



State of Oregon Department of Environmental Quality
Proposed Federal RCRA Hazardous Waste Rule Considerations

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The following are the federal rules DEQ Hazardous Waste Program is considering for adoption and will be discussed at the April 27, 2021, Hazardous Waste Rules Advisory Committee meeting.

Hazardous Waste Generator Improvements Rule

[[81 FR 85732-85829](#) – Federal Rulemaking Nov. 28, 2016, effective May 30, 2017]

Rule Lead: Sarah Wheeler, Environmental Law Specialist, Office of Compliance and Enforcement

Support: Ellie Brown, Senior Hazardous Waste Policy Analyst, Headquarters

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a) **What the rule does:** Amends existing hazardous waste generator regulatory program.

1. **Reorganizes the hazardous waste generator regulations** to make those regulations more user friendly. The main organizational changes are summarized in the table below.

Provision	Existing Citation §	New Citation §
Generator Category Determination	261.5(c)-(e)	262.13
Very Small Quantity Generator (VSQG) Provisions	261.5(a), (b), (f)-(g)	262.14
Satellite Accumulation Area Provisions (SQG and LQG)	262.34(c)	262.15
Small Quantity Generator (SQG) Provisions	262.34(d)-(f)	262.16
Large Quantity Generator (LQG) Provisions	262.34(a), (b), (g)-(i), (m)	262.17

Also of note:

- The term “conditionally exempt small quantity generator” (CEG) changes to “very small quantity generator” (VSQG).
- Generator requirements in §265, such as emergency preparedness, container management, are now in §262.
- For more detailed information on the reorganization, see the U.S. Environmental Protection Agency’s [Crosswalk of Previous Regulations to Reorganized Regulations](#).

2. **Provides further clarity and strengthens environmental protection by addressing regulatory gaps and adopting guidance:**

- Clarifies a hazardous waste determination (HWD) must be accurate and made at point of generation, and provides information on how to make and document the determination.

- Small quantity generators and large quantity generators must label containers with the hazards of the contents upon generation, as well as waste codes, prior to off-site shipment.
 - Clarifies waste counting requirements, especially relating to acute and non-acute waste, and mixing of hazardous and nonhazardous waste.
 - Clarifies difference between independent requirements (§262.10(a) (1)): hazardous waste determination, generator category determination, identification number manifesting and recordkeeping) and conditional requirements (§262.14 - .17: inspections, container management, accumulation, training and emergency preparedness).
 - Large quantity generators must notify DEQ of a facility closure 30 days prior to closing; large quantity generators must notify within 90 days after closure that performance standards were met, or that it can't clean close, in which case it must close as a landfill.
 - Large quantity generators must prepare a quick reference guide for contingency plans.
 - Must document attempts to make arrangements with local emergency responders.
 - Clarifies small quantity generators accumulating hazardous wastes on drip pads and in containment buildings must meet the standards in §265 subparts W and DD, as well as §262.16.
 - Multiple clarifications about Satellite Accumulation Areas, including: defines three days to mean three consecutive calendar days; labeling requirements made consistent with central accumulation areas; and allows for containers to remain temporarily open under limited circumstances for safety.
3. **Provides greater flexibility** for hazardous waste generators to manage hazardous waste in a cost-effective and protective manner.
 4. **Makes technical corrections** and conforming changes to address inadvertent errors and remove obsolete references to programs that no longer exist.

Optional Provisions

- Waiver of 50-foot property line rule: Allows waiver from the State Fire Marshal or other authority having jurisdiction over fire regulations, if generator cannot comply with the 50-foot property line rule for storage of ignitable or reactive waste.
- Large Quantity Generator Consolidation: Allows a very small quantity generator (VSQG) to send its hazardous waste to a large quantity generator under control of the same person without the large quantity needing a permit:
 - Very small quantity generator must label containers with the words “hazardous waste” and the hazards of contents
 - Receiving large quantity generator must notify the state, keep records, and report waste under a new source code
 - DEQ proposes to not charge the generation and management fees related to very small quantity generator waste disposal to incentivize the use of this rule
- Episodic Generation:
 - Hazardous waste generated during an episodic event does not count towards generator status; the generator can maintain its usual status and avoid the increased requirements of a higher generator status

