rule (80 FR 12264). The collection addresses information from 17 states with 30 areas designated nonattainment for the 2008 eight-hour NAAQS, including state submissions of attainment demonstrations, request for proposal plans, and reasonably available control technology determinations. Comments now are due Dec. 8, 2017. Contact: Butch Stackhouse; EPA, Office of Air Quality Planning and Standards; 919-541-5208; stackhouse.butch@epa.gov. Citations 40 CFR 50, 51

82 FR 51829 (11/08/2017)

Regulatory Update

AIR

State of the Carbon Cycle 2nd Report

AIR

Notice of the Agriculture Department, National Institute of Food and Agriculture, announces the availability of the draft 2nd State of the Carbon Cycle Science Report (SOCCR-2) on behalf of the U.S. Global Change Research Program and Carbon Cycle Interagency Working Group. The draft document provides updated North American carbon cycle scientific findings and projections for development of the fourth National Climate Assessment, which is expected in 2018. Comments are due Jan. 8, 2018. Contact: USGCRP; 202-223-6262

82 FR 51802 (11/08/2017)

Regulatory Update

COMMUNITY RIGHT-TO-KNOW

Risk Assessment, Mapping, and Planning Tool

COMMUNITY RIGHT-TO-KNOW

Notice of the CDC, Office of Public Health Preparedness and Response, announces the submission of a new information collection request to the OMB concerning development of the Risk Assessment, Mapping, and Planning (RAMP) tool. The RAMP tool is intended to determine risks, identify and map at-risk populations, and define response objectives for hazard-specific public health emergency plans across jurisdictional levels. The collection consists of

interviews/focus groups with public health and emergency management professionals from across the U.S. and an anonymous survey of visitors to Los Angeles County Department of Public Health clinics. Comments are due Dec. 8, 2017. Contact: Leroy Richardson; CDC, Office of Scientific Integrity; 404-639-7570; omb@cdc.gov

82 FR 51842 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Colorado/Town of Meeker Hydro Project

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces the receipt of a notice of intent from the White River Electric Assoc., of Meeker, Colo., to construct the Town of Meeker Hydro Project, a qualifying conduit hydropower facility along the existing Meeker Power Canal in Rio Blanco County, Colo. The project includes two turbines, two penstocks, and a small controls structure and will have an estimated annual generating capacity of up to 500,000 kilowatt-hours. FERC has preliminarily determined that the project satisfies the requirements for a qualifying conduit hydropower facility and is not required to be licensed or exempted from licensing. Motions to intervene are due Dec. 4, 2017. Comments are due Dec. 18, 2017. Contact: Christopher Chaney; FERC; 202-502-6778; Christopher.Chaney@ferc.gov

82 FR 51825 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Deepwater Horizon Spill Restoration Planning/Draft Phase V.2

GENERAL ENVIRONMENT AND SAFETY

Notice of the Department of the Interior announces the availability of the Draft Phase V.2 Restoration Plan and supplemental environmental assessment (Draft Phase V.2 RP/SEA), which supplements the 2016 Final Phase V Early Restoration Plan and environmental assessment concerning early restoration projects in the Gulf of Mexico selected by federal and state natural resource trustee agencies in connection with the April 2010 Deepwater Horizon oil spill. The Draft Phase V.2 RP/SEA also describes and proposes the second phase of the Florida Coastal Access Project to continue the process of restoring natural resources and services injured or lost as a result of the Deepwater Horizon oil spill. A meeting is scheduled for Nov. 16, 2017, in Port St. Joe, Fla. Comments are due Dec.8, 2017. Contact: Nanciann Regalado; U.S. Fish and Wildlife Service; 404-679-4161; nanciann_regalado@fws.gov

82 FR 51858 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Development of Drugs for Recurrent Herpes Labialis

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a final guidance for industry regarding the

development of drugs for treatment and prevention of recurrent herpes labialis. The guidance addresses nonclinical development, early phases of clinical development, phase 3 trial considerations, and safety considerations in the development of antiviral drug products used to treat or prevent recurrent herpes labialis lesions. The guidance has been updated to remove the requirement for a toxicity adverse event scale. Comments may be submitted at any time. Contact: Regina Alivisatos; FDA, Center for Drug Evaluation and Research; 301-796-1500

