

To: Jackson, Ryan[jackson.ryan@epa.gov]
From: Bloomberg BNA
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EHS Federal Regulatory Alert

August 02, 2017 - Number 147

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Summaries

AIR

California SIP/Photochemical Assessment Monitoring System Network

AIR

Proposed rule of the EPA would approve a revision to the California SIP. The revision concerns the establishment of a photochemical assessment monitoring system (PAMS) network in six ozone nonattainment areas within the state. The revision specifies that the South Coast Air Quality Management District (AQMD), the Sacramento Metro AQMD, the San Diego County Air Pollution Control District (APCD), the San Joaquin Valley Unified APCD, and the Ventura County APCD have implemented required PAMS networks and each district has included a provision on meeting quality assurance requirements. Additionally, the revision provides that the air districts have included a provision to assure that PAMS monitors will meet monitoring methodology requirements. Finally, the revision specifies that the air districts have provided assurance that their respective PAMS networks will be phased in over a period of not more than five years. Comments are due Sept. 1, 2017. Contact: Doris Lo; EPA Region 9; 415-972-3959; lo.doris@epa.gov. Citations: 40 CFR 52, 40 CFR 58

82 FR 35922 (08/02/2017)

Regulatory Update

AIR

North Carolina/Clean Air Act Operating Permit Petitions

AIR

Notice of the EPA announces a final order granting two petitions submitted by the Sierra Club objecting to proposed and current Clean Air Act Title V operating permits issued to Duke Energy LLC of Charlotte, N.C. The petitioner objects to the proposed permit issued by the Western North Carolina Regional Air Quality Agency to the Asheville Steam Electric Plant in Buncombe County, N.C., and to the permit issued by the North Carolina Department of Environmental Quality to the Roxboro Steam Electric Plant in Person County, N.C. The petitioner claims that each permit must contain stricter modeling-based numerical emission limits for sulfur dioxide (SO₂) to prevent

exceedances of the 2010 SO2 NAAQS. The petitioner also claims that the permits must contain a compliance schedule because each facility has violated its current permit. The EPA administrator issued orders June 30, 2017, granting the petitions. Petitions for review are due Oct. 2, 2017. Contact: Art Hofmeister; EPA Region 4, Air Permits Section; 404-562-9115; hofmeister.art@epa.gov

82 FR 35946 (08/02/2017)

Regulatory Update

AIR

Solid Waste Incineration Unit Negative Declarations/EPA Region 8

AIR

Final rule of the EPA corrects improper references to “Utah” with “Wyoming” in a June 5, 2017, direct final rule (82 FR 25734) that approved negative declarations for several categories of solid waste incineration units in Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming. The correction certifies that there are no existing large municipal waste combustion units within the state of Wyoming that are subject to 40 CFR 60, Subpart Cb. The rule is effective Aug. 4, 2017. Contact: Gregory Lohrke; EPA Region 8, Air Program; 303-312-6396; lohrke.gregory@epa.gov. Citations: 40 CFR 62.12620

82 FR 35906 (08/02/2017)

Regulatory Update

ENDANGERED SPECIES

California/Lost Hills Solar Project

ENDANGERED SPECIES

Notice of the U.S. Fish and Wildlife Service announces the availability of a draft environmental assessment regarding the Lost Hills Solar Project in Kern County, Calif. The notice also announces the receipt of an application from CED Lost Hills Solar LLC for an incidental take permit and a draft habitat conservation plan. The permit would authorize the take of the endangered San Joaquin kit fox for a 45-year period incidental to the construction, operation and maintenance, and decommissioning of the solar project. Comments are requested on biological information on the San Joaquin kit fox; the range, distribution, population size, and population trends of the species; and current or planned activities in the area and their possible impacts on the species. Comments are due Sept. 1, 2017. Contact: Justin Sloan; USFWS, San Joaquin Valley Division; 916-414-6600

