



VEOLIA NORTH AMERICA - INDUSTRIAL BUSINESS REGULATORY UPDATE - September 2015

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A. EPA Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule

On September 25, 2015, the Environmental Protection Agency (EPA) published a proposed rule (80 FR 58013-58092) to revise the regulations for the management and disposal of hazardous waste pharmaceuticals and tailor them to address the specific compliance issues at hospitals, pharmacies, and healthcare related facilities face.

Significant Proposed Revisions

EPA is proposing to add a new subpart titled “Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities” under 40 CFR 266, Subpart P. 40 CFR 266, Subpart P is tailored for the management of hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors.

If finalized, the regulations in 40 CFR 266, Subpart P will be MANDATORY requirements for the management of hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors regardless of their RCRA generator category (e.g., small quantity generators and large quantity generators will be required to manage their hazardous waste pharmaceuticals in compliance with the regulations in 40 CFR 266, Subpart P.)

Hazardous waste pharmaceuticals would include, but would not be limited to: dietary supplements, prescription drugs, over-the-counter drugs, residues in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals

If this final rule is finalized as proposed facilities that generate hazardous waste pharmaceuticals and non-pharmaceutical hazardous would be required to manage their wastes under two different regulations. The hazardous waste pharmaceuticals would be regulated under 40 CFR 266, subpart P and the non-pharmaceutical wastes would be regulated under the CESQG, SQG, or LQG regulations depending on the facilities generator status for non-pharmaceutical wastes.

Hazardous waste pharmaceuticals would NOT count towards a generators status (e.g., CESQG, SQG, LQG).

The disposal of hazardous waste pharmaceuticals down a toilet or drain will be PROHIBITED at Healthcare Facilities.

A Healthcare Facility would be allowed receive hazardous waste pharmaceuticals from an off-site CESQG healthcare facility without the use of a hazardous waste manifest of having a permit as long as the receiving healthcare facility supplies pharmaceuticals to the CESQG healthcare facility and certain conditions are met.

The proposed rule would create two categories of pharmaceutical hazardous wastes: (A) potentially creditable hazardous waste pharmaceuticals and (B) non-creditable hazardous waste pharmaceuticals.

1. Potentially Creditable Hazardous Waste Pharmaceuticals

A potentially creditable hazardous waste pharmaceutical must have the potential to receive manufacturer’s credit, be unused, and be unexpired or less than one year past the expiration date. The potentially creditable hazardous waste pharmaceuticals must be shipped to a pharmaceutical reverse distributor. The hazardous waste pharmaceuticals would be considered a solid waste but there would be no accumulation time limits, container requirements, or labeling requirements. A hazardous waste manifest would not be required for shipment but advance notification and delivery confirmation would be required. In addition, a common carrier (e.g., USPS, UPS, FedEx, etc.) could be used for shipment.

2. Non-Creditable Hazardous Waste Pharmaceuticals

There are no satellite accumulation or storage requirements other than the containers must be in good condition and compatible with the wastes placed in the container and the container must be marked with the words “Hazardous Waste Pharmaceutical.” Hazardous waste pharmaceuticals may be stored on-site for up to one year. A hazardous waste manifest must be used for shipment, but no waste codes are required and the words “hazardous waste pharmaceuticals” MUST be entered into the “Special Handling and Additional Information” section of the manifest (Box #14).

Household hazardous waste pharmaceuticals collected at household hazardous waste collection events would be exempt from the proposed 40 CFR 266, Subpart P regulations, but would be required to be disposed/destroyed at a permitted or interim status hazardous waste incinerator, or a small or large municipal waste combustor.

Hazardous waste pharmaceuticals that are also DEA Controlled Substances would be conditionally exempt from the hazardous waste regulations as long as the DEA Controlled Substances shipping requirements and the wastes are combusted at a permitted or interim status hazardous waste incinerator or a municipal solid waste combustor.

Comments Due

Comments on this proposed rule must be submitted to EPA on or before December 24, 2015.

In addition to comments on the proposed revisions to the management standards for hazardous waste pharmaceuticals, EPA is seeking comment on the regulation of additional pharmaceuticals as hazardous wastes including creating a single hazardous waste listing for all discarded pharmaceuticals that are hazardous wastes.