- Episodic event is a planned or unplanned activity not normally occurring during generator operations, such as a recall, emergency cleanup, resulting in an increase in waste generation that would bump up the generator's typical status
- Maximum of one unplanned and one planned per year, with petition to state
- For hazardous waste generated during episodic events, a generator must still dispose of such waste as hazardous waste, notify DEQ, and pay DEQ generation and management fees on the episodic hazardous waste

b) Oregon impacts:

- Hazardous Waste Program: There will be significant work associated with the implementation of this rule as citations are changing, requiring additional staff time.
- Regulated community: Regarding public outreach and training, the main substantive topics to educate generators on are labeling, Large Quantity Generator Consolidation, Episodic Generation, and the quick reference guide for Contingency Plans. Overall, the rule should benefit generators in terms of increased flexibility of hazardous waste management.

c) Fiscal impacts:

- Hazardous Waste Program: Impact to fee revenue is expected to be minimal. DEQ will lose some annual activity verification fees with the Episodic Generation provision, but would still collect generation and management fees on episodic waste.
- Regulated community: Overall, EPA has stated the rule will lessen the regulatory burden for the majority of generators and they will see cost savings.
- Both DEQ and the regulated community will have additional costs related to training and implementation, if adopted.

d) Other states: Approximately half of the states have adopted the rule, including Washington and Idaho. Washington elected to adopt the three optional provisions. State adoption map is available [here](#).

e) Recommendations:

1. Adopt all mandatory provisions by reference.
2. Adopt Large Quantity Generator Consolidation, with additional state rules to incentivize use, including waiver of DEQ generation and management fees related to Very Small Quantity Generator waste disposal.
3. Adopt Episodic Generation, with additional state rules and guidance to generators to ensure episodic events are appropriately limited to avoid abuse for deferred maintenance, etc.
4. Adopt State Fire Marshal waiver provision as written.

f) Additional Resources: [EPA FAQ](#), [McCoy & Associates](#)

Management Standards for Hazardous Waste Pharmaceuticals & Amendment to the P075 Listing for Nicotine

[[84 FR 5816-5950](#) – Federal Rulemaking Feb. 22, 2019, effective Aug. 21, 2019]

Rule Lead: Bart Collinsworth, Hazardous Waste Technical Assistance Specialist, Western Region

Support: Chris Bayham, Hazardous Waste Inspector, Western Region

Mary Fritzmann, Hazardous Waste Reporting and Invoicing Coordinator, Headquarters

a) **What the rule does:** Establishes cost savings by streamlining standards for handling hazardous waste pharmaceuticals to better fit the operations of the healthcare sector while helping protect human health and the environment.

This rule will make our drinking and surface water safer and healthier by reducing the amount of hazardous waste pharmaceuticals entering our waterways under the sewerage prohibition. Federal Drug Administration approved over-the-counter nicotine replacement therapies, such as nicotine patches, gums and lozenges, will no longer be a hazardous waste when discarded. This will result in significant cost savings and burden reduction in the management of nicotine wastes, as noted in the fiscal impact analysis summary below.

New Definitions

- **Pharmaceutical** includes, but not limited to, dietary supplements, prescription drugs, over-the-counter drugs, homeopathic drugs, compounded drugs, investigational new drugs, pharmaceuticals remaining in containers, PPE contaminated with pharmaceuticals, clean-up material from spills of pharmaceuticals.
 - Pharmaceutical does not include dental amalgam, sharps or medical waste.
- **Healthcare Facility** includes, but is not limited to, military medical logistics facilities, hospitals, ambulatory surgical centers, health clinics, physicians’ offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, veterinary clinics and hospitals.
 - Healthcare Facility does not include pharmaceutical manufacturers, reverse distributors and reverse logistics centers; and
 - Healthcare Facilities do include long-term care facilities with nursing care and hospice facilities, or independent living communities, assisted living facilities and group homes.

