

**To:** Jackson, Ryan[jackson.ryan@epa.gov]  
**From:** Bloomberg BNA  
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**Subject:** June 07 -- EHS Federal Regulatory Alert



## **EHS Federal Regulatory Alert**

June 07, 2017 - Number 108

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### Summaries

*AIR*

#### Illuminated Exit Signs Test Procedure Waiver Request

**AIR**

Notice of the Department of Energy, Office of Energy Efficiency and Renewable Energy, announces the receipt of a petition from Acuity Brands, of Atlanta, requesting a waiver from test procedures for determining the energy consumption of illuminated exit signs under 10 CFR 431.401. The company seeks to use an alternate test procedure to address issues involved in testing certain basic models of illuminated exit signs identified in its petition. The agency has proposed alternate test procedures that provide methods to test and rate the basic models at issue without the rated wattage of the light source or sources due to a finding that rated wattage of light sources had not been well documented in Acuity's product literature. Comments are due July 7, 2017. Contact: Bryan Berringer; DOE, Building Technologies Program; 202-586-0371; [AS\\_Waiver\\_Requests@ee.doe.gov](mailto:AS_Waiver_Requests@ee.doe.gov)

82 FR 26469 (06/07/2017)

#### Regulatory Update

*AIR*

#### Nevada SIP/Lake Tahoe CO Maintenance Plan

**AIR**

Final rule of the EPA amends regulations under 40 CFR 52.1470 to approve a revision to the Nevada SIP. The revision consists of a second 10-year maintenance plan for the eight-hour carbon monoxide (CO) NAAQS for the Lake Tahoe area, including the 2011 emissions inventory, the 2024 projected emissions inventory, and a revised alternative monitoring strategy and contingency plan. The rule also postpones the effective date of a March 10, 2017, direct final rule (82 FR 13235) that added these revisions to the SIP to provide a response to adverse comments prior to the rule's effectiveness. The rule is effective July 7, 2017. Contact: John Kelly; EPA Region 9, Air Planning Office; 415-947-4151; [kelly.johnj@epa.gov](mailto:kelly.johnj@epa.gov)

82 FR 26351 (06/07/2017)

Regulatory Update

**AIR**

Tennessee SIP/Reid Vapor Pressure Requirements

**AIR**

Final rule of the EPA amends regulations under 40 CFR 80.27 to approve a request from the state of Tennessee to revise the summertime federal Reid vapor pressure (RVP) standards for gasoline. The rule revises the RVP standard to 9.0 pounds per square inch for gasoline sold from June 1 to Sept. 15 each year for the Middle Tennessee area, which includes Davidson, Rutherford, Sumner, Williamson and Wilson counties. In a Feb. 24, 2017, proposed rule (82 FR 11517), the EPA proposed to approve the easing of the federal RVP requirement as a revision to the SIP. The rule is effective June 7, 2017. Contact: David Dickinson; EPA, Office of Transportation and Air Quality; 202-343-9256; dickinson.david@epa.gov

82 FR 26354 (06/07/2017)

Regulatory Update

**ENDANGERED SPECIES**

Georgia/Marine Mammals Incidental Take Permit

**ENDANGERED SPECIES**

Final rule of the National Oceanic and Atmospheric Administration, National Marine Fisheries Service, adopts regulations under 50 CFR 217.250 through 217.257 concerning taking of marine mammals incidental to conducting waterfront construction at the U.S. Naval Submarine Base in Kings Bay, Ga., requested by the U.S. Navy. The applicant requests take of bottlenose dolphins by Level B harassment incidental to impact and vibratory pile installation and removal from July 12, 2017, to July 11, 2022. The application is requested in connection with proposed repairs, construction, and modifications that will require the use of impact and vibratory pile driving, including installation and removal of steel, concrete, composite, and timber piles. The rule is effective July 12, 2017, and expires July 11, 2022. Contact: Ben Laws; NMFS, Office of Protected Resources; 301-427-8401

82 FR 26360 (06/07/2017)

Regulatory Update

**FOOD SAFETY**

Customer and Partner Service Surveys

**FOOD SAFETY**

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding customer and partner service surveys. The surveys identify strengths and weaknesses in service to various regulated entities, including food processors; cosmetic drug, biologic, and medical device manufacturers; consumers; and health professionals. Comments are due Aug. 7, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794; PRAStaff@fda.hhs.gov

82 FR 26497 (06/07/2017)

Regulatory Update

**FOOD SAFETY**

Reportable Food/Third-Party Disclosure, Recordkeeping

**FOOD SAFETY**

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding third-party disclosure and recordkeeping requirements for reportable food, which are articles of food for which the use of or exposure to will cause serious adverse health consequences or death to humans or animals. The collection addresses notification requirements through electronic communication methods for responsible parties and their previous sources and/or immediate subsequent recipients. The collection also addresses recordkeeping requirements for reports and notifications for a period of two years. Comments are due Aug. 7, 2017. Contact: Ila Mizrachi; FDA, Office of Operations; 301-796-7726; PRAStaff@fda.hhs.gov