EPA is also seeking comment on potentially excluding FDA-approved over-the-counter nicotine-containing smoking cessation products from the P075 listing. EPA is NOT proposing to exclude e-cigarettes from the P075 listing.

Link

The link below will allow you to view/print this proposed rule.

<http://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-23167.pdf>

B. EPA Hazardous Waste Generator Improvements; Proposed Rule

On September 25, 2015, EPA published a proposed rule (80 FR 57917-58012) that would revise the hazardous waste generator regulations to improve compliance and enhance protection of human health and the environment.

Overview of Significant Proposed Revisions

This rule proposes numerous changes to the hazardous waste generator regulations to make the rules easier to understand, facilitate better compliance, provide greater flexibility in how hazardous waste is managed, and close important gaps in the regulations.

Two key provisions where EPA is proposing flexibility are:

- (1) Allowing a hazardous waste generator to avoid increased burden of a higher generator status when generating episodic waste provided the episodic waste is properly managed, and

(2) Allowing a conditionally exempt small quantity generator (CESQG) to send its hazardous waste to a large quantity generator under control of the same person.

The Agency is also proposing to replace the phrase “conditionally exempt small quantity generator” (CESQG) with the phrase “very small quantity generator” (VSQG) so as to be consistent with the other two generator categories - large quantity generators (LQGs) and small quantity generators (SQGs).

Another key proposed revision includes the closure regulations for hazardous waste generators under 262.34(a)(1). The existing regulations do not expressly state whether closure provisions apply to generators accumulating hazardous waste in containment buildings only or more broadly to the accumulation of hazardous waste in containers, tanks and on drip pads. This notice proposes to revise the closure provisions for LQGs that accumulate hazardous waste in containers or container units.

Other noteworthy revisions proposed by EPA impact hazardous waste determinations, the marking and labeling of tanks and containers holding hazardous waste, and emergency preparedness planning.

In addition to proposing key flexibilities, the rule intends to enhance the safety of facilities, employees, and the general public by improving hazardous waste risk communication and ensuring that emergency management requirements satisfy today’s needs. Further, the EPA is proposing a number of clarifications without increasing burden including a reorganization of the hazardous waste generator regulations so that all of the generator regulations are located in one place.

Renaming CESQG to VSQG (40 CFR 260.10)

Currently only one of the three generator categories-CESQG-uses the words "conditionally exempt" in its title; however both SQGs and LQGs, which typically accumulate hazardous waste on site, are also conditionally exempt from obtaining a RCRA permit or complying with the interim status standards in 40 CFR parts 264 and 265, respectively, provided they meet certain conditions. This inconsistency in terminology has caused some confusion throughout the regulated community. Therefore, EPA is proposing to change the name of the category from "conditionally exempt small quantity generator (CESQG)" to "very small quantity generator (VSQG)."

Definition of Central Accumulation Area (40 CFR 260.10)

The Agency is also proposing to define the term "central accumulation area" in § 260.10 to mean any on-site hazardous waste accumulation area with hazardous waste accumulating in units subject to either § 262.16 (for small quantity generators) or § 262.17 (for large quantity generators). EPA emphasizes that proposing to define the term "central accumulation area" is only as a matter of convenience. It is helpful for both the regulated community and the implementers to have a common term to use when referring to locations where generators accumulate hazardous waste other than satellite accumulation areas. Generators may continue to have more than one central accumulation area on site; the use of the word "central" does not limit a generator to one area.

CESQG Shipments to a LQG.

Allowing CESQGs to send their hazardous waste to an LQG that is under the control of the same person would provide an additional option for CESQGs to manage their hazardous waste. EPA is also proposing some labeling and marking standards for CESQG waste being transferred to LQGs under the control of the same person under this provision. Note that aside from these two conditions, the same standards for management of CESQG waste apply to materials going to an LQG under this provision as to other CESQG waste, including the exemption from the requirement to ship using a hazardous waste manifest. DOT shipping requirements do still apply. Furthermore EPA is proposing that LQGs receiving hazardous waste from CESQGs under the control of the same person submit a notification to EPA or their authorized state using EPA form 8700-12 30 days prior to receiving the first shipment of hazardous waste from the CESQG. Notification in this instance serves to inform the regulatory authorities of which LQGs are receiving hazardous waste from which CESQGs under control of the

same person. Under this proposal, an LQG would also be required to manage all incoming hazardous waste from a CESQG in compliance with the regulations applicable to its LQG generator category.