82 FR 51844 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Maine/Barker's Mill Hydroelectric Project

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces the filing of a hydroelectric application from KEI Power Management LLC, of Lewiston, Maine, for a subsequent minor license for the Barker's Mill Hydroelectric Project located on the Little Androscoggin River in Auburn, Maine. The existing project consists of a dam, a reservoir, a 1.5 megawatt generating unit, and an underground power line generating an average of 5,087 megawatt-hours per year. A draft environmental assessment is expected to be issued in June 2018, and a final EA is expected in October 2018. Comments are due Jan. 2, 2018. Contact: Karen Sughrue; FERC; 202-502-8556; karen.sughrue@ferc.gov

82 FR 51824 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

PhUSE Analysis Data Reviewer's Guide Template

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of the proposed Pharmaceutical Users Software Exchange (PhUSE) Analysis Data Reviewer's Guide template, a potential tool for the electronic submission of animal and human study data. The agency developed the proposed template in collaboration with PhUSE, an independent, nonprofit consortium of academic, regulatory, nonprofit, and private sector entities. The agency seeks stakeholder feedback to inform its recommendation of whether to support, reject, or modify the template. Comments are due Jan. 8, 2018. Contact: Crystal Allard; FDA, Center for Drug Evaluation and Research; 301-796-8856; crystal.allard@fda.hhs.gov

82 FR 51847 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Programs to Expedite Development and Review of Drugs for Serious Conditions

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the FDA to seek OMB approval for a revised information collection request regarding a guidance for industry concerning programs to facilitate and expedite development and review of drugs and biologics for serious conditions. The collection

concerns programs for fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. The revision incorporates an information collection addressing designation, development, and application review of fast track drug development programs. Comments are due Jan. 8, 2018. Contact: Domini Bean; FDA, Office of Operations; 301-796-5733; PRAStaff@fda.hhs.gov

82 FR 51846 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Schedules I and II Controlled Substances 2018 Aggregate Production Quotas

GENERAL ENVIRONMENT AND SAFETY

Notice of the Drug Enforcement Administration announces a final order to establish the initial 2018 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The agency is adjusting the aggregate production quotas for eight controlled substances and is adjusting the assessment of annual needs for pseudoephedrine. The agency also is maintaining the proposed quotas for 16 controlled substances. The order is effective Nov. 8, 2017. Contact: Michael Lewis; DEA, Diversion Control Division; 202-598-6812. Citations: 21 CFR 1303, 1315

82 FR 51873 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Target Product Profiles/Drug Development Programs

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the submission of a new information collection request to the OMB regarding a guidance for industry concerning target product profiles (TPPs) prepared by a sponsor and shared with FDA review staff to facilitate communication for a particular drug development program. The TPPs provide for a summary of a drug development program described in terms of labeling concepts. Comments are due Dec. 8, 2017. Contact: Domini Bean; FDA, Office of Operations; 301-796-5733; PRAStaff@fda.hhs.gov

82 FR 51849 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Washington State/North Seattle Lateral Upgrade Project

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces the filing by Northwest Pipeline LLC, of Salt Lake City, of an amendment to its application to abandon and to construct and operate facilities at the North Seattle Lateral Upgrade Project, in Snohomish County, Wash. The original application sought permission to remove existing pipeline on Northwest's North Seattle Delivery Lateral line, install new pipeline, and rebuild the North Seattle/Everett meter station and install miscellaneous

appurtenances. The amendment adds a request to realign existing pipeline parallel to the new pipeline. The agency plans to complete an environmental assessment or issue a notice of schedule of environmental review by Jan. 31, 2018. Comments are due Nov. 24, 2017. Contact: FERC, Office of External Affairs; 866-208-3676; FERCONlinesupport@ferc.gov

82 FR 51828 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

West Virginia/Green Bank Observatory

GENERAL ENVIRONMENT AND SAFETY

Notice of the National Science Foundation announces the availability of a draft environmental impact statement regarding potential changes to operations at the Green Bank Observatory in Pocahontas County, W.Va. The DEIS addresses proposed operational changes resulting from a significant reduction or elimination of NSF funding for the observatory, including the potential divestment of the Green Bank Telescope from the Division of Astronomical Sciences' portfolio. The DEIS identifies the agency's preferred alternative of collaboration with interested parties for continued science- and education-focused operations with reduced NSF funding. A meeting is scheduled for Nov. 30, 2017, in Green Bank. Comments are due Jan. 8, 2018. Contact: Elizabeth Pentecost; NSF, Division of Astronomical Sciences; 703-292-4907; epenteco@nsf.gov

