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Hazardous Waste Generator Regulations Compendium

Volume 16: Counting Hazardous Waste and Generator Categories

January 2022

U.S. Environmental Protection Agency
Office of Resource Conservation and Recovery
Materials Recovery and Waste Management Division

Main Index

Volume 16: Counting Hazardous Waste and Generator Categories

This document includes the following sections:

- Resource View – outlines the document types by which resources are organized.
- Resources by Document Category – lists resources for each document category outlined in the *Resource View*.
- CFR View – provides relevant Code of Federal Regulations (CFR) language reformatted for easy reading.

These three main sections are cross-referenced, i.e., each section includes hyperlinks to the other sections. In addition, each section and its accompanying index include a hyperlink to the Main Index that allows the user to easily navigate from one section to another.

Introduction

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About the Compendium

The Hazardous Waste Generator Regulations Compendium serves as a user-friendly reference to assist regulators, industrial facilities generating and managing solid and hazardous wastes, and the general public in locating resources relevant to specific regulatory topics within the federal hazardous waste generator program.

The objective of this document is to consolidate and streamline the various resources on a topic into a user-friendly format, including references to relevant CFR language, Federal Register (FR) notices, documents posted on RCRA Online (i.e., guidance in the form of memoranda issued by EPA, Q&As, and other publications), and other resources, such as Frequent Questions webpages. The Compendium has been divided into multiple volumes that are available here: www.epa.gov/hwgenerators/hazardous-waste-generator-regulations-compendium.

This document does not change any of the existing solid or hazardous waste requirements, nor does it offer an exhaustive list of relevant resources, as new resources may come into being or older ones may be relevant to a specific issue, but not included. Certain available resources, such as superseded RCRA Online documents, have not been referenced. Rather than including or reproducing referenced resources, this document generally provides hyperlinks to individual resources. As an exception, the Compendium does include relevant sections of the most current CFR regulatory language (as of the date on the cover of the Compendium). The included CFR language has been reformatted to make it easier to read, but it is not a substitute for the official CFR itself, or for the requirements in the CFR. The Government Printing Office frequently updates the e-CFR website; where appropriate, hyperlinks to the respective CFR section at the e-CFR website are provided.

Most states are authorized to administer their own RCRA Subtitle C hazardous waste program. Therefore, states may have their own set of regulations that apply in lieu of federal regulations. State regulations must be at least as stringent as the federal standards, but they can be more stringent. Please visit the following website to determine if the state regulatory program is different from the federal program: https://www.epa.gov/hwgenerators/links-hazardous-waste-programs-and-us-state-environmental-agencies, and check with your state agency.

About the Counting Hazardous Waste and Generator Categories Volume

This volume of the Compendium lists resources and CFR language pertaining to Counting Hazardous Waste and Generator Category requirements that are found at 40 CFR 262 Subpart A (262.13). For more information regarding other topics that apply to facilities generating hazardous waste, refer to other volumes of the Compendium and EPA's Hazardous Waste Generators Webpage.

Please note that the Hazardous Waste Generator Improvements rule of 2016 created new sections in Part 262, which contains the regulations pertaining to generators. Accordingly, some citations in the generator requirements in older resources in this Compendium are outdated, including references to § 261.5, § 262.34, and others. Please see the preamble to the final Hazardous Waste Generator Improvements rule for a discussion of the reorganization of the regulations (81 FR

85735–85740, November 28, 2016). For a specific crosswalk of the regulation citation changes, refer to www.epa.gov/hwgenerators/hazardous-waste-generator-regulations-crosswalk.

For more information on these regulations and any other questions or comments concerning this document, please contact EPA's Office of Resource Conservation and Recovery:

Kathy Lett

lett.kathy@epa.gov

Mary Beth Sheridan

sheridan.marybeth@epa.gov

U.S. Environmental Protection Agency

Office of Resource Conservation and Recovery

1200 Pennsylvania Avenue, N.W. (MC: 5304T)

Washington, DC 20460

Resource View

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Counting Hazardous Waste and Generator Categories

Resource Index:

- Resource Type:
  - EPA Memoranda
  - Questions and Answers (Q&As)
  - Federal Register Notices

