

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

August 31, 2017 - Number 168

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Summaries

AIR

Georgia SIP/Materials Incorporated by Reference

AIR

Final rule of the EPA updates materials incorporated by reference into the Georgia SIP. The rule affects SIP materials that are available for public inspection. The rule is effective Aug. 31, 2017. Contact: Sean Lakeman; EPA Region 4, Air Planning and Implementation Branch; 404-562-9043; lakeman.sean@epa.gov. Citations: 40 CFR 52.570

82 FR 41337 (08/31/2017)

Regulatory Update

AIR

Greenhouse Gas Reporting Program

AIR

Notice of the EPA announces a correction to a Dec. 9, 2016, final rule (81 FR 89188) that revised requirements of the Greenhouse Gas Reporting Program. The correction removes a reference to liquid petroleum products in Table C-1 to 40 CFR 98, Subpart C, regarding default CO2 emission factors and high heat values for various types of fuel. Citations: 40 CFR 98, Subpart C

82 FR 41343 (08/31/2017)

Regulatory Update

AIR

Illinois SIP/Coal-Fired Electric Generating Units

AIR

Proposed rule of the EPA would approve portions of revisions to the Illinois SIP regarding the

control of emissions from certain coal-fired electric generating units (EGUs). The revisions require the Will County 3 and Joliet 6, 7, and 8 EGUs to permanently cease combusting coal and allow other subject EGUs to cease combusting coal as an alternative means of compliance with mercury emission standards. The revisions also exempt the Will County 4 EGU from sulfur dioxide (SO₂) control technology requirements, require all subject EGUs to comply with a group annual nitrogen oxide emission rate, and direct only those subject EGUs that combust coal to comply with a group annual SO₂ emission rate. Comments are due Oct. 2, 2017. Contact: Charles Hatten; EPA Region 5, Air Programs Branch; 312-886-6031; hatten.charles@epa.gov. Citations: 40 CFR 52

82 FR 41376 (08/31/2017)

Regulatory Update

AIR

Indiana/PM-2.5 NAAQS Infrastructure Requirements

AIR

Proposed rule of the EPA would approve portions of revisions to the Indiana SIP regarding the infrastructure requirements for the 2012 annual fine particulate matter (PM-2.5) NAAQS. The rule would take no action on revisions regarding the interstate transport provisions and visibility protection requirements (prongs 1, 2, and 4), which will be addressed in a separate action. Comments are due Oct. 2, 2017. Contact: Eric Svingen; EPA Region 5, Air Programs Branch; 312-353-4489, svingen.eric@epa.gov. Citations: 40 CFR 52

82 FR 41379 (08/31/2017)

Regulatory Update

AIR

Kentucky SIP/Louisville Metro Air Pollution Control District

AIR

Final rule of the EPA approves revisions to the Kentucky SIP concerning the Louisville Metro Air Pollution Control District's air quality regulations. The revisions add acronyms and abbreviations for consistency with EPA definitions, update open records procedures to reflect current technology options for delivering submissions, and update public hearing procedures to conform to the Strategic Toxic Air Reduction program. The revisions also update restrictions on open burning and solvent cleaning and modify board member obligations and procedures for board hearings. In addition, the revisions modify the volatile organic compounds emissions reduction strategy and combine two performance standards for solvent metal cleaning equipment. The rule is effective Oct. 2, 2017. Contact: Sean Lakeman; EPA Region 4, Air Planning and Implementation Branch; 404-562-9043; lakeman.sean@epa.gov. Citations: 40 CFR 52.920

82 FR 41335 (08/31/2017)

Regulatory Update

AIR

Nevada SIP/Washoe Oxygenated Fuels Program

AIR

Proposed rule of the EPA would approve a revision to the Nevada SIP. The revision concerns the suspension of Washoe County District Board of Health requirements for carbon monoxide emissions from passenger vehicles. Comments are due Oct. 2, 2017. Contact: Jeffrey Buss; EPA Region 9; 415-947-4152; buss.jeffrey@epa.gov. Citations: 40 CFR 52

