

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

August 22, 2017 - Number 161

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Summaries

AIR

Energy Conservation Standards/Certification and Compliance Requirements

AIR

Notice announces the intention of the Energy Department, Office of Energy Efficiency and Renewable Energy, to seek OMB approval for a revised information collection request regarding certification and compliance requirements for consumer products and commercial/industrial equipment subject to federal energy or water conservation standards. The collection addresses the gathering of data and submission of certification and compliance reports for basic models distributed in commerce in the U.S., including supplemental testing instructions for certain commercial equipment, recordkeeping, applications for test procedure waivers, applications for extension of the date by which representations must be made in compliance with a new or amended test procedure, and labeling. The revisions modify the online Compliance and Certification Management System (CCMS) to allow the California Energy Commission to accept a CCMS report in satisfaction of the state reporting requirement. Comments are due Oct. 23, 2017. Contact: Ashley Armstrong; DOE, Office of Energy Efficiency and Renewable Energy; 202-287-1445; ApplianceStandardsQuestions@ee.doe.gov. Citations: 10 CFR 429, 430, 431

82 FR 39780 (08/22/2017)

Regulatory Update

AIR

Georgia SIP/Minor New Source Review

AIR

Notice of the EPA announces the withdrawal of a June 29, 2017, direct final rule (82 FR 29418) that would have approved revisions to the Georgia SIP to clarify that existing exemptions from minor new source review permitting do not extend to sources that are subject to NSPS for stationary sources or NESHAP. The revisions also add a definition of "pollution control project" and provide that such projects are exempt from minor new source review construction permit requirements. The withdrawal, which is due to the receipt of an adverse comment, is effective

Aug. 22, 2017. Contact: Brad Akers; EPA Region 4, Pesticides and Toxics Management Division; 404-562-9089; akers.brad@epa.gov. Citations: 40 CFR 52.570

82 FR 39671 (08/22/2017)

Regulatory Update

AIR

NESHAP for Portland Cement Manufacturing Industry

AIR

Direct final rule of the EPA deletes NESHAP provisions adopted in a June 23, 2017, direct final rule (82 FR 28562) that extended a compliance alternative specified in a July 25, 2016, final rule (81 FR 48356) for Portland cement manufacturing sources. The rule restores the July 25, 2017, expiration date for the compliance alternative for sources required to use a hydrogen chloride (HCl) continuous emissions monitoring system (CEMS) to demonstrate compliance with the HCl emissions limit through a three-run stack test. The alternative was provided due to the unavailability of National Institute of Standards and Technology traceable calibration gases for HCl. The current action is due to the receipt of adverse comments. A concurrent proposed rule would adopt the provisions and address the adverse comments. The rule is effective Aug. 22, 2017. Contact: Brian Storey; EPA, Office of Air Quality Planning and Standards; 919-541-1103; storey.brian@epa.gov. Citations: 40 CFR 63.1349, 63.1350

82 FR 39671 (08/22/2017)

Regulatory Update

AIR

NESHAP for Portland Cement Manufacturing Industry

AIR

Proposed rule of the EPA would extend a NESHAP compliance alternative for Portland cement manufacturing sources specified in a July 25, 2016, final rule (81 FR 48356). The rule would allow owners and operators to demonstrate compliance with the hydrochloric acid (HCl) emissions limit through a three-run stack test. The alternative was provided due to the unavailability of National Institute of Standards and Technology traceable calibration gases for HCl. The current proposal replaces a June 23, 2017, direct final rule (82 FR 28562), which is reversed concurrently due to the receipt of adverse comments. If requested by Aug. 29, 2017, a hearing will be held Sept. 6, 2017, in Washington, D.C. Comments are due Oct. 6, 2017. Contact: Brian Storey; EPA, Office of Air Quality Planning and Standards; 919-541-1103; storey.brian@epa.gov. Citations: 40 CFR 63.1349, 63.1350

82 FR 39712 (08/22/2017)

Regulatory Update

ENDANGERED SPECIES

Hawaii/Marine Mammals Incidental Take

ENDANGERED SPECIES

Final rule of the National Marine Fisheries Service authorizes the take of marine mammals

incidental to the U.S. Air Force 86 Fighter Weapons Squadron's Long Range Strike Weapons System Evaluation Program activities in the Barking Sands Underwater Range Expansion area of the Pacific Missile Range Facility, off Kauai, Hawaii. The final rule reduces the authorized take in the proposed rule based on significant decreases to the amount of live weapon explosions per year. The rule authorizes take in the form of Level B harassment of 16 species of marine mammals, and by Level A harassment of four of those species. The rule is effective Aug. 21, 2017, and expires Aug. 22, 2022. Contact: Jaclyn Daly; NMFS, Office of Protected Resources; 301-427-8401. Citations: 50 CFR 218.50 through 218.57 (Subpart F)