Resources by Document Category

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Document Category	RCRA Online/ Resource	Resource Title	Document Date	Keyword(s) [1]	Notes
Memoranda	11021	Pesticides Containing a 261.33(e) Compound as a Sole Active Ingredient	09/18/1981	Pesticide; Counting Diluted Product; Acute Hazardous Waste; Farmer Exemption	
	11024	Paint Filter Waste	01/17/1982	Spent Paint Filters; Calculating Weight of Waste; Counting Water Weight from Treatment; Extraction Procedure (EP) Toxicity	Generators may not do thermal treatment without a permit.
	12097	Totally Enclosed Treatment Facility, Regulatory Clarification Of	02/18/1983	Counting Effluent From Totally Enclosed Treatment Facilities; Counting Derived From Waste	A brief discussion of what waste needs to be counted is on the bottom of page 6 of this memo.
	12732	Counting Dry Cleaning Industry Waste Only After Removal from the Process—SQG Rule	09/08/1986	Dry Cleaning Wastes; Closed Loop Reclamation; Reclamation; Reuse; Recycling; Removal from Process; Point of Generation; Spent Solvents; Filter Cartridges; Still Bottoms	

[1] In the November 28, 2016, Generator Improvements Final Rule, EPA made changes to the locations of multiple citations and some terminology. The most noteworthy terminology change renamed Conditionally Exempt Small Quantity Generators (CESQGs) to Very Small Quantity Generators (VSQGs). See EPA's Hazardous Waste Generator Regulations Crosswalk for a full list of the citation changes and their old and new locations.

Document Category	RCRA Online/ Resource	Resource Title	Document Date	Keyword(s) [1]	Notes
	11236	Small Quantity Generator Interpretations	04/15/1987	Still Bottoms; On-site Recycling; Recycling Without Storage; Accumulation Limits; Small Quantity Generator (SQG); Conditionally Exempt Small Quantity Generators (CESQGs)	This memo's use of the term "an otherwise exempt SQG" is a reference to CESQGs, which are now called VSQGs.
	12946	Containers Used to Hold Listed Chemotherapy Drugs	06/16/1987	Residues; Counting Container Weight; Empty Containers; U-Listed Chemotherapy Wastes	The new empty container standards for pharmaceutical vials are in § 266.507(a).
	12990	Aids to Navigation (ATON) Batteries and RCRA Requirements	07/30/1987	Batteries; Point of Generation; Generator Category Determination; Offshore Generation	Hazardous waste batteries can now be managed under the Part 273 universal waste standards, finalized in 1995.
	11308	Clarification of Small Quantity Generator Regulations	12/09/1987	On-Site Recycling; Counting Spent Solvents; Distillation Bottoms; Counting Residues; Small Quantity Generators (SQGs); Conditionally exempt Small Quantity Generators (CESQGs)	The regulations pertaining to on-site disposal and where VSQGs can send their waste are now in § 40 CFR 262.14(a)(5).
	11359	Regulatory Status of Dry Cleaners Who Recycle Spent Cartridge Filters	07/29/1988	On-Site Recycling; Recycling Without Storage; Spent Cartridge Filters; Dry Cleaning Waste	

Document Category	RCRA Online/ Resource	Resource Title	Document Date	Keyword(s) [1]	Notes
	11546	Tank Treatment System of Metal-Rich Rinsewaters	08/01/1990	Counting; On-Site Recycling; Recirculated Rinsewater; Reclamation; Legitimate Recycling; Treatment Sludge; Reclaimed Wastewater	
	11688	Conditionally Exempt Small Quantity Generator Provisions	08/25/1992	Conditionally Exempt Small Quantity Generators (CESQGs); Monthly Generation Amounts; Exceeding CESQG Generation Amounts	See question on pg. 2. Partially superseded: very small quantity generators can now send hazardous waste to 11 types of locations.
	11803	Requirements for Disposal of Discharged M-44 Cyanide Capsules That Originally Contained a Sodium Cyanide Pesticide	12/23/1993	Acute Hazardous Waste; Conditionally Exempt Small Quantity Generator (CESQG) Monthly Generation Amounts; Counting Container Weight; Containers; Empty Containers; Residues; Triple Rinsing	Partially superseded: very small quantity generators can now send hazardous waste to 11 types of locations. See the paragraph containing footnote 2 of this memo, and the preceding paragraph for discussion of the CESQG (now VSQG) regulations.
	11812	Determining Generator Status by Including Wastes Collected at Satellite Accumulation Areas	02/10/1994	Satellite Accumulation Areas (SAA); Exemptions from Counting; Counting SAA Waste	

