

To: Jackson, Ryan[jackson.ryan@epa.gov]
From: Bloomberg BNA
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Subject: May 30 -- EHS Federal Regulatory Alert



EHS Federal Regulatory Alert

May 30, 2017 - Number 102

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Summaries

AIR

California SIP/Imperial County PM-2.5 NAAQS

AIR

Final rule of the EPA corrects a March 13, 2017, direct final rule (82 FR 13392) that amended regulations under 40 CFR 52.220 and 52.247 to make a determination that the Imperial County, Calif., moderate nonattainment area has attained the 2006 24-hour fine particulate matter (PM-2.5) NAAQS, based on ambient air monitoring data for 2013-2015. The rule also approved a revision to the California SIP concerning the annual average and winter daily average inventories for the Imperial County nonattainment area for 2008. The current action clarifies that the EPA is not approving a provision of the state's SIP submittal concerning the determination of significant sources of PM-2.5. The rule is effective May 30, 2017. Contact: Ginger Vagenas; EPA Region 9; 415-972-3964; Vagenas.Ginger@epa.gov

82 FR 24527 (05/30/2017)

Regulatory Update

AIR

Delaware SIP/Materials Incorporated by Reference

AIR

Final rule of the EPA amends regulations under 40 CFR 52.420 to update materials incorporated by reference into the Delaware SIP. The rule incorporates regulations previously submitted by the state and approved by the EPA, as of July 1, 2016. The rule is effective May 30, 2017. Contact: Gavin Huang; EPA Region 3; 215-814-2042; huang.gavin@epa.gov

82 FR 24529 (05/30/2017)

Regulatory Update

AIR

District of Columbia SIP/Regional Haze

AIR

Proposed rule of the EPA amends regulations under 40 CFR 52 to approve a revision to the District of Columbia SIP for regional haze. The revision includes a five-year progress report towards reasonable progress goals for regional haze and a determination of adequacy of the existing regional haze SIP. Comments are due June 29, 2017. Contact: Sara Calcinore; EPA Region 3; 215-814-2043; calcinore.sara@epa.gov

82 FR 24617 (05/30/2017)

Regulatory Update

AIR

Indiana SIP/Muncie Area 2008 Lead Standards

AIR

Direct final rule of the EPA amends regulations under 40 CFR 52.770, 52.797 and 81.315 to approve revisions to the Indiana SIP and to approve a request to redesignate the Muncie nonattainment area in Delaware County to attainment for the 2008 lead NAAQS. The revisions address the plan for maintaining the 2008 lead NAAQS through 2030 and the 2013 attainment year emissions inventory for the area. The rule is effective July 31, 2017, if no adverse comments are received by June 29, 2017. Contact: Anthony Maietta; EPA Region 5, Air Programs Branch; 312-353-8777; maietta.anthony@epa.gov

82 FR 24553 (05/30/2017)

Regulatory Update

AIR

Indiana SIP/Muncie Area 2008 Lead Standards

AIR

Proposed rule of the EPA amends regulations under 40 CFR 52.770, 52.797 and 81.315 to approve revisions to the Indiana SIP and to approve a request to redesignate the Muncie nonattainment area in Delaware County to attainment for the 2008 lead NAAQS. The revisions address the plan for maintaining the 2008 lead NAAQS through 2030 and the 2013 attainment year emissions inventory for the area. A concurrent direct final rule adopts the revisions, effective July 31, 2017. Comments are due June 29, 2017. Contact: Anthony Maietta; EPA Region 5, Air Programs Branch; 312-353-8777; maietta.anthony@epa.gov

82 FR 24635 (05/30/2017)

Regulatory Update

AIR

Maryland SIP/Materials Incorporated by Reference

AIR

Final rule of the EPA amends regulations under 40 CFR 52.1070 to update materials incorporated

by reference into the Maryland SIP. The rule incorporates regulations that have been submitted by the state and approved by the EPA, as of July 1, 2016. The rule is effective May 30, 2017. Contact: Sharon McCauley; EPA Region 3; 215-814-3376; mccauley.sharon@epa.gov

82 FR 24549 (05/30/2017)

Regulatory Update

AIR

Maryland SIP/NOx Emissions from Coal-Fired EGUs

AIR

Final rule of the EPA amends regulations under 40 CFR 52.1070 to approve a revision to the Maryland SIP regarding control of nitrogen oxide (NOx) emissions from seven coal-fired electric generating units (EGUs) in the state. The rule specifies that it is a strengthening measure and not intended to address reasonably available control technology for coal-fired EGUs. The rule is effective June 29, 2017. Contact: Marilyn Powers; EPA Region 3; 215-814-2308; powers.marilyn@epa.gov