82 FR 39684 (08/22/2017)

Regulatory Update

FOOD SAFETY

Color and Food Additive Petitions

FOOD SAFETY

Notice of the FDA announces the submission of a continuing information collection request to the OMB 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 Sept. 21, 2017. Contact: Ila Mizrahi; FDA, Office of Operations; 301-796-7726; PRASStaff@fda.hhs.gov. Citations: 21 CFR 70.25, 71.1, 171.1, 172, 173, 179, 180

82 FR 39793 (08/22/2017)

Regulatory Update

FOOD SAFETY

Food Additive Petition/Calcium, Vitamin D3 in Juice Products

FOOD SAFETY

Notice of the FDA announces a correction to a July 26, 2017, notice (82 FR 34615) of filing of a food additive petition by the Juice Products Association, of Washington, D.C., to replace the current recommended daily intake percentage values of calcium in fruit juices and fruit juice drinks for vitamin D3 with absolute values and to update the specifications for vitamin D3. The changes would allow manufacturers of fruit juices and fruit juice drinks that are fortified with calcium to maintain the absolute level of added calcium at 330 milligrams and 100 mg, respectively. The correction clarifies that the absolute level of added calcium for fruit juice drinks is 100 mg, not 130 mg. Contact: Judith Kidwell; FDA, Center for Food Safety and Applied Nutrition; 240-402-1071. Citations: 21 CFR 172.380

82 FR 39711 (08/22/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Medical Devices/Informed Consent Exception

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the submission of a continuing information collection request to

the OMB regarding an exception from general requirements for informed consent concerning the use of medical devices in certain circumstances. The collection addresses the exception to the general rule that informed consent is required for the use of an investigational in vitro diagnostic device to identify chemical, biological, radiological, nuclear agents, or other public health emergencies if the investigator and an independent licensed physician make the determination that such action is necessary. Comments are due Sept. 21, 2017. Contact: Amber Sanford; FDA, Office of Operations; 301-796-8867; PRAStaff@fda.hhs.gov. Citations: 21 CFR 50.23

82 FR 39792 (08/22/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Pacific Northwest Military Readiness Activities
GENERAL ENVIRONMENT AND SAFETY

Notice of the Navy Department announces a supplement to a Nov. 4, 2016, final environmental impact statement/overseas environmental impact statement (EIS/OEIS) (81 FR 76937) for military readiness activities in the Northwest Training and Testing Study Area offshore of the Pacific Northwest, including the Strait of Juan de Fuca, Puget Sound, and the Behm Canal in southeastern Alaska. The supplemental EIS/OEIS will include an analysis of training and testing activities using new information available after the release of the final EIS/OEIS, including an updated acoustic effects model, updated marine mammal density data, and best available science. Comments are due Sept. 21, 2017. Contact: John Mosher; Navy Department; 360-257-3234; john.g.mosher@navy.mil

82 FR 39779 (08/22/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Pediatric Advisory Committee Meeting
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a meeting of the Pediatric Advisory Committee. The agenda includes discussion of the use of prescription opioid products containing hydrocodone or codeine for the treatment of cough in pediatric patients and pediatric-focused safety reviews of specified pharmaceuticals and medical devices. The meeting is scheduled for Sept. 11-12, 2017, in Rockville, Md. Comments are due Sept. 13, 2017. Contact: Marieann Brill; FDA, Office of the Commissioner; 240-402-3838; marieann.brill@fda.hhs.gov

82 FR 39790 (08/22/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
Voluntary Cosmetic Registration Program
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the submission of a revised information collection request to the OMB concerning the Voluntary Cosmetic Registration Program. The collection addresses

voluntary registration forms used by establishments that manufacture or package cosmetic products that provide information about establishment locations, business trade names, and types of activity (Forms FDA 2511, 2512, 2512a, and 2514). The revisions include the addition of links between Forms FDA 2511 and 2512, clarification of the information to be entered on the forms, additional self-identifying fields, removal of certain duplicative fields, and the deletion of Form FDA 2514. Comments are due Sept. 21, 2017. Contact: Ila Mizrachi; FDA, Office of Operations; 301-796-7726; PRAStaff@fda.hhs.gov. Citations: 21 CFR 710 and 720

82 FR 39795 (08/22/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP

North Carolina/Former Douglas Battery Site

HAZARDOUS WASTE CLEANUP

Notice of the EPA announces a settlement under CERCLA 122(h) with Victor Kung, Pearl Pacific Properties LLC, and East Best LLC regarding the Former Douglas Battery Site in Winston-Salem, N.C. The settlement addresses the recovery of costs for an EPA cleanup action at the site. Comments are due Sept. 21, 2017. Contact: Paula Painter; EPA Region 4, Superfund Division; 404-562-8887; Painter.Paula@epa.gov