Document Category	RCRA Online/ Resource	Resource Title	Document Date	Keyword(s) [1]	Notes
	14030	Management of Hazardous Waste Generated in Quantities Less Than 100 Kg and Those That Are Thrown Away with Ordinary Garbage	05/01/1996	Conditionally Exempt Small Quantity Generator (CESQG); Conditions for Exemption; Waste Management Programs; State and Local Requirements; Municipal Landfills	
	14032	Clarification of Requirements Involving the Counting of Wood Preserving Waters for Biennial Reporting	06/04/1996	Counting Recycled Waste; Exclusions; Wood Preserving; Recycling F-Listed Wastes; Storage Prior to Reuse; Spent Materials	
	14333	Generator On-Site Recycling of Hazardous Waste	03/02/1999	Counting Recycled Waste; On-Site Recycling; Recycling Without Storage; Silver-Bearing Solution; Conveyance of Recycled Waste	
	14619	Generator Quantity Determinations for F006 Listed Sludge	08/16/2002	Wastewater Treatment Sludge; F006; Electroplating; Hazardous Waste Recycling; Counting Wet Weight	
	14703	Frequently Asked Questions about Satellite Accumulation Areas	03/17/2004	Counting Satellite Accumulation Area (SAA) Waste	See question 12 of this document.

Document Category	RCRA Online/ Resource	Resource Title	Document Date	Keyword(s) [1]	Notes
	14827	Containers that Once Held P-Listed Pharmaceuticals	11/04/2011	Acute Hazardous Waste Generation Limit; Alternative Cleaning Method; Bag Beating; Concentration-Based Listing; Counting P-Listed Wastes; Counting Residues; Empty Containers; Hazardous Waste Pharmaceuticals; Warfarin, Counting P-Listed Rinsate	Over-the-counter nicotine replacement therapies (patches, gums, and lozenges) are no longer included in the P075 listing and containers that held P-listed hazardous waste pharmaceuticals may not be rinsed (see the 2019 Hazardous Waste Pharmaceuticals Rule).
	14842	RCRA Biennial Report Requirements for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Response Actions	12/14/2011	Biennial Report Applicability; CERCLA Response Actions; Counting CERCLA Waste; Large Quantity Generator (LQG); On-site Management; Off-site Management; Notification	
	14875	One Quart Limit for P-Listed Waste in Satellite Accumulation Areas	02/17/2016	Satellite Accumulation Area (SAA) Limit; Counting Residues; Acute Hazardous Wastes; Empty Containers; Hazardous Waste Pharmaceuticals; One Quart Accumulation Limit	This memo is partially superseded. Fully dispensed containers that are the subject of this memo would likely be considered RCRA-empty under the 2019 Hazardous Waste Pharmaceuticals Rule. See § 266.507.

Document Category	RCRA Online/ Resource	Resource Title	Document Date	Keyword(s) [1]	Notes
Q&As	12151	Weight of Container for Quantity Determinations	11/01/1983	Generator Category Determination; Counting Container Weight; CERCLA Taxes; Biennial Report	
	12241	Generator Quantity Determination for Mixtures	06/01/1984	Generator Category Determination; Spills; Clean-up Waste	
	12265	Small Quantity Generator (SQG) Accumulation	07/01/1984	Accumulation Limits; 1,000 Kilogram Accumulation Limit; Newly Generated Waste	This Q & A was written before the federal generator category we know now as SQG (i.e., generating 100–1,000 kg per month) existed. Therefore, the terms in this memo are outdated. The question would now refer to a VSQG temporarily operating as an SQG.
	12602	Small Quantity Generator (SQG) Accumulation	04/01/1986	Small Quantity Generator (SQG) Accumulation Limit; 6,000 Kilogram Accumulation Limit; Accumulating SQG and Large Quantity Generator (LQG) Waste On-Site	This memo refers to 51 FR 10146.
	12634	Small Quantity Generators/ Parts Washers/ Waste Counting	05/01/1986	Spent Mineral Spirits Solvents; Parts Washers; Point of Generation	Per RCRA Online Number 12790, these parts washers are not manufacturing process units.

