

CHECKLIST ROADMAP

Use this table to make sure you have included all required checklists. Unused checklists can be discarded or struck-through.

CHECKLIST	INCLUDED?
APPENDIX 2-1. LAND DISPOSAL RESTRICTIONS	
APPENDIX 2-2. EPISODIC GENERATION	
A. VERY SMALL QUANTITY GENERATOR (VSQG) REQUIREMENTS	
B. SMALL QUANTITY GENERATOR (SQG) REQUIREMENTS	
APPENDIX 2-3. RCRA AIR EMISSIONS	
A. PROCESS VENTS (SUBPART AA)	
B. EQUIPMENT LEAKS (SUBPART BB)	
C. TANKS, SURFACE IMPOUNDMENTS, AND CONTAINERS (SUBPART CC)	
APPENDIX 2-4. WASTES RECEIVED FROM VERY SMALL QUANTITY GENERATORS	
APPENDIX 2-5. USED OIL	
A. TRANSPORTERS AND TRANSFER CENTERS (SUBPART E)	
B. PROCESSORS AND RE-REFINERS (SUBPART F)	
C. BURNERS WHO BURN OFF-SPECIFICATION USED OIL FOR ENERGY RECOVERY (SUBPART G)	
D. USED OIL FUEL MARKETERS (SUBPART H)	
APPENDIX 2-6. UNIVERSAL WASTE	
A. LARGE QUANTITY HANDLER	
B. TRANSPORTERS (SUBPART D)	
C. DESTINATION FACILITIES (SUBPART E)	
D. IMPORT (SUBPART F)	
APPENDIX 2-7. HAZARDOUS WASTE PHARMACEUTICALS	
A. HAZARDOUS WASTE PHARMACEUTICALS (HWP)	
B. PROHIBITIONS	
C. HEALTHCARE FACILITIES (HCF)	
1. VSQG HCF (266.504)	
2. HCF MANAGING NON-CREDITABLE HWP (266.502)	
3. HCF MANAGING POTENTIALLY CREDITABLE HWP (266.503)	
D. HWP COLLECTED IN A TAKE BACK PROGRAM THAT ARE DEA CONTROLLED SUBSTANCES AND HOUSEHOLD WASTE PHARMACEUTICALS (266.506)	
E. SHIPPING	
1. SHIPPING NON-CREDITABLE HWP FROM AN HCF OR EVALUATED HWP FROM A RD (266.508)	
2. SHIPPING POTENTIALLY CREDITABLE HWP FROM AN HCF OR A RD TO A RD (266.509)	
F. RD MANAGING POTENTIALLY CREDITABLE HWP AND EVALUATED HWP AT RD (266.510)	

APPENDIX 2-7 HAZARDOUS WASTE PHARMACEUTICALS

OVERVIEW: Hazardous Waste Pharmaceuticals (HWP) must be managed under 266 Subpart P by all Healthcare Facilities (HCF) that generate above VSQG amounts of hazardous waste and by all Reverse Distributors (RD). VSQG are subject to 262.14 and 266 Subpart P only for sewer prohibition (266.505), empty containers (266.507), and optional provisions (266.504), although the VSQG can opt in and choose to comply with all Subpart P’s provisions.

Due to the nature of these rules being both waste- and sector-specific, prior to completing Appendix 2-7, identify all HW streams (including HWP, non-creditable HWP, potentially creditable HWP, and evaluated HWP) and know what sector the facility fits in.

A. HAZARDOUS WASTE PHARMACEUTICALS (HWP)

Complete **Appendix 1-4** to describe all HW streams including HWP, non-creditable HWP, potentially creditable HWP, and evaluated HWP.

