

## ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, 262, 264, 265, 266, 270, 271, and 441

[EPA-HQ-OLEM-2023-0081; FRL 8687-02-OLEM]

RIN 2050-AH23

### Hazardous Waste Generator Improvements Rule, the Hazardous Waste Pharmaceuticals Rule, and the Definition of Solid Waste Rule; Technical Corrections

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (the EPA or the Agency) is taking direct final action on a number of technical corrections that correct or clarify several parts of the Resource Conservation and Recovery Act (RCRA) hazardous waste regulations. These technical corrections correct or clarify specific provisions in the existing hazardous waste regulations that were promulgated in the Hazardous Waste Generator Improvements rule, the Hazardous Waste Pharmaceuticals rule, and the Definition of Solid Waste rule. This rule also makes other minor corrections that fall within the same sections of the hazardous waste regulations but are independent of these three rules. Examples of the types of corrections being made in this rule include, but are not limited to, correcting typographical errors, correcting incorrect or outdated citations, making minor clarifications, and updating addresses.

**DATES:** This rule is effective on December 7, 2023, without further notice unless the EPA receives adverse comment by October 10, 2023. If the EPA receives adverse comment on any individual correction, we will publish a timely withdrawal in the **Federal Register** informing the public about the specific paragraph or amendment where the correction or clarification will not take effect.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-HQ-OLEM-2023-0081. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly

available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov>.

#### FOR FURTHER INFORMATION CONTACT:

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#### SUPPLEMENTARY INFORMATION:

##### I. Why is EPA using a direct final rule?

The EPA is publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment since the technical corrections are minor fixes and clarifications. However, in the “Proposed Rules” section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposed rule to adopt the provisions in this direct final rule if adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document.

If the EPA receives adverse comment on any individual correction, we will publish a timely withdrawal in the **Federal Register** informing the public about the specific regulatory paragraph or amendment that will not take effect. The corrections that are not withdrawn will become effective on the date set out above. We would address all public comments in any subsequent final rule based on comments and new information submitted in response to the proposed rule.

##### II. Does this action apply to me?

Entities potentially affected by this action include hazardous waste generators, treatment, storage, and disposal facilities, healthcare facilities, reverse distributors, importers/exporters of hazardous waste, and users of the transfer-based exclusion to the definition of solid waste. Also affected are States and EPA Regions implementing the RCRA hazardous waste regulations.

##### III. What is the legal authority of this final rule?

This rule is authorized under sections 1004, 2002, 3001, 3002, 3003, 3004, 3005, 3006, 3007, 3010, 3017, and 3018 of the Resource Conservation and Recovery Act of 1976, as amended, 42 U.S.C. 6903, 6912, 6921, 6922, 6923, 6924, 6925, 6926, 6927, 6930, 6938, and 6939.

##### IV. Background

In the process of publishing in the **Federal Register** the three final rules that are the focus of this rulemaking, the EPA inadvertently made typographical errors, included incorrect citations, and finalized language that was unintentionally ambiguous. Similarly, while the Agency attempted to make conforming changes to all appropriate parts of the RCRA hazardous waste regulations when these three rules were promulgated, some were overlooked. The EPA has also identified a number of other regulations needing to be corrected that were not part of the three final rules that are the main focus of this rulemaking but are located in the same sections of the regulations. The Agency determined that including those additional corrections in this rulemaking would be an efficient use of Agency resources and provide sufficient benefit to merit their incorporation. These inadvertent errors and oversights have been the cause of some confusion on the part of the regulated community, as well as the Federal and State regulators implementing the hazardous waste regulatory program. Making these corrections will ease that confusion among the EPA’s stakeholders.

This rule addresses these problems by correcting and clarifying the RCRA hazardous waste management regulations—specifically the general hazardous waste management system regulations under 40 CFR part 260, the hazardous waste identification regulations under 40 CFR part 261; the standards applicable to generators of hazardous waste in 40 CFR part 262; the standards for owners and operators of hazardous waste treatment, storage, and disposal facilities in 40 CFR part 264; the interim status standards for owner and operators of hazardous waste treatment, storage, and disposal facilities in 40 CFR part 265; the regulations for specific hazardous wastes and specific types of hazardous waste management facilities in 40 CFR part 266, including the regulations for hazardous waste pharmaceuticals in 40 CFR part 266, subpart P; the regulations for EPA-administered hazardous waste permit programs under 40 CFR part 270;

the requirements for authorization of State hazardous waste programs in 40 CFR part 271; and the dental office point source category regulations in part 40 CFR part 441.

This action was developed in accordance with EPA guidance on environmental justice. As a technical correction rulemaking, it does not have any disproportionately high and adverse human health or environmental effects on the programs, policies, or activities of minority populations (people of color) and low-income populations. It does not have adverse impact on other federal agencies, states, local governments, tribes, paperwork burdens, or children's health.

Similarly, because this rule consists entirely of technical corrections, it does not have any adverse impacts on climate change nor any state and federal climate adaptation programs.

Today's action makes over 100 technical corrections to 40 CFR parts 260–262, 264–266, 270–271, and 441. The discussion of technical corrections to the regulations below is organized by the rulemaking that initially made the changes. Where a technical correction does not stem directly from one of the three main rulemakings being corrected, it has been included where it makes most sense to do so by topic. In addition, the EPA provides a description and explanation of the technical corrections in the preamble to this direct final rule.

#### V. Corrections Related to the Regulatory Revisions Implemented by the Hazardous Waste Generator Improvements Rule

This section addresses technical corrections to revisions made as part of the Hazardous Waste Generator Improvements rule. The final rule, referred to as the Generator Improvements rule, was published in the **Federal Register** on November 28, 2016 (81 FR 85732) and revised the requirements for hazardous waste generators, a regulatory term that refers to any person, by site, whose act or process produces hazardous waste or whose act first causes a hazardous waste to become subject to regulation. The Generator Improvements rule included a reorganization and renumbering of the regulations for the management of hazardous waste by generators of that waste as well as revisions that both closed regulatory gaps and, where appropriate, provided flexibility in the regulations for certain management scenarios. The technical corrections described in this action include the correction of typographical errors, the correction of citations in the regulations

that were not updated in the original Generator Improvements rule, and revisions to wording in the regulations that has caused confusion in the six years since the final rule was published.

The technical corrections in this section of the rule appear mostly in the hazardous waste generator regulations in part 262 of chapter 40 of the Code of Federal Regulations, but also in other hazardous waste provisions in 40 CFR parts 260, 261, 264, 265, 266, 270, and 271. There is also one citation updated in 40 CFR part 441.

Each of the technical corrections are discussed below. The preamble discusses typographical errors first, then updated citations, and finally wording changes. Within each section, the technical corrections are generally discussed in the order they appear in the regulations. However, to avoid repetition, similar technical corrections are discussed together in the preamble.

##### A. Typographical Errors

- Section 262.16(b) is revised to include a reference to § 262.16(c) in the list of provisions in this section describing when a small quantity generator can accumulate hazardous waste for more than 180 days. The reference to § 262.16(c) was inadvertently left off this list in the 2016 Generator Improvements rule.

- Section 262.16(b)(5) is revised to remove an “of” from the paragraph where it does not belong.

- Sections 262.16(b)(8)(iv)(A) and (B) are both revised to replace the internal cross reference to paragraph (a)(8)(ii) of this section to the correct citation: paragraph (b)(8)(ii) of this section.

- Section 262.17(a)(7)(i)(A) is revised to make the internal cross reference more specific by including the fourth paragraph level. The correct cross reference is to § 262.17(a)(7)(iv)(C), which describes what elements must be included in a large quantity generator's (LQG) training program. This revision also is consistent with the cross referencing in § 265.16, which applied to LQGs before the Generator Improvements rule reorganization.

- Section 262.17(a)(8)(iii)(A)(4) is revised to correct the regulation it references. The correct citation is paragraph (a)(8)(iii)(A)(2) of this section.

- Section 262.213(a)(1) is revised to replace a misplaced “or” with “of.”

- Section 262.232(b)(4) is revised to remove the word “waste” from a place where it does not belong.

- Section 262.232(b)(6)(iv) is revised to add “RCRA-” to the term “designated facility” to match the language of parallel provisions in this section.

- Section 265.71 is revised by removing the comment to paragraph (c). The contents of that comment were incorporated into the main text of paragraph (c) by the Generator Improvements rule, but the comment was not removed at that time.

##### B. Missed Citation Updates and Changed Terminology

The Generator Improvements rule reorganized the hazardous waste generator regulations. Two of the main changes during this reorganization were moving the regulations that had been in § 261.5 into §§ 262.13 and 262.14 and reorganizing the regulations that had been in § 262.34 into three new sections: § 262.15 for satellite accumulation areas, § 262.16 for small quantity generators, and § 262.17 for large quantity generators.

The Generator Improvements rule also replaced the § 260.10 defined term “conditionally exempt small quantity generator” throughout the regulations with a new term that more accurately describes this category of generators: “very small quantity generator.” In addition, the rule defined the terms “small quantity generator” and “large quantity generator.” The previous regulations had distinguished small quantity generators from large quantity generators by stating with each mention that the former were generators that generated greater than 100 kilograms and less than 1,000 kilograms of hazardous waste in a calendar month and the latter were generators that generated equal to or greater than 1,000 kilograms of hazardous waste per calendar month.

The Generator Improvements rule also removed from the Code of Federal Regulations several obsolete sections of the generator regulations that are no longer in effect.

Although the EPA attempted to find each reference to obsolete regulatory citations and terminology when finalizing the 2016 Generator Improvements rule, several were missed. The EPA is taking this opportunity to correct those errors in the regulations and update them with the new citations and terms or remove the citations completely, if appropriate. In addition, the EPA is updating one physical address listed in the regulations.

- The definition of “Final closure” in § 260.10 is revised to update the citation from § 262.34 to §§ 262.16 and 262.17.

- Section 261.1(a)(1) is revised to remove the reference to hazardous waste produced by very small quantity generators because the regulations for

very small quantity generators are now in part 262.

- Section 261.4(e)(1) is revised to replace the references to quantity determinations in §§ 261.5 and 262.34(d) with a reference to the counting requirements in § 262.13 and the accumulation limits in § 262.16(b)(1).
- Section 261.11(c) is removed and reserved. The Generator Improvements rule finalized regulations that directly address generator category and generation limits for each category; thus, this paragraph is redundant and could result in confusion if not removed.
- Section 261.30(d) is revised to replace the reference to § 261.5 with a reference to § 262.13, Table 1, and the text of the paragraph is revised to use the same language as the title to Table 1: Generator Category Limits.
- Three references to § 262.34 in appendix IX to part 261 are replaced with references to §§ 262.15, 262.16, and 262.17, as applicable.
- Section 262.10(k) is revised to replace a reference to § 262.34 with a reference to §§ 262.15–262.17, and the standards in those sections are identified as conditions for exemption to be consistent with the rest of the generator standards.
- Section 262.10, Note 1, is revised to replace two references to § 262.34 with references to §§ 262.15–262.17.
- Section 262.42(a)(1) and (2) and (b) are revised to replace descriptions of generator categories (e.g., “generators of 1000 kilograms or greater of hazardous waste in a calendar month”) with either “small quantity generator” or “large quantity generator,” which were terms promulgated and/or updated in the 2016 Generator Improvements rule.
- Section 262.82(e)(2) is updated to reflect the current address for hand deliveries of submittals required in part 262, subpart H, for transboundary movements of hazardous waste for recovery or disposal.
- The definition of “trained professional” in § 262.200 is revised to specifically identify the training requirements that personnel at large, small, and very small quantity generators must comply with under part 262, subpart K, to be considered a trained professional.
- Section 262.212(e)(3) is revised to replace a reference to § 261.5(c) and (d) with a reference to § 262.13.
- Section 264.1(g)(3) is revised to add generators that are accumulating waste on site in compliance with the generator standards in subparts K and L of part 262 to the list of compliant generators to which part 264 does not apply.

- Sections 264.1(g)(12), 265.1(c)(15), and 270.1(c)(2)(ix) referring to the expired New York State Utility XL project are all removed and reserved.
- Section 264.15(b)(5) referring to the expired Performance Track program is removed and reserved.
- Section 264.1030(b)(3) is revised to replace a reference to § 262.34(a) with a reference to § 262.17.
- Section 264.1050(b)(2) is revised to replace a reference to § 262.34(a) with a reference to § 262.17.
- Section 266.100(c)(3) is revised to replace the term “special requirements” with “conditions for exemption”; to replace the term “conditionally exempt small quantity generator” with “very small quantity generator”; and to replace a reference to § 261.5 with a reference to § 262.14.
- Section 266.108 is revised to replace the term “special requirements” with “conditions for exemption”; to replace the term “conditionally exempt small quantity generator” with “very small quantity generator”; and to replace a reference to § 261.5 with a reference to § 262.14.
- Section 271.10(c) is revised to add a reference to § 262.15 because the previous reference to § 262.34 should have been updated in the 2016 Generator Improvements rule to also include § 262.15.
- Section 441.50(b)(3) is revised to replace a reference to § 261.5(g)(3) with a reference to § 262.14(a)(5).

### C. Regulations To Be Reworded

In the time since the 2016 Hazardous Waste Generator Improvements rule was promulgated, the EPA has received feedback from State regulators implementing the rule, industry stakeholders, and others using the rule that some of the changes in the final rule are worded in a confusing way or could be interpreted as changing how the generator regulations work when the EPA did not discuss making such changes. In this section of the preamble, the EPA discusses and explains technical corrections to the regulations finalized by the 2016 Generator Improvements rule to address these concerns.

#### 1. Notification Requirements in Section 3010 of RCRA (Multiple Locations)

In multiple generator provisions promulgated in the 2016 Generator Improvements rule, the EPA refers to the notification requirements in section 3010 of the RCRA statute specifically. For example, in some provisions we state that the requirements for a permitted facility, including the notification requirements in section

3010 of RCRA, do not apply to those entities that meet generator conditions for exemption from permitting. Elsewhere, we state that if a generator violates a specific condition, such as an LQG accumulating longer than 90 days without an extension, they become subject to the permitting requirements, including section 3010 of RCRA.

Since the promulgation of the rule, the EPA has been asked if regulatory language in the 2016 rule means that a generator of hazardous waste does not need to notify as a generator using EPA Form 8700–12, the Site ID form. The EPA did not intend this language to have this meaning—and in fact, small and large quantity generators continue to have the requirement in § 262.18 to complete and submit the Site ID form, notifying the EPA and the implementing State that they are in operation.

The EPA has revised the regulatory text in §§ 262.1; 262.10(a)(2); and 262.16; and five places in § 262.17 (§ 262.17(b), (c), (d), (e), and (f)) to make it clear that the generators that are operating in compliance with the generator regulations are exempted from the notification requirements in section 3010 of RCRA specifically as they pertain to treatment, storage, and disposal facilities.

#### 2. Hazardous Waste Determination (§ 262.11(d) and (g))

In the 2016 Generator Improvements rule, the EPA made numerous revisions to the hazardous waste determination regulations in § 262.11 to incorporate long-standing guidance and policy. Section 262.11(c) used to read: “For purposes of compliance with 40 CFR part 268, or if the waste is not listed in subpart D of 40 CFR part 261, the generator must then determine whether the waste is identified in subpart C of 40 CFR part 261 by either . . . .”

The 2016 Generator Improvements rule moved this paragraph to § 262.11(d) and reworded the paragraph: “The person then must also determine whether the waste exhibits one or more hazardous characteristics as identified in subpart C of 40 CFR part 261 by following the procedures in paragraph (d)(1) or (2) of this section, or a combination of both.”

Rewording the paragraph has led to questions about whether it is now necessary to identify all characteristics, even when identifying a listing that already addresses the characteristic. For example, F003 solvents are listed for ignitability. The 2016 revision of § 262.11(d) could be read so that a generator must also identify the D001 characteristic for an F003 spent solvent. This was not our intent. We have been

consistent in our interpretation that as long as the listed waste code addresses the constituents or properties that cause the waste to exhibit a characteristic, then it is not necessary to also identify the characteristic. This is still the case. We are adding two sentences to the end of § 262.11(d) to clarify that we did not change this interpretation. For the same reason, § 262.11(g) is being revised to reference § 262.11(d) so they will be consistent with one another.

### 3. Very Small Quantity Generators That Accumulate Above the Threshold (§ 262.14(a)(3) and (4))

In the 2016 Generator Improvements rule, the EPA made revisions in §§ 260.10, 262.13, 262.14, and 262.16 to clarify to the regulated community which regulations apply to hazardous waste generators based on (1) The quantity of hazardous waste they generate per month; and (2) the quantity of hazardous waste they accumulate on site at any given time. Among those revisions were two lists of standards that apply when a very small quantity generator (VSQG) exceeds the VSQG limit for hazardous waste accumulated on site at any one time: one kilogram of acute hazardous waste, 100 kilograms of residue from a cleanup of a spill of acute hazardous waste, or 1,000 kilograms of non-acute hazardous waste. (See § 262.14(a)(3) and (4))

Before 2016, these provisions were in § 261.5 and stated that: (1) Accumulated acute hazardous wastes and residues from clean ups of spills of acute hazardous waste would be subject to regulation under parts 262–266, 268, and parts 270 and 124, as well as the applicable notifications requirements in section 3010 of the RCRA statute, and (2) non-acute hazardous waste would be subject to the part 262 provisions applicable to small quantity generator waste, as well as parts 263–266, 268, and parts 270 and 124, and the application notification requirements in section 3010 of the RCRA statute.

Instead of pointing generators to a long list of provisions that could apply in these situations, the revised language in the 2016 Generator Improvements rule provided two specific lists of the provisions that apply to the waste when a VSQG exceeds the accumulation threshold: one for acute hazardous wastes and one for non-acute hazardous wastes. However, the lists were focused on the conditions for exemption, and both left out several provisions that had been covered by the previous language.

This rule revises both lists—in § 262.14(a)(3) and (4)—to restore the independent requirements that were inadvertently left out of the lists,

including notification; preparation and use of the Uniform Hazardous Waste Manifest when shipping the waste off site; and complying with pre-transport requirements, recordkeeping and reporting requirements, and transboundary shipment requirements.

A VSQG that is notifying because it exceeded the accumulation threshold retains its VSQG category and prepares and submits EPA Form 8700–12 (the Site ID form) as a “very small quantity generator.”

### 4. Accumulation Limit for Small Quantity Generators Generating Acute Hazardous Waste (§ 262.16(b)(1))

The 2016 Generator Improvements rule established definitions for very small, small, and large quantity generators, reorganized the regulations for these categories of generators, and clearly distinguished the generator categories—determined by how much hazardous waste is generated per calendar month at a site—from the conditions for exemption that specify limits for how much hazardous waste small and very small quantity generators can accumulate on site at any one time.