Document Category	RCRA Online/ Resource	Resource Title	Document Date	Keyword(s) [1]	Notes
	12699	SQG Quantity Determinations	08/01/1986	On-Site Recycling; Reclamation; Monthly Counting; Reuse of Spent Material; Counting Spent Material; Small Quantity Generator (SQG)	
	12850	Small Quantity Generator Determination	02/01/1987	Spent Solvents; Still Bottoms; Counting Wastes Burned for Energy Recovery; Reclamation Exclusion;	
	12865	Generation and Recycling	03/01/1987	Spent Solvents; On-Site Recycling; Distillation; Treatment; Counting Still Bottoms; Satellite Accumulation Areas (SAAs)	
	13204	Elementary Neutralization Units	07/01/1988	Elemental Neutralization; Corrosive Wastes; Exemptions	
	13312	Generator Satellite Accumulation/ Counting Requirements	08/01/1989	Satellite Accumulation Areas (SAAs); Counting Hazardous Waste in SAAs	
	13746	Spent Lead-Acid Batteries and Counting Requirements	06/01/1995	Counting Spent Lead Acid Batteries (SLABs); Reclamation	
	14700	Amount of Waste Generated Per Month Determines Generator Status	01/01/2004	Generator Category Determination; CESQGs/ VSQGs; Accumulation Limits; Monthly Generation Limits	

Document Category	RCRA Online/ Resource	Resource Title	Document Date	Keyword(s) [1]	Notes
Federal Register Notices	45 FR 76620	Standards for Generators of Hazardous Waste	11/19/1980	Acute Hazardous Waste; Non-Acute Hazardous Waste; Mixtures	See pg. 76622.
	45 FR 86968	Standards for Generators of Hazardous Waste, and Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities and Interim Status Standards for Owners and Operators of Treatment, Storage, and Disposal Facilities	12/31/1980	Hazardous Waste Management Facilities; Residues; Generator Standards	See pg. 86969.
	51 FR 10146	Standards for Generators of Hazardous Waste	03/24/1986	Small Quantity Generators; Generator Status/Category Determination	This Federal Register establishes the category for monthly generation of 100–1000 kg of hazardous waste per month, now known as small quantity generator. See specifically pp. 10150–10154 for a discussion of the counting of hazardous waste to determine generator category.

Document Category	RCRA Online/ Resource	Resource Title	Document Date	Keyword(s) [1]	Notes
	60 FR 72912	Managing Hazardous Waste at Academic Laboratories Rule	12/01/2008	Generator Status/Generator Category Determination	See pp. 72940–72941.
	81 FR 85732	Hazardous Waste Generator Improvements Rule	11/28/2016	Generator Status/Generator Category Determination; LQGs; SQGs; VSQGs	See pp. 85740–85742 for discussion about the three generator categories. See pp. 85742–85743 for discussion about generators that generate acute and non-acute hazardous waste.
	84 FR 5816	Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine	02/22/2019	Healthcare Facilities; Empty Container Standards; Generator Category Determination; Counting Hazardous Waste Pharmaceuticals	See Section IX for the discussion about applicability. Healthcare facilities that are subject to 40 CFR part 266 subpart P are not required to count their hazardous waste pharmaceuticals when determining generator category. See Section XV for the discussion about the empty container regulations for container that held hazardous waste pharmaceuticals.

CFR View Index

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CFR Location	Title/Topic
262.13	Generator Category Determination
262.213	Counting Academic Lab Clean-out Waste
266.501	40 CFR part 266 subpart P Applicability

NOTE: The CFR language may have been excerpted, reformatted and appended with subheadings and explanations/terms in brackets.

§ 262.13 Generator Category Determination

A generator must determine its generator category. A generator's category is based on the amount of hazardous waste generated each month and may change from month to month. This section sets forth procedures to determine whether a generator is a very small quantity generator, a small quantity generator, or a large quantity generator for a particular month.

(a) **Generators of either acute hazardous waste or non-acute hazardous waste.** A generator who either generates acute hazardous waste or non-acute hazardous waste in a calendar month shall determine its generator category for that month by doing the following:

(1) Counting the total amount of hazardous waste generated in the calendar month;

(2) subtracting from the total any amounts of waste exempt from counting as described in paragraphs (c) and (d) of this section; and

(3) Determining the resulting generator category for the hazardous waste generated using Table 1 of this section.

