

WAC 173-303-555 Special requirements for management of dangerous waste pharmaceuticals. (1) **Definitions.** The following definitions apply to this section:

"Dangerous waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in WAC 173-303-016, and that exhibits a dangerous waste characteristic, criteria, or is listed as dangerous waste under WAC 173-303-070. A pharmaceutical is not a solid waste, as defined in 173-303-016, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in WAC 173-303-016, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

"Evaluated dangerous waste pharmaceutical" means a prescription dangerous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with subsection (12)(c) of this section and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

"Health care facility" means any person that is lawfully authorized to:

- Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

- Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistic centers.

"Household waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in WAC 173-303-016, but is excluded from being a dangerous waste under WAC 173-303-071 (3)(c).

"Long-term care facility" means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

"Noncreditable dangerous waste pharmaceutical" means a prescription dangerous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription dangerous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes, but is not limited to, investigational drugs, free samples of pharmaceuticals received by health care facilities, and residue of

pharmaceuticals remaining in empty containers, pharmaceutical contaminated personal protection equipment, floor sweepings, and clean-up materials from the spills of pharmaceuticals.

"Nondangerous waste pharmaceutical" means a solid waste pharmaceutical that does not meet the definition of "dangerous waste pharmaceutical" in this section.

"Nonpharmaceutical dangerous waste" means a solid waste that is a dangerous waste as defined by this chapter, but is not a pharmaceutical as defined in this section.

"Pharmaceutical" means any drug or dietary supplement for use by humans or animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., prefilled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drugs and Cosmetic Act; prescription drugs, as defined by 21 C.F.R. 203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceutical remaining in nonempty containers; personal protection equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

"Potentially creditable dangerous waste pharmaceutical" means a prescription dangerous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is:

(a) In original manufacturer packaging (except pharmaceuticals that were subject to a recall); and

(b) Undispensed; and

(c) Unexpired or less than one year past expiration date. This term does not include evaluated dangerous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

"Reverse distributor" means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable dangerous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

"State-only dangerous waste pharmaceutical" means a dangerous waste pharmaceutical that only exhibits state criteria under WAC 173-303-100.

(2) **Applicability.**

(a) A health care facility that is a small quantity generator when counting all of its dangerous waste per month, including both its dangerous waste pharmaceuticals and its nonpharmaceutical dangerous waste, remains subject to WAC 173-303-170 (2)(a)(i) and 173-303-171 and is not subject to this section except for subsections (6) and (8) of this section and the optional provisions of subsections (5) and/or (7) of this section.

(b) A health care facility that is a small quantity generator when counting all of its dangerous waste per month, including both its dangerous waste pharmaceuticals and its nonpharmaceutical dangerous waste, has the option of complying with (d) of this subsection for its dangerous waste pharmaceuticals in lieu of complying with WAC 173-303-171 and with the optional provisions of subsection (5) of this section.

(c) A health care facility or reverse distributor remains subject to all applicable dangerous waste regulations with respect to the management of its nonpharmaceutical dangerous waste.

(d) With the exception of health care facilities identified in (a) of this subsection, a health care facility is subject to the following with respect to its dangerous waste pharmaceuticals in lieu of this chapter:

(i) Subsections (3) and (6) through (10) of this section with respect to the management of:

(A) Noncreditable dangerous waste pharmaceuticals; and

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

(ii) Subsections (3)(a), (4), (6) through (8), and (11) of this section with respect to the management of potentially creditable dangerous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to subsections (6) through (15) of this section with respect to the management of dangerous waste pharmaceuticals.

(f) Dangerous waste pharmaceuticals generated or managed by entities other than health care facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to this section. These generators are subject to this chapter for the generation and accumulation of dangerous wastes, including dangerous waste pharmaceuticals.

(g) The following are not subject to this chapter except as specified:

(i) Pharmaceuticals that are not solid waste, as defined by WAC 173-303-016, because they are legitimately used/reused (e.g., lawfully donated for their intended purpose) or reclaimed.

(ii) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined in WAC 173-303-016, because they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

(iii) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 C.F.R. Part 7, Subpart C. This subpart does apply to the management of the recalled dangerous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(iv) 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 C.F.R. Part 1115. This subpart does apply to the management of the recalled dangerous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(v) 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.

(vi) 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 C.F.R. 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 dangerous waste.

(vii) 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 subsection (7)(a)(ii) and (b) of this section.

(3) Standards for health care facilities managing noncreditable dangerous waste pharmaceuticals.

(a) Notification and withdrawal from this section for health care facilities managing dangerous waste pharmaceuticals.