However, the small quantity generator conditions for exemption include an accumulation limit of 6,000 kilograms for non-acute hazardous waste but do not specify an accumulation limit for acute hazardous waste.

In the original 1980 hazardous waste generator regulations, there were only two categories of hazardous waste generator: small (generating less than 1,000 kilograms of hazardous waste per month) and large (generating more than 1,000 kilograms of hazardous waste per month). These pre-1986 small quantity generators had a total on-site hazardous waste accumulation limit of 6,000 kilograms of non-acute hazardous waste and one kilogram of acute hazardous waste. The 1986 rule that established the category and specific requirements for those generating between 100 kilograms and 1,000 kilograms per month (small quantity generators) (51 FR 10146; March 24, 1986) implemented the changes to the hazardous waste program required by the Hazardous and Solid Waste Amendments of 1984 (HSWA) and established a new category of “conditionally exempt small quantity generator” for those generating less than 100 kilograms of non-acute hazardous waste per month.

The scope of HSWA and the new regulations for conditionally exempt small quantity generators did not include acute hazardous waste. Therefore, generators generating less than one kilogram of acute hazardous

waste per month are conditionally exempt small quantity generators and those generating more than one kilogram of acute hazardous waste per month are large quantity generators. There is no separate small quantity generator category based solely on generation of acute hazardous waste.

The EPA clarified the distinctions between the three generator categories in the 2016 Generator Improvements rule and stated that a small quantity generator can only generate up to one kilogram of acute hazardous waste in a calendar month, but it was not clear in the new language whether there is a limit on the amount of acute hazardous waste a small quantity generator can accumulate on site at any one time.

Consistent with what has been historically allowed for generators of small amounts of acute hazardous waste, the EPA is revising § 262.16(b)(1) to clarify that the acute hazardous waste accumulation limit for a small quantity generator is one kilogram.

### 5. Accumulation in Tanks (§ 262.17(a)(2))

Section 262.17(a)(2) describes the requirements for hazardous waste that LQGs accumulate in tanks. This section was reorganized with some wording changes in the 2016 Generator Improvements rule. Section 262.17(a)(2) used to be in § 262.34(a)(1)(ii), where it was clear that the LQG must comply with the applicable requirements of subparts J, AA, BB, and CC of 40 CFR part 265 except §§ 265.197(c) and 265.200. The EPA was informed by stakeholders that the revised regulation is not as clear as it had been previously and is therefore revising the paragraph by replacing the offsetting commas with a set of parentheses to ensure clarity about which requirements apply to LQGs that accumulate hazardous waste in tanks.

### 6. Closure of a Waste Accumulation Unit (§ 262.17(a)(8)(i) Introductory Text and (a)(8)(i)(A))

The Generator Improvements rule added a requirement that LQGs undergoing closure of a hazardous waste accumulation unit (e.g., tank system, container accumulation area) must notify the EPA (or the authorized State). Section 262.17(a)(8)(i) describes the standards for notification when they are just closing one single accumulation unit and not all their accumulation units. In this case, LQGs have two options. They can submit the Site ID form notifying the EPA of a unit's closure at the time they close the unit (as per § 262.17(a)(8)(i)(B)) or they can put a notice in their operating record

and then, at a later date, when all the accumulation units are closing, include the earlier unit in the broader closure notification (as per § 262.17(a)(8)(i)(A)). The EPA is revising the language in this section to more clearly describe that these paragraphs apply specifically to closure of a waste accumulation unit but not the whole facility.

#### 7. Exception Reporting for an Episodic Event (§ 262.232(a)(5))

The 2016 Generator Improvements rule added new provisions and conditions under subpart L (Alternate Standards for Episodic Generation) for very small and small quantity generators allowing them to hold episodic generation events one time per year if they experience an event that pushes them above the generation threshold for their normal generator category for that calendar month. (A second event may be allowed but must be approved by the EPA or the authorizing State.)

Under the episodic event provisions, very small quantity generators must comply with certain conditions including notification; labeling of tanks and containers; managing waste in a manner that minimizes fire, explosions, or releases; and transporting the hazardous waste to a RCRA treatment, storage, and disposal facility or a hazardous waste recycler using the Uniform Hazardous Waste Manifest (EPA Form 8700–22). The intent of these conditions was to ensure that any hazardous waste from an episodic event is sent to an appropriate hazardous waste designated facility under the protections of the manifest system.

However, in the regulations finalized by the 2016 Generator Improvements rule for very small quantity generators holding episodic events, the EPA neglected to include a reference to § 262.44 of the generator regulations—recordkeeping requirements for small quantity generators—an important part of the manifest's cradle-to-grave tracking. The EPA always intended for the entire manifest tracking system to apply to hazardous waste from episodic events being held by very small quantity generators.

The EPA is revising § 262.232(a)(5) to include a reference to § 262.44, which includes maintaining records of manifests and hazardous waste determinations, completing an exception report if the generator does not receive a copy of its manifest from the designated facility indicating that the waste arrived within 60 days from the date upon which the waste was accepted by the initial transporter, and complying with requests from the Administrator for additional reports

under sections 2002(a) and 3002(a)(6) of RCRA.

#### 8. Episodic Generation for Small Quantity Generators (§ 262.232(b)(4)(ii)(C))

Section 262.232(b) describes the conditions that apply when a small quantity generator is holding an episodic event. Generators must label accumulation units with the date the episodic event begins to ensure that all hazardous waste from the event is transported off site to a RCRA-designated facility within the 60 days allowed for the entire episodic event. This standard was clear in the preamble to the 2016 Generator Improvements final rule and in the parallel regulations for VSQGs and for small quantity generators accumulating hazardous waste in containers, but the 2016 regulatory language erroneously indicated that small quantity generators accumulating hazardous waste in tanks should mark them with the day the period of accumulation begins (*i.e.*, the day that hazardous waste started accumulating in that tank), as opposed to the day the event began. The EPA is revising the regulatory language to match its intent, as indicated in the 2016 preamble and the other parallel sections of the episodic generation regulations.

### VI. Corrections Related to the Regulatory Revisions Implemented by the Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine Rule

This section addresses technical corrections to revisions made as part of the Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine rule. The final rule, referred to as the Hazardous Waste Pharmaceuticals final rule, was published in the **Federal Register** on February 22, 2019, (84 FR 5816) and added part 266 subpart P to title 40, chapter I, of the Code of Federal Regulations. The revisions described in this action include correction of typographical errors, the correction of citations in the regulations that were not updated in the original Hazardous Waste Pharmaceuticals final rule, revisions to wording in the regulations to provide consistency, and revisions to wording in the regulations that have caused confusion in the four years since the final rule was published.

All but three of the technical corrections appear in part 266, subpart P. The technical corrections that are not in part 266, subpart P, are in §§ 264.72

and 265.72 and Table 1 of § 271.1. Each of the technical corrections are discussed below. Generally, the technical corrections are discussed in the order they appear in the regulations. However, to avoid repetition, similar technical corrections are discussed together, even if that means that they are taken out of order.

#### A. Manifest Discrepancies (§§ 264.72 and 265.72)

Sections 264.72(a)(3) and 265.72(a)(3) are both being revised to include a reference to the new empty container standards in § 266.507 that were added as a component of part 266, subpart P. The current regulatory language in §§ 264.72(a) and 265.72(a) references the empty container standards in § 261.7(b). We are updating the references to include the new empty container standards in § 266.507 as well.

#### B. Applicability (§ 266.501)

Section 266.501(d)(2) of the Applicability section of part 266, subpart P, is being amended to correct a typographical error. Specifically, the regulatory citation § 262.502(a) is being revised to § 266.502(a). In fact, the citation § 262.502(a) does not exist.

#### C. Lab Pack Accumulation (§§ 266.502(d)(4) and 266.510(c)(4)(vi))

##### 1. Overview of Technical Corrections Related to Lab Packing Hazardous Waste Pharmaceuticals

Sections 266.502(d)(4) and 266.510(c)(4)(vi) are both being amended to insert the phrase, “or because it is prohibited from being lab packed due to § 268.42(c).” Section 266.502(d)(4) is within the healthcare facility standards for non-creditable hazardous waste pharmaceuticals. Section 266.510(c)(4)(vi) is within the reverse distributor standards for evaluated hazardous waste pharmaceuticals. These changes clarify that non-creditable and evaluated hazardous waste pharmaceuticals that are prohibited from being lab packed for incineration must be accumulated in separate containers at healthcare facilities and reverse distributors, respectively. These amendments are consistent with guidance the EPA issued after the rule was published in February 2019 and posted on the web page, Frequent Questions about the Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine final rule.<sup>1</sup>

<sup>1</sup> <https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and#landdisposal>.

In the Frequent Questions, we explained that in the Hazardous Waste Pharmaceuticals final rule the EPA required that healthcare facilities and reverse distributors segregate certain metal-bearing hazardous waste pharmaceuticals in separate containers. The Agency's reasoning was that, while combustion is the required treatment standard under the Land Disposal Restrictions (LDRs) for most hazardous waste pharmaceuticals, the combustion of a few metal-bearing hazardous wastes is prohibited. Therefore, a healthcare facility or reverse distributor must accumulate those particular metal-bearing hazardous waste pharmaceuticals in a separate container at the initial point of accumulation, and label them with the appropriate hazardous waste codes in order to prevent them from being combusted inadvertently. While the final rule mentions the LDR dilution prohibition as one reason for accumulating certain metal-bearing hazardous waste pharmaceuticals separately, we inadvertently omitted a reference to the LDR lab-pack regulations as a reason for accumulating certain hazardous waste pharmaceuticals separately.

In § 266.510(c)(4)(vi), we included a parenthetical with an example of a metal-bearing hazardous waste pharmaceutical that was prohibited from being combusted due to the dilution prohibition of § 268.3(c). The example we included was arsenic trioxide. Including the example caused confusion, leading some to think that arsenic trioxide was the only metal-bearing hazardous waste pharmaceutical that had to be segregated. Therefore, we are replacing the example in the parenthetical with a reference to the complete list of metal-bearing waste codes in appendix XI to part 268. Similarly, we are adding a second parenthetical that will reference appendix IV to part 268 following the new language about the lab pack prohibition. For consistency, we are adding both of these parentheticals to § 266.502(d)(4).

## 2. Detailed Explanation of Regulatory Changes Related to Lab Packing Hazardous Waste Pharmaceuticals

The standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals include a provision related to metal-bearing pharmaceuticals that are subject to the dilution prohibition under the LDRs in § 268.3. Specifically, § 266.502(d)(4) of the Hazardous Waste Pharmaceuticals final rule states that a "healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and

non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers and labeled with all applicable hazardous waste numbers (*i.e.*, hazardous waste codes)."

The standards for reverse distributors managing evaluated hazardous waste pharmaceuticals includes an analogous provision. Specifically, § 266.510(c)(4)(vi) states that a "reverse distributor . . . must . . . [a]ccumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (*e.g.*, arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor."

The healthcare facility standards and the reverse distributor standards both cite the LDR dilution prohibition found in § 268.3(c), which provides that "combustion of the hazardous waste codes listed in Appendix XI" to part 268 is "prohibited, unless the waste, at the point of generation, or after any bonafide treatment such as cyanide destruction prior to combustion, can be demonstrated to comply with one or more" of the specific criteria (unless otherwise specifically prohibited from combustion). The criteria follow:

- (1) The waste contains hazardous organic constituents or cyanide at levels exceeding the constituent-specific treatment standard found in § 268.48;
- (2) The waste consists of organic, debris-like materials (*e.g.*, wood, paper, plastic, or cloth) contaminated with an inorganic metal-bearing hazardous waste;
- (3) The waste, at point of generation, has reasonable heating value such as greater than or equal to 5000 BTU per pound;
- (4) The waste is co-generated with wastes for which combustion is a required method of treatment;
- (5) The waste is subject to Federal and/or State requirements necessitating reduction of organics (including biological agents); or
- (6) The waste contains greater than 1% Total Organic Carbon (TOC).

Appendix XI to part 268 is a table of 51 metal-bearing hazardous wastes, some of which are, or are ingredients in, pharmaceuticals. In some cases, metal-bearing hazardous waste pharmaceuticals contain more than 1% total organic carbon (TOC), in which case they can be combusted and they do not need to be accumulated separately

(see § 268.3(c)(6)). Other hazardous waste pharmaceuticals that do not contain more than 1% TOC (or do not meet any other exceptions in §§ 268.3(c)(1) through (5)), must be accumulated separately in accordance with §§ 266.502(d)(4) and 266.510(c)(4)(vi) because they are prohibited from being combusted due to the dilution prohibition. Arsenic trioxide is an example of a hazardous waste pharmaceutical that does not contain >1% TOC and therefore must be accumulated separately.

In some cases, a healthcare facility or reverse distributor will use lab packs for its hazardous waste pharmaceuticals. Lab packs, also known as "overpacked drums," are a commonly used form of waste packaging for a variety of hazardous wastes—not just hazardous waste pharmaceuticals—where many small containers such as vials or bottles containing compatible hazardous waste are placed into a larger container with sorbent material. In some cases, lab packs are used by generators as accumulation containers at the initial point of accumulation of the hazardous waste. More often, hazardous waste is lab packed later by a vendor, as the hazardous waste is prepared to be shipped off site for treatment and disposal. Lab packs are typically treated by combustion.

In many cases, the use of lab packs by healthcare facilities and reverse distributors for hazardous waste pharmaceuticals is allowed per the alternative LDR treatment standard of § 268.42(c), which provides that, "as an alternative to the otherwise applicable subpart D treatment standards, lab packs are eligible for land disposal," provided the specific requirements are met. The requirements follow:

- (1) The lab packs comply with the applicable provisions of 40 CFR 264.316 and 265.316;
- (2) The lab pack does not contain any of the wastes listed in appendix IV to part 268;
- (3) The lab packs are incinerated in accordance with the requirements of 40 CFR part 264, subpart O, or 40 CFR part 265, subpart O; and
- (4) Any incinerator residues from lab packs containing D004, D005, D006, D007, D008, D010, and D011 are treated in compliance with the applicable treatment standards specified for such wastes in subpart D of part 268.

However, the 17 hazardous waste codes in appendix IV to part 268 are not eligible for this alternative LDR treatment standard, and thus are prohibited from being lab packed for incineration (see § 268.42(c)(2)). As shown in the table below, there are

several hazardous waste pharmaceuticals among the 17 hazardous wastes listed in appendix IV to part 268. These hazardous waste pharmaceuticals are prohibited from

being included in lab packs that will be incinerated under the alternative LDR treatment standard; therefore, the result is that these also must be accumulated separately, just like the hazardous waste

pharmaceuticals that are prohibited from being incinerated due to the dilution prohibition.

TABLE 1—EXAMPLES OF HAZARDOUS WASTE PHARMACEUTICALS LISTED IN APPENDIX IV TO PART 268—WASTES EXCLUDED FROM LAB PACKS UNDER THE ALTERNATIVE TREATMENT STANDARDS OF § 268.42(c)

Hazardous waste code	Hazardous waste chemical name
D009 *	Mercury (toxicity characteristic).
P012 *	Arsenic Trioxide.
P076	Nitric Oxide.
U151 *	Mercury.

\* Also appears in Appendix XI to Part 268—Metal Bearing Wastes Prohibited From Dilution in a Combustion Unit According to 40 CFR 268.3(c).

The regulatory language in §§ 266.502(d)(4) and 266.510(c)(4)(vi) is being amended to include this additional cross-reference to the prohibition on lab packing certain hazardous waste pharmaceuticals for incineration. The prohibition in § 268.42(c)(2) applies independent of the changes finalized by the Hazardous Waste Pharmaceuticals final rule. We are including this additional reference for clarity and for the reader's convenience.

3. Marking Lab Packs for Shipping

Although there are no corresponding regulatory technical corrections, we would like to highlight a related matter about marking lab packs for shipping. Under subpart P, a healthcare facility that is accumulating and shipping non-creditable hazardous waste pharmaceuticals to a designated facility is required to mark its containers with the words "Hazardous Waste Pharmaceuticals," and it is not necessary to mark those containers with individual hazardous waste codes (see § 266.502(e)). However, be aware that the shipping standards for non-creditable and evaluated hazardous waste pharmaceuticals require that lab packs containing D004 (arsenic), D005 (barium), D006 (cadmium), D007 (chromium), D008 (lead), D010 (selenium) or D011 (silver) must be marked with the EPA hazardous waste numbers (see § 266.508(a)(1)(iii)(C)). These specific metals must be identified because § 268.42(c)(4) requires any incinerator residues from lab packs that contain any of these specific metals to undergo further treatment to meet applicable treatment standards prior to land disposal.

D. EPA Hazardous Waste Numbers (§§ 266.502, 266.508, and 266.510)

1. Clarifying Terminology

We are revising the regulatory language in six places to use consistent language when referring to EPA hazardous waste numbers, and to consistently reflect that EPA hazardous waste numbers are often referred to as hazardous waste codes. In each case, the regulatory language is being revised to read, ". . . applicable EPA hazardous waste numbers (i.e., hazardous waste codes)."

The six changes appear in the following four sections of the regulations:

- (1) One change in § 266.502(d)(4);
- (2) two changes in § 266.508(a)(1)(iii)(C);
- (3) one change in § 266.508(a)(2)(i);
- (4) two changes in § 266.510(c)(5).

2. Using Hazardous Waste Codes on the Hazardous Waste Manifest

We are amending § 266.508(a)(2)(ii) to insert a sentence at the end (using the same phrasing discussed above) clarifying that a healthcare facility may also include the applicable EPA hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of EPA Form 8700–12, in addition to the PHARMS or PHRM code.

This technical correction is a restatement of preamble from the final rule and is also consistent with guidance that the EPA has provided since the final rule was published. This change pertains to the standards for healthcare facilities shipping non-creditable hazardous waste to a designated facility (e.g., TSDF). The final rule requires the use of the word "PHARMS" on Item 13 of the manifest (see section VII.M. of this preamble for additional detail). In the preamble of the final rule, when discussing container labeling standards for non-creditable hazardous waste pharmaceuticals at

healthcare facilities, the EPA stated that "the Agency is not finalizing a requirement of healthcare facilities to label containers of non-creditable hazardous waste pharmaceuticals with hazardous waste codes, . . . although a vendor could include such a requirement in its contract with a healthcare facility."<sup>2</sup>

Since then, the EPA reinforced this statement in a Frequent Question<sup>3</sup> that is posted on our website, as well as in a memorandum.<sup>4</sup> The last paragraph of the memorandum states:

Although healthcare facilities operating under subpart P are not required to include all applicable RCRA hazardous waste codes when manifesting non-creditable hazardous waste pharmaceuticals, the EPA indicated in the preamble to the final rule that we do not object if healthcare facilities or their vendors choose to include RCRA hazardous waste codes on manifests in addition to PHRM/ PHARMS (see page 5877). Including all applicable RCRA hazardous waste codes on the manifest when shipping non-creditable hazardous waste pharmaceuticals could help receiving facilities better understand the wastes and determine the best course of management. In addition, we recommend for manifested non-creditable hazardous waste pharmaceuticals shipped from a healthcare facility operating under subpart P but passing through a state or going to a TSDF in a state that has not yet adopted subpart P, that the healthcare facility/vendor check with those states regarding whether they require all applicable waste codes to be on the manifest. Further, the regulated community should be aware that as authorized states adopt and become authorized for part 266 subpart P, it is possible that they may choose to be more stringent and require all hazardous waste codes when healthcare facilities manifest non-creditable hazardous waste pharmaceuticals.