Requirements to Complete Hazardous Waste Determinations for All Wastes

The proposed changes for hazardous waste determinations include the following:

- (1) Confirming that a generator's waste must be classified at its point of generation and, for wastes potentially exhibiting a hazardous characteristic, at any time during the course of its management when the properties of the wastes may change;
- (2) Revising the language on making a determination for a listed hazardous waste in § 262.11 to explain more fully how generators can make this kind of determination, including use of acceptable kinds of generator knowledge;
- (3) Explaining more completely in the regulations in § 262.11 how a generator should evaluate its waste for hazardous characteristics;
- (4) Revising the hazardous waste determination recordkeeping regulations to require that SQGs and LQGs maintain records of any test results, waste analyses, or other determinations made in accordance with § 262.11 for at least three years;
- (5) Including waste determinations where a solid waste (as defined in § 261.2) is found not to be a RCRA hazardous waste (as defined in § 261.3) (i.e. document the waste determination for those wastes that are not hazardous waste in the case the solid wastes that have the potential to be hazardous wastes; and
- (6) Making clear at the very beginning of § 262.11 that the hazardous waste determination must be accurate.

SQG and LQG Re-notification (40 CFR 262.12)

EPA is proposing to add a requirement to the regulations that both LQGs and SQGs re-notify EPA using the Site ID form (EPA form 8700-12). The intent of this re-notification provision is to provide current basic information to the regulatory agencies about who is generating and managing hazardous waste. The proposed rule would require LQGs, having first obtained an EPA ID number, to re-notify EPA using the Site ID form prior to March 1 of each even-numbered year, and SQGs prior to February 1 of each even-numbered year.

Requiring Hazardous Waste Numbers When Marking of Containers Prior to Shipping Hazardous Waste Off Site to a Designated RCRA Facility (40 CFR 262.32)

EPA is proposing to modify 40 CFR 262.32 to require SQGs and LQGs to mark their containers with the applicable EPA hazardous waste number (RCRA hazardous waste code) prior to transporting their hazardous waste off site to a designated RCRA facility for subsequent management. EPA is proposing this revision so that TSDFs can readily identify the contents of hazardous waste containers they are receiving from generators and effectively treat the wastes to meet land disposal restriction requirements (LDRs).

Container Marking and Labeling for LQGs and SQGs (40 CFR 262.34(a)(3))

Two modifications are proposed that would strengthen the labeling and marking conditions for LQGs and SQGs accumulating hazardous waste in containers.

- (1) The Agency is proposing that SQGs and LQGs accumulating hazardous waste in containers mark their containers with both the words "Hazardous Waste" and other words that identify the contents of the containers that a third party, such as an emergency responder, co-worker unfamiliar with the material, or even the general public may recognize. If the hazardous waste will subsequently be sent off-site for treatment and disposal, an SQG or LQG may choose to use an appropriate DOT proper shipping name found on the hazardous materials table at 49 CFR 172.101 to identify the contents of the container while it is accumulating on-site.
- (2) The second modification proposed is for labeling containers in central accumulation areas by adding a provision that SQGs and LQGs mark and label their containers with an indication of the hazards of

the contents of the containers. SQGs and LQGs will have flexibility in how to comply with this new provision. That is, generators can indicate the hazards of the contents of the container using any of several established methods, including, but not limited to an EPA hazardous waste characteristic(s) (ignitable, corrosive, reactive or toxic); a hazard class label consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the OSHA Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with NFPA code 704; or a hazard pictogram consistent with the United Nations' Global Harmonized System (GHS).

In summary, EPA is proposing to modify § 262.34(a)(3) and require LQGs and SQGs to mark containers with the following: (1) the words "Hazardous Waste," (2) other words that identify the contents of the containers, and (3) an indication of the hazards of the container's contents. EPA is not proposing to change § 262.34(a)(2), which requires LQGs and SQGs to mark clearly and visibly the date accumulation began on each container and make that marking visible for inspection.

Similarly, the Agency is proposing to change the regulations on marking and labeling of containers by the owner/operator of a hazardous waste TSD in § 268.50 to be consistent with the proposed marking and labeling changes for LQGs, for SQGs, for SAAs, and for transfer facilities.