(i) Notification. A health care facility must notify the department, using the Washington State Dangerous Waste Site Identification Form, that it is a health care facility operating under this section. A health care facility is not required to fill out Box 11 (description of hazardous/dangerous waste) on the Washington State Dangerous Waste Site Identification Form with respect to its dangerous waste pharmaceuticals. A health care facility must submit a separate notification (Washington State Dangerous Waste Site Identification Form) for each site or EPA/state identification number.

(A) A health care facility that already has an EPA/state identification number must notify the department, using the Washington State Dangerous Waste Site Identification Form, that it is a health care facility within sixty days of becoming subject to this section.

(B) A health care facility that does not have an EPA/state identification number must obtain one by notifying the department, using the Washington State Dangerous Waste Site Identification Form, that it is a health care facility within sixty days of becoming subject to this section.

(C) A health care facility must keep a copy of its notification on file for as long as the health care facility is subject to this section.

(ii) Withdrawal. A health care facility that operated under this section, but is no longer subject to this section, because it is a small quantity generator under WAC 173-303-171, and elects to withdraw from this section, must notify the department using the Washington State Dangerous Waste Site Identification Form, that it is no longer operating under this section. A health care facility is not required to fill out Box 11 (description of hazardous/dangerous waste) on the Washington State Dangerous Waste Site Identification Form with respect to its dangerous waste pharmaceuticals. A health care facility must submit a separate notification (Washington State Dangerous Waste Site Identification Form) for each site or EPA/state identification number.

(A) A health care facility must submit the Washington State Dangerous Waste Site Identification Form notifying that it is withdrawing from this section before it begins operating under WAC 173-303-171.

(B) A health care facility must keep a copy of its withdrawal on file for five years from the date of signature on the notification of its withdrawal.

(b) Training of personnel managing noncreditable dangerous waste pharmaceuticals at health care facilities. A health care facility must ensure that all personnel that manage noncreditable dangerous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) Dangerous waste determination for noncreditable pharmaceuticals. A health care facility that generates a solid waste that is a

noncreditable pharmaceutical must determine whether that pharmaceutical is a dangerous waste pharmaceutical in order to determine whether the waste is subject to this section. A health care facility may choose to manage its nondangerous waste pharmaceuticals under this section.

(d) Standards for containers used to accumulate noncreditable dangerous waste pharmaceuticals at health care facilities.

(i) A health care facility must place noncreditable dangerous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(ii) A health care facility that manages ignitable or reactive noncreditable dangerous waste pharmaceuticals, or that mixes or commingles incompatible noncreditable dangerous waste pharmaceuticals must manage the container so that it does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container;

(E) Through other like means threaten human health or the environment.

(iii) A health care facility must keep containers of noncreditable dangerous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(iv) A health care facility may accumulate noncreditable dangerous waste pharmaceuticals and noncreditable nondangerous waste pharmaceuticals in the same container, except that noncreditable dangerous waste pharmaceuticals prohibited from being combusted because of 40 C.F.R. Part 268.3(c) must be accumulated in separate containers and labeled with all applicable dangerous waste numbers (i.e., dangerous waste codes).

(e) Labeling containers used to accumulate noncreditable dangerous waste pharmaceuticals at health care facilities. A health care facility must label or clearly mark each container of noncreditable dangerous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals" or "Dangerous Waste Pharmaceuticals."

(f) Maximum accumulation time for noncreditable dangerous waste pharmaceutical at health care facilities.

(i) A health care facility may accumulate noncreditable dangerous waste pharmaceuticals on-site for one year or less without a permit or having interim status.

(ii) A health care facility that accumulates noncreditable dangerous waste pharmaceuticals on-site must demonstrate the length of time that the noncreditable dangerous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A health care facility may make this demonstration by any of the following methods:

(A) Marking or labeling the container of noncreditable dangerous waste pharmaceuticals with the date that the noncreditable dangerous waste pharmaceuticals first became a waste;

(B) Maintaining an inventory system that identifies the date the noncreditable dangerous waste pharmaceuticals first became a waste;

(C) Placing the noncreditable dangerous waste pharmaceuticals in a specific area and identifying the earliest date that any of the noncreditable dangerous waste pharmaceuticals became waste.

(g) Land disposal restrictions for noncreditable dangerous waste pharmaceuticals. The noncreditable dangerous waste pharmaceuticals generated by a health care facility are subject to the land disposal restrictions of 40 C.F.R. Part 268. A health care facility that generates noncreditable dangerous waste pharmaceuticals must comply with the land disposal restrictions of 40 C.F.R. Part 268.7(a) (as adopted by WAC 173-303-140 (2)(c) and(d)), except that it is not required to identify the dangerous waste numbers (i.e., dangerous waste codes) on the land disposal restrictions notification.