82 FR 26489 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

California/Potter Valley Project

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Federal Energy Regulatory Commission announces the receipt of a notice of intent from Pacific Gas & Electric Co., of San Francisco, to file a license application for a new license and commencing the pre-filing process for the Potter Valley Project on the Eel and East Fork Russian rivers in Lake and Mendocino counties in California. The notice specifies that a portion of the project occupies Mendocino National Forest lands administered by the U.S. Forest Service. The agency is initiating consultation with the U.S. Fish and Wildlife Service and/or the National Oceanic and Atmospheric Administration. An environmental site review will be conducted June 27, 2017. Meetings are scheduled for June 28, 2017, in Ukiah, Calif. Comments are due Aug. 4, 2017. Contact: John Mudre; FERC; 202-502-8902; john.mudre@ferc.gov

82 FR 26475 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Connecticut/Wyre Wynd Hydroelectric Project

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Federal Energy Regulatory Commission announces the filing of a notice of intent to file a license application and a request to use the traditional licensing process for the Wyre Wynd Hydroelectric Project on the Quinebaug River in New London and Windham counties in Connecticut. The project is proposed by Aspinook Hydro LLC, of Boulder, Colo. The commission is initiating consultation with the U.S. Fish and Wildlife Service and/or the National Oceanic and Atmospheric Administration regarding joint agency requirements. Contact: John Ramer; FERC; 202-502-8969; john.ramer@ferc.gov

82 FR 26479 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Humanitarian Device Exemptions and Institutional Review Boards

**GENERAL ENVIRONMENT AND SAFETY**

Final rule of the Food and Drug Administration amends regulations under 21 CFR 814.3, 814.100, 814.102, 814.124 and 814.126 regarding humanitarian device exemptions (HDEs) and institutional review boards (IRBs) for devices. The rule makes technical amendments pursuant to the 21st Century Cures Act related to HDE approval for devices to treat or diagnose a condition to increase to “not more than 8,000” the threshold for individuals in the U.S. affected by the disease or condition. The rule also removes the requirement for institutional review committees for devices to be local. The rule is effective June 7, 2017. Contact: Ian Ostermiller; FDA, Center for Devices and Radiological Health; 301-796-5678

82 FR 26348 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

National Marine Fisheries Service/Regulatory Review

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the National Oceanic and Atmospheric Administration, National Marine Fisheries Service, announces the periodic review of agency rulemaking actions to determine if they should be amended or withdrawn to address significant economic impacts on small entities, as required by Section 610 of the Regulatory Flexibility Act. The current review addresses rules issued in 2010 under 50 CFR Chapters II, III, IV, V, and VI, including domestic and international fisheries; a Feb. 19, 2010, final rule (72 FR 7383) that implemented the Harbor Porpoise Take Reduction Plan to address the mortality and serious injury of the Gulf of Maine/Bay of Fundy stock of harbor porpoises; migratory species; and endangered and threatened wildlife and plants. Comments are due July 7, 2017. Contact: Tara Scott, NOAA, National Marine Fisheries Service; 301-427-8579

82 FR 26419 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

North Carolina/Ward Mill Dam Project

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Federal Energy Regulatory Commission announces the filing of an application to surrender the license for the Ward Mill Dam Project on the Watauga River near Boone, N.C. The notice specifies that the surrender is due to the requirements of a recently issued subsequent license and certain circumstances of the licensee. The notice also specifies that the licensee plans to disconnect the generating units from the utility interconnection point and remove the generators and turbines. Comments, protests, or motions to intervene are due July 3, 2017. Contact: Diana Shannon; FERC; 202-502-6136; Diana.shannon@ferc.gov

82 FR 26474 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Oncologic Drugs Advisory Committee Meeting/Acute Lymphoblastic Leukemia  
**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Food and Drug Administration announces a meeting of the Oncologic Drugs Advisory Committee to discuss a biologics license application for tisagenlecleucel-T suspension for intravenous use (BLA 125646), submitted by Novartis Pharmaceuticals Corp., of East Hanover, N.J. The proposed indication for the product is for the treatment of pediatric and young adult patients three to 25 years of age with relapsed/refractory B-cell acute lymphoblastic leukemia. The meeting is scheduled for July 12, 2017, in Silver Spring, Md. Comments are due July 10, 2017. Contact: Jennifer Shepherd; FDA, Center for Drug Evaluation and Research; 301-796-9001; ODAC@fda.hhs.gov