82 FR 41386 (08/31/2017)

Regulatory Update

AIR

New Jersey SIP/Materials Incorporated by Reference

AIR

Notice of the EPA announces a correction to a July 3, 2017, final rule (82 FR 30758) to revise the format of materials incorporated by reference into the New Jersey SIP. The revisions reorganize the "identification of plan" section so that information on EPA-approved regulations, source specific requirements, and nonregulatory provisions are listed in tables. The correction, which replaces an incorrect docket number, is effective Aug. 31, 2017. Contact: Kirk Wieber; EPA Region 2, Air Programs Branch; 212-637-3381. Citations: 40 CFR 52.1570, 52.1587, 52.1605

82 FR 41342 (08/31/2017)

Regulatory Update

FOOD SAFETY

Hazard Analysis and Risk-Based Preventive Controls for Human Food

FOOD SAFETY

Notice of the FDA announces the availability of an additional draft chapter of the guidance for industry regarding compliance with the requirements for hazard analysis and risk-based preventive controls for human food (81 FR 57816; 08/24/2016). The additional chapter addresses the use of heat treatments as a process control. Comments are due Feb. 27, 2018. Contact: Jenny Scott; FDA, Center for Food Safety and Applied Nutrition; 240-402-2166. Citations: 21 CFR 117

82 FR 41364 (08/31/2017)

Regulatory Update

FOOD SAFETY

Meat and Poultry Products Inspection

FOOD SAFETY

Notice announces the intention of the Food Safety and Inspection Service to seek OMB approval for a continuing information collection request regarding the application for inspection, accreditation of laboratories, and exemptions for meat and poultry product establishments and import facilities. The collection addresses recordkeeping requirements that ensure such establishments provide safe, unadulterated products and that nonfederal laboratories act in accordance with FSIS requirements. The collection also addresses recordkeeping requirements to ensure that meat and poultry products that are exempted from agency inspection are not commingled with inspected products and that firms qualifying for a retail store exemption that

have violated the provisions of the exemption are no longer in violation. Comments are due Oct. 30, 2017. Contact: Gina Kouba; FSIS, Office of Policy and Program Development; 202-720-5627. Citations: 9 CFR 303.1, 304.1, 350.5, 351.4, 352.3, 362.3, 381.10, 381.17, 381.175, 439.20, 590.580

82 FR 41391 (08/31/2017)

Regulatory Update

FOOD SAFETY

Public Health Information System

FOOD SAFETY

Notice announces the intention of the Food Safety and Inspection Service to seek OMB approval for a revised information collection request concerning the Public Health Information System. The collection addresses the submission of six forms and two certificates by firms regarding the application for inspection and the export and import of meat, poultry, and egg products. The revision removes FSIS Form 9080-4 regarding product lists because the agency no longer uses the form. Comments are due Oct. 30, 2017. Contact: Gina Kouba; FSIS, Office of Policy and Program Development; 202-720-5627. Citations: 9 CFR 304.1 through 592.96 (nonconsecutive)

82 FR 41393 (08/31/2017)

Regulatory Update

FOOD SAFETY

Salmonella Initiative Program

FOOD SAFETY

Notice announces of the intention of the Food Safety and Inspection Service to seek OMB approval for a revised information collection request regarding the Salmonella Initiative Program. The program provides incentives to meat and poultry slaughter establishments to control salmonella in their operations by granting waivers of certain regulatory requirements under the condition that establishments test for salmonella or other indicator organisms and share the sample results with the FSIS. The revision reflects a reduction to the annual burden estimate due to implementation of the new poultry inspection system. Comments are due Oct. 30, 2017. Contact: Gina Kouba; FSIS, Office of Policy and Program Development; 202-720-5627

82 FR 41392 (08/31/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Alaska/Federal Hydropower Land Use Fees

GENERAL ENVIRONMENT AND SAFETY

Proposed rule of FERC would update the per-acre land value component of the methodology used to calculate the annual charges assessed to hydropower licensees for use and occupancy of federal lands in Alaska. The rule would establish a statewide average per-acre land value for all hydropower projects except those located in the Aleutian Islands. Comments are due Oct. 30, 2017. Contact: Tara DiJohn; FERC; 202-502-8671; tara.dijohn@ferc.gov. Citations: 18 CFR 11.2

82 FR 41359 (08/31/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Medical Dictionary for Regulator Activities and Data Standards Catalog

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces support for version 9 of the Medical Dictionary for Regulator Activities (MedDRA) and an update to the Data Standards Catalog for study data provided in new drug applications (NDAs), abbreviated NDAs, biologics license applications, and investigational NDAs. Version 8 of MedDRA, which is used for the coding of adverse events in studies in electronic common technical document format, will no longer be supported after March 15, 2019. Comments may be submitted at any time. Contact: Ron Fitzmartin; FDA, Center for Drug Evaluation and Research; 301-796-5333; cderdatastandards@fda.hhs.gov