(h) Procedures for health care facilities for managing rejected shipments of noncreditable dangerous waste pharmaceuticals. A health care facility that sends a shipment of noncreditable dangerous 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 provision of WAC 173-303-370(5) may accumulate the returned noncreditable dangerous waste pharmaceuticals on-site for up to an additional ninety days provided the rejected or returned shipment is managed in accordance with (d) and (e) of this subsection. Upon receipt of the returned shipment, the health care facility must:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 on the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within thirty days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the health care facility; and

(iv) Within ninety days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standard of subsection (9)(a) through (c) of this section.

(i) Annual reporting for health care facilities for noncreditable dangerous waste pharmaceuticals. Health care facilities are not subject to annual reporting requirements under WAC 173-303-220(1), with respect to noncreditable dangerous waste pharmaceuticals managed under this section.

(j) Exception reporting by health care facilities for a missing copy of the manifest in regard to noncreditable dangerous waste pharmaceuticals for shipments to a designated facility. If a health care facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within sixty days of the date the noncreditable dangerous waste pharmaceuticals were accepted by the initial transporter, the health care facility must submit:

(i) A legible copy of the original manifest, indicating that the health care facility has not received confirmation of delivery, to the department's regional office in which the health care facility is located; and

(ii) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the noncreditable dangerous waste pharmaceutical and the results of those efforts.

(k) Exception reporting by health care facilities for shipments rejected by the designated facility and shipped to an alternative facility in regard to noncreditable dangerous waste pharmaceuticals. If a health care facility does not receive a copy of the manifest for a rejected shipment of the noncreditable dangerous 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 sixty days of the date the noncreditable dangerous waste pharmaceutical was accepted by the initial transporter forwarding the shipment of noncreditable dangerous waste pharmaceuticals from the designated facility to the alternate facility, the health care facility must submit:

(i) A legible copy of the original manifest, indicating that the health care facility has not received confirmation of delivery, to the department's regional office in which the health care facility is located; and

(ii) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the noncreditable dangerous waste pharmaceuticals and the results of those efforts.

(l) Additional reports by health care facilities in regard to noncreditable dangerous waste pharmaceuticals. The department may require the health care facilities to furnish additional reports concerning the quantities, types, and disposition of noncreditable dangerous waste pharmaceuticals.

(m) Recordkeeping by health care facilities for noncreditable dangerous waste pharmaceuticals. A health care facility must comply with WAC 173-303-210 and keep all records for five years in regards to noncreditable dangerous waste pharmaceuticals. The periods of retention referred to in this paragraph are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the department. All records must be readily available upon request by an authorized state inspector.

(n) Response to spill of noncreditable dangerous waste pharmaceuticals at health care facilities. A health care facility must immediately contain all spills of noncreditable dangerous waste pharmaceuticals and manage the spill clean-up material as noncreditable dangerous waste pharmaceuticals in accordance with the requirements of this section.

(o) Accepting noncreditable dangerous waste pharmaceuticals from an off-site health care facility that is a small quantity generator. A health care facility may accept noncreditable dangerous waste pharmaceuticals from an off-site health care facility that is a small quantity generator under WAC 173-303-171, without a permit or without having interim status, provided the receiving health care facility:

(i) Is under the control of the same person (as defined in WAC 173-303-040) as the small quantity generator health care facility that is sending the noncreditable dangerous waste pharmaceuticals off-site or has a contractual or other documented business relationship whereby the receiving health care facility supplies pharmaceuticals to the small quantity generator health care facility;

(ii) Is operating under this section for the management of its noncreditable dangerous waste pharmaceuticals;

(iii) Manages the noncreditable dangerous waste pharmaceuticals that it receives from off-site in compliance with this section; and

(iv) Keeps records of the noncreditable dangerous waste pharmaceuticals shipments it receives from off-site for five years from the date the shipment is received.

(4) Standards for health care facilities managing potentially creditable dangerous waste pharmaceuticals.

(a) Dangerous waste determinations for potentially creditable pharmaceuticals. A health care facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether that potentially creditable pharmaceutical is a potentially creditable dangerous waste pharmaceutical. A health care facility may choose to manage its potentially creditable nondangerous waste pharmaceuticals as potentially creditable dangerous waste pharmaceutical under this section.

(b) Accepting potentially creditable dangerous waste pharmaceuticals from an off-site health care facility that is a small quantity generator. A health care facility may accept potentially creditable dangerous waste pharmaceuticals from an off-site health care facility that is a small quantity generator under WAC 173-303-171, without a permit or without having interim status, provided the receiving health care facility:

(i) Is under the control of the same person (as defined in WAC 173-303-040) as the small quantity generator health care facility that is sending the potentially creditable dangerous waste pharmaceuticals off-site or has a contractual or other documented business relationship whereby the receiving health care facility supplies pharmaceuticals to the small quantity generator health care facility;

(ii) Is operating under this section for the management of its potentially creditable dangerous waste pharmaceuticals;

(iii) Manages the potentially creditable dangerous waste pharmaceuticals that it receives from off-site in compliance with this section; and

(iv) Keeps records of the potentially creditable dangerous waste pharmaceuticals shipments it receives from off-site for five years from the date the shipment is received.

