Hazardous Waste Rule Updates

Department of Environment and Natural Resources

Dale Healey and Anthony Wagner

What Updates???

* Hazardous Waste Generator Improvement Rule (GIR)
* Airbag Waste Rule
* Hazardous Waste Pharmaceutical Rule (Subpart P)

Generator Improvement Rule

* Published in the Federal Register on November 28, 2016.
* Became effective at the federal level May 30, 2017 (in states not authorized for the HW program).
* South Dakota adoption in progress.

Generator Improvement Rule

* Adopts updated federal hazardous waste regulations:
  * Encompasses a reorganization to make the rules more user friendly.
  * Provides flexibility for generators.
  * Strengthen environmental protections.
  * Clarifies rules to address ambiguities and foster greater compliance.

Generator Improvement Rule (GIR)

More Stringent

* Requires Small Quantity Generators (SQGs) to re-notify of hazardous waste generation every four years.
* Requires LQG to submit Notification of Closure.
* LQG closure as landfill if closure standards cannot be met.
* All hazardous waste generated during a reporting year must be included in the biennial report.
* Requires including a quick reference guide for contingency plans.

GIR Continued

Less Stringent

* Allows very small quantity generator (VSQG) (formerly CESQG) to consolidate at LQGs.
* Allows episodic generation without changing generator class.
* Allows for a waiver from the 50 foot rule for ignitable and reactive wastes.

Re-notification

* WHY?
  * Outdated and inaccurate data.
* Rule
  * SQGs will be required to re-notify every four years.
  * Implementation 2021.

Notification of Closure

* LQGs must notify of closure at least 30 days prior to closure.
* LQGs must notify within 90 days post closure stating closure is complete.
* If closure requirements can not be met LQGs must close in accordance with landfill closure requirements.

Quick Reference Guide

* New LQGs must include a quick reference guide when developing their contingency plan.
* Existing LQGs must develop a quick reference guide to be included with a contingency plan update.

What is the Quick Reference Guide?

* List of hazardous waste generated on site.
* Estimate of the maximum quantity stored.
* Handling of hazardous waste that require unique treatment.
* Map showing generation, storage, and treatment locations.
* Map of the facility to show routes of access and evacuation.
* Water Supply Locations.
* Identification of on-site notification systems.
* Name of emergency coordinator and telephone numbers.

Emergency Preparedness and Planning

* Generators must document that they have attempted to make arrangements with local emergency responders and keep that documentation with their operating records.
* No specific form or type of document is required to allow generators flexibility when complying with documentation requirements.

Waiver to 50-Foot Requirement

* Currently generators are required to store containers holding ignitable or reactive waste at least 50 feet from the property line.
* Final Rule allows for generators to work with local fire authorities to apply for a waiver from this requirement.

Waste Consolidation

Allows companies with VSQG locations to transport waste to sites operated as LQGs.

* Will help ensure proper management of wastes.
* Currently LQGs are required to have a HW permit to receive waste.

Waste Consolidation

VSQG Waste Consolidation Requirements:

* Mark and label waste containers.

LQG Waste Consolidation Requirements:

* Submit notification that they are participating in consolidation and identify from which VSQG locations waste will be consolidated.
* Maintain records for each shipment.
* Manage the waste as a LQG.
* Report waste received as part of the biennial report.

Episodic Generation

* Maintain existing generator category if they comply with a set of streamlined requirements:
  * One event per calendar year.
  * Notify of a planned event at least 30 days prior to initiation.
  * Notify within 72 hours of an unplanned event.
  * Conclude the episodic event within 60 days of commencement.

Episodic Generation

* SQGs need to comply with existing regulations and maintain records of the episodic event.
* VSQG Requirements:
  * Obtain an identification number.
  * Manifest waste and transport to a permitted HW facility.
  * Minimize the possibility of accidents and releases.
  * Follow labeling requirements.
  * Identify an emergency coordinator.
  * Maintain records.

Marking/Labeling Changes

* Containers must indicate the hazards of the contents of the containers.
* Prior to sending hazardous waste off-site generators must mark their containers with the applicable hazardous waste codes.
  * Can be accomplished with the waste codes or with a bar-coding system that performs the same function.

Satellite Accumulation Clarifications

* Incompatible wastes can not be mixed.
* Will allow containers to remain open temporarily when necessary for safe operations.
* Three days means three consecutive calendar days.
* Made marking and labeling requirements consistent with the central accumulation area.