82 FR 24546 (05/30/2017)

Regulatory Update

AIR

Maryland SIP/Regional Haze

AIR

Proposed rule of the EPA amends regulations under 40 CFR 52 to approve revisions to the Maryland regional haze SIP regarding best available retrofit technology (BART) measures for the Verso Luke Paper Mill in Luke, Md. The revisions consist of new sulfur dioxide (SO₂) and nitrogen oxide (NO_x) emissions limits for the mill's power boiler 24 due to the boiler's transition to a natural gas fuel source, an SO₂ cap on tons emitted per year for power boiler 25, and the removal of BART emission limits for NO_x from boiler 25. The rule incorporates by reference Aug. 17, 2016, permit conditions for boilers 24 and 25, which include alternative emission requirements along with monitoring, recordkeeping and reporting requirements. Comments are due June 29, 2017. Contact: Irene Shandruk; EPA Region 3; 215-814-2166; shandruk.irene@epa.gov

82 FR 24614 (05/30/2017)

Regulatory Update

AIR

Oregon SIP

AIR

Notice of the EPA announces the reopening of the comment period for a March 22, 2017, proposed rule (82 FR 14654) to amend regulations under 40 CFR 52 to partially approve revisions to the Oregon SIP. The revisions update particulate matter emission standards, revise permitting requirements for emergency generators and small natural gas or oil-fired equipment, and establish sustainment and reattainment state air quality area designations. The revisions also

update the major and minor source preconstruction permitting programs, address public notice procedures for informational meetings, and revise the woodstove replacement program for small commercial solid fuel boilers. In addition, the revisions update the Source Sampling Manual and Continuous Monitoring Manual. Finally, the revisions reorganize the SIP and remove outdated and duplicative provisions. The EPA is proposing to not approve certain revisions that are inconsistent with Clean Air Act requirements or appropriate for SIP approval and specifies that revisions concerning annual reporting requirements for small gasoline dispensing facilities were approved in an Oct. 27, 2015, final rule (80 FR 65655). Comments now are due June 29, 2017. Contact: Kristin Hall; EPA Region 10, Office of Air and Waste; 206-553-6357; hall.kristin@epa.gov

82 FR 24621 (05/30/2017)

Regulatory Update

AIR

Tennessee SIP/Knoxville PM-2.5 Nonattainment Area

AIR

Proposed rule of the EPA amends regulations under 40 CFR 52 and 81 to redesignate the Knoxville-Sevierville-La Follette, Tenn., fine particulate matter (PM-2.5) nonattainment area to attainment for the 1997 PM-2.5 NAAQS and determine that the area is attaining the NAAQS based on 2013-2015 monitoring data. The rule also approves and incorporates into the SIP the state's reasonably available control measures determination for the area and source-specific requirements for two sources, Tennessee Valley Authority's Bull Run Fossil Plant and Kingston Fossil Plant. In addition, the rule approves the maintenance plan, including motor vehicle emission budgets for nitrogen oxides and PM-2.5 for 2014 and 2028. Comments are due June 29, 2017. Contact: Sean Lakeman; EPA Region 4, Air Planning and Implementation Branch; 404-562-9043; lakeman.sean@epa.gov

82 FR 24636 (05/30/2017)

Regulatory Update

AIR

Tennessee SIP/Knoxville PM-2.5 Nonattainment Area

AIR

Proposed rule of the EPA amends regulations under 40 CFR 52 and 81 to redesignate the Knoxville-Sevierville-La Follette, Tenn., fine particulate matter (PM-2.5) nonattainment area to attainment for the 2006 24-hour PM-2.5 NAAQS and determine that the area is attaining the NAAQS based on 2013-2015 monitoring data. The rule also approves and incorporates into the SIP the state's reasonably available control measures determination for the area. In addition, the rule approves the maintenance plan, including motor vehicle emission budgets for nitrogen oxides and PM-2.5 for 2014 and 2028. Comments are due June 29, 2017. Contact: Sean Lakeman; EPA Region 4, Air Planning and Implementation Branch; 404-562-9043; lakeman.sean@epa.gov

82 FR 24621 (05/30/2017)

Regulatory Update

AIR

Virginia SIP/Materials Incorporated by Reference

AIR

Final rule of the EPA amends regulations under 40 CFR 52.2420 to update state materials incorporated by reference into the Virginia SIP. The rule addresses regulations for source specific requirements and provisions concerning plan identification. The rule incorporates regulations previously submitted by the state and approved by the EPA, as of July 1, 2016. The rule is effective May 30, 2017, except for provisions under 40 CFR 52.2420(e), which are effective June 9, 2017. Contact: Sharon McCauley; EPA Region 3; 215-814-3376; mccauley.sharon@epa.gov