B. PROHIBITIONS

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
1.		Does not sewer any HWP – 266.505	

√ – in compliance X – not in compliance NA – not applicable

HWP Activities:

<input type="checkbox"/> Healthcare Facilities (HCF) that generate below VSQG amounts of all hazardous waste (although can opt in and choose to comply with all Subpart P’s provisions)	Complete C1 Section
<input type="checkbox"/> Healthcare Facilities (HCF) that generate above VSQG amounts of all hazardous waste	
<input type="checkbox"/> Non-creditable HWP	Complete C2 and E1 Section
<input type="checkbox"/> Potentially creditable HWP	Complete C3 and E2 Section
<input type="checkbox"/> Evaluated HWP (NOTE: Normally an HCF would not have any evaluated HWP, but if they did, then they would have to meet the RD requirements)	Complete E1, E2, and F Section
<input type="checkbox"/> Healthcare Facilities (HCF) that are DEA collector registrants & also for collectors of household pharmaceuticals (i.e., takebacks) (Become subject to Subpart P when decision is made to discard)	Complete D Section
<input type="checkbox"/> Reverse Distributors (RD)	Complete E1, E2, and F Section

C. HEALTHCARE FACILITIES (HCF)

C.1 VSQG HCF (266.504)

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
1.		Complies with 262.14 – <i>Complete Checklist Appendix 1-6, Section A</i>	
2.		Optional Provisions of 266.504	
a)		The VSQG HCF sends its potentially creditable HWP to a RD - 266.504(a)	
b)		The VSQG HCF sends its non-creditable and potentially creditable HWP off-site to another HCF that meets 266.502(l) AND 266.503(b), as applicable (i.e., the VSQG HCF sends its non-creditable and potentially creditable HWP off-site to another facility that is under the same control as the VSQG or has a business relationship whereby the HCF supplies pharmaceuticals to the VSQG – 266.504(b)(1)	
c)		The VSQG HCF sends its HWP to an LQG operating under Part 262 and meets the conditions for off-site consolidation (§ 262.10) [i.e., VSQG meet 262.14(a)(5)(viii) and the LQG meet 262.17(f)]. – 266.504(b)(2)	
d)		The VSQG HCF is a Long-term Care Facility that disposes of its HWP (excluding PPE or cleanup materials) in an on-site collection receptacle that is registered and complies with DEA controlled substances regulations (DEA collection receptacles can only be used for controlled substances that are from the ultimate user) – 266.504(c)	
e)		The VSQG HCF is a Long-term Care Facility with greater than 20 beds that operates as a VSQG per 262.14 and can demonstrate that it generates HW quantities within the VSQG limits of 260.10 – 266.504(d)	

√ – in compliance X – not in compliance NA – not applicable

C.2 HCF Managing **Non-creditable HWP** (266.502)

#	v/X/NA	REGULATORY REQUIREMENTS	COMMENTS
1.		Notification/Withdrawal	
a)		If already has an EPA ID number, and if <u>not</u> required to submit a BR for other HW (i.e., they are an SQG), submitted a one-time notification that it is an HCF operating under 266 Subpart P using Site ID Form 8700-12 within 60 days of rule's effective date (10/20/19 for non-authorized states) or within 60 days of becoming subject to the rule - 266.502(a)(1)(i)	
b)		If already has an EPA ID number, and if required to submit a BR for other HW (i.e., they are an LQG for at least 1 month in reporting cycle), submitted a one-time notification that it is an HCF operating under 266 Subpart P on their normal biennial reporting cycle (3/1/2020 Biennial Report for non-authorized states) - 266.502(a)(1)(i)	
c)		If do <u>not</u> already have an EPA ID number, and if <u>not</u> required to submit a BR for other HW (i.e., an SQG), submitted a one-time notification that it is an HCF operating under 266 Subpart P using Site ID Form 8700-12 within 60 days of rule's effective date (10/20/19 for non-authorized states) or within 60 days of becoming subject to the rule - 266.502(a)(1)(ii)	
d)		If do <u>not</u> already have an EPA ID number, and if required to submit a BR for other HW (i.e., they are an LQG for at least 1 month in reporting cycle), submitted a one-time notification that it is an HCF operating under 266 Subpart P on their normal biennial reporting cycle (3/1/2020 Biennial Report for non-authorized states) - 266.502(a)(1)(ii)	
e)		Maintains copy of notification on file as long as facility is subject to 266 Subpart P. - 266.502(a)(1)(iii)	
f)		If no longer operating under 266 Subpart P because it is a VSQG operating under 262.14, submitted a notification that it is withdrawing using Site ID Form 8700-12 before it begins operating under 262.14. – 266.502(a)(2)(i)	
g)		Keeps a copy of the withdrawal on file for 3 years of date of signature on form. - 266.502(a)(2)(ii)	
2.		Training	
		Ensures that all personnel that manage non-creditable HWP are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies – 266.502(b)	
3.		Non-creditable HWP Determination	
		Determines whether a non-creditable waste pharmaceutical is a non-creditable HWP (may choose to manage the non-hazardous non-creditable waste pharmaceuticals as non-creditable HWP) – 266.502(c)	