Biennial Reporting

Clarifications:

* Rules will not list specific data elements to be reported, but will refer generators directly to the form instructions.
* All hazardous waste generated during a reporting year must be included in the biennial report.
* Generators must report hazardous waste generated throughout the calendar year, even for months when they are an SQG.

Additional Clarifications

* Defined new terms in 260.10.
* Clarified RCRA 3004 (c) prohibiting liquids in landfills.
* Deleted obsolete provisions.
* Made technical corrections throughout.

Major Changes of Final Rule by Generator Category

New Provision	VSQG	SQG	LQG
Reorganization	X	X	X
LQG Consolidation	X		X
Episodic Generation	X		
50-Foot Waiver			X
Marking and Labeling		X	X
Marking Waste Codes		X	X
SQG Re-Notification		X	
Quick Reference Quide			X
Closure Notification			X
Closure as Landfill			X

Safe Management of Airbag Waste

Key Terms Used In New Rule

* Airbag waste – hazardous waste airbag modules and airbag inflators.
* Airbag handler – person who generates airbag waste (e.g., auto dealers).
* Airbag collection facility – a facility that collects and stores airbag waste for more than ten days and is under the control of a vehicle manufacturer or their authorized representative, or under the control of an authorized party administering a remedy program in response to a DOT recall.
* Designated facility – HW facility permitted by EPA or the authorized state to accept airbag waste for treatment, disposal or recycling.
* ARSD 74:28:22:01/40 CFR 261.4(j): Citation for new airbag waste conditional exemption. This optional provision exempts airbag waste from hazardous waste requirements while at the airbag waste handler and during transportation to airbag waste collection facility or designated facility, provided certain conditions are met.

Airbag Module Within A Steering Column

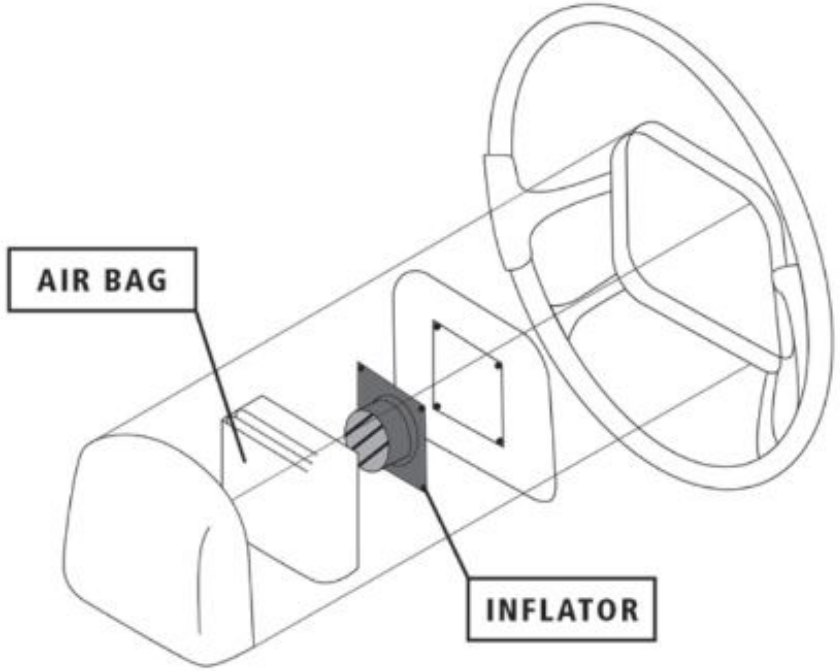

Figure 1: Diagram Showing Placement of Airbag and Inflator in a Steering Column

Goal of Interim Final Rule

* The goal of the interim final rule is to structure the hazardous waste regulations in such a way that:
  * There is no regulatory delay for the swift removal of recalled Takata airbag inflators from vehicles.
  * The removed airbag inflators and airbag modules (i.e., airbag waste) are managed safely during accumulation and transport, and are tracked to their destination.
  * The airbag waste is properly disposed of at a hazardous waste facility in a timely manner, and long-term storage is discouraged.
  * The recalled airbag inflators are not diverted back into vehicles.
* While the exemption provides alternative standards for auto dealers and other entities that remove the recalled airbag inflators, it does not change their obligation to safely manage and dispose of the airbag waste.