82 FR 35986 (08/02/2017)

Regulatory Update

FOOD SAFETY

Animal Drug User Fees

FOOD SAFETY

Notice of the FDA announces the fee rates and payment procedures for fiscal year 2018 for certain animal drug applications and supplements, certain animal drug products, certain

establishments where such products are made, and certain sponsors of such applications and/or investigational drug submissions. The fees are effective for applications submitted on or after Oct. 1, 2017, and expire Sept. 30, 2018. Contact: Lisa Kable; FDA, Center for Veterinary Medicine; 240-402-6888; cvmadufa@fda.hhs.gov

82 FR 35966 (08/02/2017)

Regulatory Update

FOOD SAFETY

Animal Generic Drug User Fees

FOOD SAFETY

Notice of the FDA announces the fee rates and payment procedures for fiscal year 2018 for certain abbreviated applications for generic new animal drugs, certain generic new animal drug products, and certain sponsors of such abbreviated applications and/or investigational submissions for generic new animal drugs. The fees are effective for applications submitted on or after Oct. 1, 2017, and expire Sept. 30, 2018. Contact: Lisa Kable; FDA, Center for Veterinary Medicine; 240-402-6888; cvmagdufa@fda.hss.gov

82 FR 35957 (08/02/2017)

Regulatory Update

FOOD SAFETY

Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fees

FOOD SAFETY

Notice of the FDA announces the fiscal year 2018 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections. The fees are effective Oct. 1, 2017, and expire Sept. 30, 2018. Contact: Jason Lewis; FDA, Office of Regulatory Affairs; 301-796-5957; Jason.Lewis@fda.hhs.gov

82 FR 35954 (08/02/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Advisory Committee on Human Research Protections/Request for Nominations

GENERAL ENVIRONMENT AND SAFETY

Notice of the Department of Health and Human Services seeks nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections. The committee provides advice and recommendations on matters relating to the continuance and improvement of functions directed toward protections for human subjects in research. The request seeks nominees for four positions that will be vacated during the 2018 calendar year. Nominations are due Sept. 18, 2017. Contact: Julia Gorey; SACHRP, Office for Human Research Protections; 240-453-8141

82 FR 35974 (08/02/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Biomass Research and Development Technical Advisory Committee

GENERAL ENVIRONMENT AND SAFETY

Notice of the Energy Department, Office of Energy Efficiency and Renewable Energy, announces a meeting of the Biomass Research and Development Technical Advisory Committee. The tentative agenda includes updates on Agriculture Department and DOE biomass research and development activities and presentations on biomass interface with fossil fuels addressing gasification, refineries, carbon dioxide utilization, and current activities by the state of California. The meeting is scheduled for Aug. 15-16, 2017, in Los Angeles. Comments may be submitted at any time. Contact: Mark Elless; DOE, Office of Energy Efficiency and Renewable Energy; 410-997-7778; Mark.Elless@EE.Doe.Gov

82 FR 35939 (08/02/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

California/General Conservation Plan for Oil and Gas Activities

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the U.S. Fish and Wildlife Service to prepare a draft environmental analysis/document concerning the proposed issuance of an incidental take permit for the draft general conservation plan for oil and gas activities in Santa Barbara County, Calif. The permit would authorize take of the California tiger salamander, the California red-legged frog, and the Lompoc yerba santa that could result from activities relating to geophysical exploration, development, extraction, storage, transport, remediation, and/or distribution of crude oil, natural gas, and/or other petroleum products. Comments are due Sept. 1, 2017. Contact: Rachel Henry; USFWS; 805-677-3312

82 FR 35988 (08/02/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

De Novo Classification Process for Medical Devices

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the submission of a new information collection request to the OMB regarding draft guidance entitled De Novo Classification Process (Evaluation of Automatic Class III Designation). The collection addresses requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) that provide a path to class I or class II designation for medical devices for which general controls, or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. The FDA requests responses from medical device manufacturers seeking to market medical device products that have been classified into class III under the FD&C Act. The FDA also corrects an error in the agency's 60-day notice (79 FR 47651; 08/14/2014) regarding the estimated hour burden for certain requests. Comments are due Sept. 1, 2017. Contact: Amber Sanford; FDA, Office of Operations; 301-796-8867; PRASstaff@fda.hhs.gov