#	v/X/NA	REGULATORY REQUIREMENTS	COMMENTS
4.		Non-creditable HWP Containers	
a)		Non-creditable HWP containers are structurally sound, good condition, and compatible with contents – 266.502(d)(1)	
b)		Containers of ignitable or reactive non-creditable HWP or mixed/co-mingled incompatible non-creditable HWP are managed so that it does not have the potential to: (i) generate heat, pressure, fire, explosion or violent reaction; (ii) produce uncontrolled toxic mists, fumes, dust or gases in sufficient quantity to threaten human health; (iii) produce uncontrolled flammable fumes/gases to pose a risk of fire/explosion; (iv) damage structural integrity of container; or (v) threaten human health or the environment through other like means – 266.502(d)(2)(i) – (v)	
c)		Non-creditable HWP containers remain closed and secured in a manner that prevents unauthorized access to its contents – 266.502(d)(3)	
d)		Non-creditable HWP containers of co-mingled HWP and non-HWP do not contain HWP that are prohibited from being combusted due to the dilution prohibition (268.3(c)) – 266.502(d)(4)	
e)		Non-creditable HWP that are prohibited from being combusted due to the dilution prohibition (268.3(c)) are accumulated in separate containers and labeled with all applicable HW codes – 266.502(d)(4)	
f)		Each non-creditable HWP container is clearly marked or labeled with the words “Hazardous Waste Pharmaceuticals” – 266.502(e)	
5.		Accumulation Time Limits	
a)		Non-creditable HWP are accumulated on-site less than 1 year without a permit – 266.502(f)(1)	
b)		Able to demonstrate the length of time that the non-creditable HWP been on-site from the date it first becomes a waste – 266.502(f)(2)	
6.		LDR Requirements	
		Meet LDR Part 268 requirements, except for the 268.7(a) requirement (i.e., do not need) to identify the HW codes on the LDR notification – 266.502(g)	
7.		Returned Rejected Shipments from a Designated Facility	
a)		The rejected shipment is accumulated for up to an additional 90 days – 266.502(h)	
b)		The rejected shipment is managed in accordance with 266.502(d) [container standards] and 266.502(e) [container labeling] – 266.502(h)	

#	v/X/NA	REGULATORY REQUIREMENTS	COMMENTS
c)		The HCF meets the returned manifest requirements of 266.502(h)(1) – (3) to include: (1) sign either Item 18c of the original manifest or Item 20 of the new manifest; (2) provide the transporter a copy of the manifest; and (3) within 30 days send a copy of the manifest to the designated facility that returned the manifest. - 266.502(h)(1) – (3)	
d)		The HCF within 90 days of receipt, transports the returned shipment in accordance with 266.508(a) - 266.502(h)(4)	
8.	Exception Reporting for Missing Manifests		
a)		The HCF completes an Exception Report if the HCF does not receive a signed copy of the manifest from the designated facility within 60 days of initial transport acceptance – 266.502(i)(2)(i)	
b)		If a rejected shipment is shipped to an alternate facility by the designated facility, the HCF completes an Exception Report if the HCF does not receive a signed copy of the manifest from the alternate designated facility within 60 days of initial transport forwarding shipment – 266.502(i)(2)(ii)	
9.	Recordkeeping		
a)		HCF maintains signed manifests for 3 years and make readily available upon request by an inspector– 266.502(j)(1) and (5)	
b)		Exception reports maintained for 3 years and made readily available upon request by an inspector - 266.502(j)(2) and (5)	
c)		HW determination support documentation (test results, waste analyses, other) consistent with 262.11(f) maintained for 3 years and made readily available upon request by an inspector (unless the HCF manages all of their non-creditable non-HWP as non-creditable HWP) – 266.502(j)(3) and (5)	
10	Non-creditable HWP Spills		
		HCF immediately contains all non-creditable HWP spills and manage the cleanup material as non-creditable HWP – 266.502(k)	
11	HCF Receiving VSQG HWP without a Permit		
a)		The receiving HCF is under the same control as the VSQG or has a business relationship whereby the HCF supplies pharmaceuticals to the VSQG – 266.502(l)(1)	
b)		The receiving HCF is managing its non-creditable HWP under 266 Subpart P – 266.502(l)(2)	
c)		The receiving HCF is managing the non-creditable HWP received from off-site under 266 Subpart P – 266.502(l)(3)	
d)		The receiving HCF keeps records of the non-creditable HWP received from off-site for 3 years – 266.502(l)(4)	