82 FR 24537 (05/30/2017)

Regulatory Update

AIR

Washington SIP/Energy Facility Site Evaluation Council Air Quality Regulations

AIR

Final rule of the EPA amends regulations under 40 CFR 52.2470, 52.2497 and 52.2498 to approve revisions to the Washington SIP to incorporate by reference updated Energy Facility Site Evaluation Council (EFSEC) air quality regulations that implement the preconstruction permitting program for major source facilities in attainment and unclassifiable areas and the visibility protection permitting program. The rule also revises the federal implementation plan governing the prevention of significant deterioration program for major energy facilities under EFSEC jurisdiction. In addition, the rule approves state submissions regarding enforcement and other general authorities to implement and enforce the SIP, but does not incorporate by reference the provisions. Finally, the rule transfers the EPA-issued permits for the Chehalis Generation Facility and Grays Harbor Energy Center facilities to EFSEC. The rule is effective June 29, 2017. Contact: Jeff Hunt; EPA Region 10, Office of Air and Waste; 206-553-0256; hunt.jeff@epa.gov

82 FR 24531 (05/30/2017)

Regulatory Update

COMMUNITY RIGHT-TO-KNOW

Toxic Chemical Release Reporting

COMMUNITY RIGHT-TO-KNOW

Notice announces the intention of the EPA to seek OMB approval for a revised information collection request regarding toxic chemical release reporting under 40 CFR 372, Subpart B, including the Toxics Release Inventory Form R, Form A Certification Statement, and Form R Schedule 1. The collection addresses annual reporting requirements for certain facilities that manufacture, process or use specified toxic chemicals in amounts above reporting threshold levels, including information relating to pollution prevention, waste management and recycling. The revisions make technical changes and adjust the total estimated respondent burden hours. Comments are due July 31, 2017. Contact: Cassandra Vail; EPA, Office of Pollution Prevention and Toxics; 202-566-0753; vail.cassandra@epa.gov

82 FR 24702 (05/30/2017)

Regulatory Update

ENDANGERED SPECIES

Alaska/U.S. Navy Training Marine Mammals Incidental Take

ENDANGERED SPECIES

Notice of the National Oceanic and Atmospheric Administration, National Marine Fisheries Service, announces the issuance of a letter of authorization to allow the unintentional taking of marine mammals incidental to U.S. Navy training activities in the Gulf of Alaska Temporary Maritime Activities Area Study Area from May 2017 through May 2022. The letter allows the incidental take of 19 species of marine mammals during activities and time frames in the same level and type as specified in an April 27, 2017, final rule (82 FR 19530). The authorization is effective April 26, 2017, and expires April 26, 2022. Contact: Jolie Harrison; NMFS, Office of Protected Resources; 301-427-8477

82 FR 24679 (05/30/2017)

Regulatory Update

ENDANGERED SPECIES

Migratory Birds and Eagles/Federal Permit Applications and Reports

ENDANGERED SPECIES

Notice of the U.S. Fish and Wildlife Service announces the submission of a revised information collection request to the OMB regarding federal fish and wildlife permit applications and reports for migratory birds and eagles. The collection addresses various application forms and reporting requirements the agency uses to determine applicant eligibility for activities otherwise prohibited under specified wildlife conservation laws (50 CFR 10, 13, 21 and 22). The revision consolidates two previous ICRs. Comments are due July 31, 2017. Contact: Madonna Baucum; USFWS; 703-358-2503; madonna_baucum@fws.gov

82 FR 24732 (05/30/2017)

Regulatory Update

ENDANGERED SPECIES

Texas Hornshell Endangered Listing

ENDANGERED SPECIES

Notice of the U.S. Fish and Wildlife Service announces hearings on and the reopening of the comment period for an Aug. 10, 2016, proposed rule (81 FR 52796) to amend regulations under 50 CFR 17.11 to list the Texas hornshell, a freshwater mussel species from New Mexico and Texas, as an endangered species. The hearings are scheduled for June 13 and 15, 2017, in Laredo, Texas, and Carlsbad, N.M., respectively. Comments now are due June 29, 2017. Contact: Chuck Ardizzone; USFWS, Texas Coastal Ecological Services Field Office; 281-286-8282