Goal of Interim Final Rule (Continued)

* **Every day counts:** The propensity for Takata airbag inflators to rupture increases over time, especially when exposed to high temperatures and high absolute humidity.
  * On July 13, 2017, two days before his car was scheduled to be repaired, a man was killed in a minor collision by metal shards from a defective airbag.
* EPA promulgated the airbag waste exemption as an interim final rule under the federal Administrative Procedure Act "good cause" exemption, effective immediately upon publication, with a 60-day public comment period that ended on January 29, 2019.
* As an interim final rule, EPA will consider the public comments and determine if further revisions are needed, but in the meantime, the exemption remains in effect.

Regulation of Used Airbags under Hazardous Waste Rules

* Gas-generating airbag systems (both Takata and non-Takata) contain an explosive propellant that causes airbag waste (i.e., discarded airbag inflators and airbag modules) to exhibit the hazardous waste characteristics of ignitability and reactivity.
* A number of different exemptions and exclusions can apply, depending on how the airbag waste is managed. These provisions are not affected by the new rule. See July 19, 2018, EPA memo.

https://www.epa.gov/hw/regulatory-status-automotive-airbag-inflators-and-fully-assembled-airbag-modules

* However, because they can not be safely reused, nor safely deployed, used Takata airbags that have been removed from vehicles must be managed as hazardous waste when discarded.

Takata Recalls

* Takata airbag recalls affect 65-70 million airbag inflators due to a defect that causes the metal inflator inside the airbag to rupture and explode violently when deployed.

* There have been 15 deaths in the US and at least 250 injuries as of August 2018.

Takata Recalls (continued)

* The phase-stabilized ammonium nitrate (PSAN) propellant used in the recalled Takata airbag inflators degrades over time, and can cause the inflator to over-pressurize during deployment.
* In some cases, this over-pressurization causes the metal canister to rupture, producing shrapnel-like metal shards that can seriously injure or kill vehicle occupants even in low impact accidents.

DOT Preservation Order and the June 2017 EPA memo

* Until recently, Takata airbag inflators that have been collected as part of the recall effort have been stored under a February 2015 DOT Preservation Order.
* In June 2017, EPA issued a memo explaining that Takata airbags held under the Preservation Order have not been discarded, and are therefore not solid or hazardous waste under federal regulations.
* Thus Takata has collected the recalled airbag inflators from dealers and stored them without being subject to hazardous waste requirements.
* Once the Preservation Order no longer applies to them, then these collected Takata airbag inflators must be managed as hazardous waste.

Takata Bankruptcy and Amended DOT Preservation Order

* Takata went through bankruptcy proceedings, which ended February 2018 and went into effect April 2018.

* As a result, the Original Equipment Manufacturers (OEMs) (i.e., auto manufacturers) now finance the recall, rather than Takata.

* DOT also amended the Preservation Order in April 2018, allowing Takata to reduce the number of preserved airbag inflators (while still requiring the preservation at least 5% of inflators, proportionate to the overall number of inflators received from each state and each type of inflator).

Takata Bankruptcy and Amended DOT Preservation Order (cont'd)

* This changing landscape affects how the recall of the remaining Takata airbag inflators proceeds.
* Auto dealers may continue to send the recalled inflators to Takata under the Preservation Order, but OEMs must pay Takata for this service.
* If OEMs choose instead to have their dealers dispose of the recalled inflators directly, then the dealers would become potentially subject to hazardous waste generator requirements.
  * This could have a chilling effect on the pace of Takata airbag replacements.
  * Such a two-tiered system also favors long-term storage of recalled inflators (rather than swift disposal), which is less preferable from a risk perspective.

Diversion of Recalled Airbag Inflators Back Into Vehicles

* Diversion of recalled Takata airbag inflators back into vehicles is extremely dangerous because a vehicle repaired with a scavenged airbag inflator will likely have no record of its origin.
  * In addition, recalled airbag inflators in scrapped vehicles are more likely to have been exposed to the heat and humidity that can cause the propellant to degrade.
* There is at least one documented case of a driver seriously injured by a recalled inflator from a salvage yard vehicle used to repair a damaged vehicle.
* To address this risk, some OEMs have commissioned salvage vendors to buy recalled airbag inflators from salvage yards and send them for destruction.
* However, because the DOT preservation order does not cover inflators from scrap vehicles, inflators collected from salvage yards are subject to hazardous waste requirements, once the determination is made that they are part of the recall.