v – in compliance X – not in compliance NA – not applicable

C.3 HCF Managing **Potentially Creditable HWP** (266.503)

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
1. Potentially Creditable HWP Determination			
		Determines whether a potentially creditable waste pharmaceutical is a potentially creditable HWP (may choose to manage the potentially creditable non-HWP as potentially creditable HWP) – 266.503(a)	
2. HCF Receiving Potentially Creditable HWP from a VSQG without a Permit			
a)		The receiving HCF is under the same control as the VSQG or has a business relationship whereby the HCF supplies pharmaceuticals to the VSQG – 266.503(b)(1)	
b)		The receiving HCF is managing its potentially creditable HWP under 266 Subpart P – 266.503(b)(2)	
c)		The receiving HCF is managing the potentially creditable HWP received from off-site under 266 Subpart P – 266.503(b)(3)	
d)		The receiving HCF keeps records of the potentially creditable HWP received from off-site for 3 years – 266.503(b)(4)	
3. HCF Does not send HW to a RD			
		Does not send HW, other than potentially creditable HWP, to a Reverse Distributor – 266.503(c)	
4. HCF Sending Potentially Creditable HWP to a RD			
a)		The HCF maintains the confirmation of delivery for each shipment for 3 years and make readily available to the inspector upon request – 266.503(e)(1)(i) and (3)	
b)		The HCF maintains the DOT shipping papers according to 49 CFR Part 172, if applicable for each shipment for 3 years and make readily available to the inspector upon request– 266.503(e)(1)(ii) and (3)	
5. Potentially Creditable HWP Spills			
		The HCF immediately contains all potentially creditable HWP spills and manage the cleanup material as non-creditable HWP – 266.503(f)	

√ - in compliance X – not in compliance NA – not applicable

D. HWP COLLECTED IN A TAKE BACK PROGRAM THAT ARE DEA CONTROLLED SUBSTANCES AND HOUSEHOLD WASTE PHARMACEUTICALS (266.506)

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
1.		DEA controlled substances and Household Waste Pharmaceuticals collected in a take-back are exempt if:	
a)		The collected HWP are not sewerred according to 266.505 – 266.506(b)(1);	
b)		The HWP are managed in compliance with DEA regulations for controlled substances – 266.506(b)(2); AND	
c)		The HWP are destroyed by (1) a DEA publicly written non-retrievable standard; or combusted at a (duly) permitted: (1) large municipal waste combustor subject to 40 CFR 62 subpart FFF (existing) or 40 CFR 60 subpart Eb (new); (2) small municipal waste combustor subject to 40 CFR 62 subpart JJJ (existing) or 40 CFR 60 subpart AAAA (new); (3) hospital, medical and infectious waste incinerator subject to 40 CFR 62 subpart HHH (existing) or 40 CFR 60 subpart Ec (new); (4) commercial and industrial solid waste incinerator subject to 40 CFR 62 subpart III (existing) or 40 CFR 60 subpart CCCC (new); or (5) combusted at a permitted HW combustor subject to 40 CFR Part 63 Subpart EEE. – 266.506(b)(3)	

√ - in compliance X – not in compliance NA – not applicable

E. SHIPPING

*E.1 Shipping **Non-creditable HWP** from an HCF or Evaluated HWP from a RD (266.508)*