<sup>2</sup> 84 FR 5816, February 22, 2019. See page 5877.

<sup>3</sup> <https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and#e2>.

<sup>4</sup> From Johnson to EPA Regions, December 19, 2019, RCRA Online #14919.

*E. Calendar Days (§§ 266.502 and 266.510)*

We are adding the word “calendar” to modify the word “days” in 15 citations within part 266, subpart P. The word “calendar” is already used to modify the word “days” in seven citations within part 266, subpart P, but we were not consistent throughout the subpart P regulatory language. In the preamble to the proposed and final rules, however, the term “calendar days” is used consistently such that the EPA believes our intention was clear that whenever “days” is mentioned, it refers to “calendar days.” Thus, these 15 regulatory citations are being amended for clarity and consistency.

Five of the corrected regulatory citations are in the healthcare facility standards for non-creditable hazardous waste pharmaceuticals in § 266.502. The other ten corrected regulatory citations are in the reverse distributor standards for evaluated hazardous waste pharmaceuticals in § 266.510(c). The 15 citations that are being amended to include the word “calendar” are:

- (1) Section 266.502(h);
- (2) Section 266.502(h)(3);
- (3) Section 266.502(h)(4);
- (4) Section 266.502(i)(2)(i)(A);
- (5) Section 266.502(i)(2)(ii)(A);
- (6) Section 266.510(b)(1);
- (7) Section 266.510(b)(2);
- (8) Section 266.510(c)(2);
- (9) Section 266.510(c)(7);
- (10) Section 266.510(c)(7)(iii);
- (11) Section 266.510(c)(7)(iv);
- (12) Section 266.510(c)(9)(ii)(A)(1);
- (13) Section 266.510(c)(9)(ii)(A)(2);
- (14) Section 266.510(c)(9)(ii)(B)(1);
- (15) Section 266.510(c)(9)(ii)(B)(2).

*F. Rejected Shipments (§§ 266.502 and 266.510)*

We are replacing the word “returned” with “rejected” in two places in § 266.502(h) when discussing the procedures for the management of rejected shipments of non-creditable hazardous waste pharmaceuticals. Additionally, we are removing the words “or returned” from a third place in § 266.502(h).

This is being done for consistency and clarity. Given that the title of § 266.502(h) is “Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals,” it is more appropriate to consistently refer to the rejected loads as “rejected” rather than “returned.” We are making identical changes to the procedures for reverse distributors managing rejected shipment that are in § 266.510(c)(7).

*G. Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503)*

We are amending § 266.503(b)(1) to be consistent with § 266.502(l)(1). Sections 266.502(l)(1) and 266.503(b)(1) each contain one of the conditions that receiving healthcare facilities must meet when accepting hazardous waste pharmaceuticals from an off-site VSQG healthcare facility. Section 266.502 pertains to non-creditable hazardous waste pharmaceuticals, while § 266.503 pertains to potentially creditable hazardous waste pharmaceuticals. For the reader’s convenience, when drafting § 266.502(l)(1), we included a parenthetical with the definition of “control,” but we did not do the same in § 266.503(b)(1). We are amending § 266.503(b)(1) to include the same parenthetical with the definition of “control” that appears in § 266.502(l)(1). In both cases, the definition of “control” originates from an exclusion from the definition of solid waste that appears in § 261.4(a)(23)(i)(B).

*H. Off-Site Collection of Hazardous Waste Pharmaceuticals Generated by Healthcare Facilities That Are VSQGs That Are Not Operating Under Part 266, Subpart P (§ 266.504)*

There are three changes to § 266.504. First, the heading of § 266.504 is being amended by adding “that are not operating under this subpart.” Since part 266, subpart P, was published in 2019, there has been some confusion about the applicability of § 266.504. A healthcare facility must count all of its hazardous waste generated in a calendar month—including hazardous waste pharmaceuticals—in determining whether it is required to operate under part 266, subpart P. A healthcare facility that generates above VSQG amounts of hazardous waste must operate under subpart P. A healthcare facility that generates below VSQG amounts of hazardous waste is not required to operate under subpart P, but may choose to opt in. While the preamble to the final rule made it clear that all of the optional provisions in § 266.504 only apply to VSQG healthcare facilities that have not opted into part 266, subpart P,<sup>5</sup> the heading was not as clear. Therefore, we are amending the heading of § 266.504 to make it clear that the four optional provisions in § 266.504 are only available to VSQG healthcare facilities that have not opted into subpart P and therefore are not operating under subpart P. Conversely,

a VSQG healthcare facility that opts into part 266, subpart P, would no longer be able to use the optional provisions in § 266.504.

We reiterate that a VSQG healthcare facility that elects to use any of the optional provisions in § 266.504 will not be considered to be opting into part 266, subpart P, and does not need to notify as a healthcare facility.

The second change to § 266.504 is correcting the spelling of off site. In § 266.504(b), the word “off-site” appears twice. The first time it appears it is correctly hyphenated because it is modifying the word “collection.” However, the second time it appears it is incorrectly hyphenated because it is being used as a noun. Section 266.504(b) is being revised to remove the hyphen from the word “off-site” the second time it appears, so that “off-site” becomes “off site.”

The third change is that § 266.504(b) is being amended by replacing the term “healthcare facility” with the word “generator” toward the end of the paragraph. Normally the RCRA regulations do not allow a generator to send its waste off site to another generator. However, in the 2015 Generator Improvements proposed rule, we included a provision to allow VSQGs to consolidate their hazardous waste off site at a large quantity generator, provided certain conditions are met. The Hazardous Waste Pharmaceuticals rule, which was published the same day as the Generator Improvements proposed rule, included a similar off-site consolidation provision. Specifically, in the Hazardous Waste Pharmaceuticals rule we proposed § 266.504(b) to allow a healthcare facility that is a VSQG to send its hazardous waste pharmaceuticals off site to another healthcare facility provided certain similar conditions are met. When the Generator Improvements final rule was published on November 28, 2016, we finalized the off-site consolidation provision. When we finalized the Hazardous Waste Pharmaceuticals final rule on February 22, 2019, we provided options within the off-site consolidation provision of § 266.504(b), allowing VSQG healthcare facilities to use either version of the off-site consolidation provision: the version in the Generator Improvements final rule, or the version in the Hazardous Waste Pharmaceuticals final rule. As stated in the preamble of the Hazardous Waste Pharmaceuticals final rule, we included “added flexibility for VSQGs to meet the consolidation provisions that were added as part of the 2016 Hazardous Waste Generator Improvements final

<sup>5</sup> See 84 FR 5858; February 22, 2019.



rule in lieu of the subpart P off-site consolidation provisions. In this case, the receiving LQG would have to meet the conditions in § 262.17(f) while the VSQG healthcare facility would have to meet the conditions in § 262.14(a)(5)(viii).” The regulations in § 266.504(b) state (emphasis added), “A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided [ . . . ].” The final rule included two options for complying with the off-site consolidation provisions and they are set out in § 266.504(b)(1) and (2).

In adding these options, however, we neglected to remove the term “healthcare facility” from the introductory text of paragraph (b) when describing to whom the VSQG could send its hazardous waste pharmaceuticals. If a VSQG healthcare facility is using the subpart P off-site consolidation option described in § 266.504(b)(1), then it must send its hazardous waste pharmaceuticals to a healthcare facility that is operating under subpart P. On the other hand, if a VSQG healthcare facility is using the off-site consolidation option described in § 266.504(b)(2), then it must send its hazardous waste pharmaceuticals to an LQG that meets the conditions under § 262.17(f). It was not our intention to require the receiving LQG to be a healthcare facility. Therefore, we are removing the term “healthcare facility” from the final line of § 266.504(b) and replacing it with the word “generator.”

#### *I. Prohibition on Sewering Hazardous Waste Pharmaceuticals (§ 266.505)*

The second and final sentence of § 266.505 currently reads, “Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).” We are revising the citation 40 CFR 403.5(b)(1) to 40 CFR 403.5(b). Section 403 is part of the Clean Water Act (CWA) regulations; specifically, it is part of the Effluent Guidelines and Standards. Section 403.5 is entitled “National pretreatment standards: Prohibited discharges.” Section 403.5(b) includes a list of eight “Specific prohibitions.” Healthcare facilities and reverse distributors remain subject to all the prohibitions in 40 CFR 403.5(b), not just the prohibition in 40 CFR 403.5(b)(1). The cross-reference to the CWA regulations did not appear in the proposed rule; we added it into the final regulations in response to comments. In

the preamble to the final rule, we used the correct citation, § 403.5(b).<sup>6</sup>

#### *J. Conditional Exemption for Hazardous Waste Pharmaceuticals That Are Also Controlled Substances (§ 266.506)*

We are revising the title of § 266.506 and paragraph (a)(2) of § 266.506 to remove the reference to take-back events or programs. There are several methods of providing household pharmaceutical take-backs. For example, retail pharmacies can amend their DEA registration to become DEA authorized collectors and install collection receptacles (often referred to as kiosks) for take-back of household pharmaceuticals. Another example is DEA’s very popular national take-back days that are scheduled for the last Saturday in April and October each year. “Take-back events” and “take-back programs” are terms that are typically used to refer to take-back methods that require the involvement of law enforcement. Subpart P applies to healthcare facilities (e.g., retail pharmacies) and reverse distributors; it does not apply to law enforcement. Since subpart P does not apply to law enforcement, we should not have included a reference to take-back methods that involve law enforcement. Therefore, to help reduce confusion, we are removing the reference to take-back events and programs.

Our memorandum from September 11, 2018, for law enforcement conducting take-backs, continues to apply. It explains the regulatory status of household pharmaceuticals collected by law enforcement and the type of permitted incinerators that may be used to destroy the collected household pharmaceuticals.<sup>7</sup> We are also revising § 266.506(b)(3) to replace the periods with “; or” after paragraphs (b)(3)(iii) and (iv) to be consistent with how the rest of the list is punctuated.

#### *K. Residues of Hazardous Waste Pharmaceuticals in Empty Containers (§ 266.507)*

We are making several corrections and clarifications to the empty container standards in § 266.507. Each is explained separately below.

##### **1. Intravenous (IV) Bags**

The first sentence of § 266.507(c) defines when an IV bag is considered “RCRA empty”; that is, when the contents have been fully administered to a patient. The second sentence of § 266.507(c) sets out how IV bags that

are not RCRA empty must be managed. At the end of the second sentence, however, we include a clause that references the § 261.7(b)(1) definition of “RCRA empty” and we allow it to be used as an alternative, but only for IV bags that contain non-acute hazardous waste pharmaceuticals. We are moving the clause that references § 261.7(b)(1) to the end of the first sentence so the first sentence of § 266.507(c) will include both definitions of when an IV bag is considered RCRA empty.

##### **2. Other Containers, Including Delivery Devices**

We are amending the opening of § 266.507(d) by inserting the words “At healthcare facilities operating under this subpart.” We are making this change for two reasons. First, while § 266.507(a) through (c) pertain to specific types of containers at healthcare facilities, § 266.507(d) is a catch-all for other types of containers (including delivery devices) at healthcare facilities that are not addressed specifically by paragraphs (a) through (c). Given that the new definitions of “empty containers” in § 266.507 apply beyond healthcare facilities and reverse distributors operating under subpart P, “other containers” could be read very broadly to include large containers of hazardous waste pharmaceuticals, such as 55-gallon drums. This was not our intent. Rather, our intent with § 266.507(d) was to address “other containers” that are commonly found in the healthcare setting. This is clear from the examples we include at the end of § 266.507(d): inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

The second reason we are amending the opening of § 266.507(d) is to clarify that it does not apply to healthcare facilities that are VSQGs, unless the VSQG healthcare facility has opted into subpart P. The current regulatory language in § 266.507(d) could be read to mean that any entity, including healthcare facilities that are VSQGs, must manage their non-empty containers of hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals, even if they are not operating under subpart P. This was not our intent. Healthcare facilities that are VSQGs have the option of operating under subpart P with respect to their hazardous waste pharmaceuticals, including their non-empty containers.

##### **3. Managing Non-Empty Containers**

For a similar reason, we are inserting the words “At healthcare facilities operating under this subpart” into the second sentence of both § 266.507(b)

<sup>6</sup> 84 FR 5816, February 22, 2019. See preamble on page 5894.

<sup>7</sup> From Wheeler to U.S. Law Enforcement, September 11, 2018, RCRA Online #14906.

and (c). While the revised definitions of “empty containers” in § 266.507 apply to any hazardous waste generator, regardless of whether it is a healthcare facility operating under subpart P, the portions of § 266.507(b) through (d) that address how to manage non-empty containers of hazardous waste pharmaceuticals only apply to a healthcare facility operating under subpart P. If a reverse distributor is using the revised definitions of “empty containers” in § 266.507, it must manage non-empty containers as evaluated hazardous waste pharmaceuticals. If another type of facility is using the revised definitions of “empty containers” in § 266.507 and is not operating under subpart P, it must continue to manage non-empty containers as hazardous waste, under the applicable regulations (e.g., part 262).

Finally, we note that a pharmaceutical in a non-empty container (stock, dispensing and unit-dose; syringe; IV bag; or “other container”) may meet the definition of “potentially creditable hazardous waste pharmaceutical,” if it has a reasonable expectation of receiving manufacturer credit and is:

- In its original manufacturer packaging;
- undispensed, and
- unexpired or less than one year past expiration.

A non-empty container could include either a full, unopened container or a partial container. If the hazardous waste pharmaceutical does meet the definition of “potentially creditable,” § 266.507 does not preclude a non-empty container with a potentially creditable hazardous waste pharmaceutical from being sent to a reverse distributor. After a reverse distributor evaluates the potentially creditable hazardous waste pharmaceuticals for manufacturer credit, the reverse distributor must manage them as evaluated hazardous waste pharmaceuticals.

#### *L. Radio Frequency Identification (§§ 266.508 and 266.510)*

We are revising §§ 266.508(a)(1)(iii)(C) and 266.510(c)(5) to insert the noun “tag” following the phrase “radio frequency identification.” Section 266.508 is standards for shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor. Section 266.510(c) is standards for reverse distributors managing evaluated hazardous waste pharmaceuticals. In both cases, we used the modifying phrase “radio frequency identification” without including the

noun to which it applied, and so we are now including the noun “tag.”

#### *M. PHARMS Code (§ 266.508)*

When part 266, subpart P, was promulgated, the EPA required healthcare facilities to use the word “PHARMS” on Item 13 of the manifest for non-creditable hazardous waste pharmaceuticals being shipped to a designated facility (e.g., TSDF). As explained in the preamble to the final rule (see 84 FR 5909), we used six characters because the e-Manifest system can accommodate six characters, and because PHARMS communicates the nature of the waste. However, since the final rule was published, the EPA became aware of two issues related to using six characters. First, although the e-Manifest system can accommodate six characters and PHARMS can be selected from a prepopulated menu within the e-Manifest system, most generators are currently initiating shipments using paper manifests, not fully electronic manifests. The paper manifest was designed to accommodate four-character hazardous waste codes which has made it difficult to fit the entire PHARMS code in the box without exceeding the allotted space. Second, some States and industry stakeholders have told us that their databases are not designed to accommodate six characters, which means that a redesign of their database is required for them to exchange data with the EPA’s e-Manifest system.

To assist implementation, the EPA issued a memorandum on this issue allowing the use of the four-character code PHRM on both paper manifests and electronic manifests when shipping non-creditable hazardous waste pharmaceuticals under subpart P.<sup>8</sup> This four-character code achieves the same result as the six-character code; therefore, either code satisfies the requirement at § 266.508(a)(2)(ii). The EPA is now amending the regulations to be consistent with the guidance included in the memorandum.

Both PHRM/PHARMS codes have been and will continue to be available for use in the e-Manifest system, with identical “Hazardous Waste Pharmaceuticals” descriptions.

This change is also consistent with guidance the EPA included in the Hazardous Waste Pharmaceuticals final rule Frequent Questions web page.<sup>9</sup>

<sup>8</sup> Johnson to Land, Chemicals and Redevelopment Division Directors, December 19, 2019, RCRA Online #14919.

<sup>9</sup> <https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and#e1>.

#### *N. Reverse Distributor Standards (§ 266.510)*

##### 1. Unauthorized Waste Reports

When a reverse distributor receives waste from off site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste or regulated medical waste), it must submit an unauthorized waste report to the EPA Regional Administrator (or authorized State) within 45 calendar days. Section 266.510(a)(9)(i)(A) through (F) includes the list of elements that must be included in an unauthorized waste report. Paragraph (a)(9)(i)(C) of § 266.510 specifies that the EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste must be included in the report, if available. However, healthcare facilities are not the only entities that may ship to a reverse distributor. Other reverse distributors may also ship to a reverse distributor. Further, because this section addresses situations of non-compliance, it is possible that a reverse distributor could wrongly receive a shipment from another entity that includes unauthorized waste. Therefore, we are revising § 266.510(a)(9)(i)(C) by adding the parenthetical “(or other entity)” after healthcare facility, to reflect that possibility.

##### 2. Hazardous Waste Numbers

Section 266.510(c)(5) applies to reverse distributors, and states “[P]rior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable [EPA] hazardous waste numbers (i.e., hazardous waste codes).” Earlier in this preamble, we explained the addition of “EPA” prior to “hazardous waste numbers,” wherever it appears in subpart P.

Section 266.508(a)(1)(iii)(C) allows for an exception to having to mark containers with the applicable hazardous waste numbers. Specifically, it allows that lab packs that will be incinerated in compliance with § 268.42(c) are not required to be marked with EPA hazardous waste numbers, except D004, D005, D006, D007, D008, D010, and D011, where applicable.

In § 266.510(c)(5), we are adding a cross-reference to the lab pack marking exception in § 266.508(a)(1)(iii)(C). The exception for marking lab packs with most EPA hazardous waste numbers applies regardless of this addition; nevertheless, we are adding the cross-reference for clarity and to aid the reader.

### 3. Reporting by a Reverse Distributor for Evaluated Hazardous Waste Pharmaceuticals

Section 266.510(c)(9)(ii) includes instructions for how a reverse distributor must file an exception report when it is missing a copy of the manifest for evaluated hazardous waste pharmaceuticals that it shipped to a designated facility.

