

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

June 19, 2017 - Number 116

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Summaries

AIR

Ambient Air Monitoring Reference and Equivalent Methods

AIR

Notice of the EPA announces the designation of new ambient air monitoring reference methods and equivalent methods in accordance with regulations under 40 CFR 53. The notice specifies the designation of a new reference method for measuring concentrations of carbon monoxide and a new equivalent method for measuring concentrations of nitrogen dioxide in ambient air. Contact: Robert Vanderpool; EPA, National Exposure Research Laboratory; 919-541-7877; Vanderpool.Robert@epa.gov

82 FR 27816 (06/19/2017)

[Regulatory Update](#)

AIR

Light-Duty Vehicle GHG Emissions Standards/Off-Cycle Credits

AIR

Notice of the EPA announces a request for comments on applications from BMW of North America, Ford Motor Co., and Hyundai Motor Group for off-cycle carbon dioxide credits under the light-duty vehicle greenhouse gas (GHG) emissions standards (40 CFR 86.1869-12). The notice describes each manufacturer's off-cycle credit calculation methodologies for various technologies, including an air conditioning compressor manufactured by Denso, a high-efficiency alternator, and glass/glazing and solar reflective surface coating technologies. Comments are due July 19, 2017. Contact: Roberts French; EPA, Office of Transportation and Air Quality; 734-214-4380; french.roberts@epa.gov

82 FR 27819 (06/19/2017)

[Regulatory Update](#)

AIR

Texas/Alternative Emissions Limitations for Ground Flares

AIR

Notice of the EPA announces the approval of two requests from Chevron Phillips Chemical Co., of The Woodlands, Texas, for alternative means of emission limitation (AMEL) for the use of a multipoint ground flare (MPGF) at certain new facilities in Texas. The approval allows for the operation of an MPGF during limited high-pressure maintenance, startup, and shutdown events and during upset events at an ethylene plant in Baytown. The approval also allows for the operation of an MPGF during the first two stages of routine operations and periods of maintenance, startup, shutdown, and upset at a polyethylene plant in Old Ocean. The notice specifies the operating conditions and monitoring, recordkeeping, and reporting requirements necessary to achieve volatile organic compound and hazardous air pollutant emissions reductions that are at least equivalent to those required under the applicable emissions standards at 40 CFR 60, 61, and 63. The approval is effective June 19, 2017. Contact: Andrew Bouchard; EPA, Office of Air Quality Planning and Standards; 919-541-4036; bouchard.andrew@epa.gov

82 FR 27822 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Direct-to-Consumer Advertising for Prescription Drugs and Biological Products

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Food and Drug Administration, Office of Prescription Drug Promotion, to seek OMB approval for a new information collection request regarding direct-to-consumer (DTC) print advertising for prescription drugs and biological products for rheumatoid arthritis and overactive bladder. The collection includes one pilot study and two main studies in five U.S. cities, using eye tracking technology to measure participants' attention to the important safety information, the brief summary, and the indication and benefit claims in the DTC print ads. Comments are due Aug. 18, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794; PRAStaff@fda.hhs.gov

82 FR 27842 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

FDA Electronic Records, Electronic Signatures

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding the acceptance of electronic recordkeeping and electronic signatures (21 CFR 11). The collection addresses standard operating procedures and controls for persons using closed and open systems to create, modify, maintain, or transmit electronic records. The collection also addresses procedures and controls for persons using electronic signatures, the use of identification codes and passwords, and the requirement for persons to certify in writing to the agency that they will regard electronic signatures used in their systems as legal equivalents to handwritten signatures. Comments are due Aug. 18, 2017.

Contact: Domini Bean; FDA, Office of Operations; 301-796-5733; PRAStaff@fda.hhs.gov

82 FR 27838 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Louisiana/Sabine Pass Expansion Project

GENERAL ENVIRONMENT AND SAFETY

Notice of the Federal Energy Regulatory Commission announces the availability of the schedule of environmental review for the Sabine Pass Expansion Project in Acadia, Cameron, and Evangeline parishes in Louisiana. The project, proposed by Kinder Morgan Louisiana Pipeline LLC, of Downers Grove, Ill., includes modifications to four existing meter stations, construction of one delivery interconnect at the Sabine Pass Liquefaction Facility, installation of three compressor units at Compressor Station 760 as part of the Lake Charles Expansion Project, construction of header pipelines, and replacement of a meter and increase in capacity at the existing Pine Prairie Meter Station. The issuance of the environmental assessment is scheduled for July 28, 2017, and the 90-day federal authorization decision is due Oct. 26, 2017. Contact: FERC, Office of External Affairs; 866-208-3676; FERCONlinesupport@ferc.gov