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
1.		Shipping Non-creditable HWP from a HCF or Evaluated HWP from a RD	
a)		HCF ships non-creditable HWP to a TSDF – 266.508(a)	
b)		RD ships evaluated HWP to a TSDF – 266.508(a)	
c)		Both non-creditable and/or evaluated HWP are packaged in accordance with applicable DOT hazardous materials (49 CFR 173, 178, and 180) – 266.508(a)(1)(i)	
d)		Both non-creditable and/or evaluated HWP are labeled in accordance with applicable DOT hazardous materials (49 CFR 172 subpart E) – 266.508(a)(1)(ii)	
e)		Both non-creditable and/or evaluated HWP are marked in accordance with applicable DOT hazardous materials (49 CFR 172 subpart D) – 266.508(a)(1)(iii)(A)	
f)		For containers of 119 gallons or less, both non-creditable and/or evaluated HWP are marked in accordance with 49 CFR 172.304 “Hazardous Waste---Federal Law Prohibits Improper Disposal. If found....” in accordance with applicable DOT hazardous materials (49 CFR 172 subpart E) – 266.508(a)(1)(iii)(B)	

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
g)		Lab packs of non-creditable and/or evaluated HWP that will be incinerated and contain D004, D005, D006, D007, D008, D010, and D011 are marked with the EPA HW numbers/codes (a barcode or radio frequency ID system may be used) – 266.508(a)(1)(iii)(C)	
h)		The HCF and RD offer the appropriate placards to the initial transporter in accordance with DOT 49 CFR Part 172 Subpart F – 266.508(a)(1)(iv)	
i)		The HCF and RD uses manifests meeting the requirements of 40 CFR 262 Subpart B (including using a HW transporter) and maintains for 3 years, except that (1) the HCF is not required to list the HW codes for the non-creditable HWP in Item 13 of the manifest (EPA form 8700-22); and (2) HCF must write the word “PHARMS” in Item 13. – 266.508(a)(2)	
j)		Both HCF and RD that export non-creditable and/or evaluated HWP meet 40 CFR Part 262 Subpart H – 266.508(b)	
k)		HCF and RD that import non-creditable and evaluated HWP meet 40 CFR Part 262 Subpart H and have a RCRA permit or interim status to accept HW from off-site – 266.508(c)	

√ - in compliance X – not in compliance NA – not applicable

E.2 Shipping **Potentially Creditable HWP** from an HCF or a RD to a RD (266.509)

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
1.		Shipping Potentially Creditable HWP from an HCF or a RD to a RD (266.509)	
a)		The HCF and RD that offers potentially creditable HWP for transport to a RD complies with all applicable DOT 49 CFR Parts 171 through 180 for any potentially creditable HWP that meets the definition of hazardous material in 49 CFR 171.8 – 266.509(a)	
b)		Upon receipt of each potentially creditable HWP shipment, the receiving RD provides confirmation (paper or electronic) to the HCF or RD that the shipment has arrived and under the RD’s custody and control – 266.509(b)	
c)		If confirmation is not received in 35 days, the HCF or RD that initiated the shipment contacted the carrier and the intended RD promptly to report the delivery confirmation was not received and to determine the status of the potentially creditable HWP – 266.509(c)	
d)		HCF and RD that export potentially creditable HWP meet 40 CFR Part 262 Subpart H, except the manifesting requirements of 262.83(c). They must also comply with 266.509(a) through (c) – 266.509(d)	

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
e)		HCF and RD that import potentially creditable HWP meet 266.509(a) through (c) in lieu of 40 CFR Part 262 Subpart H. (Immediately after the potentially creditable HWP enter the US, they are subject to all applicable subpart P requirements.) – 266.509(e)	

√ - in compliance X – not in compliance NA – not applicable

F. RD MANAGING POTENTIALLY CREDITABLE HWP AND EVALUATED HWP (266.510)

Without a permit or interim status, an RD may accept potentially creditable HWP from off-site and accumulate potentially creditable HWP or evaluated HWP on-site provided that the following conditions are met:

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
1.		Notification	
a)		If RD already has an EPA ID number, then the RD notified the EPA/state using EPA Form 8700-12 that it is a RD within 60 days of the effective date of this subpart (10/20/19 for non-authorized states) or within 60 days of becoming subject to the rule – 266.510(a)(1)(i)	
b)		If RD does not have an EPA ID number, then the RD obtained one by notifying the EPA/state using EPA Form 8700-12 that it is a RD within 60 days of the effective date of this subpart (10/20/19 for non-authorized states) or within 60 days of becoming subject to the rule – 266.510(a)(1)(ii)	
c)		The RD maintains (paper or electronically) and makes readily available to an inspector upon request a copy of its notification on file for as long as the facility is subject to this subpart – 266.510(a)(10)(i)	
2.		Maintain Inventory	
a)		The RD maintains a current inventory of all potentially creditable and evaluated HWP that are accumulated on-site – 266.510(a)(2)	
b)		The RD inventories each potentially creditable HWP within 30 calendar days of each waste arriving at the RD – 266.510(a)(2)(i)	
c)		The RD maintains (paper or electronically) and makes readily available to an inspector upon request a copy of the delivery confirmation and the shipping papers for each shipment of potentially credible HWP that it receives, and a copy of each unauthorized report for at least 3 years – 266.510(a)(10)(ii)	
d)		The inventory includes the identity (e.g., name or national drug code), and quantity of each potentially creditable HWP and each evaluated HWP (may use inventories that already meet these requirements that are required by other regulatory requirements) – 266.510(a)(2)(ii) and (iii)	
e)		The RD maintains (paper or electronically) and makes readily available to an inspector upon request a copy of its current inventory as long as subject to this subpart – 266.510(a)(10)(iii)	

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
3.		Evaluating the Potentially Creditable HWP	
a)		The RD that is not a pharmaceutical manufacturer evaluates the potentially creditable HWP within 30 days of the waste arriving at the RD to establish whether it is destined for another RD for further evaluation or verification of manufacturer credit or for a TSDF – 266.510(a)(3)	
b)		The RD that is a pharmaceutical manufacturer evaluates the potentially creditable HWP within 30 days of the waste arriving for verification of manufacturer credit and following the evaluation must manage any evaluated HWP in accordance with 266.510(c) – 266.510(a)(4)	
4.		Accumulation Time Limits	
a)		The RD accumulates potentially creditable HWP and evaluated HWP on-site for 180 calendar days or less. The 180 days start after the potentially creditable HWP has been evaluated and applies to all HWP accumulated on-site, regardless of whether they are destined for another RD (i.e., potentially creditable HWP) or a TSDF (i.e., an evaluated HWP). – 266-510(a)(5)(i)	
b)		Aging pharmaceuticals [unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue)] are accumulated for up to 180 days after the expiration date provided that: (1) the unexpired pharmaceuticals are managed in accordance with 266.510(a); and (2) the containers are labeled and managed according to 266.510(c)(4)(i) through (vi). – 266-510(a)(5)(ii)	
5.		Security	
		The RD prevents unknowingly entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable HWP and evaluated HWP are kept (e.g., 24-hour surveillance system, fence, keycard access) – 266.510(a)(6)	
6.		Contingency Plan and Emergency Procedures	
		A RD that accepts potentially creditable HWP from off-site has a contingency plan and meets the other requirements of Part 262 Subpart M – 266.510(a)(7)	
7.		Closure	
		The RD complies with 262.17(a)(8)(ii) and (iii) when closing an area where potentially creditable HWP or evaluated HWP are accumulated. – 266.510(a)(8)	