Section 266.510(c)(9)(ii)(B) addresses the situation when a shipment is rejected by the designated facility and is shipped to an alternate facility. Paragraph (c)(9)(ii)(B)(2)(i) of § 266.510 states that a legible copy of the manifest for which the generator does not have confirmation of delivery must be included in the exception report. When the EPA adapted the generator exception reporting regulations for reverse distributors, we neglected to revise “generator” to “reverse distributor,” as we had intended. We are now revising the regulations to replace the word “generator” with “reverse distributor.”

#### *O. Hazardous and Solid Waste Amendments of 1984 (§ 271.1)*

Table 1 in § 271.1 includes a list of RCRA Subtitle C regulations that have been added pursuant to HSWA. As the EPA explained in the preamble to the Hazardous Waste Pharmaceuticals final rule, the sewer prohibition was added to part 266, subpart P, pursuant to HSWA;<sup>10</sup> however, the EPA neglected to update Table 1 in § 271.1. This omission has no bearing on whether the sewer prohibition is considered a HSWA provision since the statute and preamble to the Pharmaceuticals final rule make clear that it is. For the sake of completeness and convenience to the reader, however, the EPA is making a technical correction to update Table 1 in § 271.1, with the addition of a row to add the Hazardous Waste Pharmaceuticals final rule and which will appear in chronological order.

#### *P. Correction to a Preamble Statement in the Hazardous Waste Pharmaceuticals Final Rule*

When discussing the management of residues in pharmaceutical containers in the preamble to the Hazardous Waste Pharmaceuticals final rule, we cited an EPA memorandum from November 2011, with the subject “Containers that Once Held P-Listed Pharmaceuticals.”<sup>11</sup>

On page 5903 of the preamble to the final rule, we stated:

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations . . . Today’s new “empty container” regulations in § 266.507 will replace the November 2011 guidance as it pertained to residues of hazardous waste pharmaceuticals in containers, although the memo will remain in effect for non-pharmaceutical hazardous wastes.

In this rule, we are clarifying that while there are portions of the November 2011 memorandum that were made moot by the final rule, there are other portions of the November 2011 memorandum that are still valid with respect to acute (P-listed) hazardous waste pharmaceuticals.

The November 2011 memorandum provided guidance about containers that once held P-listed pharmaceuticals outlining three regulatory approaches for generators:

(1) Count only the weight of the hazardous waste residues toward their monthly generator category determination;

(2) Demonstrate an equivalent removal method to triple rinsing to render containers RCRA empty; and

(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration.

#### 1. Portion of the November 11, 2011, Memorandum That Is Still Valid With Respect to Acute Hazardous Waste Pharmaceuticals

The first approach outlined in the memorandum states that it is only necessary to count the weight of the actual hazardous waste, not the weight of the container holding the hazardous waste. This approach is not relevant to reverse distributors, because all reverse distributors must operate under subpart P, regardless of the amount of hazardous waste pharmaceuticals that are on site. On the other hand, this is still an allowable approach for a healthcare facility managing P-listed pharmaceutical waste, although it is probably only useful to a limited universe of healthcare facilities. The reason its utility is limited is that all healthcare facilities operating under subpart P are regulated the same as each other with respect to their hazardous waste pharmaceuticals. Put another way, there are no generator categories under subpart P. As a result, if a healthcare facility is operating under subpart P, it is not necessary to count the weight of the hazardous waste pharmaceuticals that it generates each month. If, however, a healthcare facility

is not operating under subpart P, then this approach might be useful to determine whether it is required to operate under subpart P or prove that it is a VSQG and therefore not required to operate under subpart P (likewise, other generators might find this approach useful to determine whether they are required to operate as SQGs or LQGs under part 262 or prove that they are VSGQs). A healthcare facility must operate under subpart P for its hazardous waste pharmaceuticals if it generates more than VSQG amounts of any hazardous waste (*i.e.*, more than 1 kilogram of acute hazardous waste or more than 100 kilogram of non-acute hazardous waste per calendar month). Including the weight of containers may impact whether a healthcare facility exceeds the 1 kilogram acute hazardous waste monthly threshold, and, in turn, the requirement to operate under subpart P.

Note that if a container is considered RCRA empty, the residues are not regulated as hazardous waste; therefore, it is not necessary to count the weight of the P-listed pharmaceutical residues or the weight of the container. On the other hand, if a container is not RCRA empty, the residues are regulated as RCRA hazardous waste. For non-empty containers, it is only necessary to count the weight of the P-listed pharmaceutical residues, not the weight of the container. If a healthcare facility has containers of P-listed pharmaceutical waste that are not RCRA empty and is determining whether it is subject to subpart P, it may be useful for a healthcare facility to count only the weight of the P-listed acute hazardous waste and not count the weight of the container.

#### 2. Portions of the November 11, 2011, Memorandum That Have Been Superseded With Respect to Acute Hazardous Waste Pharmaceuticals

In contrast, the second and third approaches outlined in the November 2011 memorandum have been superseded by the hazardous waste pharmaceuticals final rule. The reason each approach has been made moot by the rule is explained separately below.

The second approach in the November 2011 memorandum for managing containers that held P-listed pharmaceuticals could have been used to demonstrate an equivalent removal method to render containers RCRA empty. This was an existing regulatory mechanism that was offered as an alternative to triple rinsing containers to render them RCRA empty. Section 261.7(b)(3)(i) specifies that a container that held an acute hazardous waste is

<sup>10</sup> 84 FR 5816, February 22, 2019. See pages 5892 and 5936.

<sup>11</sup> Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827.

empty if the container (or inner liner) has been triple rinsed using an appropriate solvent. Section 261.7(b)(3)(ii) offers an alternative whereby a container that held an acute hazardous waste is empty if the container (or inner liner) has been “cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generators, to achieve equivalent removal.” Section 266.507 of subpart P makes § 261.7(b)(3) moot for hazardous waste pharmaceuticals. That is because under § 266.507, triple rinsing (or an equivalent method) is either not required, or not allowed, depending on the type of container:

(1) *Stock, dispensing and unit-dose containers*: triple rinsing is not required to meet the definition of “RCRA empty” for a container that held an acute hazardous waste pharmaceutical. For these types of containers, a container is considered RCRA empty if the pharmaceuticals have been removed from the container using practices commonly employed to remove materials of that type from the container. For these types of containers, the definition of “empty” is the same for all pharmaceuticals, including P-listed pharmaceuticals.

(2) *Syringes*: triple rinsing is not required to meet the definition of “RCRA empty” for a syringe that held an acute hazardous waste pharmaceutical. For syringes, the syringe is considered RCRA empty if the plunger of the syringe has been fully depressed. For syringes, the definition of “empty” is the same for all pharmaceuticals, including P-listed pharmaceuticals.

(3) *IV bags*: triple rinsing of IV bags with acute hazardous waste pharmaceuticals is not allowed. If the P-listed pharmaceutical in the IV bag has not been completely administered, a healthcare facility operating under subpart P must manage it as a non-creditable hazardous waste pharmaceutical.

(4) *Other containers*: triple rinsing “other containers” of acute hazardous waste pharmaceuticals is not allowed and there is no method to make such containers RCRA empty. A healthcare facility operating under subpart P must manage a P-listed drug in an “other container” as a non-creditable hazardous waste pharmaceutical.

The third approach in the November 2011 memorandum for managing containers that held P-listed pharmaceuticals pertains only to warfarin, which is one of the two concentration-based P-listings. When warfarin is present at concentrations

greater than 0.3%, it is an acute hazardous waste with the waste code P001. When warfarin is present at concentrations at or below 0.3%, it is a non-acute hazardous waste with the waste code U248. The memorandum offered the option of showing that the concentration in the residue in the container is below the P-listed concentration. Our thinking was that perhaps the residues would consist primarily of a non-warfarin coating on the outside of the pills, rather than warfarin itself, and thus the residue might have a concentration of warfarin that would be U-listed. Whether the warfarin is P-listed or U-listed was relevant because it drove the method that must be used to render the container RCRA empty. That is, under § 261.7, if the residues remaining in the container were U248 instead of P001, then the container would not need to be triple rinsed to render it RCRA empty. Under subpart P, however, triple rinsing is no longer required to render a warfarin container RCRA empty, so it is now unnecessary to demonstrate that the residues are U-listed rather than P-listed.

## VII. Corrections to 40 CFR Part 261 Identification and Listing of Hazardous Waste

This section addresses technical corrections to the changes made in response to a partial vacatur of the 2015 Definition of Solid Waste (DSW) final rule. It also includes technical corrections of typographical errors and missing or incorrect citations found in 40 CFR part 261.

### A. Corrections Related to the 2018 Vacatur of the Definition of Solid Waste Rule

On July 7, 2017, and March 6, 2018,<sup>12</sup> the United States Court of Appeals for the District of Columbia Circuit issued opinions on the 2015 DSW final rule<sup>13</sup> that, among other things,<sup>14</sup> (1) vacated the 2015 verified recycler exclusion for hazardous waste that is recycled off site (except for certain provisions); (2) reinstated the 2008 transfer-based exclusion to replace the now-vacated 2015 verified recycler exclusion; and (3) upheld the 2015 containment and emergency preparedness provisions and the eligibility of spent petroleum

<sup>12</sup> *American Petroleum Institute v. Environmental Protection Agency*, 862 F.3d 50 (D.C. Cir. 2017), decision modified on rehearing, 883 F.3d 918 (D.C. Cir. 2018).

<sup>13</sup> See 80 FR 1694, January 13, 2015.

<sup>14</sup> The court also vacated factor four of the 2015 definition of legitimate recycling found at 40 CFR 260.43 and reinstated the 2008 version of factor four to replace the now-vacated 2015 version of factor four.

catalysts and applied these to the reinstated transfer-based exclusion. As a result, the EPA issued the 2018 DSW final rule that implemented the court’s decision on May 23, 2018. See 83 FR 24664.

However, several references to the vacated provisions remained in 40 CFR part 261 subpart M—Emergency Preparedness and Response for Management of Excluded Hazardous Secondary Materials. In this rule, the EPA is correcting that error by removing all references to § 260.31(d) (vacated provision). Provisions affected are §§ 261.400(a), (b); 261.410(e), (f)(1) and (2); 261.411 introductory text, (b), (c), and (d)(3); and 261.420 introductory text, (a)(1), and (b)(2).

In addition, the 2018 vacatur response reinstated the export provisions for the transfer-based exclusion, found at § 261.4(a)(25). However, those reinstated provisions did not reflect the revisions the EPA had made to RCRA export requirements in the interim. In 2016, the EPA finalized changes to existing regulations regarding the export and import of hazardous wastes and other RCRA regulated materials from and into the United States (81 FR 85696, November 28, 2016). The final rule established: (1) Improved export and import shipment tracking; (2) one consolidated and streamlined set of requirements applying to all imports and exports; (3) mandatory electronic reporting to the EPA; and (4) a link between the consent to export and the electronic export information submitted to U.S. Customs and Border Protection.

However, these changes did not apply to hazardous secondary material recycled under the exclusion at § 261.4(a)(24) and (25), because the EPA had removed the export provisions in the 2015 DSW final rule. When the export provisions were reinstated in 2018 in response to the court vacatur, they did not reflect the improvements made to all the other RCRA export-import provisions. This rule updates the hazardous secondary material export requirements in § 261.4(a)(25) to be consistent with other RCRA export requirements.

### B. Correction of Typographical Errors and Missing or Incorrect References

The EPA is also correcting a number of typographical errors and missing or incorrect references found in 40 CFR part 261 to:

- Add containment buildings (subpart DD of 40 CFR parts 264 and 265) to the list of management methods applicable to recyclable materials in § 261.6(c)(1).

- Change cited regulations from § 265.113(d) (incorrect) to § 265.113(d) (correct). See § 261.142(a)(3) and (4).
- Change cited regulations from § 265.143(i) (incorrect) to § 261.143(i) (correct) See § 261.143(a)(7).
- Change cited regulations from § 264.151(g)(2) (incorrect) to § 261.151(g)(2) (correct). See § 261.147(g)(2)(i)(B).
- Change cited regulations from § 261.151(h)(2) (incorrect) to § 261.151(g)(2) (correct). See § 261.147(g)(2)(ii)(B).
- Correct numbering at § 261.151(g)(2). Remove the number for current paragraph 10 of the required agreement language under “RECITALS.” Correct the reference to paragraph 10 in paragraph 8 to read paragraph 9. Renumber the subsequent paragraphs of the required agreement language under “RECITALS.”
- Correct truncated text at § 261.151(l)(2). Consistent with the corresponding provision in § 264.151(m)(2), the final sentence is corrected to read: “State requirements may differ on the proper content of this acknowledgement.”
- Change cited regulation from § 262.410(f) (incorrect) to § 261.410(f) (correct). See § 261.420(b)(3).
- Revise “subpart X of this part” (incorrect) to “subpart X of part 264” (correct). See § 261.1033(n)(1)(i).
- Change cited regulations from § 261.1082(c)(1) (incorrect) to § 261.1082(c) (correct). See § 261.1083(a)(1), (a)(1)(i); and § 261.1084(j)(2)(i).
- Change cited regulations from § 261.1085(b)(1)(i) (incorrect) to § 261.1084(b)(1)(i) (correct). See § 261.1083(c)(4).
- Change cited regulations from § 261.1082(c)(2) (incorrect) to § 264.1082(c)(2) (correct). See § 261.1084(j)(2)(ii).
- Change cited regulations from § 261.1082(c)(4) (incorrect) to § 264.1082(c)(4) (correct). See § 261.1084(j)(2)(iii).
- Change cited regulations from § 261.1080(b)(7) or (d) (incorrect) to § 261.1080(a) (correct). See § 261.1089(a).
- Change cited regulations from § 261.1082(c)(1) or (c)(2)(i) through (vi) (incorrect) to § 261.1082(c) (correct). See § 261.1089(f).
- Remove incorrect reference to § 261.1085(g) (does not exist). See § 261.1089(g).

## VIII. State Authorization

### A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, the EPA may authorize a qualified State to administer its own hazardous waste program within the State in lieu of the Federal program. Following authorization, the EPA retains enforcement authority under sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of the EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and the EPA could not issue permits for any facilities in that State, since only the State was authorized to issue RCRA permits. When new, more stringent Federal requirements were promulgated, the State was obligated to enact equivalent authorities within specified time frames. However, the new Federal requirements did not take effect in an authorized State until the State adopted the Federal requirements as State law.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized States at the same time that they take effect in unauthorized States. The EPA is directed by the statute to implement these requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA related provisions as State law to retain final authorization, the EPA implements the HSWA provisions in authorized States until the States do so.

Authorized States are required to modify their program only when the EPA enacts Federal requirements that are more stringent or broader in scope than the existing Federal requirements. RCRA section 3009 allows the States to impose standards more stringent than those in the Federal program (see also 40 CFR 271.1). Therefore, authorized States may, but are not required to, adopt Federal regulations, both HSWA and non-HSWA, that are considered less stringent than or equally as stringent as the previous Federal regulations.

### B. Effect on State Authorization

This direct final rule finalizes technical corrections to a number of the regulations in 40 CFR parts 260, 261, 262, 264, 265, 266, 270, 271, and 441 that are being promulgated in part under the authority of HSWA, and in part under non-HSWA authority. Thus, the technical corrections and clarifications finalized in this direct final rule under non-HSWA authority would be applicable on the effective date only in those States that do not have final authorization of their base RCRA programs. The technical corrections to regulations in § 262.16(b)(1) are promulgated under the authority of HSWA and would be effective on the effective date of this direct final rule in all States unless the State is not authorized for the underlying provisions. Moreover, authorized States are required to modify their programs only when the EPA promulgates Federal regulations that are more stringent or broader in scope than the authorized State regulations. For those changes that are less stringent or reduce the scope of the Federal program, States are not required to modify their program. This is a result of section 3009 of RCRA, which allows States to impose more stringent regulations than the Federal program. This direct final rule is considered to be neither more nor less stringent than the current standards. Therefore, authorized States would not be required to modify their programs to adopt the technical corrections promulgated in this direct final rule, although we would strongly urge the States to adopt these technical corrections to avoid any confusion or misunderstanding by the regulated community and the public.

Although this rule makes a correction to Table 1 in § 271.1 which lists the provisions that have been promulgated under HSWA authority, the correction to the table is not itself being promulgated under HSWA.

## IX. Statutory and Executive Order Reviews

### A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

### B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the

PRA because it does not contain any information collection activities. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2050–0213, 2050–0202, and 2050–0212.

#### *C. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This action simply corrects typographical errors, incorrect citations, and omissions; provides clarifications; and makes conforming changes where they have not been made previously. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

#### *D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

#### *E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175. Because the rule does not make any substantive change, it will not impose substantial direct costs on Tribal governments. Thus, Executive Order 13175 does not apply to this action.

#### *G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive order.

Therefore, this action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health, EPA’s Policy on Children’s Health also does not apply.

#### *H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

#### *I. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

#### *J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color) and low-income populations.

The EPA believes that these technical corrections do not directly impact human health or environmental conditions and therefore cannot be evaluated with respect to potentially disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples because this final rule does not create any new regulatory requirements, but rather clarifies existing requirements and makes conforming changes.

#### *K. Congressional Review Act (CRA)*

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United

States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

#### **List of Subjects**

##### *40 CFR Part 260*

Environmental protection, Administrative practice and procedure, Air pollution control, Confidential business information, Hazardous waste, Intergovernmental relations, Licensing and registration, Reporting and recordkeeping requirements.

##### *40 CFR Part 261*

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

##### *40 CFR Part 262*

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

##### *40 CFR Part 264*

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

##### *40 CFR Part 265*

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

##### *40 CFR Part 266*

Environmental protection, Energy, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

##### *40 CFR Part 270*

Environmental Protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

##### *40 CFR Part 271*

Environmental Protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians—lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 441

Environmental Protection, Health facilities, Mercury, Waste treatment and disposal, Water pollution control.

Michael S. Regan, Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

■ 1. The authority for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, 6939g, and 6974.

§ 260.10 [Amended]

■ 2. Section 260.10 is amended in the definition of “Final closure” by removing “§ 262.34” and adding “§§ 262.16 and 262.17” in its place.

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 3. The authority for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 4. Section 261.1 is amended by revising paragraph (a)(1) to read as follows:

§ 261.1 Purpose and scope.

(a) \* \* \* (1) Subpart A defines the terms “solid waste” and “hazardous waste”, identifies those wastes which are excluded from regulation under parts 262 through 266, 268, and 270 of this subchapter and establishes special management requirements for hazardous waste which is recycled.

■ 5. Section 261.4 is amended by revising paragraphs (a)(25)(i)(I), (a)(25)(vi) and (vii), (a)(25)(xi)(D), and (e)(1) introductory text to read as follows:

§ 261.4 Exclusions.