82 FR 26492 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Oncologic Drugs Advisory Committee Meeting/Acute Myeloid Leukemia  
**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Food and Drug Administration announces a meeting of the Oncologic Drugs Advisory Committee to discuss a biologics license application for Mylotarg (BLA 761060), submitted by Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc., of New York. The proposed indication for the product is in combination therapy with daunorubicin and cytarabine for the treatment of adult patients with previously untreated, de novo acute myeloid leukemia. The meeting is scheduled for July 11, 2017, in Silver Spring, Md. Comments are due July 10, 2017. Contact: Jennifer Shepherd; FDA, Center for Drug Evaluation and Research; 301-796-9001; ODAC@fda.hhs.gov

82 FR 26495 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Oncologic Drugs Advisory Committee Meeting/Avastin, Herceptin Biosimilars  
**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Food and Drug Administration announces a meeting of the Oncologic Drugs Advisory Committee to discuss a biologics license application for ABP 215 (BLA 761028), a proposed biosimilar product to Genentech/Roche's Avastin (bevacizumab), submitted by Amgen Inc., of Thousand Oaks, Calif. The proposed indications for the product include treatment of patients with metastatic colorectal cancer, certain nonsmall cell lung cancers, glioblastoma, metastatic renal cell carcinoma, or carcinoma of the cervix. The agenda also includes discussion of MYL-14010 (BLA 761074), a proposed biosimilar product to Genentech Inc.'s Herceptin (trastuzumab), submitted by Mylan GmbH, of Zurich. The proposed indications for the product

include treatment of patients with HER2-overexpressing node positive or node negative breast cancer, HER2-overexpressing metastatic breast cancer, or HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. The meeting is scheduled for July 13, 2017, in Silver Spring, Md. Comments are due July 10, 2017. Contact: Jay Fajiculay; FDA, Center for Drug Evaluation and Research; 301-796-9001; ODAC@fda.hhs.gov

82 FR 26488 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Pennsylvania/Line QP, Line Q and Queen Storage Project

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Federal Energy Regulatory Commission announces the availability of an environmental assessment for the Line QP, Line Q, and Queen Storage Project proposed by National Fuel Gas Supply Corp., of Williamsville, N.Y. The project involves construction and operation of facilities, abandonment by sale of a natural gas storage system and associated pipeline, replacement of a compromised portion of the pipeline, and installation of a new pipeline to maintain National Fuel's distribution capability in Forest and Warren counties in Pennsylvania. Comments are due July 1, 2017. Contact: Kimberly Bose; FERC; 866-208-3676; FERCOOnlineSupport@ferc.gov

82 FR 26480 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Texas/Central Texas Gathering System

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Federal Energy Regulatory Commission announces the filing of an application by Transcontinental Gas Pipe Line Co., of Houston, for authorization to abandon offshore gathering laterals at the Central Texas Gathering System (CTGS) offshore of Texas. The applicant proposes to abandon the CTGS West Facilities that consist of an approximately 11-mile offshore gathering lateral extending from the Brazos Block A-133A platform to the Brazos Block A-76 subsea tie-in and a 30-mile lateral extending from the Brazos Block A-76 subsea tie-in to the Brazos Block 538 platform. The notice specifies that the agency will complete an environmental assessment or issue a notice of schedule for environmental review by Aug. 30, 2017. Comments are due June 22, 2017. Contact: FERC; 866-208-3676; FERCOOnlineSupport@ferc.gov

82 FR 26478 (06/07/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Texas/Existing NuStar Burgos Pipeline Presidential Permit

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Department of State announces the issuance of a presidential permit to NuStar Logistics LP, of San Antonio, to operate and maintain existing Burgos Pipeline facilities at the

U.S.-Mexico border near Edinburg, Texas, for the transport of refined petroleum products, including naphtha, liquefied petroleum gas, natural gas liquids, jet fuel, regular and premium gasoline, and diesel. The permit requires NuStar to take necessary mitigation measures identified in the final environmental assessment and measures approved in the future by the State Department or other relevant agencies. The permit is effective May 30, 2017. Contact: Matthew McManus; Department of State, Office of Policy Analysis and Public Diplomacy; 202-736-7149

82 FR 26563 (06/07/2017)

Regulatory Update

**HAZARDOUS MATERIALS TRANSPORTATION**

Railroads/System Safety Programs

**HAZARDOUS MATERIALS TRANSPORTATION**

Final rule of the Federal Railroad Administration further delays until Dec. 4, 2017, the effective date of an Aug. 12, 2016, final rule (81 FR 53850) that adopts regulations under 49 CFR 270.1 through 270.305 (nonconsecutive) to establish the System Safety Program for commuter and intercity passenger railroads. The agency previously delayed (82 FR 14476; 03/21/2017) the effective date until May 22, 2017, in response to a presidential memorandum establishing a regulatory freeze, and then again (82 FR 23150; 05/22/2017) until June 5, 2017, to provide additional time for review. Contact: Matthew Navarrete; FRA, Office of Chief Counsel; 202-493-0138; Matthew.Navarrete@dot.gov