Overview of Airbag Waste Interim Final Rule

* The federal interim final rule promulgates a new conditional exemption at 40 CFR 261.4(j) adopted in ARSD 74:28:22:01 for airbag waste, provided that the airbag handler sends the airbag waste either to a hazardous waste facility or to a airbag collection facility, and also meets the other conditions of the exemption.

* Conditions of exemption are modeled after current industry practices and are designed to ensure that the exempted airbag waste is managed safely and is appropriately destroyed and not diverted back into vehicles. The conditions for the airbag waste handler are:
  * Maximum 250 discarded airbag modules or airbag inflators stored at the airbag handler
  * Storage time limit of 180 days
  * Packaged and shipped in a container designed to address risk posed by inflator
  * Container labeled "Airbag Waste – Do Not Reuse"
  * Maintain shipping records and confirmation of receipt for 3 years (Ordinary business records such as bills of lading are sufficient; electronic records acceptable.)

Overview of Airbag Waste Interim Final Rule (continued)

* The designated facility or airbag collection facility then acts as the hazardous waste generator for the airbag waste.
* In addition, the reuse of recalled defective airbag modules or airbag inflators is prohibited under ARSD 74:28:22:01/40 CFR 261.2(g) as sham recycling.
* Scope of the exemption includes all airbag waste, not just Takata airbag waste.
  * While the Takata recall is the source behind the urgency for this rulemaking, it makes sense from a risk perspective to have one airbag waste collection system.
  * A two-tiered system for Takata and non-Takata airbag waste would create unnecessary confusion.
  * In addition, the much smaller volume of non-Takata airbag waste could result in it being a VSQG and therefore, possibly diverted to the municipal waste stream.
* Note that the non-Takata airbag modules and inflators may also still be eligible for reuse and other exclusions and exemptions. (see July 19, 2018 EPA memo)

Next Steps

* The Interim Final Rule was published on November 30, 2018 in the Federal Register.

https://www.federalregister.gov/documents/2018/11/30/2018-25892/safe-management-of-recalled-airbags

* The 60-day comment period ended January 29, 2019; EPA is currently evaluating comments to determine if any further revisions to the regulations are needed. Currently, EPA plans to publish a "final" final rule by September 2019.
* In the meantime, EPA is working with the states on implementing the rule. To be protective, South Dakota is including this rule in the proposed hazardous waste rules.

Hazardous Waste Pharmaceuticals

ARSD 74:28:27:01 adopting by reference 40 CFR part

266 Subpart P

P075 Nicotine Listing Amendment

Goals

* Create regulations to better fit the healthcare sector.
* Eliminate intentional sewering of hazardous waste pharmaceuticals.
* Reduce overlapping regulations with DEA, FDA, etc.
* Provide clarity on how the hazardous waste regulations apply to reverse distribution and reverse logistics.
* Reevaluate nicotine replacement therapies.

Nicotine Listing

* The P075 listing for nicotine is being amended so that FDA approved over the counter nicotine replacement therapies will no longer be considered a hazardous waste.
  * Patches, gums, and lozenges will no longer be considered an acute hazardous waste.
  * These products will be treated as non hazardous wastes.

However

* Other unused formulations of nicotine will still be a P075 acute hazardous waste, including:
  * E-liquids/juices contained in e-cigarettes, or vials.
  * Prescription nicotine found in nasal sprays, or inhalers.
  * Legacy pesticides.
  * Nicotine used in research and manufacturing.

Subpart P – New Terms Defined

* Pharmaceutical
* Hazardous waste pharmaceutical
  * Non-creditable
  * Potentially creditable
  * Evaluated
* Healthcare facility
  * Long-term care facility
* Reverse distributor
* Household waste pharmaceutical
* Non-hazardous waste pharmaceutical

Pharmaceutical

* Is a drug for use by humans or other animals to include but not limited to:
  * Prescription drugs
  * Over the counter drugs
  * Investigational drugs
  * Dietary supplements
  * Homeopathic drugs
  * E-liquids/juice to be used in e-cigarettes or vaping pens

Hazardous Waste Pharmaceuticals

* Three types:
  * Non-creditable hazardous waste pharmaceutical
  * Potentially creditable hazardous waste pharmaceutical
  * Evaluated hazardous waste pharmaceutical

Non-Creditable

Non-creditable hazardous waste pharmaceuticals must be transported to a hazardous waste treatment, storage, or disposal facility.