(a) \* \* \* (25) \* \* \* (j) \* \* \* (I) The name of any countries of transit through which the hazardous secondary material will be sent and a description of the approximate length of time it will remain in such countries and the nature of its handling while there (for purposes of this section, the terms “EPA Acknowledgment of Consent”, “country of import” and

“country of transit” are used as defined in 40 CFR 262.81 with the exception that the terms in this section refer to hazardous secondary materials, rather than hazardous waste):

\* \* \* \* \*

(vi) The export of hazardous secondary material under this paragraph (a)(25) is prohibited unless the hazardous secondary material generator receives from EPA an EPA Acknowledgment of Consent documenting the consent of the country of import to the receipt of the hazardous secondary material. Where the country of import objects to receipt of the hazardous secondary material or withdraws a prior consent, EPA will notify the hazardous secondary material generator in writing. EPA will also notify the hazardous secondary material generator of any responses from countries of transit.

(vii) Prior to each shipment, the hazardous secondary material generator or a U.S. authorized agent must:

(A) Submit Electronic Export Information (EEI) for each shipment to the Automated Export System (AES) or its successor system, under the International Trade Data System (ITDS) platform, in accordance with 15 CFR 30.4(b).

(B) Include the following items in the EEI, along with the other information required under 15 CFR 30.6:

- (1) EPA license code; (2) Commodity classification code per 15 CFR 30.6(a)(12); (3) EPA consent number; (4) Country of ultimate destination per 15 CFR 30.6(a)(5); (5) Date of export per 15 CFR 30.6(a)(2);

(6) Quantity of waste in shipment and units for reported quantity, if required reporting units established by value for the reported commodity classification number are in units of weight or volume per 15 CFR 30.6(a)(15); or

(7) EPA net quantity reported in units of kilograms, if required reporting units established by value for the reported commodity classification number are not in units of weight or volume.

\* \* \* \* \*

(xi) \* \* \*

(D) By reclaimer and intermediate facility, for each hazardous secondary material exported, a description of the hazardous secondary material and the EPA hazardous waste number that would apply if the hazardous secondary material was managed as hazardous waste, the DOT hazard class, the name and U.S. EPA ID number (where applicable) for each transporter used, the consent number(s) under which the

hazardous secondary material was shipped and for each consent number, the total amount of hazardous secondary material shipped and the number of shipments exported during the calendar year covered by the report;

\* \* \* \* \*

(e) \* \* \*

(1) Except as provided in paragraphs (e)(2) and (4) of this section, persons who generate or collect samples for the purpose of conducting treatability studies as defined in 40 CFR 260.10, are not subject to any requirement of this part and 40 CFR parts 262 and 263 or to the notification requirements of section 3010 of RCRA, nor are such samples included in the quantity determinations of 40 CFR 262.13 and the accumulation limits in 40 CFR 262.16(b)(1) when:

\* \* \* \* \*

■ 6. Section 261.6 is amended by revising paragraph (c)(1) to read as follows:

§ 261.6 Requirements for recyclable materials.

\* \* \* \* \*

(c)(1) Owners and operators of facilities that store recyclable materials before they are recycled are regulated under all applicable provisions of subparts A through L and AA through DD of 40 CFR parts 264 and 265, and under 40 CFR parts 124, 266, 267, 268, and 270 and the notification requirements under section 3010 of RCRA, except as provided in paragraph (a) of this section. (The recycling process itself is exempt from regulation except as provided in paragraph (d) of this section.)

\* \* \* \* \*

§ 261.11 [Amended]

■ 7. Section 261.11 is amended by removing paragraph (c).

■ 8. Section 261.30 is amended by revising paragraph (d) to read as follows:

§ 261.30 General.

\* \* \* \* \*

(d) The following hazardous wastes listed in § 261.31 are subject to the generator category limits for acutely hazardous wastes established in table 1 of § 262.13 of this subchapter: EPA Hazardous Wastes Nos. F020, F021, F022, F023, F026 and F027.

■ 9. Section 261.142 is amended by revising paragraphs (a)(2) through (4) to read as follows:

§ 261.142 Cost estimate.

(a) \* \* \*

(2) The cost estimate must be based on the costs to the owner or operator of hiring a third party to conduct these activities. A third party is a party who is neither a parent nor a subsidiary of the owner or operator. (See definition of “parent corporation” in § 265.141(d) of this subchapter.) The owner or operator may use costs for on-site disposal in accordance with applicable requirements if he can demonstrate that on-site disposal capacity will exist at all times over the life of the facility.

(3) The cost estimate may not incorporate any salvage value that may be realized with the sale of hazardous secondary materials, or hazardous or non-hazardous wastes if applicable under § 265.113(d) of this subchapter, facility structures or equipment, land, or other assets associated with the facility.

(4) The owner or operator may not incorporate a zero cost for hazardous secondary materials, or hazardous or non-hazardous wastes if applicable under § 265.113(d) of this subchapter that might have economic value.

\* \* \* \* \*

■ 10. Section 261.143 is amended by revising paragraph (a)(7) to read as follows:

**§ 261.143 Financial assurance condition.**

\* \* \* \* \*

(a) \* \* \*

(7) Within 60 days after receiving a request from the owner or operator for release of funds as specified in paragraph (a)(5) or (6) of this section, the Regional Administrator will instruct the trustee to release to the owner or operator such funds as the Regional Administrator specifies in writing. If the owner or operator begins final closure under subpart G of 40 CFR part 264 or 265, an owner or operator may request reimbursements for partial or final closure expenditures by submitting itemized bills to the Regional Administrator. The owner or operator may request reimbursements for partial closure only if sufficient funds are remaining in the trust fund to cover the maximum costs of closing the facility over its remaining operating life. No later than 60 days after receiving bills for partial or final closure activities, the Regional Administrator will instruct the trustee to make reimbursements in those amounts as the Regional Administrator specifies in writing, if the Regional Administrator determines that the partial or final closure expenditures are in accordance with the approved closure plan, or otherwise justified. If the Regional Administrator has reason to believe that the maximum cost of closure over the remaining life of the

facility will be significantly greater than the value of the trust fund, he may withhold reimbursements of such amounts as he deems prudent until he determines, in accordance with paragraph (i) of this section that the owner or operator is no longer required to maintain financial assurance for final closure of the facility. If the Regional Administrator does not instruct the trustee to make reimbursements, he will provide to the owner or operator a detailed written statement of reasons.

\* \* \* \* \*

■ 11. Section 261.147 is amended by revising paragraphs (g)(2)(i)(B) and (g)(2)(ii)(B) to read as follows:

**§ 261.147 Liability requirements.**

\* \* \* \* \*

(g) \* \* \*  
(2)(i) \* \* \*

(B) Each State in which a facility covered by the guarantee is located have submitted a written statement to EPA that a guarantee executed as described in this section and § 261.151(g)(2) is a legally valid and enforceable obligation in that State.

(ii) \* \* \*

(B) The Attorney General or Insurance Commissioner of each State in which a facility covered by the guarantee is located and the State in which the guarantor corporation has its principal place of business, has submitted a written statement to EPA that a guarantee executed as described in this section and § 261.151(g)(2) is a legally valid and enforceable obligation in that State.

\* \* \* \* \*

■ 12. Section 261.151 is amended by revising paragraphs (g)(2) and (l)(2) to read as follows:

**§ 261.151 Wording of the instruments.**

\* \* \* \* \*

(g) \* \* \*

(2) A guarantee, as specified in § 261.147(g), must be worded as follows, except that instructions in brackets are to be replaced with the relevant information and the brackets deleted:

*Guarantee for Liability Coverage*

Guarantee made this [date] by [name of guaranteeing entity], a business corporation organized under the laws of [if incorporated within the United States insert “the State of \_\_\_\_\_” and insert name of State; if incorporated outside the United States insert the name of the country in which incorporated, the principal place of business within the United States, and the name and address of the registered agent in the State of the principal place of business], herein referred to as guarantor. This guarantee is made on behalf of [owner or operator] of [business address], which is one of the

following: “our subsidiary;” “a subsidiary of [name and address of common parent corporation], of which guarantor is a subsidiary;” or “an entity with which guarantor has a substantial business relationship, as defined in 40 CFR [either 264.141(h) or 265.141(h)]”, to any and all third parties who have sustained or may sustain bodily injury or property damage caused by [sudden and/or nonsudden] accidental occurrences arising from operation of the facility(ies) covered by this guarantee.

*Recitals*

1. Guarantor meets or exceeds the financial test criteria and agrees to comply with the reporting requirements for guarantors as specified in 40 CFR 261.147(g).

2. [Owner or operator] owns or operates the following facility(ies) covered by this guarantee: [List for each facility: EPA identification number (if any issued), name, and address; and if guarantor is incorporated outside the United States list the name and address of the guarantor’s registered agent in each State.] This corporate guarantee satisfies RCRA third-party liability requirements for [insert “sudden” or “nonsudden” or “both sudden and nonsudden”] accidental occurrences in above-named owner or operator facilities for coverage in the amount of [insert dollar amount] for each occurrence and [insert dollar amount] annual aggregate.

3. For value received from [owner or operator], guarantor guarantees to any and all third parties who have sustained or may sustain bodily injury or property damage caused by [sudden and/or nonsudden] accidental occurrences arising from operations of the facility(ies) covered by this guarantee that in the event that [owner or operator] fails to satisfy a judgment or award based on a determination of liability for bodily injury or property damage to third parties caused by [sudden and/or nonsudden] accidental occurrences, arising from the operation of the above-named facilities, or fails to pay an amount agreed to in settlement of a claim arising from or alleged to arise from such injury or damage, the guarantor will satisfy such judgment(s), award(s) or settlement agreement(s) up to the limits of coverage identified above.

4. Such obligation does not apply to any of the following:

(a) Bodily injury or property damage for which [insert owner or operator] is obligated to pay damages by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for damages that [insert owner or operator] would be obligated to pay in the absence of the contract or agreement.

(b) Any obligation of [insert owner or operator] under a workers’ compensation, disability benefits, or unemployment compensation law or any similar law.

(c) Bodily injury to:

(1) An employee of [insert owner or operator] arising from, and in the course of, employment by [insert owner or operator]; or

(2) The spouse, child, parent, brother, or sister of that employee as a consequence of, or arising from, and in the course of, employment by [insert owner or operator]. This exclusion applies:



(A) Whether [insert owner or operator] may be liable as an employer or in any other capacity; and

(B) To any obligation to share damages with or repay another person who must pay damages because of the injury to persons identified in paragraphs (1) and (2).

(d) Bodily injury or property damage arising out of the ownership, maintenance, use, or entrustment to others of any aircraft, motor vehicle or watercraft.

(e) Property damage to:

(1) Any property owned, rented, or occupied by [insert owner or operator];

(2) Premises that are sold, given away or abandoned by [insert owner or operator] if the property damage arises out of any part of those premises;

(3) Property loaned to [insert owner or operator];

(4) Personal property in the care, custody or control of [insert owner or operator];

(5) That particular part of real property on which [insert owner or operator] or any contractors or subcontractors working directly or indirectly on behalf of [insert owner or operator] are performing operations, if the property damage arises out of these operations.

5. Guarantor agrees that if, at the end of any fiscal year before termination of this guarantee, the guarantor fails to meet the financial test criteria, guarantor shall send within 90 days, by certified mail, notice to the EPA Regional Administrator[s] for the Region[s] in which the facility[ies] is[are] located and to [owner or operator] that he intends to provide alternate liability coverage as specified in 40 CFR 261.147, as applicable, in the name of [owner or operator]. Within 120 days after the end of such fiscal year, the guarantor shall establish such liability coverage unless [owner or operator] has done so.

6. The guarantor agrees to notify the EPA Regional Administrator by certified mail of a voluntary or involuntary proceeding under title 11 (Bankruptcy), U.S. Code, naming guarantor as debtor, within 10 days after commencement of the proceeding. Guarantor agrees that within 30 days after being notified by an EPA Regional Administrator of a determination that guarantor no longer meets the financial test criteria or that he is disallowed from continuing as a guarantor, he shall establish alternate liability coverage as specified in 40 CFR 261.147 in the name of [owner or operator], unless [owner or operator] has done so.

7. Guarantor reserves the right to modify this agreement to take into account amendment or modification of the liability requirements set by 40 CFR 261.147, provided that such modification shall become effective only if a Regional Administrator does not disapprove the modification within 30 days of receipt of notification of the modification.

8. Guarantor agrees to remain bound under this guarantee for so long as [owner or operator] must comply with the applicable requirements of 40 CFR 261.147 for the above-listed facility(ies), except as provided in paragraph 9 of this agreement.

9. [Insert the following language if the guarantor is (a) a direct or higher-tier

corporate parent, or (b) a firm whose parent corporation is also the parent corporation of the owner or operator]:

Guarantor may terminate this guarantee by sending notice by certified mail to the EPA Regional Administrator(s) for the Region(s) in which the facility(ies) is(are) located and to [owner or operator], provided that this guarantee may not be terminated unless and until [the owner or operator] obtains, and the EPA Regional Administrator(s) approve(s), alternate liability coverage complying with 40 CFR 261.147.

[Insert the following language if the guarantor is a firm qualifying as a guarantor due to its "substantial business relationship" with the owner or operator]:

Guarantor may terminate this guarantee 120 days following receipt of notification, through certified mail, by the EPA Regional Administrator(s) for the Region(s) in which the facility(ies) is(are) located and by [the owner or operator].

10. Guarantor hereby expressly waives notice of acceptance of this guarantee by any party.

11. Guarantor agrees that this guarantee is in addition to and does not affect any other responsibility or liability of the guarantor with respect to the covered facilities.

12. The Guarantor shall satisfy a third-party liability claim only on receipt of one of the following documents:

(a) Certification from the Principal and the third-party claimant(s) that the liability claim should be paid. The certification must be worded as follows, except that instructions in brackets are to be replaced with the relevant information and the brackets deleted:

Certification of Valid Claim

The undersigned, as parties [insert Principal] and [insert name and address of third-party claimant(s)], hereby certify that the claim of bodily injury and/or property damage caused by a [sudden or nonsudden] accidental occurrence arising from operating [Principal's] facility should be paid in the amount of \$.

[Signatures]
Principal
(Notary) Date
[Signatures]
Claimant(s)
(Notary) Date

(b) A valid final court order establishing a judgment against the Principal for bodily injury or property damage caused by sudden or nonsudden accidental occurrences arising from the operation of the Principal's facility or group of facilities.

13. In the event of combination of this guarantee with another mechanism to meet liability requirements, this guarantee will be considered [insert "primary" or "excess"] coverage.

I hereby certify that the wording of the guarantee is identical to the wording specified in 40 CFR 261.151(g)(2) as such regulations were constituted on the date shown immediately below.

Effective date:
[Name of guarantor]
[Authorized signature for guarantor]
[Name of person signing]
[Title of person signing]

Signature of witness or notary:

\* \* \* \* \*

(1) \* \* \*

(2) The following is an example of the certification of acknowledgement which must accompany the trust agreement for a trust fund as specified in § 261.147(j). State requirements may differ on the proper content of this acknowledgement.

State of
County of
On this [date], before me personally came [owner or operator] to me known, who, being by me duly sworn, did depose and say that she/he resides at [address], that she/he is [title] of [corporation], the corporation described in and which executed the above instrument; that she/he knows the seal of said corporation; that the seal affixed to such instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation, and that she/he signed her/his name thereto by like order.

[Signature of Notary Public]

\* \* \* \* \*

■ 13. Section 261.400 is amended by revising paragraphs (a) and (b) to read as follows:

§ 261.4009 Applicability.

\* \* \* \* \*

(a) A generator of hazardous secondary material, or an intermediate or reclamation facility, that accumulates 6000 kg or less of hazardous secondary material at any time must comply with §§ 261.410 and 261.411.

(b) A generator of hazardous secondary material, or an intermediate or reclamation facility that accumulates more than 6000 kg of hazardous secondary material at any time must comply with §§ 261.410 and 261.420.

■ 14. Section 261.410 is amended by revising paragraphs (e), (f)(1) introductory text, and (f)(2) to read as follows:

§ 261.410 Preparedness and prevention.

\* \* \* \* \*

(e) Required aisle space. The hazardous secondary material generator or intermediate or reclamation facility must maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency, unless aisle space is not needed for any of these purposes.

(f) \* \* \*

(1) The hazardous secondary material generator or an intermediate or reclamation facility must attempt to make the following arrangements, as appropriate for the type of waste handled at his facility and the potential

need for the services of these organizations:

\* \* \* \* \*

(2) Where State or local authorities decline to enter into such arrangements, the hazardous secondary material generator or an intermediate or reclamation facility must document the refusal in the operating record.

■ 15. Section 261.411 is amended by revising the introductory text and paragraphs (b) introductory text, (c), and (d)(3) introductory text to read as follows:

**§ 261.411 Emergency procedures for facilities generating or accumulating 6000 kg or less of hazardous secondary material.**

A generator or an intermediate or reclamation facility that generates or accumulates 6000 kg or less of hazardous secondary material must comply with the following requirements:

\* \* \* \* \*

(b) The generator or intermediate or reclamation facility must post the following information next to the telephone:

\* \* \* \* \*

(c) The generator or an intermediate or reclamation facility must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal facility operations and emergencies;

(d) \* \* \*

(3) In the event of a fire, explosion, or other release which could threaten human health outside the facility or when the generator or an intermediate or reclamation facility has knowledge that a spill has reached surface water, the generator or an intermediate or reclamation facility operating under a verified recycler variance under § 260.31(d) of this subchapter must immediately notify the National Response Center (using their 24-hour toll free number 800/424-8802). The report must include the following information:

\* \* \* \* \*

■ 16. Section 261.420 is amended by revising the introductory text and paragraphs (a)(1) and (b)(2) and (3) to read as follows:

**§ 261.420 Contingency planning and emergency procedures for facilities generating or accumulating more than 6000 kg of hazardous secondary material.**

A generator or an intermediate or reclamation facility that generates or accumulates more than 6000 kg of hazardous secondary material must comply with the following requirements:

(a) \* \* \*

(1) Each generator or an intermediate or reclamation facility that accumulates more than 6000 kg of hazardous secondary material must have a contingency plan for his facility. The contingency plan must be designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous secondary material or hazardous secondary material constituents to air, soil, or surface water.

\* \* \* \* \*

(b) \* \* \*

(2) If the generator or an intermediate or reclamation facility accumulating more than 6000 kg of hazardous secondary material has already prepared a Spill Prevention, Control, and Countermeasures (SPCC) Plan in accordance with part 112 of this chapter, or some other emergency or contingency plan, he need only amend that plan to incorporate hazardous waste management provisions that are sufficient to comply with the requirements of this part. The hazardous secondary material generator or an intermediate or reclamation facility operating under a verified recycler variance under § 260.31(d) of this subchapter may develop one contingency plan which meets all regulatory requirements. EPA recommends that the plan be based on the National Response Team's Integrated Contingency Plan Guidance ("One Plan"). When modifications are made to non-RCRA provisions in an integrated contingency plan, the changes do not trigger the need for a RCRA permit modification.