#	v/X/NA	REGULATORY REQUIREMENTS	COMMENTS
8.		Unauthorized Waste Report	
a)		If the RD receives waste that it is not authorized to receive (e.g., non-pharmaceutical HW, regulated medical waste), they submit an unauthorized waste report to the EPA/state within 45 calendar days and sends a copy to the HCF (or other entity) that sent the unauthorized waste. – 266.510(a)(9)(i)	
b)		The unauthorized report was signed by the owner or operator of the RD, or its authorized representative - 266.510(a)(9)(i); and	
c)		The unauthorized report contained the EPA ID number, name and address of the RD – 266.510(a)(9)(i)(A)	
d)		The unauthorized report contained the date the unauthorized waste was received - 266.510(a)(9)(i)(B)	
e)		The unauthorized report contained the EPA ID number, name and address of the HCF that shipped it if available – 266.510(a)(9)(i)(C)	
f)		The unauthorized report contained a description and quantity of each unauthorized waste received. - 266.510(a)(9)(i)(D)	
g)		The unauthorized report contained the method of treatment, storage, or disposal for each unauthorized waste 266.510(a)(9)(i)(E)	
h)		The unauthorized report contained a brief explanation of why the waste was unauthorized, if known - 266.510(a)(9)(i)(F)	
i)		The RD manages the unauthorized waste in accordance with all applicable regulations – 266.510(a)(9)(i)	
9.		RD that Ships Potentially Creditable HWP to Another RD	
a)		The RD sends the potentially creditable HWP from a HCF to another RD within 180 days after it has been evaluated or follow 266.510(c) for evaluated HWP - 266.510(b)(1)	
b)		The RD sends the potentially creditable HWP from a RD to another RD within 180 days after it has been evaluated or follow 266.510(c) for evaluated HWP - 266.510(b)(2)	
c)		The RD ships the potentially creditable HWP in accordance with 266.509 - 266.510(b)(3)	
d)		The RD maintains (paper or electronically) and make readily available to an inspector upon request a copy of the delivery conformation for each shipment of potentially credible HWP that it ships for at least 3 years – 266.510(b)(4)(i)	
e)		The RD maintains (paper or electronically) and make readily available to an inspector upon request the DOT shipping papers prepared in accordance with 49 CFR Part 172 Subpart C (as applicable) for each shipment of potentially credible HWP that it ships for at least 3 years – 266.510(b)(4)(ii)	

#	v/X/NA	REGULATORY REQUIREMENTS	COMMENTS
10.		Training	
		The RD complies with the LQG training requirements in 262.17(a)(7) – 266.510(c)(3)	
11.		On-site Accumulation Area	
a)		The RD designated an on-site accumulation area for the evaluated HWP – 266.510(c)(1)	
b)		The RD inspects the containers of evaluated HWP in the on-site accumulation areas once every 7 days for integrity and lack of diversion – 266.510(c)(2)	
12.		Containers of Evaluated HWP in the On-site Accumulation Area	
a)		Labeled “Hazardous Waste Pharmaceuticals” – 266.510(c)(4)(i)	
b)		Ensure the containers are in good condition and managed to prevent leaks – 266.510(c)(4)(ii)	
c)		Containers are compatible with the evaluated HWP – 266.510(c)(4)(iii)	
d)		Containers are closed if holding a liquid or a gel evaluated HWP (to include original or replacement sealed packaging that meets the definition of closed) – 266.510(c)(4)(iv)	
e)		Containers of ignitable or reactive evaluated HWP or of mixed/co-mingled incompatible HWP are manage so that it does not have the potential to (i) generate heat, pressure, fire, explosion or violent reaction; (ii) produce uncontrolled toxic mists, fumes, dust or gases in sufficient quantity to threaten human health; (iii) produce uncontrolled flammable fumes/gases to pose a risk of fire/explosion; (iv) damage structural integrity of container; or (v) threaten human health or the environment through other like means – 266.510(c)(4)(v)	
f)		Containers of evaluated HWP that are prohibited from being combusted due to the dilution prohibition (268.3(c)) are accumulated in separate containers– 266.510(c)(4)(vi)	
g)		Containers of evaluated HWP are marked with the applicable EPA HW numbers/codes (a barcode or radio frequency ID system may be used) prior to being shipped off-site. – 266.510(c)(5)	
13.		Shipments	
		The RD ships evaluated HWP to a RCRA permitted/interim status facility in accordance to 266.508(a) or (b) – 266.510(c)(6)	
14.		Returned Rejected Shipments from a Designated Facility	
a)		The rejected shipment is accumulated for up to an additional 90 days or less – 266.510(c)(7)	
b)		The rejected shipment managed in accordance with 266.510(a) [container standards] and 266.510(c) [container labeling] – 266.510(c)(7)	