82 FR 24654 (05/30/2017)

Regulatory Update

FOOD SAFETY

Color and Food Additive Petitions
FOOD SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding color additive petition (CAP) and food additive petition (FAP) submissions. The collection addresses CAPs and FAPs for new additive approval or additive amendments that meet specified labeling and safety requirements submitted using Form 3503. Comments are due July 31, 2017. Contact: Ila Mizrachi; FDA, Office of Operations; 301-796-7726; PRASStaff@fda.hhs.gov

82 FR 24718 (05/30/2017)

Regulatory Update

FOOD SAFETY
Food Additive Petition/Formic Acid
FOOD SAFETY

Notice of the Food and Drug Administration announces the filing of a petition by BASF Corp., of Florham Park, N.J., requesting amendments to food additive regulations under 21 CFR 573 to provide for the safe use of formic acid as a feed acidifying agent in complete poultry feeds. If the FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. Contact: Chelsea Trull; FDA, Center for Veterinary Medicine; 240-402-6729; Chelsea.trull@fda.hhs.gov

82 FR 24611 (05/30/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Department of Energy Regulatory Reform
GENERAL ENVIRONMENT AND SAFETY

Notice of the Department of Energy requests comments regarding agency regulations that may be appropriate for repeal, replacement or modification in response to Executive Order 13771 (82 FR 9339; 02/03/2017). The notice seeks comments concerning existing regulations, paperwork requirements and other regulatory obligations that can be modified or repealed. The notice also seeks regulatory reform information pursuant to Executive Order 13777 (82 FR 12285; 03/01/2017), which required agencies to establish regulatory reform task forces to evaluate existing regulations and make recommendations based on factors including impacts on job creation, necessity, effectiveness, cost-benefits and consistency with other regulatory reform initiatives. Comments are due July 14, 2017. Contact: Daniel Cohen; DOE, Office of the General Counsel; 202-586-5000; Regulatory.Review@hq.doe.gov

82 FR 24582 (05/30/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
EPA Board of Scientific Counselors Nominations
GENERAL ENVIRONMENT AND SAFETY

Notice of the EPA announces a correction to a May 25, 2017, request (82 FR 24120) for nominations of individuals to serve on the Office of Research and Development's Board of Scientific Counselors. The correction changes the date for submitting nominations. Nominations now are due June 30, 2017. Contact: Tom Tracy; EPA, Office of Research and Development; 202-564-6518; tracy.tom@epa.gov

82 FR 24703 (05/30/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

FDA Approved Information Collection Requests

GENERAL ENVIRONMENT AND SAFETY

Notice of the Food and Drug Administration announces the approval of 11 information collection requests by the OMB. The collections address current good manufacturing practice, over-the-counter drug product labeling, medical device third-party review, and categorical exclusion claims or environmental assessments submitted to the Center for Food Safety and Applied Nutrition. The collections also address the application for the Medical Device Fellowship Program (FDA 3608), drug labeling for cardiovascular outcome claims, and safety reporting requirements for investigational new drugs and bioavailability and bioequivalence studies in humans. In addition, the collections address Dear Health Care Provider letters, informed consent, requests for feedback on medical device submissions and the national direct-to-consumer advertising survey. Contact: Ila Mizrachi; FDA; 301-796-7726; PRASStaff@fda.hhs.gov

82 FR 24722 (05/30/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Medical Devices and Radiological Products/Health Risk Allegations

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 allegations of actual or potential health risk concerns from a medical device or radiological product or its use. The collection addresses the process for voluntary electronic submission of such allegations to the Center for Devices and Radiological Health. Comments are due July 31, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794

82 FR 24716 (05/30/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Over-the-Counter Drugs/Safety and Effectiveness

GENERAL ENVIRONMENT AND SAFETY

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a revised information collection request regarding the evaluation of over-the-counter (OTC) drugs

introduced into the U.S. market after OTC drug review began and OTC drug products without any marketing experience in the U.S. under the monograph process (21 CFR 330.14). The collection addresses the time and extent application for demonstrating that OTC drug conditions are eligible for inclusion in the monograph system. The collection also addresses safety and effectiveness data submission requirements, sponsor completeness statements, and sponsor withdrawal requests. The revisions incorporate new requirements under 21 CFR 330 (81 FR 84465; 11/23/2016) regarding content and format of data submissions and informal conference requests. Comments are due July 31, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794; PRAStaff@fda.hhs.gov

82 FR 24723 (05/30/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Pediatric Advisory Committee and Pediatric Ethics Subcommittee Meeting

GENERAL ENVIRONMENT AND SAFETY

Notice of the Food and Drug Administration announces a meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. The agenda includes discussion of issues concerning diseases to be studied; patient populations to be included; and possible study designs in the development of the products APX-005M, PMO1183 (lurbinectedin), ASP2215 (gilteritinib), prexasertib and olaratumab for pediatric use. The meeting is scheduled for June 21-22, 2017, in Silver Spring, Md. Comments are due June 7, 2017. Contact: Lauren Tesh; FDA, Center for Drug Evaluation and Research; 301-796-9001; ODAC@fda.hhs.gov