(3) The plan must describe arrangements agreed to by local police departments, fire departments, hospitals, contractors, and State and local emergency response teams to coordinate emergency services, pursuant to § 261.410(f).

\* \* \* \* \*

■ 17. Section 261.1033 is amended by revising paragraph (n)(1)(i) as follows:

**§ 261.1033 Standards: Closed-vent systems and control devices.**

\* \* \* \* \*

(n) \* \* \*

(1) \* \* \*

(i) The owner or operator of the unit has been issued a final permit under 40 CFR part 270 which implements the requirements of 40 CFR part 264, subpart X; or

\* \* \* \* \*

■ 18. Section 261.1083 is amended by revising paragraphs (a)(1) introductory

text, (a)(1)(i), and (c)(4) to read as follows:

**§ 261.1083 Material determination procedures.**

(a) \* \* \*

(1) Determining average VO concentration at the point of material origination. A remanufacturer or other person that stores or treats the hazardous secondary material shall determine the average VO concentration at the point of material origination for each hazardous secondary material placed in a hazardous secondary material management unit exempted under the provisions of § 261.1082(c) from using air emission controls in accordance with standards specified in §§ 261.1084 through 261.1087, as applicable to the hazardous secondary material management unit.

(i) An initial determination of the average VO concentration of the material stream shall be made before the first time any portion of the material in the hazardous secondary material stream is placed in a hazardous secondary material management unit exempted under the provisions of § 261.1082(c) from using air emission controls, and thereafter an initial determination of the average VO concentration of the material stream shall be made for each averaging period that a hazardous secondary material is managed in the unit; and

\* \* \* \* \*

(c) \* \* \*

(4) Use of knowledge to determine the maximum organic vapor pressure of the hazardous secondary material. Documentation shall be prepared and recorded that presents the information used as the basis for the knowledge by the remanufacturer or other person that stores or treats the hazardous secondary material that the maximum organic vapor pressure of the hazardous secondary material is less than the maximum vapor pressure limit listed in § 261.1084(b)(1)(i) for the applicable tank design capacity category. An example of information that may be used is documentation that the hazardous secondary material is generated by a process for which at other locations it previously has been determined by direct measurement that the hazardous secondary material's waste maximum organic vapor pressure is less than the maximum vapor pressure limit for the appropriate tank design capacity category.

\* \* \* \* \*

■ 19. Section 261.1084 is amended by revising paragraphs (j)(2)(i) through (iii) to read as follows:

**§ 261.1084 Standards: tanks.**

\* \* \* \* \*  
 (j) \* \* \*  
 (2) \* \* \*

(i) The hazardous secondary material meets the average VO concentration conditions specified in § 261.1082(c) at the point of material origination.

(ii) The hazardous secondary material has been treated by an organic destruction or removal process to meet the requirements in § 264.1082(c)(2).

(iii) The hazardous secondary material meets the requirements of § 264.1082(c)(4).

\* \* \* \* \*

■ 20. Section 261.1089 is amended by revising paragraphs (a), (f), and (g) to read as follows:

**§ 261.1089 Recordkeeping requirements.**

(a) Each remanufacturer or other person that stores or treats the hazardous secondary material subject to requirements of this subpart shall record and maintain the information specified in paragraphs (b) through (j) of this section, as applicable to the facility. Except for air emission control equipment design documentation and information required by paragraphs (i)

and (j) of this section, records required by this section shall be maintained at the facility for a minimum of 3 years. Air emission control equipment design documentation shall be maintained at the facility until the air emission control equipment is replaced or otherwise no longer in service. Information required by paragraphs (i) and (j) of this section shall be maintained at the facility for as long as the hazardous secondary material management unit is not using air emission controls specified in §§ 261.1084 through 261.1087 in accordance with the conditions specified in § 261.1080(a).

(f) The remanufacturer or other person that stores or treats the hazardous secondary material using a tank or container exempted under the hazardous secondary material organic concentration conditions specified in § 261.1082(c), shall prepare and maintain at the facility records documenting the information used for each material determination (e.g., test results, measurements, calculations, and other documentation). If analysis results for material samples are used for the material determination, then the

remanufacturer or other person that stores or treats the hazardous secondary material shall record the date, time, and location that each material sample is collected in accordance with applicable requirements of § 261.1083.

(g) A remanufacturer or other person that stores or treats the hazardous secondary material designating a cover as “unsafe to inspect and monitor” pursuant to § 261.1084(l) shall record and keep at facility the following information: The identification numbers for hazardous secondary material management units with covers that are designated as “unsafe to inspect and monitor,” the explanation for each cover stating why the cover is unsafe to inspect and monitor, and the plan and schedule for inspecting and monitoring each cover.

\* \* \* \* \*

■ 21. Amend appendix IX to part 261 by revising the entries for “Bekaert Corp” and “Saturn Corporation” in table 1 and by revising the entry for “American Chrome & Chemical” in table 2 to read as follows:

**Appendix IX to Part 261—Wastes Excluded Under §§ 260.20 and 260.22**

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
Bekaert Corp	Dyersburg, TN	<p>Dewatered wastewater treatment plant (WWTP) sludge (EPA Hazardous Waste Nos. F006) generated at a maximum rate of 1250 cubic yards per calendar year after May 27, 2004, and disposed in a Subtitle D landfill. For the exclusion to be valid, Bekaert must implement a verification testing program that meets the following paragraphs:</p> <p>(1) Delisting Levels: All leachable concentrations for those constituents must not exceed the maximum allowable concentrations in mg/l specified in this paragraph. Bekaert must use the leaching method specified at § 261.24 to measure constituents in the waste leachate.</p> <p>(A) Inorganic Constituents TCLP (mg/l): Cadmium—0.672; Chromium—5.0; Nickel—127; Zinc—1260.0.</p> <p>(B) Organic Constituents TCLP (mg/l): Methyl ethyl ketone—200.0.</p> <p>(2) Waste Holding and Handling:</p> <p>(A) Bekaert must accumulate the hazardous waste dewatered WWTP sludge in accordance with the applicable regulations of §§ 262.15, 262.16, and 262.17 of this subchapter, as applicable, and continue to dispose of the dewatered WWTP sludge as hazardous waste.</p> <p>(B) Once the first quarterly sampling and analyses event described in paragraph (3) is completed and valid analyses demonstrate that no constituent is present in the sample at a level which exceeds the delisting levels set in paragraph (1), Bekaert can manage and dispose of the dewatered WWTP sludge as nonhazardous according to all applicable solid waste regulations.</p> <p>(C) If constituent levels in any sample taken by Bekaert exceed any of the delisting levels set in paragraph (1), Bekaert must do the following: (i) notify EPA in accordance with paragraph (7) and (ii) manage and dispose the dewatered WWTP sludge as hazardous waste generated under Subtitle C of RCRA.</p> <p>(D) Quarterly Verification Testing Requirements: Upon this exclusion becoming final, Bekaert may begin the quarterly testing requirements of paragraph (3) on its dewatered WWTP sludge.</p> <p>(3) Quarterly Testing Requirements: Upon this exclusion becoming final, Bekaert may perform quarterly analytical testing by sampling and analyzing the dewatered WWTP sludge as follows:</p> <p>(A)(i) Collect four representative composite samples of the hazardous waste dewatered WWTP sludge at quarterly (ninety (90) day) intervals after EPA grants the final exclusion. The first composite sample may be taken at any time after EPA grants the final approval.</p> <p>(ii) Analyze the samples for all constituents listed in paragraph (1). Any roll-offs from which the composite sample is taken exceeding the delisting levels listed in paragraph (1) must be disposed as hazardous waste in a Subtitle C landfill.</p> <p>(iii) Within forty-five (45) days after taking its first quarterly sample, Bekaert will report its first quarterly analytical test data to EPA. If levels of constituents measured in the sample of the dewatered WWTP sludge do not exceed the levels set forth in paragraph (1) of this exclusion, Bekaert can manage and dispose the nonhazardous dewatered WWTP sludge according to all applicable solid waste regulations.</p> <p>(4) Annual Testing:</p> <p>(A) If Bekaert completes the quarterly testing specified in paragraph (3) above and no sample contains a constituent with a level which exceeds the limits set forth in paragraph (1), Bekaert may begin annual testing as follows: Bekaert must test one representative composite sample of the dewatered WWTP sludge for all constituents listed in paragraph (1) at least once per calendar year.</p>

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		<p>(B) The sample for the annual testing shall be a representative composite sample for all constituents listed in paragraph (1).</p> <p>(C) The sample for the annual testing taken for the second and subsequent annual testing events shall be taken within the same calendar month as the first annual sample taken.</p> <p>(5) Changes in Operating Conditions: If Bekaert significantly changes the process described in its petition or starts any processes that generate(s) the waste that may or could affect the composition or type of waste generated as established under paragraph (1) (by illustration, but not limitation, changes in equipment or operating conditions of the treatment process), it must notify the EPA in writing; it may no longer handle the wastes generated from the new process as nonhazardous until the wastes meet the delisting levels set in paragraph (1) and it has received written approval to do so from the EPA.</p> <p>(6) Data Submittals: Bekaert must submit the information described below. If Bekaert fails to submit the required data within the specified time or maintain the required records on-site for the specified time, the EPA, at its discretion, will consider this sufficient basis to reopen the exclusion as described in paragraph (7). Bekaert must:</p> <p>(A) Submit the data obtained through paragraph (3) to the Chief, North Section, RCRA Enforcement and Compliance Branch, Waste Division, U. S. Environmental Protection Agency Region 4, 61 Forsyth Street, SW., Atlanta, Georgia, 30303, within the time specified.</p> <p>(B) Compile records of analytical data from paragraph (3), summarized, and maintained on-site for a minimum of five years.</p> <p>(C) Furnish these records and data when either the EPA or the State of Tennessee request them for inspection.</p> <p>(D) Send along with all data a signed copy of the following certification statement, to attest to the truth and accuracy of the data submitted:</p> <p>“Under civil and criminal penalty of law for the making or submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code, which include, but may not be limited to, 18 U.S.C. 1001 and 42 U.S.C. 6928), I certify that the information contained in or accompanying this document is true, accurate and complete.</p> <p>As to the (those) identified section(s) of this document for which I cannot personally verify its (their) truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate and complete. If any of this information is determined by the EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of waste will be void as if it never had effect or to the extent directed by the EPA and that the company will be liable for any actions taken in contravention of the company’s RCRA and CERCLA obligations premised upon the company’s reliance on the void exclusion.”</p> <p>(7) Reopener:</p> <p>(A) If, any time after disposal of the delisted waste Bekaert possesses or is otherwise made aware of any environmental data (including but not limited to leachate data or ground water monitoring data) or any other data relevant to the delisted waste indicating that any constituent identified for the delisting verification testing is at level higher than the delisting level allowed by the Regional Administrator or his delegate in granting the petition, then the facility must report the data, in writing, to the Regional Administrator or his delegate within ten (10) days of first possessing or being made aware of that data.</p> <p>(B) If either the quarterly or annual testing of the waste does not meet the delisting requirements in paragraph (1), Bekaert must report the data, in writing, to the Regional Administrator or his delegate within ten (10) days of first possessing or being made aware of that data.</p> <p>(C) If Bekaert fails to submit the information described in paragraphs (5), (6)(A) or (6)(B) or if any other information is received from any source, the Regional Administrator or his delegate will make a preliminary determination as to whether the reported information requires the EPA action to protect human health or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment.</p> <p>(D) If the Regional Administrator or his delegate determines that the reported information requires action the EPA, the Regional Administrator or his delegate will notify the facility in writing of the actions the Regional Administrator or his delegate believes are necessary to protect human health and the environment. The notification shall include a statement of the proposed action and a statement providing the facility with an opportunity to present information as to why the proposed the EPA action is not necessary. The facility shall have ten (10) days from the date of the Regional Administrator or his delegate’s notice to present such information.</p> <p>(E) Following the receipt of information from the facility described in paragraph (6)(D) or (if no information is presented under paragraph (6)(D)) the initial receipt of information described in paragraphs (5), (6)(A) or (6)(B), the Regional Administrator or his delegate will issue a final written determination describing the EPA actions that are necessary to protect human health or the environment. Any required action described in the Regional Administrator or his delegate’s determination shall become effective immediately, unless the Regional Administrator or his delegate provides otherwise.</p> <p>(8) Notification Requirements: Bekaert must do following before transporting the delisted waste:</p> <p>(A) Provide a one-time written notification to any State Regulatory Agency to which or through which it will transport the delisted waste described above for disposal, sixty (60) days before beginning such activities.</p> <p>(B) Update the one-time written notification if Bekaert ships the delisted waste into a different disposal facility.</p> <p>(C) Failure to provide this notification will result in a violation of the delisting variance and a possible revocation of the decision.</p>
Saturn Corporation .....	Spring Hill, Tennessee	<p>Dewatered wastewater treatment plant (WWTP) sludge (EPA Hazardous Waste No. F019) generated at a maximum rate of 3,000 cubic yards per calendar year. The sludge must be disposed in a lined, Subtitle D landfill with leachate collection that is licensed, permitted, or otherwise authorized to accept the delisted WWTP sludge in accordance with 40 CFR part 258. The exclusion becomes effective on December 23, 2005.</p> <p>For the exclusion to be valid, Saturn must implement a verification testing program that meets the following conditions:</p>

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		<p>1. Delisting Levels: The constituent concentrations in an extract of the waste must not exceed the following maximum allowable concentrations in mg/l: antimony—0.494; arsenic—0.224; total chromium—3.71; lead—5.0; nickel—68; thallium—0.211; and zinc—673. Sample collection and analyses, including quality control procedures, must be performed using appropriate methods. As applicable to the method-defined parameters of concern, analyses requiring the use of SW-846 methods incorporated by reference in 40 CFR 260.11 must be used without substitution. As applicable, the SW-846 methods might include Methods 0010, 0011, 0020, 0023A, 0030, 0031, 0040, 0050, 0051, 0060, 0061, 1010B, 1020C, 1110A, 1310B, 1311, 1312, 1320, 1330A, 9010C, 9012B, 9040C, 9045D, 9060A, 9070A, (uses EPA Method 1664, Rev. A), 9071B, and 9095B. Methods must meet Performance Based Measurement System Criteria in which the Data Quality Objectives are to demonstrate that representative samples of Saturn's sludge meet the delisting levels in this condition.</p> <p>2. Waste Holding and Handling:</p> <p>(a) Saturn must accumulate the hazardous waste dewatered WWTP sludge in accordance with the applicable regulations of §§ 262.15, 262.16, and 262.17 of this subchapter, and continue to dispose of the dewatered WWTP sludge as hazardous waste until the results of the first quarterly verification testing are available.</p> <p>(b) After the first quarterly verification sampling event described in Condition (3) has been completed and the laboratory data demonstrates that no constituent is present in the sample at a level which exceeds the delisting levels set in Condition (1), Saturn can manage and dispose of the dewatered WWTP sludge as nonhazardous according to all applicable solid waste regulations.</p> <p>(c) If constituent levels in any sample taken by Saturn exceed any of the delisting levels set in Condition (1), Saturn must do the following:</p> <p>(i) Notify EPA in accordance with Condition (7) and</p> <p>(ii) Manage and dispose the dewatered WWTP sludge as hazardous waste generated under Subtitle C of RCRA.</p> <p>3. Quarterly Testing Requirements: Upon this exclusion becoming final, Saturn may perform quarterly analytical testing by sampling and analyzing the dewatered WWTP sludge as follows:</p> <p>(i) Collect one representative composite sample (consisting of four grab samples) of the hazardous waste dewatered WWTP sludge at any time after EPA grants the final delisting. In addition, collect the second, third, and fourth quarterly samples at approximately ninety (90)-day intervals after EPA grants the final exclusion.</p> <p>(ii) Analyze the samples for all constituents listed in Condition (1). Any roll-offs from which the composite sample is taken exceeding the delisting levels listed in Condition (1) must be disposed as hazardous waste in a Subtitle C landfill.</p> <p>(iii) Within forty-five (45) days after taking its first quarterly sample, Saturn will report its first quarterly analytical test data to EPA and will include the certification statement required in condition (6). If levels of constituents measured in the sample of the dewatered WWTP sludge do not exceed the levels set forth in Condition (1) of this exclusion, Saturn can manage and dispose the nonhazardous dewatered WWTP sludge according to all applicable solid waste regulations.</p> <p>4. Annual Verification Testing:</p> <p>(i) If Saturn completes the quarterly testing specified in Condition (3) above, and no sample contains a constituent with a level which exceeds the limits set forth in Condition (1), Saturn may begin annual verification testing on an annual basis. Saturn must collect and analyze one sample of the WWTP sludge on an annual basis as follows: Saturn must test one representative composite sample of the dewatered WWTP sludge for all constituents listed in Condition (1) at least once per calendar year.</p> <p>(ii) The sample collected for annual verification testing shall be a representative composite sample consisting of four grab samples that will be collected in accordance with the appropriate methods described in Condition (1).</p> <p>(iii) The sample for the annual testing for the second and subsequent annual testing events shall be collected within the same calendar month as the first annual verification sample. Saturn will report the results of the annual verification testing to EPA on an annual basis and will include the certification statement required by Condition (6).</p> <p>5. Changes in Operating Conditions: Saturn must notify EPA in writing when significant changes in the manufacturing or wastewater treatment processes are implemented. EPA will determine whether these changes will result in additional constituents of concern. If so, EPA will notify Saturn in writing that Saturn's sludge must be managed as hazardous waste F019 until Saturn has demonstrated that the wastes meet the delisting levels set forth in Condition (1) and any levels established by EPA for the additional constituents of concern, and Saturn has received written approval from EPA. If EPA determines that the changes do not result in additional constituents of concern, EPA will notify Saturn, in writing, that Saturn must verify that Saturn's sludge continues to meet Condition (1) delisting levels.</p> <p>6. Data Submittals: Saturn must submit data obtained through verification testing at Saturn or as required by other conditions of this rule to: Chief, North Section, RCRA Enforcement and Compliance Branch, Waste Management Division, U.S. Environmental Protection Agency Region 4, Sam Nunn Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, Georgia 30303. If Saturn fails to submit the required data within the specified time or maintain the required records on-site for the specified time, the EPA, at its discretion, will consider this sufficient basis to re-open the exclusion as described in Condition (7). Saturn must:</p> <p>(A) Submit the data obtained through Condition (3) within the time specified. The quarterly verification data must be submitted to EPA in accordance with Condition (3). The annual verification data and certification statement of proper disposal must be submitted to EPA annually upon the anniversary of the effective date of this exclusion. All data must be accompanied by a signed copy of the certification statement in 40 CFR 260.22(i)(12).</p> <p>(B) Compile, Summarize, and Maintain Records: Saturn must compile, summarize, and maintain at Saturn records of operating conditions and analytical data records of analytical data from Condition (3), summarized, and maintained on-site for a minimum of five years. Saturn must furnish these records and data when either the EPA or the State of Tennessee requests them for inspection.</p> <p>(C) Send along with all data a signed copy of the following certification statement, to attest to the truth and accuracy of the data submitted: "I certify under penalty of law that I have personally examined and am familiar with the information submitted in this demonstration and all attached documents, and that, based on my inquiry of those individuals immediately responsible for getting the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for sending false information, including the possibility of fine and imprisonment."</p> <p>7. Reopener.</p> <p>(A) If, at any time after disposal of the delisted waste, Saturn possesses or is otherwise made aware of any data (including but not limited to leachate data or groundwater monitoring data) relevant to the delisted WWTP sludge at Saturn indicating that any constituent is at a level in the leachate higher than the specified delisting level or TCLP regulatory level, then Saturn must report the data, in writing, to the Regional Administrator within ten (10) days of first possessing or being made aware of that data.</p>