* Broken or leaking
* Repackaged
* Dispensed
* Expired for greater than one year
* Investigational new drugs
* Contaminated PPE
* Clean-up material

Potentially Creditable

Transported to a reverse distributor

* Original manufacturer packaging (except recalls)
* Undispensed
* Unexpired
* Or less than one year past expiration

Evaluated

Evaluated pharmaceuticals must then be transported to a hazardous waste treatment, storage, or disposal facility.

* Refers to any hazardous waste pharmaceutical which requires no further evaluation to determine manufacturer credit.

Healthcare Facility

Includes:

* Hospitals
* Pharmacies
* Surgical Centers
* Health Clinics
* Physicians' offices
* Optical and Dental Offices
* Long-term care facilities
* Veterinary Clinics

Does not include:

* Pharmaceutical manufacturers
* Reverse distributors
* Reverse logistics centers

Long-Term Care Facility

A licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility.

* **Examples Include:**
  * Nursing Facilities
  * Hospice Facilities
  * Skilled Nursing Facilities
* **Not Included:**
  * Independent living centers
  * Group Homes
  * Assisted Living facilities

Reverse Distributor

Any person that receives or accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit

* **Examples Include:**
  * Forward distributors
  * 3rd Party logistics providers
  * Pharmaceutical mfr

Household Waste Pharmaceutical

* A pharmaceutical that is a solid waste according to ARSD 74:28:22:01 adopting 40 CFR 261.2, but is excluded as a hazardous waste in 261.4 (b)(1)

Non-Hazardous Waste Pharmaceutical

A pharmaceutical that is a solid waste but is not listed in ARSD 74:28:22:01/40 CFR part 261 subpart D, and does not exhibit a HW characteristic identified in 261 subpart C

Applicability

Hazardous waste pharmaceuticals must be managed under Subpart P by:

* All healthcare facilities that generate above VSQG amounts of hazardous waste.
* All reverse distributors.

Key Points

Once adopted:

* There will be NO generator categories
  * And NO biennial report
* All healthcare facilities and reverse distributors will be regulated the same for hazardous waste pharmaceuticals.
* Healthcare facilities and reverse distributors will not have to:
  * Keep track of how much hazardous waste pharmaceuticals they generate per month.
  * Segregate the acute and non-acute hazardous waste pharmaceuticals.

Notification

* Facilities that are not required to submit a biennial report for their other hazardous waste must notify within 60 days of the rule going into effect.
* Facilities that are required to submit a biennial report may notify through their normal biennial reporting cycle.

Training

* All personnel managing non–creditable hazardous waste pharmaceuticals must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities.

Waste Determination

* Applies to both potentially creditable and non-creditable waste pharmaceuticals.
* Exception – if a healthcare facility manages all of its waste pharmaceuticals as hazardous, individual waste determinations are not necessary.

Commingling

Accumulating both hazardous and non-hazardous waste pharmaceuticals in the same container.

* Applies to both potentially creditable and non-creditable waste pharmaceuticals.

Accumulation and Storage

* Non-creditable hazardous waste pharmaceuticals:
  * Labeling
    * Accumulation containers must be labeled with the words "Hazardous Waste Pharmaceuticals"
    * No hazardous waste codes or other labeling requirements
  * Container Standards
    * Structurally sound, will not react with contents
    * Must remain closed and secured in a manner that prevents unauthorized access to its contents
  * Accumulation time limit of one year
* Potentially creditable hazardous waste pharmaceuticals:
  * No labeling, containers standards, or accumulation time

Shipping

Non-creditable and evaluated hazardous waste pharmaceuticals:

* Both must be sent directly to a TSDF
* Both must be manifested and sent with a hazardous waste transporter
  * Non-creditable pharmaceuticals from a healthcare facility can use code PHARMS on the manifest
  * Evaluated pharmaceuticals from a reverse distributor must list all applicable hazardous waste codes

Shipping

Potentially creditable hazardous waste pharmaceuticals:

* Can be sent to a reverse distributor before a TSDF
* Manifest and hazardous waste transporter are not required (USPS, UPS, FedEx are acceptable)
* Shipper must receive delivery confirmation within 35 days of shipment date.