82 FR 27808 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Louisiana/St. James Supply Project

GENERAL ENVIRONMENT AND SAFETY

Notice of the Federal Energy Regulatory Commission announces the availability of the schedule of environmental review for the St. James Supply Project in Pointe Coupee, St. Helena and St. James parishes in Louisiana. The project, proposed by Transcontinental Gas Pipe Line Co., of Houston, consists of several facilities that will provide 161,500 dekatherms per day of firm transportation capacity to deliver natural gas from the existing Compressor Station 65 to the Yuhuang Chemical Plant in St. James Parish. The issuance of the environmental assessment is scheduled for July 24, 2017, and the 90-day federal authorization decision is due Oct. 22, 2017. Contact: FERC, Office of External Affairs; 866-208-3676; FERCONlinesupport@ferc.gov

82 FR 27812 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Minerals Leases/Suspensions Pending Appeal and Bonding

GENERAL ENVIRONMENT AND SAFETY

Notice of the Department of the Interior, Office of Natural Resources Revenue, announces the submission of a continuing information collection request to the OMB regarding suspensions pending appeal and bonding (30 CFR 1243). The collection addresses the submission of appropriate surety instruments to suspend compliance with orders or decisions and to stay the accrual of civil penalties pending administrative appeals for minerals leases on federal and Indian

lands. Comments are due Aug. 18, 2017. Contact: Kimberly Werner; ONRR, Office of Enforcement; 303-231-3801; Kimberly.Werner@onrr.gov

82 FR 27868 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Nevada/Trout Creek Hydroelectric Project
GENERAL ENVIRONMENT AND SAFETY

Notice of the Federal Energy Regulatory Commission announces the filing of a hydroelectric application by Wells Rural Electric Co. of Wells, Nev., for a minor new license for the Trout Creek Hydroelectric Project in Elko County, Nev. The existing project includes an intake structure, pipeline, a penstock, and a powerhouse with a 125-kilowatt turbine-generator unit. Comments are due Aug. 14, 2017. Contact: Alan Mitchnick; FERC; 202-502-6074; alan.mitchnick@ferc.gov

82 FR 27803 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Oncology Prescription Drug Promotion/Disclosures
GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a new information collection request regarding the impact of disclosures as they relate to presentations of preliminary or descriptive scientific and clinical data in promotional labeling and advertising for oncology products. The collection concerns a three-phase study of oncologists, primary care physicians, and nononcology mid-level practitioners recruited via the internet. The study will assess whether disclosures mitigate potentially misleading presentations of preliminary or descriptive data in oncology drug product promotion, whether the language of the disclosure influences effectiveness, and if a general statement about the clinical utility of the data in addition to a specific disclosure influences processing of claims and disclosures. The study will also assess whether primary care physicians, oncologists, and mid-level practitioners differ in their processing of claims and disclosures about preliminary or descriptive data and physician preference for disclosures. Comments are due Aug. 18, 2017. Contact: Ila Mizrahi; FDA, Office of Operations; 301-796-7726; PRAStaff@fda.hhs.gov

82 FR 27845 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Orphan Drug Medicinal Product Designation
GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request concerning the Common European Medicines Agency/FDA application form for orphan drug medicinal product designation (21 CFR 316), which allows sponsors to apply for incentives provided for orphan drugs. The collection addresses

applications for designation, requests for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications, and application amendments (Form FDA 3671). Comments are due Aug. 18, 2017. Contact: Amber Sanford; FDA Office of Operations; 301-796-8867; PRAStaff@fda.hhs.gov

82 FR 27836 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Pharmacogenomic Data Submissions

GENERAL ENVIRONMENT AND SAFETY

Notice of the Food and Drug Administration announces the submission of a continuing information collection request to the OMB regarding pharmacogenomic data submissions by sponsors of investigational new drug applications, new drug applications, or biologics license applications (21 CFR 312, 314, and 601). The collection addresses agency guidance regarding when pharmacogenomics data must be submitted during the drug development process and the voluntary genomic data submission process. Comments are due July 19, 2017. Contact: Jonnalynn Capezutto; FDA, Office of Operations; 301-796-3794; PRAStaff@fda.hhs.gov

82 FR 27841 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Sensitive Security Information Threat Assessments

GENERAL ENVIRONMENT AND SAFETY

Notice of the Transportation Security Administration announces the submission of a revised information collection request to the OMB regarding an individual's access to sensitive security information made contingent upon satisfactory completion of a security threat assessment (49 CFR 1520). The revision allows members of the TSA PreCheck Application Program to provide a known traveler number to facilitate the assessment. Comments are due July 19, 2017. Contact: Christina Walsh, TSA, Office of Information Technology; 571-227-2062; TSAPRA@tsa.dhs.gov