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		<p>(B) Based upon the information described in Paragraph (A) and any other information received from any source, the EPA Regional Administrator will make a preliminary determination as to whether the reported information requires EPA action to protect human health or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment.</p> <p>(C) If the Regional Administrator determines that the reported information does require EPA action, the Regional Administrator will notify Saturn in writing of the actions the Regional Administrator believes are necessary to protect human health and the environment. The notification shall include a statement of the proposed action and a statement providing Saturn with an opportunity to present information as to why the proposed EPA action is not necessary. Saturn shall have ten (10) days from the date of the Regional Administrator's notice to present the information.</p> <p>(D) Following the receipt of information from Saturn, or if Saturn presents no further information after 10 days, the Regional Administrator will issue a final written determination describing the EPA actions that are necessary to protect human health or the environment. Any required action described in the Regional Administrator's determination shall become effective immediately, unless the Regional Administrator provides otherwise.</p> <p>8. Notification Requirements: Before transporting the delisted waste, Saturn must provide a one-time written notification to any State Regulatory Agency to which or through which it will transport the delisted WWTP sludge for disposal. The notification will be updated if Saturn transports the delisted WWTP sludge to a different disposal facility. Failure to provide this notification will result in a violation of the delisting variance and a possible revocation of the decision.</p>
*	*	* * * * *

TABLE 2—WASTES EXCLUDED FROM SPECIFIC SOURCES

Facility	Address	Waste description
American Chrome & Chemical.	Corpus Christi, Texas	<p>Dewatered sludge (the EPA Hazardous Waste No. K006) generated at a maximum generation of 1450 cubic yards per calendar year after September 21, 2004 and disposed in a Subtitle D landfill. ACC must implement a verification program that meets the following Paragraphs:</p> <p>(1) Delisting Levels: All leachable constituent concentrations must not exceed the following levels (mg/l). The petitioner must use the method specified in §261.24 to measure constituents in the waste leachate. Dewatered wastewater sludge: Arsenic-0.0377; Barium-100.0; Chromium-5.0; Thallium-0.355; Zinc-1130.0.</p> <p>(2) Waste Holding and Handling:</p> <p>(A) ACC is a 90 day facility and does not have a RCRA permit, therefore, ACC must store the dewatered sludge following the requirements specified in §§262.15, 262.16, and 262.17 of this subchapter, as applicable, or continue to dispose of as hazardous all dewatered sludge generated, until they have completed verification testing described in Paragraph (3), as appropriate, and valid analyses show that paragraph (1) is satisfied.</p> <p>(B) Levels of constituents measured in the samples of the dewatered sludge that do not exceed the levels set forth in Paragraph (1) are non-hazardous. ACC can manage and dispose the non-hazardous dewatered sludge according to all applicable solid waste regulations.</p> <p>(C) If constituent levels in a sample exceed any of the delisting levels set in Paragraph (1), ACC must retreat the batches of waste used to generate the representative sample until it meets the levels. ACC must repeat the analyses of the treated waste.</p> <p>(D) If the facility does not treat the waste or retreat it until it meets the delisting levels in Paragraph (1), ACC must manage and dispose the waste generated under Subtitle C of RCRA.</p> <p>(E) The dewatered sludge must pass paint filter test as described in SW 846, Method 9095 or another appropriate method found in a reliable source before it is allowed to leave the facility. ACC must maintain a record of the actual volume of the dewatered sludge to be disposed of-site according to the requirements in Paragraph (5).</p> <p>(3) Verification Testing Requirements: ACC must perform sample collection and analyses, including quality control procedures, according to appropriate methods such as those found in SW-846 or other reliable sources (with the exception of analyses requiring the use of SW-846 methods incorporated by reference in 40 CFR 260.11, which must be used without substitution. ACC must conduct verification testing each time it decides to evacuate the tank contents. Four (4) representative composite samples shall be collected from the dewatered sludge. ACC shall analyze the verification samples according to the constituent list specified in Paragraph (1) and submit the analytical results to EPA within 10 days of receiving the analytical results. If the EPA determines that the data collected under this Paragraph do not support the data provided for the petition, the exclusion will not cover the generated wastes. The EPA will notify ACC the decision in writing within two weeks of receiving this information.</p> <p>(4) Changes in Operating Conditions: If ACC significantly changes the process described in its petition or starts any processes that may or could affect the composition or type of waste generated as established under Paragraph (1) (by illustration, but not limitation, changes in equipment or operating conditions of the treatment process), they must notify the EPA in writing; they may no longer handle the wastes generated from the new process as nonhazardous until the test results of the wastes meet the delisting levels set in Paragraph (1) and they have received written approval to do so from the EPA.</p> <p>(5) Data Submittals: ACC must submit the information described below. If ACC fails to submit the required data within the specified time or maintain the required records on-site for the specified time, the EPA, at its discretion, will consider this sufficient basis to reopen the exclusion as described in Paragraph 6. ACC must:</p> <p>(A) Submit the data obtained through Paragraph 3 to the Section Chief, Corrective Action and Waste Minimization Section, Environmental Protection Agency, 1445 Ross Avenue, Dallas, Texas 75202-2733, Mail Code, (6PD-C) within the time specified.</p> <p>(B) Compile records of operating conditions and analytical data from Paragraph (3), summarized, and maintained on-site for a minimum of five years.</p> <p>(C) Furnish these records and data when the EPA or the State of Texas request them for inspection.</p>

TABLE 2—WASTES EXCLUDED FROM SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		<p>(D) Send along with all data a signed copy of the following certification statement, to attest to the truth and accuracy of the data submitted: Under civil and criminal penalty of law for the making or submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code, which include, but may not be limited to, 18 U.S.C. 1001 and 42 U.S.C. 6928), I certify that the information contained in or accompanying this document is true, accurate and complete. As to the (those) identified section(s) of this document for which I cannot personally verify its (their) truth and accuracy, I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate and complete. If any of this information is determined by the EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of waste will be void as if it never had effect or to the extent directed by the EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's reliance on the void exclusion.</p> <p>(6) Reopener:</p> <p>(A) If, any time after disposal of the delisted waste, ACC possesses or is otherwise made aware of any environmental data (including but not limited to leachate data or ground water monitoring data) or any other data relevant to the delisted waste indicating that any constituent identified for the delisting verification testing is at level higher than the delisting level allowed by the Division Director in granting the petition, then the facility must report the data, in writing, to the Division Director within 10 days of first possessing or being made aware of that data.</p> <p>(B) If the verification testing of the waste does not meet the delisting requirements in Paragraph 1, ACC must report the data, in writing, to the Division Director within 10 days of first possessing or being made aware of that data.</p> <p>(C) If ACC fails to submit the information described in paragraphs (5), (6)(A), or (6)(B) or if any other information is received from any source, the Division Director will make a preliminary determination as to whether the reported information requires Agency action to protect human health or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment.</p> <p>(D) If the Division Director determines that the reported information does require Agency action, the Division Director will notify the facility in writing of the actions the Division Director believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing the facility with an opportunity to present information as to why the proposed Agency action is not necessary. The facility shall have 10 days from the date of the Division Director's notice to present such information.</p> <p>(E) Following the receipt of information from the facility described in paragraph (6)(D) or (if no information is presented under paragraph (6)(D)) the initial receipt of information described in paragraphs (5), (6)(A), or (6)(B), the Division Director will issue a final written determination describing the Agency actions that are necessary to protect human health or the environment. Any required action described in the Division Director's determination shall become effective immediately, unless the Division Director provides otherwise.</p> <p>(7) Notification Requirements: ACC must do the following before transporting the delisted waste: Failure to provide this notification will result in a violation of the delisting petition and a possible revocation of the decision.</p> <p>(A) Provide a one-time written notification to any State Regulatory Agency to which or through which they will transport the delisted waste described above for disposal, 60 days before beginning such activities. If ACC transports the excluded waste to or manages the waste in any state with delisting authorization, ACC must obtain delisting authorization from that state before it can manage the waste as nonhazardous in the state.</p> <p>(B) Update the one-time written notification if they ship the delisted waste to a different disposal facility.</p> <p>(C) Failure to provide the notification will result in a violation of the delisting variance and a possible revocation of the exclusion.</p>

**PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE**

■ 22. The authority for part 262 continues to read as follows:  
**Authority:** 42 U.S.C. 6906, 6912, 6922–6925, 6937, 6938 and 6939g.

■ 23. Section 262.1 is amended by revising the definition of “Condition for exemption” to read as follows:

**§ 262.1 Terms used in this part.**

\* \* \* \* \*  
*Condition for exemption* means any requirement in § 262.14, § 262.15, § 262.16, § 262.17, § 262.70, or subpart K or L of this part that states an event, action, or standard that must occur or be met in order to obtain an exemption from any applicable requirement in parts 124, 264 through 268, and 270 of this chapter, or from any requirement

for notification under section 3010 of RCRA for treatment storage, and disposal facilities.

\* \* \* \* \*

■ 24. Section 262.10 is amended by:

- a. Revising paragraphs (a)(2) introductory text and (k);
- b. Redesignating notes 1 and 2 following paragraph (l) as notes 1 and 2 to § 262.10 appearing at the end of the section; and
- c. Revising newly redesignated note 1 to § 262.10.

The revisions read as follows:

**§ 262.10 Purpose, scope, and applicability.**

- (a) \* \* \*
- (2) A generator that accumulates hazardous waste on site is a person that stores hazardous waste; such generator is subject to the applicable requirements of parts 124, 264 through 267, and 270 of this chapter and section 3010 of

RCRA for treatment, storage, and disposal facilities, unless it is one of the following:

\* \* \* \* \*

(k) Generators in the Commonwealth of Massachusetts may comply with the State regulations regarding Class A recyclable materials in 310 C.M.R. 30.200, when authorized by the EPA under 40 CFR part 271, with respect to those recyclable materials and matters covered by the authorization, instead of complying with the hazardous waste accumulation conditions for exemption in §§ 262.15 through 262.17, the reporting requirements of § 262.41, the storage facility operator requirements of 40 CFR parts 264, 265, and 267, and the permitting requirements of 40 CFR part 270. Such generators must also comply with any other applicable requirements, including any applicable authorized State regulations governing hazardous

wastes not being recycled and any applicable Federal requirements which are being directly implemented by the EPA within Massachusetts pursuant to the Hazardous and Solid Waste Amendments of 1984.

\* \* \* \* \*

**Note 1 to § 262.10:** The provisions of §§ 262.15 through 262.17 are applicable to the on-site accumulation of hazardous waste by generators. Therefore, the provisions of §§ 262.15 through 262.17 only apply to owners or operators who are shipping hazardous waste which they generated at that facility.

**Note 2 to § 262.10:** \* \* \*

\* \* \* \* \*

■ 25. Section 262.11 is amended by revising paragraphs (d) introductory text and (g) to read as follows:

**§ 262.11 Hazardous waste determination and recordkeeping.**

\* \* \* \* \*

(d) The person then must also determine whether the waste exhibits one or more hazardous characteristics as identified in subpart C of 40 CFR part 261 by following the procedures in paragraph (d)(1) or (2) of this section, or a combination of both. Where a waste is both listed and exhibits a characteristic, the listed waste code is sufficient, provided that the listed waste code addresses the constituents and/or properties that cause the waste to exhibit the characteristic. Otherwise, the waste codes must be identified for all applicable listings and characteristics.

\* \* \* \* \*

(g) *Identifying hazardous waste numbers for small and large quantity generators.* Consistent with paragraph (d) of this section, if the waste is determined to be hazardous, small quantity generators and large quantity generators must identify all applicable EPA hazardous waste numbers (EPA hazardous waste codes) in subparts C and D of part 261 of this subchapter. Prior to shipping the waste off site, the generator also must mark its containers with all applicable EPA hazardous waste numbers (EPA hazardous waste codes) according to § 262.32.

■ 26. Section 262.14 is amended by revising paragraphs (a)(3) and (4) to read as follows:

**§ 262.14 Conditions for exemption for a very small quantity generator.**

(a) \* \* \*

(3) If the very small quantity generator accumulates at any time greater than 1 kilogram (2.2 lbs) of acute hazardous waste or 100 kilograms (220 lbs) of any residue or contaminated soil, water, or

other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) of this subchapter, all quantities of that acute hazardous waste are subject to the following additional conditions for exemption and independent requirements:

(i) Such waste is held on site for no more than 90 days beginning on the date when the accumulated wastes exceed the amounts provided in paragraph (a)(3) of this section;

(ii) The conditions for exemption in § 262.17(a) through (g);

(iii) Notification as a “very small quantity generator” under § 262.18(a) through (c);

(iv) Preparation and use of the manifest in subpart B of this part;

(v) Pre-transport requirements in subpart C of this part;

(vi) Recordkeeping and reporting requirements in subpart D of this part; and

(vii) Requirements for transboundary movements of hazardous wastes in subpart H of this part.

(4) If the very small quantity generator accumulates at any time 1,000 kilograms (2,200 lbs) or greater of non-acute hazardous waste, all quantities of that hazardous waste are subject to the following additional conditions for exemption and independent requirements:

(i) Such waste is held on site for no more than 180 days, or 270 days, if applicable, beginning on the date when the accumulated waste exceed the amounts provided in paragraph (a)(4) of this section;

(ii) The quantity of waste accumulated on site never exceeds 6,000 kilograms (13,200 lbs);

(iii) The conditions for exemption in § 262.16(b)(2) through (f);

(iv) Notification as a “very small quantity generator” under § 262.18(a) through (c);

(v) Preparation and use of the manifest in subpart B of this part;

(vi) Pre-transport requirements in subpart C of this part;

(vii) Recordkeeping and reporting requirements in subpart D of this part; and

(viii) Requirements for transboundary movements of hazardous wastes in subpart H of this part.

\* \* \* \* \*

■ 27. Section 262.16 is amended by revising the introductory text and paragraphs (b) introductory text, (b)(1), (b)(5) introductory text, and (b)(8)(iv)(A) and (B) to read as follows:

**§ 262.16 Conditions for exemption for a small quantity generator that accumulates hazardous waste.**

A small quantity generator may accumulate hazardous waste on site without a permit or interim status, and without complying with the requirements of parts 124, 264 through 267, and 270 of this chapter, or the notification requirements of section 3010 of RCRA for treatment, storage, and disposal facilities, provided that all the conditions for exemption listed in this section are met:

\* \* \* \* \*

(b) *Accumulation.* The generator accumulates hazardous waste on site for no more than 180 days, unless in compliance with the conditions for exemption for longer accumulation in paragraphs (c), (d), and (e) of this section. The following accumulation conditions also apply:

(1) *Accumulation limit.* The quantity of acute hazardous waste accumulated on site never exceeds 1 kilogram (2.2 pounds) and the quantity of non-acute hazardous waste accumulated on site never exceeds 6,000 kilograms (13,200 pounds);

\* \* \* \* \*

(5) *Accumulation of hazardous waste in containment buildings.* If the waste is placed in containment buildings, the small quantity generator must comply with 40 CFR part 265 subpart DD. The generator must label its containment buildings with the words “Hazardous Waste” in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, or other persons on site and also in a conspicuous place provide an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172, subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704). The generator must also maintain:

\* \* \* \* \*

(8) \* \* \*

(iv) \* \* \*

(A) Whenever hazardous waste is being poured, mixed, spread, or otherwise handled, all personnel involved in the operation must have



immediate access (e.g., direct or unimpeded access) to an internal alarm or emergency communication device, either directly or through visual or voice contact with another employee, unless such a device is not required under paragraph (b)(8)(ii) of this section.

(B) In the event there is just one employee on the premises while the facility is operating, the employee must have immediate access (e.g., direct or unimpeded access) to a device, such as a telephone (immediately available at the scene of operation) or a hand-held two-way radio, capable of summoning external emergency assistance, unless such a device is not required under paragraph (b)(8)(ii) of this section.

\* \* \* \* \*

■ 28. Section 262.17 is amended by revising the introductory text and paragraphs (a)(2), (a)(7)(i)(A), (a)(8)(i) introductory text, (a)(8)(i)(A), (a)(8)(iii)(A)(4), (b), (c) introductory text, (d), (e), and (f) introductory text to read as follows:

§ 262.17 Conditions for exemption for a large quantity generator that accumulates hazardous waste.

A large quantity generator may accumulate hazardous waste on site without a permit or interim status, and without complying with the requirements of parts 124, 264 through 267, and 270 of this chapter, or the notification requirements of section 3010 of RCRA for treatment, storage, and disposal facilities, provided that all of the following conditions for exemption are met:

\* \* \* \* \*

(a) \* \* \*

(2) *Accumulation of hazardous waste in tanks.* If the waste is placed in tanks, the large quantity generator must comply with the applicable requirements of subpart J (except §§ 265.197(c) and 265.200 of this subchapter) as well as the applicable requirements of 40 CFR part 265, subparts AA through CC.

\* \* \* \* \*

(7) \* \* \*

(i)(A) Facility personnel must successfully complete a program of classroom instruction, online training (e.g., computer-based or electronic), or on-the-job training that teaches them to perform their duties in a way that ensures compliance with this part. The large quantity generator must ensure that this program includes all the elements described in the document required under paragraph (a)(7)(iv)(C) of this section.

\* \* \* \* \*

(8) \* \* \*

(i) Notification for closure of a waste accumulation unit. A large quantity generator must perform one of the following when closing a waste accumulation unit but not undergoing final closure:

(A) Place a notice in the operating record within 30 days after closure of a unit that identifies the location of the waste accumulation unit being closed within the facility; or

\* \* \* \* \*

(iii) \* \* \*

(A) \* \* \*

(4) If the generator demonstrates that any contaminated soils and wastes cannot be practicably removed or decontaminated as required in paragraph (a)(8)(iii)(A)(2) of this section, then the waste accumulation unit is considered to be a landfill and the generator must close the waste accumulation unit and perform post-closure care in accordance with the closure and post-closure care requirements that apply to landfills (§ 265.310 of this subchapter). In addition, for the purposes of closure, post-closure, and financial responsibility, such a waste accumulation unit is then considered to be a landfill, and the generator must meet all of the requirements for landfills specified in 40 CFR part 265, subparts G and H.