Tank Marking and Labeling for LQGs and SQGs (40 CFR 262.34(a)(3))

The Agency is proposing to modify the regulations at § 262.34(a)(3) to require LQGs and SQGs to use inventory logs, monitoring equipment, or records indicating the date the hazardous waste first entered the tank in order to support a generator's determination that it has not exceeded its 90 day accumulation time limit, or in the case of an SQG, its 180-day time limitation. Generators may use any method that clearly demonstrates the date hazardous waste first entered the tank and was subsequently emptied within 90 (or 180 days as applicable) of the date hazardous waste first entered that tank and EPA is clarifying that a generator is not required to actually mark the accumulation date on the tank.

The same issue applies to a generator physically marking and labeling the contents of the tank and its associated hazards. The Agency is proposing that generators may use inventory logs or records to identify the contents of the tank and its associated hazards, rather than actually placing the marking on the tanks, to accommodate those instances where the tank contents and associated hazards frequently change. Consistent with the existing regulations for tanks at § 262.34(a)(3), the Agency will continue to require that hazardous waste tanks be labeled with the words "Hazardous Waste."

Generator Closure Regulations

For LQGs that accumulate hazardous waste in containers or container units, EPA is proposing closure regulations. The Agency believes the closure regulations are applicable to LQGs who have accumulated hazardous waste in containers as well as to LQGs who have accumulated hazardous waste in tanks, drip pads and containment buildings in order to prevent adverse impacts to human health and environment. Therefore, as with LQGs that accumulate hazardous wastes in tanks, drip pads, and containment buildings, should a generator decide to close a container or stop accumulating hazardous waste in containers at the site altogether, it would be responsible for complying with the regulations proposed at § 262.17(a)(8)(ii) and removing all relevant hazardous wastes accumulated within 90 days of generating it and any hazardous wastes that also may have been accumulated in SAAs. Otherwise, the generator would fail to meet the conditions for the exemption from permitting and would be subject to the requirements of 40 CFR parts 264, 265, 267 and the permit requirements of part 270.

EPA is also proposing that an LQG notify either EPA or its authorized state at least 30 days prior to closure of a hazardous waste accumulation unit, such as a container, tank, drip pad, or containment building, or closure of the site altogether. EPA is also proposing that such generators subsequently notify EPA or its authorized state no later than 90 days after closure of the site or a hazardous waste

accumulation unit that they have either clean closed (e.g., complied with the applicable generator closure regulations) or, if they cannot clean close, that they must close as a landfill.

Changes to the Preparedness, Prevention, and Emergency Procedures Provisions (40 CFR 262.34(a)(4) and 262.34(d)(4) and (5))

EPA is proposing a numerous modifications to the conditions for exemption for both SQGs and LQGs regarding preparedness, prevention and emergency procedures. The proposed revisions include the following:

- (1) Revising the scope of the contingency planning and emergency procedures regulations by proposing that the regulations apply only to those areas of a generator's site where hazardous waste is generated and accumulated and, where applicable, to those areas where allowable treatment may occur in accumulation units;
- (2) Revising § 265.37(a) to state that when making arrangements with local authorities regarding emergency procedures, an SQG or LQG must first attempt to make emergency preparedness and procedures agreements with its Local Emergency Planning Committee (LEPC), and, if this attempt is not successful (or there is no LEPC in the area), the generator must make an arrangement with its local fire department and other emergency responders;
- (3) Modifying the regulations for contingency plans for LQGs in § 265.52 and 265.53 to add an executive summary to the plan that a new LQG would submit to the LEPC and to adjust the content of an element of the required contingency plan;
- (4) Making two revisions to the technical standards regarding required equipment that are part of the preparedness and prevention regulations in part 265 subpart C that are applicable to both SQGs and LQGs;
- (5) Modifying the preparedness and prevention provisions for SQGs at § 262.34(d)(5) regarding posted emergency coordinator information and responsibility for cleaning up a spill; and
- (6) Modifying the personnel training provision for LQGs to allow a generator to use online computer training, in addition to classroom instruction and on-the-job training.