(b) **Generators of both acute and non-acute hazardous wastes**. A generator who generates both acute hazardous waste and non-acute hazardous waste in the same calendar month shall determine its generator category for that month by doing the following:

(1) Counting separately the total amount of acute hazardous waste and the total amount of non-acute hazardous waste generated in the calendar month;

(2) Subtracting from each total any amounts of waste exempt from counting as described in paragraphs (c) and (d) of this section;

(3) Determining separately the resulting generator categories for the quantities of acute and non-acute hazardous waste generated using Table 1 of this section; and

(4) Comparing the resulting generator categories from paragraph (b)(3) of this section and applying the more stringent generator category to the accumulation and management of both non-acute hazardous waste and acute hazardous waste generated for that month.

Table 1 – Generator Categories Based on Quantity of Waste Generated in a Calendar Month

Quantity of Acute Hazardous Waste Generated in a Calendar Month	Quantity of Non-Acute Hazardous Waste Generated in a Calendar Month	Quantity of Residues from a Cleanup of Acute Hazardous Waste Generated in a Calendar Month	Generator Category
> 1 kg	Any amount	Any amount	Large quantity generator
Any amount	≥ 1,000 kg	Any amount	Large quantity generator
Any amount	Any amount	> 100 kg	Large quantity generator
≤ 1 kg	> 100 kg and < 1,000 kg	≤ 100 kg	Small quantity generator
≤ 1 kg	≤ 100 kg	≤ 100 kg	Very small quantity generator

(c) When making the monthly quantity-based determinations required by this part, the generator must include all hazardous waste that it generates, except hazardous waste that:

(1) Is exempt from regulation under 40 CFR 261.4(c) through (f), 261.6(a)(3), 261.7(a)(1), or 261.8;

(2) Is managed immediately upon generation only in on-site elementary neutralization units, wastewater treatment units, or totally enclosed treatment facilities as defined in 40 CFR 260.10;

(3) Is recycled, without prior storage or accumulation, only in an on-site process subject to regulation under 40 CFR 261.6(c)(2);

(4) Is used oil managed under the requirements of 40 CFR 261.6(a)(4) and 40 CFR part 279;

(5) Is spent lead-acid batteries managed under the requirements of 40 CFR part 266 subpart G;

(6) Is universal waste managed under 40 CFR 261.9 and 40 CFR part 273;

(7) Is a hazardous waste that is an unused commercial chemical product (listed in 40 CFR part 261 subpart D or exhibiting one or more characteristics in 40 CFR part 261 subpart C) that is generated solely as a result of a laboratory clean-out conducted at an eligible academic entity pursuant to § 262.213. For purposes of this provision, the term eligible academic entity shall have the meaning as defined in § 262.200; or

(8) Is managed as part of an episodic event in compliance with the conditions of subpart L of this part.

(9) Is a hazardous waste pharmaceutical, as defined in § 266.500, that is subject to or managed in accordance with 40 CFR part 266 subpart P or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under § 266.506.

(d) In determining the quantity of hazardous waste generated in a calendar month, a generator need not include:

(1) Hazardous waste when it is removed from on-site accumulation, so long as the hazardous waste was previously counted once;

(2) Hazardous waste generated by on-site treatment (including reclamation) of the generator's hazardous waste, so long as the hazardous waste that is treated was previously counted once; and

(3) Hazardous waste spent materials that are generated, reclaimed, and subsequently reused on site, so long as such spent materials have been previously counted once.

(e) Based on the generator category as determined under this section, the generator must meet the applicable independent requirements listed in § 262.10. A generator's category also determines which of the provisions of §§ 262.14, 262.15, 262.16 or 262.17 must be met to obtain an exemption from the storage facility permit, interim status, and operating requirements when accumulating hazardous waste.

(f) Mixing hazardous wastes with solid wastes –

(1) Very small quantity generator wastes.

(i) Hazardous wastes generated by a very small quantity generator may be mixed with solid wastes. Very small quantity generators may mix a portion or all of [their] hazardous waste with solid waste and remain subject to § 262.14 even though the resultant mixture exceeds the quantity limits identified in the definition of very small quantity generator at § 260.10 of this chapter, unless the mixture exhibits one or more of the characteristics of hazardous waste identified in part 261 subpart C of this chapter.