82 FR 27852 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Testing of Regulated Drug Products Communications

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding drug product communications. The collection addresses the testing of messages in advance of communications campaigns for regulated drug products on a variety of subjects concerning perceptions and the use of such products. Comments are due Aug. 18, 2017. Contact: Domini Bean; FDA, Office of Operations; 301-796-5733; PRAStaff@fda.hhs.gov

82 FR 27840 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Wisconsin/White River Hydroelectric Project

GENERAL ENVIRONMENT AND SAFETY

Notice of the Federal Energy Regulatory Commission announces the filing of an application by Northern States Power Co., of Eau Claire, Wis., for a noncapacity amendment of license for the White River Hydroelectric Project in Ashland County, Wis. The applicant requests approval to replace one of the two turbine generator units, to increase the total authorized installed capacity of the project to 1.2 megawatts, and to increase the hydraulic capacity of the project to 350 cubic feet per second. Comments, motions to intervene, and protests are due July 13, 2017. Contact: Steven Sachs; FERC; 202-502-8666; Steven.Sachs@ferc.gov

82 FR 27801 (06/19/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Wyoming/Ryckman Creek Resources Storage Field

GENERAL ENVIRONMENT AND SAFETY

Notice of the Federal Energy Regulatory Commission announces the filing of a prior notice request by Ryckman Creek Resources LLC, of Houston, to perform certain activities at its natural gas storage field in Uinta County, Wyo. The applicant proposes to convert certain existing observation wells to vertical injection/withdrawal wells, reenter and recomplete certain former oil production wells to use as other well types, and construct related connecting flow lines, access roads, and appurtenances. The notice specifies that the agency will complete an environmental assessment or issue a notice of schedule of environmental review by Sept. 11, 2017. Protests and motions to intervene are due Aug. 11, 2017. Contact: FERC; 866-208-3676; FERCOOnlineSupport@ferc.gov

82 FR 27802 (06/19/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION

Serious Injury Reporting Using the Model Minimum Uniform Crash Criteria

HAZARDOUS MATERIALS TRANSPORTATION

Notice announces the intention of the Federal Highway Administration to seek OMB approval for a new information collection request regarding state compliance with serious injury reporting using the Model Minimum Uniform Crash Criteria (MMUCC) 4th edition. The MMUCC is a collaborative effort to generate uniform crash data that are accurate, reliable, and credible for data-driven highway safety decisions within a state, between states, and at the national level. The collection concerns the ability of states to report serious injuries using the new federal definition of "suspected serious injury," including states' maintenance of a statewide crash database capable of aggregating each injury status attribute for suspected serious injury, use of verbatim terminology and definitions for the injury status attribute, and ensuring the seven serious injury

types are not included in any other attributes in the states' injury status data elements. Comments are due Aug. 18, 2017. Contact: Keith Williams; FHWA, Office of Safety Programs; 202-366-9212

82 FR 27952 (06/19/2017)

Regulatory Update

NOISE

Highway Noise Barrier Inventory

NOISE

Notice announces the intention of the Federal Highway Administration to seek OMB approval for a new information collection request regarding the highway noise barrier inventory maintained by state departments of transportation (23 CFR 772.13). The collection will update the current inventory to include noise barriers constructed from 2014 through 2016 and will be distributed nationally for use in the highway traffic noise program. Comments are due Aug. 18, 2017. Contact: Mark Ferroni; FHWA, Office of Planning, Environment, and Realty; 202-366-3233

82 FR 27955 (06/19/2017)

Regulatory Update

RADIATION

Illinois/Metropolis Works Facility

RADIATION

Notice of the Nuclear Regulatory Commission announces the receipt of a license renewal application from Honeywell International Inc., of Morris Plains, N.J., for the source materials license (SUB-526) for the Metropolis Works facility in Metropolis, Ill. The license authorizes the facility to convert uranium ore into pure uranium hexafluoride, via the dry conversion process, for use in enrichment operations. The licensee is requesting a renewed term of 40 years. Hearing requests or petitions for leave to intervene are due Aug. 18, 2017. Contact: Tilda Liu; NRC, Office of Nuclear Material Safety and Safeguards; 404-997-4730; Tilda.Liu@nrc.gov

82 FR 27880 (06/19/2017)

Regulatory Update

RADIATION

Standard Specifications for Granting of Patent Licenses

RADIATION

Notice announces the intention of the Nuclear Regulatory Commission to seek OMB approval for a continuing information collection request concerning standard specifications for granting of patent licenses (10 CFR 81). The rule allows the NRC to grant nonexclusive licenses or limited exclusive licenses for patented inventions and requires periodic submission of reports on efforts to bring the invention to a point of practical application and the extent to which licensees are making the benefits of the invention reasonably accessible to the public. The collection addresses information from license holders seeking to extend their licenses, issue sublicenses, or transfer the licenses and the submission of pleadings or other papers filed in any patent

infringement lawsuit and evidence from proceedings relating to a licensed patent. Comments are due Aug. 18, 2017. Contact: David Cullison; NRC; 301-415-2084; INFOCOLLECTS.Resource@NRC.GOV