Revisions to Satellite Accumulation Area Regulations for SQGs and LQGs (40 CFR 262.34(c))

The Agency is proposing a number of changes that would revise and strengthen the conditions for exemption for satellite accumulation areas (SAA) at § 262.34(c). These include:

- (1) Requiring SQGs and LQGs accumulating hazardous waste in SAAs to comply with the special requirements for incompatible wastes found at § 265.177;
- (2) Providing limited exceptions to the regulation requiring generators to keep containers closed at all times, containers of hazardous waste in SAAs may be open when it is necessary either for the operation of equipment to which the SAA container is attached or to prevent dangerous situations, such as the build-up of extreme pressure or heat;
- (3) Strengthening the marking and labeling standards for SAAs (note these marking and labeling changes are the same as those proposed for containers in central accumulation areas);
- (4) Confirming that three days means three consecutive calendar days, not business days;
- (5) Providing a maximum weight for the accumulation of acute hazardous waste in SAAs in addition to a volume;
- (6) Rewording the regulations for when the maximum volume or weight is exceeded in an SAA;
- (7) Rescinding a guidance memo regarding the accumulation of reactive (D003) hazardous waste away from the point of generation; and
- (8) Providing examples in the preamble to help generators better understand the term "under the control of the operator," which is used in the SAA regulations.

Clarification of Biennial Reporting Requirements (40 CFR 262.41, 264.75, 265.75)

EPA proposes to modify the biennial reporting regulations for generators in order to make the regulations consistent with Agency guidance, including its biennial report instructions and forms. More

specifically, the proposal includes the following revisions or clarifications: (1) Only LQGs need to submit biennial reports; (2) LQGs must report all of the hazardous waste they generate for the entire reporting year, not just the month(s) the generator was an LQG; (3) LQGs completing a biennial report must report all hazardous wastes they generated in the reporting year, regardless of whether they transferred the waste off site during the reporting year; and (4) a reference to the biennial report form (EPA form 8700-13) at § 262.41 to replace the list of specific data elements that currently are included in the citation. Similar revisions are proposed for the biennial reports submitted by TSDFs.

EPA is also proposing to modify 40 CFR 261.6(c)(2) to require owners or operators of facilities that recycle hazardous waste without storing it prior to recycling to comply with the biennial reporting requirements at 40 CFR 265.75. Because these entities receive hazardous waste using a hazardous waste transporter and hazardous waste manifest, similar to a permitted TSDF or a facility with interim status, the Agency is proposing to amend its regulations and instructions to specify that such facilities must complete and submit a biennial report to EPA.

New Episodic Event Provisions for Generators that Temporarily Change Generator Category

EPA is proposing to allow a CESQG or an SQG to maintain its existing generator category if, as a result of a planned or unplanned episodic event, they would generate a quantity of hazardous waste in a calendar month sufficient to bump the facility into a more stringent generator. This proposed change would allow a CESQG or SQG to generate additional quantities of hazardous waste-exceeding its normal generator category limits temporarily-and still maintain its existing regulatory category provided it complies with specified conditions. Unplanned episodic events, include production process upsets, product recalls, excess inventory, accidental spills, or "acts of nature," such as a tornado, hurricane, or flood.

For both CESQGs and SQGs taking advantage of this provision, the following conditions must be met:

- (1) Episodic events are limited to one per calendar year;
- (2) The generator must notify EPA at least 30 calendar days prior to initiating a planned episodic event or within 24 hours after an unplanned episodic event or as soon as possible; identify the start and end dates, which may be no more than 45 days apart, as well as other information about the event; and identify a facility contact and/or emergency coordinator with 24-hour telephone access to discuss notification submittal or respond to emergency;
- (3) The generator, if a CESQG, must obtain an EPA ID number;
- (4) The generator must comply with specified hazardous waste management conditions as the waste is accumulated on-site including marking tanks or containers with the words "Episodic Hazardous Waste";
- (5) The generator must use a hazardous waste manifest and hazardous waste transporter to ship the waste generated by the episodic event to a RCRA-designated facility within 45 calendar days from the start of the episodic event;
- (6) The generator must complete and maintain specified records.
- (7) EPA is also proposing a petition process to allow hazardous waste generators to request from EPA one additional episodic event within the same calendar year and/or an extension of up to 30 calendar days to complete an episodic event and still be eligible to maintain its generator category.