(ii) If the resulting mixture exhibits a characteristic of hazardous waste, this resultant mixture is a newly generated hazardous waste. The very small quantity generator must count both the resultant mixture amount [and] the other hazardous waste generated in the calendar month to determine whether the total quantity exceeds the very small quantity generator calendar month quantity limits identified in the definition of generator categories found in § 260.10 of this chapter. If so, to remain exempt from the permitting, interim status, and operating standards, the very small quantity generator must meet the conditions for exemption applicable to either a small quantity generator or a large quantity generator. The very small quantity generator must also comply with the applicable

independent requirements for either a small quantity generator or a large quantity generator.

(iii) If a very small quantity generator's wastes are mixed with used oil, the mixture is subject to 40 CFR part 279. Any material produced from such a mixture by processing, blending, or other treatment is also regulated under 40 CFR part 279.

(2) Small quantity generator and large quantity generator wastes.

(i) Hazardous wastes generated by a small quantity generator or large quantity generator may be mixed with solid waste. These mixtures are subject to the following: the mixture rule in §§ 261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i); the prohibition of dilution rule at § 268.3(a); the land disposal restriction requirements of § 268.40 if a characteristic hazardous waste is mixed with a solid waste so that it no longer exhibits the hazardous characteristic; and the hazardous waste determination requirement at § 262.11.

(ii) If the resulting mixture is found to be a hazardous waste, this resultant mixture is a newly generated hazardous waste. A small quantity generator must count both the resultant mixture amount [and] the other hazardous waste generated in the calendar month to determine whether the total quantity exceeds the small quantity generator calendar monthly quantity limits identified in the definition of generator categories found in § 260.10 of this chapter. If so, to remain exempt from the permitting, interim status, and operating standards, the small quantity generator must meet the conditions for exemption applicable to a large quantity generator. The small quantity generator must also comply with the applicable independent requirements for a large quantity generator.

§ 262.213 Lab Clean-outs

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(a) One time per 12 month period for each laboratory, an eligible academic entity may opt to conduct a laboratory clean-out that is subject to all the applicable requirements of this subpart, except that:

[…]

(2) For the purposes of on-site accumulation, an eligible academic entity is not required to count a hazardous waste that is an unused commercial chemical product (listed in 40 CFR part 261, subpart D or exhibiting one or more characteristics in 40 CFR part 261, subpart C) generated solely during the laboratory clean-out toward its hazardous waste generator category, pursuant to § 262.13. An unwanted material that is generated prior to the beginning of the laboratory clean-out and is still in the laboratory at the time the laboratory clean-out commences must be counted toward hazardous

waste generator category, pursuant to § 262.13, if it is determined to be hazardous waste; and

(3) For the purposes of off-site management, an eligible academic entity must count all its hazardous waste, regardless of whether the hazardous waste was counted toward generator category under paragraph (a)(2) of this section, and if it generates more than 1 kg/month of acute hazardous waste or more than 100 kg/month of non-acute hazardous waste (i.e., the very small quantity generator limits as defined in § 260.10 of this chapter), the hazardous waste is subject to all applicable hazardous waste regulations when it is transported off site; and […]

§ 266.501 Applicability [Healthcare Facilities]

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(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to this subpart, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with § 266.501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with § 262.14 and the optional provisions of § 266.504.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in paragraph (a) of this section, a healthcare facility is subject to the following in lieu of parts 262 through 265:

(1) Sections 266.502 and 266.505 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

(2) Sections 262.502(a), 266.503, 266.505 through 266.507, and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to §§ 266.505 through 266.510 of this subpart in lieu of parts 262 through 265 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (*e.g.,* pharmaceutical manufacturers and reverse logistics centers) are not subject to this subpart. Other generators are subject to 40 CFR part 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to 40 CFR parts 260 through 273, except as specified:

(1) Pharmaceuticals that are not solid waste, as defined by § 261.2, because they are legitimately used/reused (*e.g.,* lawfully donated for their intended purpose) or reclaimed.

(2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by § 261.2, because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

(3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(5) Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.

(6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. This subpart does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

(7) Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement

Administration), provided the authorized collector complies with the conditional exemption in §§ 266.506(a)(2) and 266.506(b).