82 FR 24720 (05/30/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION

Unified Carrier Registration Plan Board of Directors Meeting

HAZARDOUS MATERIALS TRANSPORTATION

Notice of the Federal Motor Carrier Safety Administration announces a meeting of the Unified Carrier Registration Plan Board of Directors to continue the development and implementation of the unified carrier registration plan and agreement. The meeting is scheduled for June 7, 2017, in Santa Fe, N.M., and via teleconference. Contact: Avelino Gutierrez; FMCSA, Unified Carrier Registration Board of Directors; 505-827-4565

82 FR 24775 (05/30/2017)

Regulatory Update

RADIATION

ACRS Advanced Power Reactor 1400 Subcommittee Meeting

RADIATION

Notice of the Nuclear Regulatory Commission announces a meeting of the Advisory Committee on Reactor Safeguards Subcommittee on Advanced Power Reactor 1400 (APR1400). The agenda includes presentations by NRC staff and Korea Hydro & Nuclear Power Co., of Gyeongju, South

Korea, concerning Chapter 3 of the APR1400 Design Control Document regarding the design of structures, systems, components and equipment. The meeting is scheduled for June 5, 2017, in Rockville, Md. Comments are due June 5, 2017. Contact: Christopher Brown; NRC, Advisory Committee on Reactor Safeguards; 301-415-7111; Christopher.Brown@nrc.gov

82 FR 24746 (05/30/2017)

Regulatory Update

RADIATION

List of Approved Spent Fuel Storage Casks

RADIATION

Notice of the Nuclear Regulatory Commission confirms the effective date of a March 24, 2017, direct final rule (82 FR 14987) that amended regulations under 10 CFR 72.214 to add 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 No. 1042. The rule specifies that the NUHOMS® EOS system provides horizontal storage of high burnup spent pressurized water reactor and boiling water reactor fuel assemblies in dry shielded canisters. The rule is effective June 7, 2017. Contact: Edward Lohr; NRC, Office of Nuclear Material Safety and Safeguards; 301-415-0253; Edward.Lohr@nrc.gov

82 FR 24457 (05/30/2017)

Regulatory Update

RADIATION

Medical Use of Byproduct Material

RADIATION

Notice of the Nuclear Regulatory Commission announces the submission of a continuing information collection request to the OMB regarding medical use of byproduct material (10 CFR 35). The collection addresses requirements for physicians and medical institutions holding licenses authorizing the administration of byproduct material or radiation to humans to report medical events, doses to an embryo/fetus or nursing child, or leaking sources on occurrence. The collection also addresses requirements for specialty boards to submit requests for NRC recognition. Comments are due June 29, 2017. Contact: David Cullison; NRC, Office of the Chief Information Officer; 301-415-2084; INFOCOLLECTS.Resource@nrc.gov

82 FR 24750 (05/30/2017)

Regulatory Update

RADIATION

Patient Release Program Review

RADIATION

Notice of the Nuclear Regulatory Commission announces an extension of the comment period for an April 11, 2017, request for comments (82 FR 17465) on the commission's patient release program. The request provided questions that stakeholders, including the NRC's Advisory Committee on the Medical Use of Isotopes, professional organizations, physicians, patients,

patient advocacy groups, licensees, agreement states and other interested individuals, can answer to help the commission determine whether additional or alternate criteria are needed and whether to clarify the NRC's current patient release requirements. Comments now are due June 27, 2017. Contact: Donna-Beth Howe; NRC, Office of Nuclear Material Safety and Safeguards; 301-415-4848; Donna-Beth.Howe@nrc.gov

82 FR 24745 (05/30/2017)

Regulatory Update

WATER

Massachusetts/Clean Water Act Stipulation and Order

WATER

Notice of the Department of Justice announces a proposed stipulation and order in United States v. NSTAR Electric Co. (Civil Action No. 16-11470-RGS), lodged on May 23, 2017, with the U.S. District Court for the District of Massachusetts. The stipulation and order resolves claims against the defendants for alleged violation of a 1989 U.S. Army Corps of Engineers permit related to the improper installation of a submarine cable across Boston Harbor, from an electrical substation in South Boston to Deer Island. The stipulation and order requires the defendants to lay a new cable and then remove, or partly remove and abandon, the existing cable. Comments are due June 29, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 24737 (05/30/2017)

Regulatory Update

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