Revisions to the Marking and Labeling Requirements for Transporters Handling Hazardous Waste at Transfer Facilities

The Agency is proposing to change the marking and labeling requirements for transporters handling hazardous waste at transfer facilities, found at § 263.12, to be consistent with the proposed changes for marking and labeling conditions for containers for SQGs, for LQGs, and in SAAs. In addition to these proposed changes, EPA is also proposing to require that containers of hazardous waste at transfer facilities be labeled prior to being transported off site to a RCRA-designated facility with the applicable EPA hazardous waste number(s) (EPA hazardous waste codes), which will assist the TSDF receiving the hazardous waste comply with the LDR regulations in 40 CFR part 268. Given that containers received by the transfer facility will already be appropriately marked and labeled by the generator, the Agency believes the additional burden on the transfer facility will be minimal.

Special Requirements for Ignitable and Reactive Wastes

Current regulations for LQGs state that containers holding ignitable or reactive waste must be located at least 15 meters (50 feet) from the facility's property line. (SQGs are not required to comply with this provision.) However, there are some cases for a LQG where it may not be physically possible to meet this standard given the constraints on a site's property boundaries. The Agency is therefore proposing to modify the regulatory text to allow LQGs to apply for a site-specific waiver from their local fire department if they are unable to meet this hazardous waste accumulation property line condition. LQGs would then be required to keep the written waiver in their records.

Comments Due

Comments on this proposed rule must be submitted to EPA on or before December 24, 2015.

Link

The link below will allow you to view/print this proposed rule.

<http://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-23166.pdf>

C. California Emergency Guidance on Wildfires; Handling Ash, Debris and other Hazardous Materials from Burned Structures and Management Options for Expedited Collection of Hazardous Wastes from Burned Areas

On September 14, 2015, the California Department of Toxic Substances Control (DTSC) published two Emergency Guidance on Wildfire Documents. The guidance documents are titled "Emergency Guidance on Wildfires #1 – Handling Ash, Debris and other Hazardous Materials from Burned Structures" and "Emergency Guidance on Wildfires #2 – Management Options for Expedited Collection of Hazardous Wastes from Burned Areas."

Actions taken to immediately mitigate, contain, and control hazardous waste releases are exempt from hazardous waste permit requirements after the Governor has declared a county to be in a State of Emergency. To minimize exposure to emergency personnel, the general public, and workers involved with restoration efforts and to minimize dispersion to the air and run-off to surface waters, the ash and contaminated debris should be cleaned up and contained as quickly as possible. The following guidance applies only to the emergency actions taken to clean up, contain, and dispose of the ash and debris from burned structures and areas.

EMERGENCY GUIDANCE ON WILDFIRES #1 – HANDLING ASH, DEBRIS AND OTHER HAZARDOUS MATERIALS FROM BURNED STRUCTURES

During emergency cleanup efforts, readily identifiable hazardous wastes must be segregated and managed separately from the ash and debris if this can be done safely. If hazardous materials cannot be separated safely, it is permissible to contain and dispose of these materials with the ash and contaminated debris. Uncontaminated and unburned hazardous materials (i.e., hazardous materials with smoke damage) should not be commingled with ash and debris.

Ash and contaminated debris from residential and commercial structures may be disposed of at a municipal solid waste landfill (class three) under the direction of the local solid waste enforcement agency.

The disposal of ash and contaminated debris from an industrial structure in a class three municipal solid waste landfill may not be appropriate. The local certified hazardous materials program and/or DTSC should be contacted for assistance.

MANAGEMENT OPTIONS FOR EXPEDITED COLLECTION OF HAZARDOUS WASTES FROM BURNED AREAS

Segregated hazardous wastes from households and commercial businesses may be transferred to the local household hazardous waste collection program for management.

Industrial businesses must be examined on an individual basis. Charles Corcoran at (916) 327-4499 should be contacted for guidance. Under this exemption, released wastes may be cleaned up, wastes in damaged containers or tanks may be repackaged, and wastes that pose an imminent and substantial risk may be treated to remove the immediate hazardous without a permit or other authorization or notification.

Links

The link below will allow you to view/print Emergency Guidance on Wildfires #1.

<http://www.mrwmd.org/wp-content/uploads/2013/12/Emergency-Guidance-on-Wildfires-1-DTSC-2007.pdf>

The link below will allow you to view/print Emergency Guidance on Wildfires #2.

<http://www.mrwmd.org/wp-content/uploads/2013/12/Emergency-Guidance-on-Wildfires-2-DTSC-2007.pdf>

D. EPA Office of Civil Rights Releases a Draft Five-Year Strategic Plan

On September 10, 2015, EPA published their Draft “External Compliance and Complaints Program Strategic Plan” for Fiscal Years 2015-2020 for review.