82 FR 51878 (11/08/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Wisconsin/Arpin Dam Project

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces the filing of a hydroelectric application by Flambeau Hydro LLC, of Neshkoro, Wis., for a subsequent minor license for the Arpin Dam Project located on Chippewa River in Sawyer County, Wis. The project consists of masonry dams, an impoundment, canal headworks, a power canal, an intake structure, steel penstocks, a powerhouse, an underground generator lead line, an above-ground transmission line, a tailrace, recreation facilities, and appurtenant facilities. The project currently is manually operated in run-of-river mode with an annual generation of 7,336 megawatt-hours. Flambeau Hydro seeks to continue to release a year-round minimum flow of 40 cubic feet per second to the bypassed reach, to operate and maintain existing recreation facilities, and to develop a historic properties management plan. The commission intends to prepare a single environmental assessment. Comments are due Dec. 4, 2017. Contact: Amy Chang; FERC; 202-502-8250; amy.chang@ferc.gov

82 FR 51829 (11/08/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH

Federal Mine Safety and Health Review Commission Meeting

OCCUPATIONAL SAFETY AND HEALTH

Notice of the Federal Mine Safety and Health Review Commission announces a meeting to consider Secretary of Labor v. American Coal Co. (Docket Nos. LAKE 2011-701) regarding whether the judge erred by not adequately explaining the basis for the assessed penalty amounts. The meeting is scheduled for Nov. 29, 2017, in Washington, D.C., and via teleconference. Contact: Emogene Johnson; FMSHRC; 202-434-9935

82 FR 51833 (11/08/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH

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82 FR 51833 (11/08/2017)

Regulatory Update

RADIATION

Nuclear Power Plant Instrumentation for Earthquakes

RADIATION

Notice of the NRC announces the issuance of Revision 3 of Regulatory Guide 1.12 regarding nuclear power plant instrumentation for earthquakes. The revision incorporates advances in seismic instrumentation and operating experience since Revision 2 was issued in 1997, including lessons learned from the recent earthquakes that impacted the North Anna nuclear power plant in Louisa County, Va., and the Fukushima-Dai-ichi nuclear power plant in Japan. The revision also describes the seismic instrumentation criteria, including instrumentation type, locations, characteristics, and maintenance, that the NRC staff considers acceptable for nuclear power plants. Contact: Sarah Tabatabai; NRC, Office of Nuclear Regulatory Research; 301-415-2982; Sarah.Tabatabai@nrc.gov

82 FR 51879 (11/08/2017)

Regulatory Update

TOXIC SUBSTANCES

Healthy Homes and Lead Poisoning Surveillance System

TOXIC SUBSTANCES

Notice announces the intention of the CDC to seek OMB approval for a continuing information collection request regarding the Healthy Homes and Lead Poisoning Surveillance System (HHLPSS). The HHLPSS includes up to 40 state and local programs that report information regarding the presence of lead paint, age of housing, occupation of adults, and type of housing to support the CDC's efforts for primary prevention of childhood and adult lead poisoning. The

HHPSS allows the CDC to track how state and local programs conduct case management and follow up of residents with housing-related health outcomes and to identify other housing-related risk factors. Comments are due Jan. 8, 2018. Contact: Leroy Richardson; CDC, Office of Scientific Integrity; 404-639-7570; omb@cdc.gov

82 FR 51841 (11/08/2017)

Regulatory Update

WATER

Susquehanna River Basin Commission Meeting

WATER

Notice of the Susquehanna River Basin Commission announces a meeting to consider resolutions concerning fiscal year 2019 federal funding of the Groundwater and Streamflow Information Program and bylaw amendments. The agenda also includes a presentation regarding the Lower Susquehanna Subbasin area, ratification and approval of grants and contracts, and a report on delegated settlements. In addition, the agenda includes discussion of an Oct. 12, 2017, proposed rule (82 FR 47407) to codify the existing policy for access to commission records and Regulatory Program projects. The meeting is scheduled for Dec. 8, 2017, in Annapolis, Md. Comments on the rulemaking and the Regulatory Program projects are due Nov. 13, 2017, and comments on other agenda items are due Dec. 1, 2017. Contact: Jason Oyler; SRBC; 717-238-0423. Citations: 18 CFR 801, 806, 807, 808

82 FR 51903 (11/08/2017)

Regulatory Update

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