(c) Prohibition. Health care facilities are prohibited from sending dangerous waste other than potentially creditable dangerous waste pharmaceuticals to a reverse distributor.

(d) Annual reporting by health care facilities. Health care facilities are not subject to the annual reporting requirements of WAC 173-303-220(1), with respect to potentially creditable dangerous waste pharmaceuticals managed under this section.

(e) Recordkeeping by health care facilities.

(i) A health care facility that initiates a shipment of potentially creditable dangerous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable dangerous waste pharmaceuticals for five years from date of shipment:

(A) The confirmation of delivery; and

(B) The shipping papers prepared in accordance with 49 C.F.R. Part 172, Subpart C, if applicable.

(ii) The periods of retention referred to in this subsection are extended automatically during the course of any unresolved enforcement actions regarding the regulated activity, or as requested by the department.

(iii) All records must be readily available upon request by an authorized state inspector.

(f) Response to spill of potentially creditable dangerous waste pharmaceuticals at health care facilities. A health care facility must immediately contain all spills of potentially creditable dangerous waste pharmaceuticals and manage the spill clean-up material as non-creditable dangerous waste pharmaceuticals in accordance with the requirements of this section.

(5) Health care facilities that are small quantity generators for both dangerous waste pharmaceuticals and nonpharmaceutical dangerous waste.

(a) Potentially creditable dangerous waste pharmaceuticals. A health care facility that is a small quantity generator for both dangerous waste pharmaceuticals and nonpharmaceutical dangerous waste may send its potentially creditable dangerous waste pharmaceuticals to a reverse distributor.

(b) Off-site collection of dangerous waste pharmaceuticals generated by a health care facility that is a small quantity generator. A health care facility that is a small quantity generator for both dangerous waste pharmaceuticals and nonpharmaceutical dangerous waste may send its dangerous waste pharmaceuticals to another health care facility, provided:

(i) The receiving health care facility meets the conditions in subsections (3)(o) and (4)(b) of this section, as applicable; or

(ii) The small quantity generator health care facility meets the conditions in WAC 173-303-171 (1)(e)(ix) and the receiving large quantity generator meets the conditions in WAC 173-303-200(15).

(c) Long-term care facilities that are small quantity generators. A long-term care facility that is a small quantity generator for both dangerous waste pharmaceuticals and nonpharmaceutical dangerous waste may dispose of its dangerous waste pharmaceuticals (excluding contaminated personal protection equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(6) Prohibition of sewerage of dangerous waste pharmaceuticals. All health care facilities, including small quantity generators operating under WAC 173-303-171 in lieu of this section, and reverse distributors are prohibited from discharging dangerous waste pharmaceuticals to a sewer system that passes through to a publicly owned treatment works or to an on-site disposal system. Health care facilities and reverse distributors remain subject to the prohibitions in 40 C.F.R. 403.5(b) of the Clean Water Act.

(7) Conditional exemptions for dangerous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

(a) Conditional exemptions. Provided the conditions of (b) of this subsection are met, the following are exempt from this chapter except for WAC 173-303-050, 173-303-145, and 173-303-960:

(i) Dangerous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 C.F.R. Part 1308; and

(ii) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commin-

gles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) Conditions for exemption. The dangerous waste pharmaceuticals must be:

(i) Managed in compliance with the sewer prohibition of subsection (6) of this section; and

(ii) Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(iii) Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their nonretrievable standard of destruction or combusted at one of the following:

(A) A permitted large municipal waste combustor, subject to 40 C.F.R. Part 62, Subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 C.F.R. Part 60, Subpart Eb for new large municipal waste combustors; or

(B) A permitted small municipal waste combustor, subject to 40 C.F.R. Part 62, Subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 C.F.R. Part 60, Subparts AAAA for new small municipal waste combustors; or

(C) A permitted hospital, medical and infectious waste incinerator, subject to 40 C.F.R. Part 62, Subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 C.F.R. Part 60, Subpart Ec for new hospital, medical and infectious waste incinerators; or

(D) A permitted commercial and industrial solid waste incinerator, subject to 40 C.F.R. Part 62, Subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 C.F.R. Part 60, Subpart CCCC for new commercial and industrial solid waste incinerators.

(E) A permitted dangerous (hazardous) waste combustor subject to 40 C.F.R. Part 63, Subpart EEE.

(8) Residues of dangerous waste pharmaceuticals in empty containers.