\* \* \* \* \*

(b) *Accumulation time limit extension.* A large quantity generator who accumulates hazardous waste for more than 90 days is subject to the requirements of 40 CFR parts 124, 264 through 268, and part 270 of this chapter, and the notification requirements of section 3010 of RCRA for treatment, storage, and disposal facilities, unless it has been granted an extension to the 90-day period. Such extension may be granted by EPA if hazardous wastes must remain on site for longer than 90 days due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(c) *Accumulation of F006.* A large quantity generator who also generates wastewater treatment sludges from electroplating operations that meet the listing description for the EPA hazardous waste number F006, may accumulate F006 waste on site for more than 90 days, but not more than 180 days without being subject to parts 124, 264 through 267, and 270 of this chapter, and the notification requirements of section 3010 of RCRA for treatment, storage, and disposal

facilities, provided that it complies with all of the following additional conditions for exemption:

\* \* \* \* \*

(d) *F006 transported over 200 miles.* A large quantity generator who also generates wastewater treatment sludges from electroplating operations that meet the listing description for the EPA hazardous waste number F006, and who must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more for off-site metals recovery, may accumulate F006 waste on site for more than 90 days, but not more than 270 days without being subject to parts 124, 264 through 267, and 270 of this chapter, and the notification requirements of section 3010 of RCRA for treatment, storage, and disposal facilities, if the large quantity generator complies with all of the conditions for exemption of paragraphs (c)(1) through (4) of this section.

(e) *F006 accumulation time extension.* A large quantity generator accumulating F006 in accordance with paragraphs (c) and (d) of this section who accumulates F006 waste on site for more than 180 days (or for more than 270 days if the generator must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more), or who accumulates more than 20,000 kilograms of F006 waste on site is an operator of a storage facility and is subject to the requirements of 40 CFR parts 124, 264, 265, 267, and 270, and the notification requirements of section 3010 of RCRA for treatment, storage, and disposal facilities, unless the generator has been granted an extension to the 180-day (or 270-day if applicable) period or an exception to the 20,000 kilogram accumulation limit. Such extensions and exceptions may be granted by EPA if F006 waste must remain on site for longer than 180 days (or 270 days if applicable) or if more than 20,000 kilograms of F006 waste must remain on site due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days or an exception to the accumulation limit may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(f) *Consolidation of hazardous waste received from very small quantity generators.* Large quantity generators may accumulate on site hazardous waste received from very small quantity generators under control of the same person (as defined in § 260.10 of this subchapter), without a storage permit or interim status and without complying with the requirements of parts 124, 264

through 268, and 270 of this chapter, and the notification requirements of section 3010 of RCRA for treatment, storage, and disposal facilities, provided that they comply with the following conditions. "Control," for the purposes of this section, means the power to direct the policies of the generator, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator facilities on behalf of a different person shall not be deemed to "control" such generators.

Subpart D [Amended]

29. Section 262.42 is amended by revising paragraphs (a)(1), (a)(2) introductory text, (b) (and the note following (b)) to read as follows:

262.42 Exception reporting.

(a)(1) A large quantity generator who does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the waste was accepted by the initial transporter must contact the transporter and/or the owner or operator of the designated facility to determine the status of the hazardous waste.

(2) A large quantity generator must submit an Exception Report to the EPA Regional Administrator for the Region in which the generator is located if he has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the waste was accepted by the initial transporter. The Exception Report must include:

(b) A small quantity generator of hazardous waste who does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 60 days of the date the waste was accepted by the initial transporter must submit a legible copy of the manifest, with some indication that the generator has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the generator is located.

Note 1 to paragraph (b): The submission to EPA need only be a handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received.

30. Section 262.82 is amended by revising paragraph (e)(2) to read as follows:

262.82 General conditions.

(2) For hand-delivery, the Office of Land and Emergency Management, Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, International Branch (Mail Code 2255T), Environmental Protection Agency, William Jefferson Clinton West Building, Room 1329, 1301 Constitution Ave. NW, Washington, DC 20004.

31. Section 262.200 is amended by revising the definition of "Trained professional" to read as follows:

262.200 Definitions for this subpart.

Trained professional means a person who has completed the applicable RCRA training requirements of 262.17(a)(7) for large quantity generators, or is knowledgeable about normal operations and emergencies in accordance with 262.16(b)(9)(iii) for small quantity generators and for very small quantity generators that opt into subpart K of this part. A trained professional may be an employee of the eligible academic entity or may be a contractor or vendor who meets the requisite training requirements.

32. Section 262.212 is amended by revising paragraph (e)(3) to read as follows:

262.212 Making the hazardous waste determination at an on-site interim status or permitted treatment, storage, or disposal facility.

(3) Count the hazardous waste toward the eligible academic entity's generator status, pursuant to 262.13 in the calendar month that the hazardous waste determination was made, and

33. Section 262.213 is amended by revising paragraph (a)(1) to read as follows:

262.213 Laboratory clean-outs.

(1) If the volume of unwanted material in the laboratory exceeds 55 gallons (or 1 quart of liquid reactive acutely hazardous unwanted material, or 1 kg of solid reactive acutely hazardous unwanted material), the eligible academic entity is not required to remove all unwanted materials from

the laboratory within 10 calendar days of exceeding 55 gallons (or 1 quart of liquid reactive acutely hazardous unwanted material, or 1 kg of solid reactive acutely hazardous unwanted material), as required by 262.208. Instead, the eligible academic entity must remove all unwanted materials from the laboratory within 30 calendar days from the start of the laboratory clean-out; and

34. Section 262.232 is amended by revising the paragraphs (a)(5), (b)(4) introductory text, (b)(4)(ii)(C), and (b)(6)(iv) to read as follows:

262.232 Conditions for a generator managing hazardous waste from an episodic event.

(5) The very small quantity generator must comply with the hazardous waste manifest provisions of subpart B of this part and the recordkeeping provisions for small quantity generators in 262.44 when it sends its episodic event hazardous waste off site to a designated facility, as defined in 260.10 of this subchapter.

(4) Accumulation by small quantity generators. A small quantity generator is prohibited from accumulating hazardous wastes generated from an episodic event on drip pads and in containment buildings. When accumulating hazardous waste generated from an episodic event in containers and tanks, the following conditions apply:

(ii) (C) Use inventory logs, monitoring equipment or other records to identify the date upon which each episodic event begins; and

(6) (iv) A description of how the hazardous waste was managed as well as the name of the RCRA-designated facility (as defined by 260.10 of this subchapter) that received the hazardous waste;

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

35. The authority for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6939g.

■ 36. Section 264.1 is amended by revising paragraph (g)(3) and by removing and reserving paragraph (g)(12).

The revision reads as follows:

§ 264.1 Purpose, scope, and applicability.

\* \* \* \* \*

(g) \* \* \*

(3) A generator accumulating waste on site in compliance with § 262.14, § 262.15, § 262.16, § 262.17, or subpart K or L of part 262 of this subchapter.

\* \* \* \* \*

§ 264.15 [Amended]

■ 37. Section 264.15 is amended by removing paragraph (b)(5).

■ 38. Section 264.72 is amended by revising paragraph (a)(3) to read as follows:

§ 264.72 Manifest discrepancies.

(a) \* \* \*

(3) Container residues, which are residues that exceed the quantity limits for “empty” containers set forth in 40 CFR 261.7(b) and 266.507.

\* \* \* \* \*

■ 39. Section 264.1030 is amended by revising paragraph (b)(3) to read as follows:

§ 264.1030 Applicability.

\* \* \* \* \*

(b) \* \* \*

(3) A unit that is exempt from permitting under the provisions of 40 CFR 262.17 (i.e., a “90-day” tank or container) and is not a recycling unit under the provisions of 40 CFR 261.6.

\* \* \* \* \*

■ 40. Section 264.1050 is amended by revising paragraph (b)(2) to read as follows:

§ 264.1050 Applicability.

\* \* \* \* \*

(b) \* \* \*

(2) A unit (including a hazardous waste recycling unit) that is not exempt from permitting under the provisions of 40 CFR 262.17 (i.e., a hazardous waste recycling unit that is not a “90-day” tank or container) and that is located at a hazardous waste management facility otherwise subject to the permitting requirements of 40 CFR part 270; or

\* \* \* \* \*

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 41. The authority for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, 6937, and 6939g.

§ 265.1 [Amended]

■ 42. Section 265.1 is amended by removing and reserving paragraph (c)(15).

§ 265.71 [Amended]

■ 43. Section 265.71 is amended by removing the undesignated “Comment” paragraph following paragraph (c).

■ 44. Section 265.72 is amended by revising paragraph (a)(3) to read as follows:

§ 265.72 Manifest discrepancies.

(a) \* \* \*

(3) Container residues, which are residues that exceed the quantity limits for “empty” containers set forth in 40 CFR 261.7(b) and 266.507.

\* \* \* \* \*

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

■ 45. The authority for part 266 continues to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

■ 46. Section 266.100 is amended by revising paragraph (c)(3) to read as follows:

§ 266.100 Applicability.

\* \* \* \* \*

(c) \* \* \*

(3) Hazardous wastes that are exempt from regulation under §§ 261.4 and 261.6(a)(3)(iii) and (iv) of this subchapter, and hazardous wastes that are subject to the conditions for exemption for very small quantity generators under § 262.14 of this subchapter; and

\* \* \* \* \*

■ 47. Section 266.108 is amended by redesignating the note following paragraph (c) as note 1 to § 266.108(c) and revising it to read as follows:

§ 266.108 Small quantity on-site burner exemption.

\* \* \* \* \*

(c) \* \* \*

Note 1 to paragraph (c): Hazardous wastes that are subject to the conditions for exemption for very small quantity generators under § 262.14 of this subchapter may be burned in an off-site device under the exemption provided by this section but must

be included in the quantity determination for the exemption.

\* \* \* \* \*

■ 48. Section 266.501 is amended by revising paragraph (d)(2) to read as follows:

§ 266.501 Applicability.

\* \* \* \* \*

(d) \* \* \*

(2) Sections 266.502(a), 266.503, 266.505 through 266.507, and 266.509 with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

\* \* \* \* \*

■ 49. Section 266.502 is amended by revising paragraphs (d)(4), (h) introductory text, (h)(3) and (4), (i)(2)(i)(A) introductory text, and (i)(2)(ii)(A) introductory text to read as follows:

§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

\* \* \* \* \*

(d) \* \* \*

(4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) of this subchapter (i.e., metal-bearing waste codes listed in appendix XI of part 268 of this subchapter, unless one or more criteria in § 268.3(c)(1) through (6) are met), or because it is prohibited from being lab packed due to § 268.42(c) (i.e., waste codes listed in appendix IV of part 268), must be accumulated in separate containers, and labeled with all applicable EPA hazardous waste numbers (i.e., hazardous waste codes).

\* \* \* \* \*

(h) Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this subchapter may accumulate the rejected non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 calendar days provided

the rejected shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the rejected shipment, the healthcare facility must:

\* \* \* \* \*

(3) Within 30 calendar days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Within 90 calendar days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) \* \* \*

(2) \* \* \*

(i) \* \* \*

(A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 calendar days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

\* \* \* \* \*

(ii) \* \* \*

(A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 calendar days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

\* \* \* \* \*

■ 50. Section 266.503 is amended by revising paragraph (b)(1) to read as follows:

**§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.**

\* \* \* \* \*

(b) \* \* \*

(1) Is under the control of the same person (as defined in § 260.10 of this subchapter) as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site (“control,” for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person

as defined in § 260.10 of this subchapter shall not be deemed to “control” such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

\* \* \* \* \*

■ 51. Section 266.504 is amended by revising the section heading and paragraph (b) introductory text to read as follows:

**§ 266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste that are not operating under this subpart.**

\* \* \* \* \*

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off site to another generator, provided:

\* \* \* \* \*

■ 52. Section 266.505 is revised to read as follows:

**§ 266.505 Prohibition on sewerage hazardous waste pharmaceuticals.**

All healthcare facilities—including very small quantity generators operating under § 262.14 of this subchapter in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b).

■ 53. Section 266.506 is amended by revising the section heading and paragraphs (a)(2) and (b)(3)(iii) and (iv) to read as follows:

**§ 266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected by an authorized collector.**

(a) \* \* \*

(2) Household waste pharmaceuticals that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) \* \* \*

(3) \* \* \*

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62, subpart HHH, or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60, subpart Ec, for new hospital, medical and infectious waste incinerators; or

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62, subpart III, or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60, subpart CCCC, for new commercial and industrial solid waste incinerators; or

\* \* \* \* \*

■ 54. Section 266.507 is amended by revising paragraphs (b), (c), and (d) to read as follows:

**§ 266.507 Residues of hazardous waste pharmaceuticals in empty containers.**

\* \* \* \* \*

(b) *Syringes.* A syringe is considered empty and the residues are not regulated as hazardous waste under this subpart provided the contents have been removed by fully depressing the plunger of the syringe. At healthcare facilities operating under this subpart, if a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) *Intravenous (IV) bags.* An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient, or if the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1) of this subchapter. At healthcare facilities operating under this subpart, if an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart.

(d) *Other containers, including delivery devices.* At healthcare facilities operating under this subpart, hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subpart, unless the container held non-acute

hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1) or (2) of this subchapter. This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

■ 55. Section 266.508 is amended by revising paragraphs (a)(1)(iii)(C) and (a)(2)(i) and (ii) to read as follows:

**§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility of evaluated hazardous waste pharmaceuticals from a reverse distributor.**

- (a) \* \* \*
- (1) \* \* \*
- (iii) \* \* \*

(C) Lab packs that will be incinerated in compliance with § 268.42(c) of this subchapter are not required to be marked with EPA hazardous waste numbers (*i.e.*, hazardous waste codes), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification tag, may be used to identify the applicable EPA hazardous waste numbers (*i.e.*, hazardous waste codes).

\* \* \* \* \*

- (2) \* \* \*

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable EPA hazardous waste numbers (*i.e.*, hazardous waste codes) in Item 13 of EPA Form 8700–22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word “PHRM” or “PHARMS” in Item 13 of EPA Form 8700–22. A healthcare facility may also include the applicable EPA hazardous waste numbers (*i.e.*, hazardous waste codes) in Item 13 of EPA Form 8700–22.

\* \* \* \* \*

■ 56. Section 266.510 is amended by revising paragraphs (a)(9)(i)(C), (b)(1) and (2), (c)(2), (c)(4)(vi), (c)(5), (c)(7) introductory text, (c)(7)(iii) and (iv), (c)(9)(ii)(A)(1), (c)(9)(ii)(A)(2) introductory text, (c)(9)(ii)(B)(1), (c)(9)(ii)(B)(2) introductory text, and (c)(9)(ii)(B)(2)(i) to read as follows:

**§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.**

\* \* \* \* \*

- (a) \* \* \*
- (9) \* \* \*
- (i) \* \* \*

(C) The EPA identification number, name, and address of the healthcare

facility (or other entity) that shipped the unauthorized waste, if available;

\* \* \* \* \*

- (b) \* \* \*

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 calendar days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 calendar days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

\* \* \* \* \*

- (c) \* \* \*

(2) *Inspections of on-site accumulation area.* A reverse distributor must inspect its on-site accumulation area at least once every seven calendar days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

\* \* \* \* \*

- (4) \* \* \*

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) of this subchapter (*i.e.*, metal-bearing waste codes listed in appendix XI of part 268 of this subchapter, unless one or more criteria in § 268.3(c)(1) through (6) are met), or because it is prohibited from being lab packed due to § 268.42(c) of this subchapter (*i.e.*, waste codes listed in appendix IV of part 268 of this subchapter), in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) *Hazardous waste numbers.* Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable EPA hazardous waste numbers (*i.e.*, hazardous waste codes), except as provided in § 266.508(a)(1)(iii)(C). A nationally recognized electronic system, such as bar coding or radio frequency identification tag, may be used to identify the applicable EPA hazardous

waste numbers (*i.e.*, hazardous waste codes).

\* \* \* \* \*

- (7) *Procedures for a reverse distributor for managing rejected shipments.* A

reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this subchapter, may accumulate the rejected evaluated hazardous waste pharmaceuticals on site for up to an additional 90 calendar days in the on-site accumulation area provided the rejected shipment is managed in accordance with paragraphs (a) and (c) of this section. Upon receipt of the rejected shipment, the reverse distributor must:

\* \* \* \* \*

(iii) Within 30 calendar days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within 90 calendar days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of § 266.508(a) or (b).

\* \* \* \* \*

- (9) \* \* \*
- (ii) \* \* \*
- (A) \* \* \*

(1) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 calendar days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

\* \* \* \* \*

- (B) \* \* \*

(1) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(2) A reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the alternate

facility within 45 calendar days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The Exception Report must include:

(i) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

\* \* \* \* \*

**PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM**

■ 57. The authority for part 270 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

**§ 270.1 [Amended]**

■ 58. Section 270.1 is amended by removing and reserving paragraph (c)(2)(ix).

**PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS**

■ 59. The authority for part 271 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6926, and 6939g.

■ 60. In § 271.1, table 1 is amended by adding an entry for “February 22, 2019” in chronological order to read as follows:

**§ 271.1 Purpose and scope.**

\* \* \* \* \*

TABLE 1—REGULATIONS IMPLEMENTING THE HAZARDOUS AND SOLID WASTE AMENDMENTS OF 1984

Promulgation date	Title of regulation reference	Federal Register	Effective date
February 22, 2019 ...	Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine: § 266.505.	84 FR 5816 .....	August 21, 2019.

\* \* \* \* \*

■ 61. Section 271.10 is amended by revising paragraph (c) to read as follows:

**§ 271.10 Requirements for generators of hazardous wastes.**

\* \* \* \* \*

(c) The State program must require that generators who accumulate hazardous wastes for short periods of time comply with requirements that are equivalent to the requirements for accumulating hazardous wastes for short periods of time under 40 CFR 262.15, 262.16, or 262.17.

\* \* \* \* \*

**PART 441—DENTAL OFFICE POINT SOURCE CATEGORY**

■ 62. The authority for part 441 continues to read as follows:

**Authority:** 33 U.S.C. 1251, 1311, 1314, 1316, 1317, 1318, 1342, and 1361. 42 U.S.C. 13101–13103.

■ 63. Section 441.50 is amended by revising paragraph (b)(3) to read as follows:

**§ 441.50 Reporting and recordkeeping requirements.**

\* \* \* \* \*

(b) \* \* \*

(3) Documentation of all dates that collected dental amalgam is picked up or shipped for proper disposal in accordance with 40 CFR 262.14(a)(5), and the name of the permitted or licensed treatment, storage or disposal facility receiving the amalgam retaining containers.

\* \* \* \* \*

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