Options for VSQG Healthcare Facilities

* Subpart P optional provisions:
  * Continue to send potentially creditable hazardous waste pharmaceuticals to a reverse distributor
  * Send hazardous waste pharmaceuticals off-site to another facility provided the receiving facility is either
    * A healthcare facility operating under ARSD 74:28:27:01 adopting part 266 subpart P and meets certain conditions, *or*
    * An LQG operating under ARSD 74:28:23:01 adopting part 262 and meets the conditions for off-site consolidation

Options for VSQG Long-Term Care Facilities

* Long-term care facilities that are VSQGs can dispose of its hazardous waste pharmaceuticals in an on-site collection receptacle that complies with DEA regulations.
  * DEA collection receptacles can only be used for controlled substances that are from the ultimate user.
* Long-term care facilities with 20 beds or fewer will be presumed to be a VSQG and not subject to Subpart P, except the sewer prohibition.

Sewer Prohibition

* Hazardous waste pharmaceuticals may not be sewered.
* Applies to:
  * All healthcare facilities, including healthcare facilities that are VSQGs.
  * All reverse distributors.
* Sewer prohibition is effective in all states on August 21, 2019.

Empty Container Standards

* Residues remaining in "RCRA empty" containers are not regulated as hazardous waste.
  * Four standards for different types of containers found in a healthcare setting.
* Triple rinsing of containers with acute hazardous waste pharmaceuticals is not required or allowed.

Empty Container Standards

	Non-Acute HW Pharms	Acute HW Pharms
Stock Dispensing Bottle	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents Or 261.7(b)(1)	Fully administer contents
Other Containers	261.7(b)(1) or (2)	Can not be RCRA empty

DEA Controlled Substances

* Conditional exemptions for:
  * Hazardous waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances.
  * Household waste pharmaceuticals collected in DEA authorized kiosks.
    * Retail pharmacies and hospitals that are already DEA registrants can amend their DEA registration to become collectors and install kiosks for permanent take-back programs for household pharmaceuticals.
    * DEA regulation states collected household pharmaceuticals have to be destroyed to a "non-retrievable" standard.

HW and DEA Controlled Substances

Name of Drug	Other Names	Medical Use	RCRA Code	DEA CS Schedule
Chloral/ Chloral Hydrate	Acetaldehyde, Trichloro, Somnote	Sedative	U034 Toxic	IV
Fentanyl sublingual spray	Subsys	Analgesic	D001 Ignitable	II
Phenobarbital	Bellergal-S Donnantal	Anticonvulsant	D001 Ignitable	IV
Testosterone	Androgel, Axiron	Hormone	D001 Ignitable	III
Valium	Diazepam Diastat	Anti-anxiety	D001 Ignitable	IV

DEA Controlled Substances

* In both cases listed previously the waste pharmaceuticals are exempt from the hazardous waste regulations, provided they meet the following conditions:
  * Not sewered;
  * Managed in compliance with DEA regulations;
  * Destroyed by a method that the DEA has publicly deemed in writing to meet their non-retrievable standard; or
  * Combusted at one of the following permitted facilities:
    * Large or small municipal waste combustor
    * Hospital, medical and infectious waste incinerator
    * Commercial and industrial solid waste incinerator
    * Hazardous waste combustor

Summary

	Standards for Healthcare Facility	Standards for Reverse Distributors
	Potentially Creditable	**Potentially Creditable**
On-site accumulation	• No standards • No time limit	• Evaluate within 30 days
Shipping to a reverse distributor	• Confirmation of delivery • Common carrier	• Confirmation of delivery • Common carrier
	Non-Creditable	**Evaluated**
On-site accumulation	• UW-like standards • 1 year maximum	• LQG-like standards • 180 days after evaluation
Shipping to a TSDF	• Manifest as PHARMS • HW transporter	• Manifest w/waste codes • HW transporter

Questions

Dale Healey

Joe Foss Building
523 East Capitol
Pierre, SD 57501
Dale.healey@state.sd.us
(605) 773-3153

Anthony Wagner

Joe Foss Building
523 East Capitol
Pierre, SD 57501
Anthony.wagner@state.sd.us
(605) 773-3153

Website: https://denr.sd.gov/des/wm/hw/hwmainpage.aspx