(a) Stock, dispensing and unit-dose containers. A stock bottle, dispensing bottle, vial, or ampule (not to exceed one liter or ten thousand pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as dangerous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) Syringes. A syringe is considered empty and the residues are not regulated as dangerous waste under this section provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining dangerous waste pharmaceuticals into a container that is managed and disposed of as a noncreditable dangerous waste pharmaceutical under this section and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) Intravenous (IV) bags.

(i) An IV bag is considered empty and the residues are not regulated as dangerous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient.

(ii) If an IV bag is not empty, the IV bag must be placed with its remaining dangerous waste pharmaceuticals into a container that is

managed and disposed of as a noncreditable dangerous waste pharmaceutical under this section, unless the IV bag held nonacute dangerous waste pharmaceutical and is empty as defined in WAC 173-303-160 (2) (a).

(iii) If an IV bag is not empty and held an acute hazardous waste or a toxic EHW waste, the IV bag must be placed with its remaining dangerous waste pharmaceuticals into a container that is managed and disposed of as a noncreditable dangerous waste pharmaceutical under this section, unless the IV bag is empty as defined by WAC 173-303-160 (2) (b).

(d) Other containers, including delivery devices.

(i) Nonacute dangerous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as noncreditable dangerous waste pharmaceuticals under this section, unless the container that held nonacute dangerous waste pharmaceuticals is empty as defined in WAC 173-303-160 (2) (a). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

(ii) Acute hazardous waste pharmaceuticals and toxic EHW dangerous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed and disposed as noncreditable dangerous waste pharmaceuticals under this section, unless the container that held acute dangerous waste pharmaceuticals or toxic EHW dangerous waste pharmaceuticals is empty as defined in WAC 173-303-160 (2) (b). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

(9) Shipping noncreditable dangerous waste pharmaceuticals from a health care facility or evaluated dangerous waste pharmaceuticals from a reverse distributor.

(a) A health care facility must ship noncreditable dangerous waste pharmaceuticals and a reverse distributor must ship evaluated dangerous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage or disposal facility).

(i) The following pretransport requirements, before transporting or offering for transport off-site must be complied with:

(A) Packaging. Package the waste in accordance with the applicable U.S. Department of Transportation regulations on hazardous materials under 49 C.F.R. Parts 173, 178, and 180.

(B) Labeling. Label each package in accordance with the applicable U.S. Department of Transportation regulations on hazardous materials under 49 C.F.R. Part 172, Subpart E.

(C) Marking.

(I) Mark each package of dangerous waste pharmaceuticals in accordance with the applicable U.S. Department of Transportation regulations on hazardous materials under 49 C.F.R. Part 172, Subpart D.

(II) Mark each container of one hundred nineteen gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 C.F.R. 172.304:

HAZARDOUS WASTE - Federal Law Prohibits Improper Disposal.

If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Health care Facility's or Reverse distributor's
Name and Address

Health care Facility's or Reverse distributor's EPA

Identification Number _____
Manifest Tracking Number _____

(III) Labpacks. Labpacks that will be incinerated in compliance with 40 C.F.R. 268.42(c) are not required to be marked with dangerous waste number(s), except for D004, D005, D006, D007, D008, D010 and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the dangerous waste numbers.

(D) Placarding. Placard or offer the initial transporter the appropriate placards according to U.S. Department of Transportation regulations for hazardous materials under 49 C.F.R. Part 172, Subpart F.

(ii) Manifesting. The health care facility and reverse distributor must comply with the manifest requirements of WAC 173-303-180, except that:

(A) A health care facility shipping noncreditable dangerous waste pharmaceuticals is not required to list all applicable dangerous waste numbers (i.e., dangerous waste codes) in Item 13 EPA Form 8700-22.

(B) A health care facility shipping noncreditable dangerous waste pharmaceuticals must write the word "PHRM" in Item 13 on EPA Form 8700-22.

(b) Exporting noncreditable dangerous waste pharmaceuticals or evaluated dangerous waste pharmaceuticals. A health care facility or reverse distributor that exports noncreditable dangerous waste pharmaceuticals or evaluated dangerous waste pharmaceuticals is subject to WAC 173-303-230(1).

(c) Importing noncreditable dangerous waste pharmaceuticals or evaluated dangerous waste pharmaceuticals. Any person that imports noncreditable dangerous waste pharmaceuticals or evaluated dangerous waste pharmaceuticals is subject to WAC 173-303-230(2) and 40 C.F.R. Part 262, Subpart H. A health care facility or reverse distributor may not accept imported noncreditable dangerous waste pharmaceuticals or evaluated dangerous waste pharmaceuticals unless they have a permit or interim status that allow them to accept dangerous waste from off-site.

(10) Disposal of state-only dangerous waste pharmaceuticals.