82 FR 26359 (06/07/2017)

Regulatory Update

**HAZARDOUS WASTE CLEANUP**

Puerto Rico/Palo Seco Superfund Site

**HAZARDOUS WASTE CLEANUP**

Notice of the EPA announces a proposed cost recovery settlement agreement under CERCLA with the Puerto Rico Electric Power Authority (PREPA) for response costs incurred by the EPA at the Palo Seco Superfund Site in Toa Baja, Puerto Rico. The agreement requires PREPA to pay \$1 million to reimburse assessment costs and cover cleanup actions at the site. The proposed agreement also includes a covenant from the EPA not to sue or to take administrative action against PREPA with regard to the response costs. Comments are due July 7, 2017. Contact: Margo Ludmer; EPA Region 2, New York/Caribbean Superfund Branch; 212-637-3187; ludmer.margo@epa.gov

82 FR 26482 (06/07/2017)

Regulatory Update

**OIL AND GAS INDUSTRY**

Puerto Rico/Oil Pollution Act Consent Decree

**OIL AND GAS INDUSTRY**

Notice of the Department of Justice announces a proposed consent decree in United States v. Port Stewart GmbH&Co. Kg of Germany (Civil Action No. 3:17-cv-01742), lodged on June 1, 2017,

with the U.S. District Court for the District of Puerto Rico. The consent decree resolves claims under the Oil Pollution Act for damages to a coral reef habitat resulting from alleged discharges of oil due to the grounding of the T/V Port Stewart oil tanker at the entrance of the Yabucoa Channel. The consent decree requires the defendant to pay \$550,000, including \$412,000 for restoration, \$128,000 of NOAA costs, and \$10,000 of the Puerto Rico Department of Natural and Environmental Resources costs. Comments are due July 7, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 26518 (06/07/2017)

Regulatory Update

**RADIATION**

ACRS Subcommittee on Northwest Medical Isotopes Meeting

**RADIATION**

Notice of the Nuclear Regulatory Commission announces a meeting of the Advisory Committee on Reactor Safeguards (ACRS) Subcommittee on Northwest Medical Isotopes. The agenda includes discussion of the construction permit application preliminary safety analysis report for a radioisotope production facility at the Discovery Ridge Research Park in Columbia, Mo., and associated agency safety evaluation reports. The meeting is scheduled for June 19, 2017, in Rockville, Md. Comments are due June 19, 2017. Contact: Kathy Weaver; NRC; 301-415-6236; Kathy.Weaver@nrc.gov

82 FR 26519 (06/07/2017)

Regulatory Update

**TOXIC SUBSTANCES**

Schedule I Controlled Substances/Acetyl Fentanyl

**TOXIC SUBSTANCES**

Notice of the Drug Enforcement Administration announces a final order amending regulations under 21 CFR 1308.11 to temporarily place the synthetic opioid acetyl fentanyl and its isomers; esters; ethers; salts; and salts of isomers, esters, and ethers into Schedule I of the Controlled Substances Act. The final order is effective June 7, 2017. Contact: Michael Lewis; DEA, Office of Diversion Control; 202-598-6812

82 FR 26349 (06/07/2017)

Regulatory Update

**WATER**

California/National Marine Sanctuaries Discharge Requirements

**WATER**

Notice of the National Oceanic and Atmospheric Administration, National Ocean Service, further delays until Dec. 9, 2017, the effectiveness of the discharge requirements under 15 CFR 922 regarding U.S. Coast Guard activities in the Gulf of the Farallones (now renamed Greater Farallones) and Cordell Bank national marine sanctuaries offshore of California, as set forth in a March 12, 2015, final rule (80 FR 13077). The current action extends several prior postponements

of the discharge requirements in both sanctuary expansion areas with regard to Coast Guard activities. The delay is intended to give the agency additional time to development alternatives for an environmental assessment. Contact: Maria Brown; NOAA, Greater Farallones National Marine Sanctuary; 415-561-6622; Maria.Brown@noaa.gov

82 FR 26339 (06/07/2017)

Regulatory Update

**WATER**

Payments for Benefits from Headwater Improvements

**WATER**

Notice of the Federal Energy Regulatory Commission announces the submission of a continuing information collection request to the OMB regarding payment for benefits from headwater improvements, which provide additional energy production from the regulation of river flows by an upstream storage reservoir (FERC-521; 18 CFR 11, Subpart B). The collection addresses data reporting requirements for downstream federal and nonfederal hydropower project owners. The data also is used to determine annual charges for nonfederal hydropower projects. Comments are due July 7, 2017. Contact: Ellen Brown; FERC; 202-502-8663; DataClearance@FERC.gov

82 FR 26476 (06/07/2017)

Regulatory Update

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