82 FR 39785 (08/22/2017)

Regulatory Update

RADIATION

Nuclear Power Plants/Identifying and Reporting Human Performance Incidents

RADIATION

Notice of the NRC announces the availability of a draft regulatory issue summary (RIS) for industry concerning identification and reporting of human performance incidents at nuclear power plants. The guidance addresses the requirements for reporting on human performance-related causes of safety-significant events and how to properly report such incidents. Comments are due Sept. 21, 2017. Contact: Carmen Franklin; NRC, Office of Nuclear Regulatory Research; 301-415-2386; Carmen.Franklin@nrc.gov

82 FR 39915 (08/22/2017)

Regulatory Update

RADIATION

Uranium Recovery Sites/Comprehensive Decommissioning Program

RADIATION

Notice of the NRC announces the submission of a continuing information collection request to the OMB concerning the comprehensive decommissioning program. The collection addresses annual submission by agreement states of information on uranium recovery and complex sites undergoing decommissioning. Comments are due Sept. 21, 2017. Contact: David Cullison; NRC; 301-415-2084; INFOCOLLECTS.Resource@NRC.GOV

82 FR 39917 (08/22/2017)

Regulatory Update

WATER

Definition of Waters of the U.S. Under the CWA

WATER

Notice of the U.S. Army Corps of Engineers and the EPA announces the extension of the comment period for a July 27, 2017, proposed rule (82 FR 34899) that would reinstate the definition of “waters of the United States” that existed prior to a June 29, 2015, final rule (80 FR 37054). The 2015 rule clarified the scope of waters that are protected under the Clean Water Act and therefore are within U.S. regulatory jurisdiction, in light of U.S. Supreme Court decisions in 2001 and 2006. The rule is issued in response to a stay of the final rule by the U.S. Court of Appeals for the Sixth Circuit and Executive Order 13778 (82 FR 12497; 03/03/2017). The executive order directed the agencies to review the final rule for consistency with certain policies and to issue a proposed rule amending or rescinding the final rule. The rule is the first of a two-step process for the substantive reevaluation of the definition of “waters of the United States.” Comments now are due Sept. 27, 2017. Contact: Donna Downing; EPA, Office of Water; 202-566-2428; CWAwotus@epa.gov. Citations: 33 CFR 328.3, 40 CFR 110.1 through 401.11 (nonconsecutive)

82 FR 39712 (08/22/2017)

Regulatory Update

WATER

Mid-Atlantic Region Regulated Navigation Areas

WATER

Final rule of the U.S. Coast Guard establishes 11 safety zones on ice-covered waterways in the Fifth Coast Guard District, which includes the Mid-Atlantic Region. A July 19, 2015, proposed rule (80 FR 39403) would have established one regulated navigation area (RNA) on the navigable waters of the district to allow the USCG to impose and enforce restrictions on vessels operating within the RNA where a threat to navigation exists due to ice covered waterways. The final rule instead adopts the provisions of a Feb. 9, 2017, supplemental proposed rule (82 FR 9978). The final rule also requires vessels to gain permission from the cognizant captains of the ports (COTP) or district commander to enter or continue transiting a zone if the vessel encounters ice of a given thickness, unless the COTP or district commander has set an ice condition for the zone and the vessel meets the associated requirements to transit the zone. In addition, the final rule specifies the three ice conditions and vessel requirements to transit, establishes restrictions on nonsteel-hull-vessels in such conditions, and provides an exemption for vessels that must transit in protected waters. The rule is effective Sept 21, 2017. Contact: Doug Simpson; USGC, Fifth Coast Guard District; 757-398-6346; douglas.c.simpson@uscg.mil. Citations: 33 CFR 165.550

82 FR 39665 (08/22/2017)

Regulatory Update

WATER

Navigation Safety Advisory Council/Membership Requests

WATER

Notice of the U.S. Coast Guard announces a request for applications for membership on the Navigation Safety Advisory Council. The council provides advice and recommendations to the Secretary of Homeland Security on matters relating to maritime collisions, rammings, groundings; Inland Rules of the Road; International Rules of the Road; navigation regulations; and equipment, routing measures, marine information, diving safety, and aids to navigation systems. The Coast Guard seeks applications for seven positions that will be vacant on Nov. 4, 2017, in the commercial vessel owners and operators, professional mariners, recreational boaters, recreational boating industry, and Maritime Law Association membership categories only. Applications are due Oct. 23, 2017. Contact: George Detweiler; USCG, Navigation Safety Advisory Council; 202-372-1566; George.H.Detweiler@uscg.mil

82 FR 39880 (08/22/2017)

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