The draft plan established three Strategic Goals:

1. Enhance Strategic Docket Management
2. Develop a Proactive Compliance Program
3. Strengthen the Office of Civil Rights (OCR’s) Workforce to Promote a High-Performing Organization

The OCR will also promulgate a rule to improve their enforcement capabilities.

Comments Due

Comments on the Draft External Compliance and Complaints Program Strategic Plan must be submitted to EPA by November 9, 2015.

Link

The link below will allow you to view/print the Draft External Compliance and Complaints Strategic Plan for Fiscal Years 2015-2020.

http://www2.epa.gov/sites/production/files/2015-10/documents/strategic_plan.pdf

E. EPA Office of Pollution Prevention and Toxics Launches New Websites

On September 30, 2015, EPA announced that the Pollution Prevention and Toxics website had been updated with a new name, look and address. The new website is titled “Chemicals under the Toxic Substances Control Act.” With this update webpage addresses to pages from the old pollution

prevention and toxics pages have also been changed. Below are the updated URLs from some of the most popular webpages.

Links

1. Chemicals under the Toxic Substances Control Act - <http://www2.epa.gov/chemicals-under-tsca>
2. Assessing and Managing Chemicals under TSCA – <http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca>
3. Chemical Data Reporting - <http://www2.epa.gov/chemical-data-reporting>
4. TSCA Chemical Substance Inventory - <http://www2.epa.gov/tsca-inventory>
5. Import-Export Requirements - <http://www2.epa.gov/tsca-import-export-requirements>
6. Asbestos - <http://www2.epa.gov/asbestos>
7. Mercury - <http://www2.epa.gov/mercury>

F. DOT/PHMSA Hazardous Materials: Special Permit and Approvals Standard Operating Procedures and Evaluation Process (HM-233E); Final Rule

On September 10, 2015, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a final rule (80 FR 54418-54440) adopting regulations to include the standard operating procedures (SOPs) and criteria used to evaluate applications for special permits and approvals to a new Appendix A to 49 CFR Part 107, Subpart B.

These amendments do not change previously established special permit and approval policies.

Summary

This rulemaking provides clarity regarding what conditions need to be satisfied to promote completeness of the applications submitted. An application that contains the required information reduces processing delays that result from rejection, and further facilitates the transportation of hazardous materials in commerce while maintaining an appropriate level of safety.

49 CFR PART 107, APPENDIX A – STANDARD OPERATING PROCEDURES FOR SPECIAL PERMITS AND APPROVALS

This appendix sets forth the SOPs for processing an application for a special permit or an approval in conformance with 49 CFR Parts 107 and 171-180. It is used by PHMSA for the internal management of its special permit and approval programs. The SOP review process includes several phases such as Completeness, Publication, Evaluation, and Disposition.

The evaluation phase consists of two assessments, which may be conducted concurrently, a technical evaluation and a safety profile evaluation. A technical evaluation considers whether the proposed special permit or approval will achieve a level of safety at least equal to that required under the hazardous materials regulations (HMR). In addition each applicant for a special permit or non-classification approval is subject to a safety profile evaluation to assess if the applicant is fit to conduct the activity authorized by the special permit or approval application.

In an application for a special permit is issued, PHMSA provides the applicant, in writing, with a special permit and an authorization letter if party status is authorized. If an application for approval is issued, PHMSA provides the applicant, in writing, with an approval, which may come in various forms, including:

1. An “EX” approval number for classifying an explosive (including fireworks; see 49 CFR 173.56, 173.124, 173.128, and 173.168(a));
2. An “RIN” (requalification identification number) to uniquely identify a cylinder requalification, repair, or rebuilding facility (49 CFR 180.203);

3. A “VIN” (visual identification number) to uniquely identify a facility that performs an internal or external visual inspection, or both, of a cylinder in conformance with 49 CFR 180, Subpart C, or applicable CGA Pamphlet or HMR provision;
4. An “M” number for identifying packaging manufacturers (49 CFR 178.3); or
5. A “CA” (competent authority) for general approvals (49 CFR 107.705, 173.183, and 173.230).

An application for special permit or approval may be denied in whole or in part. If an application for a special permit or an approval is denied, the applicant may request reconsideration, and if reconsideration is denied, may file an appeal.