(a) As an alternative to off-site disposal at a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) state-only dangerous waste pharmaceuticals may be disposed at one of the following types of units provided (b) through (d) of this subsection are complied with:

(i) A combustor or incinerator listed in subsection (7)(b)(iii)(A) through (E) of this section; or

(ii) As an option for law enforcement agencies, incinerate in a controlled combustion unit with a heat input rate greater than 250 million British thermal units/hour, and a combustion zone temperature greater than 1500 degrees Fahrenheit.

(b) The state-only dangerous waste pharmaceuticals are managed in compliance with all applicable requirements of this section.

(c) If a uniform hazardous waste manifest is not being used, a document must accompany the state-only noncreditable dangerous waste pharmaceuticals during transit which:

(i) Identifies the type and amount of state-only noncreditable dangerous waste pharmaceuticals;

(ii) The date of shipment;

(iii) The identity of the health care facility or reverse distributor; and

(iv) The facility to which it is directed.

(d) The health care facility or reverse distributor has on file a letter or copy of a letter signed by the local regulatory or permitting authority that the receiving incinerator or combustion facility may accept the waste.

(11) Shipping potentially creditable dangerous waste pharmaceuticals from a health care facility or reverse distributor to a reverse distributor.

(a) Shipping potentially creditable dangerous waste pharmaceuticals. A health care facility or a reverse distributor who transports or offers for transport potentially creditable dangerous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 C.F.R. Parts 171 through 180 for any potentially creditable dangerous waste pharmaceutical that meets the definition of hazardous materials in 49 C.F.R. 171.8.

(b) Delivery confirmation. Upon receipt of each shipment of potentially creditable dangerous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the health care facility or reverse distributor that initiated the shipment that the shipment of potentially creditable dangerous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) Procedures for when delivery confirmation is not received within thirty-five calendar days. If a health care facility or reverse distributor initiates a shipment of potentially creditable dangerous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within thirty-five calendar days from the date that the shipment of potentially creditable dangerous waste pharmaceuticals was sent, the health care facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.e., the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable dangerous waste pharmaceuticals.

(d) Exporting potentially creditable dangerous waste pharmaceuticals. A health care facility or reverse distributor that sends potentially creditable dangerous waste pharmaceuticals to a foreign destination must comply with WAC 173-303-230(1) in addition to (a) through (c) of this subsection.

(e) Importing potentially creditable dangerous waste pharmaceuticals. Any person that imports potentially creditable dangerous waste pharmaceuticals into the United States is subject to (a) through (c) of this subsection in lieu of WAC 173-303-230(2). Immediately after potentially creditable dangerous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this section.

(12) Standards for reverse distributors managing potentially creditable dangerous waste pharmaceuticals and evaluated dangerous waste pharmaceuticals. A reverse distributor may accept potentially creditable dangerous waste pharmaceuticals from off-site (not evaluated dangerous waste pharmaceuticals from off-site) and accumulate potentially creditable dangerous waste pharmaceuticals and evaluated dangerous waste pharmaceuticals on-site without a dangerous waste permit or interim status, provided that it complies with the requirements of subsections (13) through (15) of this section and with the following conditions.

(a) Notification.

(i) A reverse distributor that already has an EPA/state identification number must notify the department, using the Washington State Dangerous Waste Site Identification Form, that it is a reverse distributor (as defined in subsection (1) of this section) operating under this section, within sixty days of the effective date of this section, or within sixty days of becoming subject to this section.

(ii) A reverse distributor that does not have an EPA/state identification number must obtain one by notifying the department, using the Washington State Dangerous Waste Site Identification Form, that it is a reverse distributor (as defined in subsection (1) of this section) operating under this section, within sixty days of the effective date of this section, or within sixty days of becoming subject to this section.

(b) Inventory by the reverse distributor. A reverse distributor must maintain a current inventory of all the potentially creditable dangerous waste pharmaceuticals and evaluated dangerous waste pharmaceuticals that are accumulated on-site.

(i) A reverse distributor must inventory each potentially creditable dangerous waste pharmaceutical within thirty calendar days of each waste arriving at the reverse distributor.

(ii) The inventory must include the identity (e.g., name or national drug code) and quantity of each potentially creditable dangerous waste pharmaceutical and evaluated dangerous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of this paragraph because of other regulatory requirements, such as state board of pharmacy regulations, the facility is not required to provide a separate inventory pursuant to this subsection.

(c) Evaluation by a reverse distributor that is not a manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate potentially creditable dangerous waste pharmaceutical within thirty calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment storage or disposal facility.

(i) A potentially creditable dangerous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable dangerous waste pharmaceutical" and must be managed in accordance with the requirements of subsection (13) of this section in addition to the requirements of this subsection.