82 FR 35971 (08/02/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Guidance for Antibacterial Therapies

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a guidance for industry concerning antibacterial therapies for patients with unmet medical need for the treatment of serious bacterial diseases. The guidance is intended to assist sponsors in the development of new antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need, including patients who have a serious bacterial disease for which effective antibacterial drugs are limited or lacking. Comments may be submitted at any time. Contact: Joseph Toerner; FDA, Center for Drug Evaluation and Research; 301-796-1300

82 FR 35973 (08/02/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Human Drug Compounding Outsourcing Facility Fees

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the fiscal year 2018 establishment and reinspection fees for registered outsourcing facilities that compound human drugs. The small business establishment fee is \$5,364, the non-small business establishment fee is \$17,364, and the reinspection fee for outsourcing facilities is \$16,093. The notice provides information on how the FY 2018 fees were determined and specifies the payment procedures for outsourcing facilities. The fees are effective Oct. 1, 2017, and expire Sept. 30, 2018. Contact: Monica Vega; FDA, Office of Financial Management; 301-796-2127

82 FR 35962 (08/02/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Over-the-Counter Monograph Drugs User-Fee Program Meeting

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a meeting to provide an update on discussions regarding a nonprescription (over-the-counter) monograph drug user-fee program that began in July 2016 and an overview of proposed performance goals and procedures related to the potential program. The program would provide funding to supplement congressional nonuser-fee appropriations and would support FDA review of the efficacy and safety of ingredients included in or proposed for inclusion in a monograph. The meeting is scheduled for Aug. 23, 2017, via webcast. Contact: Mary Vienna; FDA, Center for Drug Evaluation and Research; 301-796-4150; OTCMonographUserFeeProgram@fda.hhs.gov

82 FR 35965 (08/02/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION

Oil and Hazardous Materials Transfer Procedures

HAZARDOUS MATERIALS TRANSPORTATION

Notice announces the intention of the U.S. Coast Guard to seek OMB approval for a continuing information collection request concerning oil and hazardous materials transfer procedures. The collection addresses the requirement for vessels with a cargo capacity of 250 barrels or more of oil or hazardous materials to develop and maintain transfer procedures to provide basic safety information for operating transfer systems. Comments are due Oct. 2, 2017. Contact: Anthony Smith; USCG, Office of Information Management; 202-475-3532. Citations: 33 CFR 155

82 FR 35980 (08/02/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH

Commercial Diving Operations Variance

OCCUPATIONAL SAFETY AND HEALTH

Notice of OSHA announces the receipt of an application from Jardon and Howard Technologies Inc., of Orlando, Fla., for an interim order and permanent variance from OSHA regulations regarding commercial diving operations that the company conducts as a contractor for NOAA. The variance request addresses requirements concerning the use of inflatable flotation devices and decompression chambers. The agency announces its preliminary finding to grant the permanent variance and to grant an interim order based on the conditions specified in the application. The interim order is effective Aug. 2, 2017. Comments and hearing requests are due Sept. 1, 2017. Contact: Kevin Robinson; OSHA, Directorate of Technical Support and Emergency Management; 202-693-2110; robinson.kevin@dol.gov. Citations: 29 CFR 1905.11

82 FR 35995 (08/02/2017)

Regulatory Update

RADIATION

Electrical Equipment High-Energy Arcing Faults Testing

RADIATION

Notice of the NRC announces a draft test plan for phase 2 of high-energy arcing faults (HEAF) in electrical equipment. The test plan is intended to assess the fire risk presented by HEAF phenomena and to characterize physical parameters, including thermal conditions, pressure effects, and electrical conductive products of combustion created HEAFs occurring in electrical cabinets and bus ducts. Data will be used by the NRC to determine the adequacy of existing HEAF zone of influences damage models. Phase 2 testing will focus on the HEAFs involving aluminum components related to increased physical damage states and potential product of combustion electrical conductivity concerns. Comments are due Sept. 1, 2017. Contact: Nicholas Melly; NRC, Office of Nuclear Regulatory Research; 301-415-2392; Nicholas.Melly@nrc.gov