82 FR 27879 (06/19/2017)

Regulatory Update

SOLID WASTE

Illinois Municipal Solid Waste Landfill Program

SOLID WASTE

Notice of the EPA announces a determination of adequacy for proposed revisions to Illinois' Research, Development, and Demonstration Permit Program for municipal solid waste landfills. The revisions incorporate by reference May 10, 2016, amendments to federal standards under 40 CFR 258.4 that increased the permissible number of three-year permit renewals from three to six, for a total permit term of up to 21 years. The determination is effective Aug, 18, 2017, unless adverse comments are received by July 19, 2017. Contact: Carol Staniec; EPA Region 5, Land and Chemicals Division; 312-886-1436; staniec.carol@epa.gov

82 FR 27814 (06/19/2017)

Regulatory Update

SOLID WASTE

Michigan Municipal Solid Waste Landfill Program

SOLID WASTE

Notice of the EPA announces a determination of adequacy for proposed revisions to Michigan's Research, Development, and Demonstration Permit Program for municipal solid waste landfills. The revisions incorporate by reference May 10, 2016, amendments to federal standards under 40 CFR 258.4 that increased the permissible number of three-year permit renewals from three to six, for a total permit term of up to 21 years. The determination is effective Aug, 18, 2017, unless adverse comments are received by July 19, 2017. Contact: Cynthia Meyer; EPA Region 5, Land and Chemicals Division; 312-886-5868; meyer.cynthia@epa.gov

82 FR 27816 (06/19/2017)

Regulatory Update

SOLID WASTE

Minnesota Municipal Solid Waste Landfill Program

SOLID WASTE

Notice of the EPA announces a determination of adequacy for proposed revisions to Minnesota's Research, Development, and Demonstration Permit Program for municipal solid waste landfills. The revisions incorporate by reference May 10, 2016, amendments to federal standards under 40 CFR 258.4 that increased the permissible number of three-year permit renewals from three to six, for a total permit term of up to 21 years. The determination is effective Aug, 18, 2017, unless adverse comments are received by July 19, 2017. Contact: Camille Lukey; EPA Region 5, Land and Chemicals Division; 312-886-0880; lukey.camille@epa.gov

82 FR 27815 (06/19/2017)

Regulatory Update

WATER

Florida/Miami Anchorage

WATER

Final rule of the U.S. Coast Guard amends regulations under 33 CFR 110.188 to divide the Miami anchorage into two separate anchorage areas. The rule establishes two anchorage areas with a combined area of approximately 1.5 square miles and reduces the total anchorage area by approximately 3 square nautical miles. The rule also requires vessels anchored in the Miami anchorage to maintain a 24-hour bridge watch with a licensed or credentialed desk officer proficient in English, prohibits vessels from anchoring with engines off or in a “dead ship” status, and requires vessels to seek permission of the captain of the port prior to anchoring for longer than 72 hours. The rule is intended to reduce potential damage to threatened coral posed by anchoring vessels. The rule is effective July 19, 2017. Contact: Paul Lehmann; USCG, Sector Miami Waterways Management Division; 305-415-6796; Paul.D.Lehmann@uscg.mil

82 FR 27773 (06/19/2017)

Regulatory Update

WATER

Oregon and Washington State/NPDES Permit for Offshore Seafood Processors

WATER

Notice of the EPA announces the availability of proposed revisions to a draft National Pollutant Discharge Elimination System general permit (WAG520000) for offshore seafood processors in federal waters off the coasts of Oregon and Washington. The agency is re-proposing the draft general permit issued Aug. 24, 2015 (80 FR 51253) and the associated fact sheet and biological evaluation based on comments received. The agency seeks comments on revised permit conditions, including a seasonal prohibition on wastewater discharges in waters shallower than 100 meters and a year-round discharge prohibition over the Heceta/Stonewall Banks complex. The revisions also clarify the jurisdiction of the permit, add a best management practice that vessels be moving while discharging to aid dispersion of the discharge, and clarify sea surface monitoring requirements. In addition, the revisions add provisions to mitigate impact to seabirds, update standard NPDES language and conditions, and modify the notice of intent for permit coverage and the annual report. Comments and hearing requests are due Aug. 3, 2017. Contact: Catherine Gockel; EPA Region 10, Office of Water and Watersheds; 206-553-0325; gockel.catherine@epa.gov

82 FR 27817 (06/19/2017)

Regulatory Update

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