(ii) A potentially creditable dangerous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated dangerous waste pharmaceutical" and must be managed in accordance with the requirements of subsection (14) of this section in addition to the requirements of this subsection.

(d) Evaluation by a reverse distributor that is a manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable dangerous waste pharmaceutical to verify manufacturer credit within thirty calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated dangerous waste pharmaceutical in accordance with the requirements of subsection (14) of this section in addition to the requirements of this subsection.

(e) Maximum accumulation time for dangerous waste pharmaceuticals at a reverse distributor.

(i) A reverse distributor may accumulate potentially creditable dangerous waste pharmaceuticals and evaluated dangerous waste pharmaceuticals on-site for one hundred eighty calendar days or less. The one hundred eighty days start after the potentially creditable dangerous waste pharmaceuticals have been evaluated and applies to all dangerous waste pharmaceuticals accumulated on-site, regardless of whether they are destined for another reverse distributor (i.e., potentially creditable dangerous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.e., evaluated dangerous waste pharmaceuticals).

(ii) Aging pharmaceuticals. Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to one hundred eighty days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with (a) through (j) of this subsection and the container labeling and management standards in subsection (14)(d)(i) through (vi) of this section.

(f) Security at the reverse distributor facility. A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable dangerous waste pharmaceuticals and evaluated dangerous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(A) A twenty-four-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration or state board of pharmacy regulations, the facility is not required to provide separate security measures pursuant to this subsection.

(g) Contingency plan and emergency procedures at a reverse distributor. A reverse distributor that accepts potentially creditable dangerous waste pharmaceuticals from off-site must prepare a contingency plan and comply with other requirements of WAC 172-303-201.

(h) Closure of a reverse distributor. When closing an area where a reverse distributor accumulates potentially creditable dangerous waste pharmaceuticals or evaluated dangerous waste pharmaceuticals, the reverse distributor must comply with WAC 173-303-200 (12)(a) through (c).

(i) Reporting by a reverse distributor.

(i) Unauthorized waste report. A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off-site that it is not authorized to receive (e.g., nonpharmaceutical dangerous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the department's regional office it is located in within forty-five calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the health care facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor and contain the following information:

(A) The EPA/state identification number, name and address of the reverse distributor;

(B) The date the reverse distributor received the unauthorized waste;

(C) The EPA/state identification number, name and address of the health care facility that shipped the unauthorized waste, if available;

(D) A description and the quantity of each unauthorized waste the reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) Additional reports. The department may require reverse distributors to furnish additional reports and documents of potentially creditable dangerous waste pharmaceuticals and evaluated dangerous waste pharmaceuticals.

(j) Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this subsection are extended automatically during the course of any unresolved enforcement actions regarding the regulated activity, or as requested by the department.

(i) A copy of its notification on file for as long as the facility is subject to this section;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable dangerous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least five years from the date the shipment arrives at the reverse distributor;

(iii) A copy of its current inventory for as long as the facility is subject to this section.

(13) Additional standards for reverse distributors managing potentially creditable dangerous waste pharmaceuticals destined for another reverse distributor. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of subsection (12) of this section, for the management of potentially creditable dangerous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(a) A reverse distributor that receives potentially creditable dangerous waste pharmaceuticals from a health care facility must send those potentially creditable dangerous waste pharmaceuticals to another reverse distributor within one hundred eighty days after the potentially creditable dangerous waste pharmaceuticals have been evaluated or follow subsection (14) of this section for evaluated dangerous waste pharmaceuticals.

(b) A reverse distributor that receives potentially creditable dangerous waste pharmaceuticals from another reverse distributor must send those potentially creditable dangerous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within one hundred eighty days after the potentially creditable dangerous waste pharmaceuticals have been evaluated or follow subsection (14) of this section for evaluated dangerous waste pharmaceuticals.

(c) A reverse distributor must ship potentially creditable dangerous waste pharmaceuticals destined for another reverse distributor in accordance with subsection (11) of this section.

(d) Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable dangerous waste pharmaceuticals that it initiates to another reverse distributor, for at least five years from the date of shipment. The periods of retention referred to in this subsection are extended automatically during the course of any unresolved, enforcement actions regarding the regulated activity, or as requested by the department.

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 C.F.R. Part 172, Subpart C, if applicable.

(14) Additional standards for reverse distributors managing evaluated dangerous waste pharmaceuticals. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of subsection (12) of this section, for the management of evaluated dangerous waste pharmaceuticals:

(a) Accumulation area at the reverse distributor. A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated dangerous waste pharmaceuticals.

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

(c) Personnel training at a reverse distributor. Personnel at a reverse distributor that handle evaluated dangerous waste pharmaceuticals are subject to the training requirements of WAC 173-303-200(9).