82 FR 36006 (08/02/2017)

Regulatory Update

RADIATION

Environmental Management Advisory Board/Oak Ridge Reservation

RADIATION

Notice of the Energy Department announces a meeting of the Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation. The board makes recommendations to DOE-EM and site management in the areas of environmental restoration, waste management, and related activities. The agenda includes a discussion of member survey results, presentations by various governmental agency liaisons, presentation of candidates for fiscal year 2018 board officers, and recommendations on FY 2019 Oak Ridge EM budget priorities. The meeting is scheduled for Aug. 19, 2017, in Townsend, Tenn. Comments are requested, but a due date is not specified. Contact: Melyssa Noe; DOE, Oak Ridge Office of Environmental Management; 865-241-3315; Melyssa.Noel@orem.doe.gov

82 FR 35938 (08/02/2017)

Regulatory Update

RADIATION

Environmental Management Advisory Board/Paducah

RADIATION

Notice of the Energy Department announces a meeting of the Environmental Management Site-Specific Advisory Board, Paducah. The board makes recommendations to DOE-EM and site management in the areas of environmental restoration, waste management, and related activities. The meeting is scheduled for Aug. 17, 2017, in Paducah, Ky. Comments are requested, but a due date is not specified. Contact: Jennifer Woodard; DOE, Paducah Site Office; 270-441-6825

82 FR 35939 (08/02/2017)

Regulatory Update

RADIATION

Uranium and Thorium Mill Tailing Standards

RADIATION

Notice of the EPA announces the reopening of the comment period for a Jan. 19, 2017, proposed rule (82 FR 7400) concerning health and environmental protection standards for uranium and thorium mill tailings. The rule would establish standards for byproduct materials produced by uranium in-situ recovery for implementation by the Nuclear Regulatory Commission and NRC agreement states, including both surface and subsurface standards for groundwater protection, monitoring, restoration, and stability. A corrective action approach would be provided to meet constituent concentration standards, specific criteria and procedures for approving termination of long-term stability monitoring would be added, and the NRC and agreement states would determine on a site-specific basis the constituents for which concentration based standards are set. The requirement that the NRC obtain EPA concurrence prior to making site-specific alternate concentration limit determinations would be removed. The proposal supersedes a Jan. 26, 2015, proposed rule (80 FR 4155). Comments now are due Oct. 16, 2017. Contact: Ingrid Rosencrantz;

EPA, Office of Radiation and Indoor Air; 202-343-9286; Rosencrantz.ingrid@epa.gov. Citations: 40 CFR 192.20, 192.31, 192.32, 192.50 through 192.56 (Subpart F)

82 FR 35924 (08/02/2017)

Regulatory Update

TOXIC SUBSTANCES

TSCA Statements of Findings

TOXIC SUBSTANCES

Notice of the EPA announces the availability of two statements of findings that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. The notice specifies that the statements apply to premanufacture notices, microbial commercial activity notices, and significant new use notices submitted to the EPA under TSCA Section 5(a) from April 1-30, 2017. Contact: Greg Schweer; EPA, Office of Pollution Prevention and Toxics; 202-564-8469; schweer.greg@epa.gov

82 FR 35944 (08/02/2017)

Regulatory Update

WATER

Vessel Inspections, Waivers, and Continuous Synopsis Records

WATER

Notice announces the intention of the U.S. Coast Guard to seek OMB approval for a continuing information collection request regarding applications for vessel inspection, waiver, and continuous synopsis record. The collection concerns the requirement for vessel owners, operators, agents, or masters to apply in writing to the Coast Guard before the commencement of inspections for certification (Form CG-3752), to request waivers from the requirements of navigation and vessel inspection (Form CG-2633), or to request continuous synopsis records (Form CG-6039). Comments are due Oct. 2, 2017. Contact: Anthony Smith; USCG, Office of Information Management; 202-475-3532

82 FR 35979 (08/02/2017)

Regulatory Update

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