#	v/X/NA	REGULATORY REQUIREMENTS	COMMENTS
c)		The RD meets the returned manifest requirements of 266.510(c)(7)(i) - (iii) to include: (1) sign either Item 18c of the original manifest or Item 20 of the new manifest]; (2) provide the transporter a copy of the manifest; and (3) within 30 days send a copy of the manifest to the designated facility that returned the manifest. - 266.510(c)(7)(i) - (iii)	
d)		The RD within 90 days of receipt, transports the returned shipment in accordance with 266.508(a) or (b) - 266.510(c)(7)(iv)	
15.	LDR Requirements		
a)		The RD must comply with the LDR requirements of 40 CFR 268 - 266.510(c)(8)	
b)		The RD must comply with the LDR requirements of 40 CFR 268.7(a) for potentially creditable HWP accepted from off-site - 266.510(c)(8)	
16.	Biennial Reports		
		The RD that ships evaluated HWP off-site submits a Biennial Report by March 1 of each even numbered year in accordance with 262.41 – 266.510(c)(9)	
17.	Exception Reporting for Missing Manifests from a Designated Facility		
a)		If the RD did not receive the signed copy of the manifest from the designated facility within 35 days from the initial transporter signature, the RD contacted the transporter of the designated facility to determine the status of the HWP – 266.510(c)(9)(ii)(A)(1)	
b)		The RD submitted an Exception Report to the EPA/state if had not received the signed manifest from the designated facility within 45 days of the HWP being accepted by the initial transporter. – 266.510(c)(9)(ii)(A)(2)	
c)		The exception report included a legible copy of the manifest that does not have confirmation of delivery and a cover letter signed by the RD explaining the efforts taken to locate the evaluated the HWP and the results of the effort. – 266.510(c)(9)(ii)(A)(2)(i) and (ii)	
18.	Exception Reporting for a Rejected Shipment by a Designated Facility that was Shipped to an Alternate Facility		
a)		If a rejected shipment is shipped to an alternate facility by the designated facility, the RD completes an Exception Report if RD did not receive the signed copy of the manifest from the alternate designated facility within 35 days from the forwarding transporter signature – 266.510(c)(9)(ii)(B)(1)	
b)		The RD submitted an Exception Report to the EPA/state if it had not received the signed manifest from the designated facility within 45 days of the HWP being accepted by the forwarding transporter. – 266.510(c)(9)(ii)(B)(2)	
c)		The Exception Report includes a legible copy of the manifest that does not have confirmation of delivery and a cover letter signed by the RD explaining the efforts taken to locate the evaluated the HWP and the results of the effort. – 266.510(c)(9)(ii)(B)(2)(i) and (ii)	

#	√/X/NA	REGULATORY REQUIREMENTS	COMMENTS
19.		Evaluated HWP Recordkeeping	
a)		The RD maintains a log (written or electronic) of the inspections of the containers of evaluated HWP in the on-site accumulation areas once every 7 days for 3 years and make readily available upon request by an inspector – 266.510(c)(10)(i) and (vi)	
b)		The RD maintains a copy of the manifests for 3 years or until it receives a signed copy from the designated facility that received the evaluated HWP which shall then be maintained for 3 years and make readily available upon request by an inspector. – 266.510(c)(10)(ii) and (vi)	
c)		The RD maintain a copy of the Biennial Report for 3 years and make readily available upon request by an inspector – 266.510(c)(10)(iii) and (vi)	
d)		The RD maintains a copy of the Exception Report for 3 years and make readily available upon request by an inspector. – 266.510(c)(10)(iv) and (vi)	
e)		The RD maintain the LQG training record requirements in 262.17(a)(7)(iv) and make readily available upon request by an inspector – 266.510(c)(10)(v) and (vi)	
20.		When a Permit is Required	
		The RD has a RCRA permit if it does not meet the conditions of Section 266.510, accepts HW from off-site, and/or treats or disposes of HWP on-site. – 266.510(d)	

√ - in compliance X – not in compliance NA – not applicable