Effective Date

This final rule will become effective on November 9, 2015.

Link

The link below will allow you to view/print this final rule.

<http://www.gpo.gov/fdsys/pkg/FR-2015-09-10/pdf/2015-22617.pdf>

G. OSHA General Accountability Office (GAO) Reports on the Ability of OSHA and other Agencies to Develop and Distribute Regulatory Guidance Documents

On September 23, 2015, the General Accountability Office (GAO) published a document titled “Regulatory Guidance Processes – Agencies Could Benefit from Stronger Internal Control Practices” following a review of 25 agencies, including the Occupational Safety and Health Administration (OSHA), programs for clarifying and interpreting regulations.

Summary

The GAO determined that regulatory guidance is an important tools agencies use to communicate timely information about regulatory programs to regulated parties and the public and that regulatory guidance provides agencies flexibility to articulate their interpretations of regulations, clarify policies, and address new issues more quickly than may be possible using rulemaking. Even though regulatory guidance is not legally binding, guidance documents can have a significant effect on regulated entities and the public because of agencies’ reliance on large volumes of guidance documents.

Findings

GAO determined that the issuance of guidance documents is an effective tool used by the agencies to provide interpretations of regulations and address new issues more quickly than through the rulemaking procedures. However, there is a need for consistent processes for the development, review, dissemination, and evaluation of regulatory guidance documents.

In the document GAO proposes the following steps that agencies can utilize to ensure more effective guidance processes.

1. A stronger application of internal controls for guidance processes could achieve desired results and prevent errors;
2. Determine appropriate level of review to manage risk;
3. Maintain written policies and procedures for the production of non-significant guidance;
4. Ensure communication during the guidance development and review process; and
5. Regularly evaluate whether issued guidance is effective and up to date.

Link

The link below will allow you to view/print the GAO's Report.

<http://www.gao.gov/assets/680/672687.pdf>

H. **OSHA Clarification of Employer's Continuing Obligation to Make and Maintain an Accurate Record of Each Recordable Injury and Illness; Extension of Comment Period**

On September 25, 2015, the Occupational Safety and Health Administration (OSHA) published an extension of the comment period (80 FR 57765-57766) on the "Clarification of Employer's Continuing Obligation to Make and Maintain an Accurate Record of Each Recordable Injury and Illness," notice of proposed rulemaking.

Summary

On July 15, 2015, OSHA published the "Clarification of Employer's Continuing Obligation to Make and Maintain an Accurate Record of Each Recordable Injury and Illness" notice of proposed rulemaking (NPRM). Comments on the NPRM were required to be submitted by September 28, 2015. The National Association of Home Builders requested that the comment deadline be extended 60 days to provide additional time for a legal analysis and review and discussion of the NPRM.

OSHA agreed to an extension, but only a 30-day extension.

A summary of the NPRM is included in the July 2015 Regulatory Update.

Comments Due

Comments must now be submitted to OSHA on or before October 28, 2015.

Link

The link below will allow you to view/print the extension of the comment period.

<http://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-24319.pdf>

I. **DOJ/DEA Schedules of Controlled Substances: Removal of [¹²³I]ioflupane from Schedule II of the Controlled Substances Act; Final Rule**

On September 11, 2015, the Department of Justice, Drug Enforcement Administration (DEA) published a final rule (80 FR 54715-54718) removing [¹²³I]ioflupane from the schedules of the Controlled Substances Act (CSA).

Summary

[¹²³I]ioflupane is currently listed as a schedule II controlled substance because it is derived from cocaine and is an active ingredient in the drug DaTscan which is used in visualizing striatal DATs in the brains of adult patients with suspected Parkinsonian syndromes. On November 2, 2010, the Department of Health and Human Services (HHS) recommended that approved products containing [¹²³I]ioflupane be removed from schedule II of the CSA.

Based on a review of the scientific and medical information, the comments submitted, and a review of the eight-factor analysis, DEA has determined that [¹²³I]ioflupane does not meet the requirements for inclusion in any schedule and is removed from control under the CSA.

Effective Date

This final rule became effective on the date of publication, September 11, 2015.

Link

The link below will allow you to view/print this final rule.

<http://www.gpo.gov/fdsys/pkg/FR-2015-09-11/pdf/2015-22919.pdf>