82 FR 41416 (08/31/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Real-World Evidence for Medical Device Decision-Making

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a final guidance for industry and agency staff concerning the use of real-world evidence to support regulatory decision-making for medical devices. The guidance describes the characteristics and sources of real-world data used to determine whether it may be sufficiently relevant and reliable to generate real-world evidence for use in regulatory decision-making for medical devices. The guidance also describes some examples of actual uses of real-world data that have already led to FDA decisions. Contact: Benjamin Eloff; FDA, Center for Devices and Radiological Health; 301-796-8528

82 FR 41418 (08/31/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Ultrasonic Diathermy Devices Industry Guidance

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a draft guidance regarding ultrasonic diathermy devices. The guidance clarifies FDA policy related to compliance with applicable performance standards and conformance to International Electrotechnical Commission consensus standards for ultrasonic diathermy devices. The guidance also provides recommendations for information to provide in 510(k) premarket notification submissions for such devices. Comments are due Oct. 30, 2017. Contact: Jismi Johnson; FDA, Center for Devices and Radiological Health; 301-796-6424

82 FR 41417 (08/31/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP
New York/Wolff-Alport Superfund Site
HAZARDOUS WASTE CLEANUP

Notice of the EPA announces a proposed settlement agreement under CERCLA with the city of New York regarding the Wolff-Alport Superfund Site in Queens County. The agreement requires the city to pay \$659,037 in reimbursement of the EPA's past response costs at or in connection with the site. The settlement also includes a covenant not to sue. Comments are due Oct. 2, 2017. Contact: Jean Regna; EPA Region 2, New York/Caribbean Superfund Branch; 212-637-3164; regna.jean@epa.gov

82 FR 41414 (08/31/2017)

Regulatory Update

OIL AND GAS INDUSTRY
OCS Geological and Geophysical Explorations
OIL AND GAS INDUSTRY

Notice announces the intention of the Bureau of Ocean Energy Management to seek OMB approval for a continuing information collection request regarding the application for a permit to conduct geological and geophysical explorations for mineral resources or scientific research on the Outer Continental Shelf (BOEM-0327). Comments are due Oct. 30, 2017. Contact: Anna Atkinson; BOEM; 703-787-1025; anna.atkinson@boem.gov. Citations: 30 CFR 551

82 FR 41424 (08/31/2017)

Regulatory Update

RADIATION
List of Approved Spent Fuel Storage Casks
RADIATION

Notice of the NRC announces corrections to a Jan. 6, 2016, direct final rule (81 FR 371) and a March 14, 2016, direct final rule (81 FR 13265) that revised the Holtec International HI-STORM 100 cask system listing in the list of approved spent fuel storage casks. The direct final rules included Amendment No. 9, Revision No. 1, and Amendment No. 10, respectively, to Certificate of Compliance (CoC) No. 1014. The corrections address editorial and nonsubstantive errors in Appendix A of the CoC. The corrections are effective Aug. 31, 2017. Contact: John-Chau Nguyen; NRC, Office of Nuclear Material Safety and Safeguards; 301-415-0262; John-Chau.Nguyen@nrc.gov. Citations: 10 CFR 72.214

82 FR 41321 (08/31/2017)

Regulatory Update

TOXIC SUBSTANCES
Draft NTP Approach to Genomic Dose-Response Modeling Peer Review
TOXIC SUBSTANCES

Notice of the NIH, National Toxicology Program (NTP), announces an expert panel meeting for the peer review of a draft approach to genomic dose-response modeling. The proposed approach would use the BMDEExpress software to perform gene and pathway-level genomic dose-response modeling as part of Tox21 Phase 3 and in vivo screening level studies. The draft document, preliminary agenda, and additional documents are available on the NTP website. Pre-meeting webinars are scheduled for Aug. 30 and Sept. 1, 13, and 25, 2017. The expert panel meeting is scheduled for Oct. 23-25, 2017, in Research Triangle Park, N.C., and via webcast. Comments are due Oct. 13, 2017. Contact: Anna Stamatogiannakis; ICF; 919-293-1652; anna.stamatogiannakis@icf.com

82 FR 41420 (08/31/2017)

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