(d) Labeling and management of containers at on-site accumulation areas. A reverse distributor accumulating evaluated dangerous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, "hazardous waste pharmaceuticals" or "dangerous waste pharmaceuticals";

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated dangerous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated dangerous waste pharmaceuticals. If the liquid or gel evaluated dangerous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated dangerous waste pharmaceuticals, or any container of commingled incompatible evaluated dangerous waste pharmaceuticals so that the container does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gas in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of dangerous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated dangerous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of 40 C.F.R. 268.3(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated dangerous waste pharmaceuticals at the reverse distributor.

(e) Dangerous waste numbers. Prior to shipping evaluated dangerous waste pharmaceuticals off-site, all containers must be marked with the applicable dangerous waste numbers (i.e., dangerous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the dangerous waste number(s).

(f) Shipments. A reverse distributor must ship evaluated dangerous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility with the applicable shipping standards in subsection (9)(a) or (b) of this section.

(g) Procedures for a reverse distributor for managing rejected shipments. A reverse distributor that sends a shipment of evaluated dangerous 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 provision of WAC 173-303-370(5), may accumulate the evaluated dangerous waste pharmaceuticals on-site for up to an additional ninety days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with subsection (12) of this section and the requirements of this subsection. Upon receipt of the returned shipment, the reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

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

(iv) Within ninety days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated dangerous waste pharmaceuticals in accordance with the applicable shipping standards of subsection (9)(a) or (b) of this section.

(h) Land disposal restrictions. Evaluated dangerous waste pharmaceuticals are subject to the land disposal restrictions of 40 C.F.R. Part 268. A reverse distributor that accepts potentially creditable dangerous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with 40 C.F.R. Part 268.7(a) requirements, as adopted by WAC 173-303-140 (2)(c) and (d).

(i) Annual reporting by a reverse distributor for evaluated dangerous waste pharmaceuticals. A reverse distributor that ships evaluated dangerous waste pharmaceuticals off-site must prepare and submit an annual report to the department, according to the instructions on the Dangerous Waste Annual Report form, no later than March 1st for the preceding calendar year.

(j) Exception reporting by a reverse distributor for a missing copy of the manifest.

(i) For shipments from a reverse distributor to a designated facility.

(A) 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 thirty-five days of the date the evaluated dangerous 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 dangerous waste pharmaceuticals.

(B) A reverse distributor must submit an exception report to the department's regional office 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 forty-five days of the date the evaluated dangerous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

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

(II) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated dangerous waste pharmaceutical and the results of those efforts.

(ii) For shipments rejected by the designated facility and shipped to an alternate facility.

(A) 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 thirty-five days of the date the evaluated dangerous 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 dangerous waste. The thirty-five-day time frame begins the date the evaluated dangerous waste pharmaceuticals are accepted by the transporter forwarding the dangerous waste shipment from the designated facility to the alternate facility.

(B) A reverse distributor must submit an exception report to the department's regional office 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 forty-five days of the date the evaluated dangerous waste pharmaceutical were accepted by the initial transporter. The forty-five-day time frame begins the date the evaluated dangerous waste pharmaceuticals are accepted by the transporter forwarding the dangerous waste shipment from the designated facility to the alternate facility. The exception report must include:

(I) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(II) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated dangerous waste pharmaceutical and the results of those efforts.

(k) Recordkeeping by a reverse distributor for evaluated dangerous waste pharmaceuticals.

(i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, as required by (b) of this subsection. This log must be retained as a record for at least five years from the date of the inspection.

(ii) A reverse distributor must keep a copy of each manifest signed in accordance with WAC 173-303-180 (3) (a) for five years or un-

til it receives a signed copy from the designated facility that received the evaluated dangerous waste pharmaceutical. This signed copy must be retained as a record for at least five years from the date the evaluated dangerous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor must keep a copy of each annual report for at least five years from the due date of the report.

(iv) A reverse distributor must keep a copy of each exception report for at least five years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with WAC 173-303-200 (9)(b).

(vi) All records must be readily available upon request by an inspector. The periods of retention referred to in this subsection are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as required by the department.

(15) **When a reverse distributor must have a permit.** A reverse distributor is an operator of a dangerous waste treatment, storage, or disposal facility and is subject to the requirements of WAC 173-303-600 and the permit requirements of WAC 173-303-800 if the reverse distributor:

(i) Does not meet the conditions of subsections (12) through (15) of this section;

(ii) Accepts manifested dangerous waste from off-site; or

(iii) Treats or disposes of dangerous waste pharmaceuticals on-site.

[Statutory Authority: Chapter 70.105, 70.105D RCW and Subtitle C of RCRA. WSR 20-20-045 (Order 19-07), § 173-303-555, filed 9/30/20, effective 10/31/20.]