Applicability

The Pharmaceutical Rule is both sector- and waste-specific. The rule applies to small quantity generators and large quantity generators that are healthcare facilities, and it applies to the management of pharmaceutical hazardous waste. Very small quantity generators may opt-in. However, VSQG healthcare facilities are automatically subject to the sewer ban. Reverse distributors are also subject to this rule. The rule regulates potentially creditable, non-creditable, and evaluated hazardous pharmaceutical waste. Facilities are also encouraged, but not required, to include nonhazardous pharmaceuticals.

Pharmaceutical hazardous wastes will no longer be counted or reported at healthcare facilities subject to the Pharmaceutical Rule. Reverse distributors are subject to reporting the pharmaceutical waste they evaluate. The P075 revision is not sector specific, but it is waste specific, for lozenges, gum, and nicotine patches only.

Notify	Healthcare Facilities (HCF)		Reverse Distributors (RD)	
	Yes*		Yes*	
	potentially creditable	non-creditable	potentially creditable	evaluated
Container standards	No	Yes	No	Yes
Labelling	No	Yes	No	Yes
Accumulation times	No	1-year**	30 days (210 max)	180 days
Weekly inspections	No	No	No	Yes
Employee training	No	Yes	No	Yes–LQG like
Contingency planning	No	No	Yes	Yes

Notify	Healthcare Facilities (HCF)		Reverse Distributors (RD)	
	Yes*		Yes*	
	potentially creditable	non-creditable	potentially creditable	evaluated
Record keeping/tracking	Yes	Yes	Yes	Yes
Reporting	No	No	No	Biennial***
Manifest	No	Yes	No	Yes
Hazardous waste transporter	No	Yes	No	Yes
Shipping to	Reverse distributor	Transfer, Storage, Disposal Facility (TSDF)	Another reverse distributor	Transfer, Storage, Disposal Facility (TSDF)
Empty containers ****	Yes	Yes	Yes	Yes

*Notification will be done in DEQ timeframe on state Site Identification form;

**1-year accumulation time-frame can be proven with flexible options- DEQ to be more stringent (dates on containers only);

***Biennial reporting for RDs will be changed to annual reporting for DEQ.

****Empty container standards found in 266 subpart P can be used by any generator of haz waste pharmaceuticals, not just healthcare facilities.

b) **Oregon impact:** In addition to the reduced management standards in the table above, the rule reduces fiscal and regulatory impact by:

- Eliminating certain nonprescription pharmaceutical waste from the P075 listing
- Removing LQG-like training requirements for healthcare facilities, not for reverse distributors
- Providing more flexibility for determinations for HW pharms
- Creating conditional exemption for Drug Enforcement Agency-controlled substances
- Clarifying RCRA-empty hazardous waste pharmaceutical containers to reduce unnecessary hazardous waste

c) **Fiscal impact:**

- Hazardous Waste Program: Annual generator activity verification fees may decline by up to approximately \$13,500. There will need to be additional staff to document updates and generator outreach.
- Regulated Community: EPA's small business fiscal impact analysis finds:
 - Cost of compliance represents only 0.13% of revenue at healthcare facilities and 0.002% of revenue at hospitals.
 - Cost impact to small entity reverse distributors at \$5,300 annually, and do not anticipate this to be a hardship.

d) **Other states:**

- Optional Nicotine P075 rule: Washington has adopted, California may not
- Pharmaceutical Rule: Washington has adopted with one state-only amendment
- State adoption map can be found [here](#)

e) **Recommendations:**

P075: Adopt by reference

Pharmaceutical Rule: Adopt by reference, **except:**

- Notification on Oregon Site Identification form for all healthcare facilities and reverse distributors within 60 days of being subject to the rule.

- Do not adopt the presumption that long-term care facilities with less than 20 beds are very small quantity generators.
- Do not adopt more flexible options for proving one-year accumulation, use only option for labelling each container.
- Reverse distributors report annually to DEQ, not biennially to EPA.
- For empty container residuals follow 110 gals not 119 gals, per DEQ established definitions.

f) **Additional Resources:** [EPA FAQ](#), [McCoy & Associates](#)

Alternative formats

DEQ can provide documents in an alternate format or in a language other than English upon request. Call DEQ at 800-452-4011 or email deqinfo@deq.state.or.us.