

NEWMOA Hazardous Waste Conference Call September 22, 2015

Topic: Results of State Inspections of Pharmacies that Have Notified as LQGs

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Participants: CT DEEP (7 people); ME DEP (2 people); Mass DEP (5 people); NH DES (7 people); NJ DEP (4 people); NYS DEC (10 people); VT DEC (2 people); EPA HQ (1 person); EPA Region 1 (1 person); EPA Region 2 (1 person); NEWMOA (1 person)

Call leader: Connecticut DEEP

Note-taker: Cindy Grimes & Steve Simoes, VT DEC, with assistance from Terri Goldberg, NEWMOA

Background

In response to several enforcement actions taken by States for the improper management of hazardous waste pharmaceuticals, many large retail pharmacy chains and "big box stores" that operate pharmacies within their store are notifying at an unprecedented rate under RCRA as LQGs of hazardous waste. These notifications are being made primarily in response to their "generation" of P-listed pharmaceuticals and over-the-counter consumer products (e.g., warfarin and nicotine) that are non-salable for a variety of reasons (e.g., expired or overstocked) and therefore must be disposed of. As a result, the LQG universe in Region 1 has increased significantly over the last couple of years. To address this, Region 1 States proposed to EPA a "Pharmacy Flex" initiative to inspect 5 percent of pharmacies that were notified as LQGs; a full CEI would be conducted at each of the selected facilities. After EPA accepted the proposal, three Region 1 states – CT, NH and VT – implemented this initiative in FY 2015, and they shared the results of their inspection during the call as summarized below.

Terri Goldberg reminded the participants to be aware that there may be certain enforcement information shared during the call and asked everyone to not identify individual locations or facilities if there was any chance that the information was confidential.

Connecticut

CT has 178 retail pharmacies that have notified as LQGs; they inspected 9 facilities, 7 of which were Rite-Aids and 2 of which were Costco. In FY 2015-2016, CT will be conducting inspections at another 9 retail pharmacies, which have not yet been identified. CT DEEP's inspections found:

- Waste generated in two areas of the store:
 1. Front (retail = non-pharmaceutical)
 - Non-hazardous materials that are outdated, slightly damaged, or not selling well are removed from shelves through an internal process → materials (considered as consumer commodities) go to a Central Distribution Center in CT, where they might be sold downstream; two to three types of materials including outdated food and over the counter medicines
 - Materials determined to be non-saleable → accumulation of damaged products destined for offsite disposal; these products can include damaged goods and outdated medications.
 - Materials destroyed on site → placed in dumpster, down the drain. These products might be food items (i.e., solid waste). CT DEEP still has questions about this.
 - No photo fixer waste is being generated anymore in the stores they visited
 - No photo fixer found in stores
 2. Store pharmacy
 - Materials that pharmacy has determined not to have credit value → offsite disposal
 - Materials that pharmacy has determined to have a potential for credit → reverse distribution (RD) (characterized and listed as hazardous waste). Didn't focus on packaging and shipping standards for RD – will handle later on larger scale
- Inspections of retail section of the stores with materials sent for offsite disposal observed:
 1. **Manifests:** Many were illegible; some showed incorrect EPA ID# (either temporary #s or CEG #s)
 2. **Container Management:** Potential for storage of incompatibles - once waste is determined to be hazardous, it goes into sealable bag (which Rite-Aid considers to be a container) and then into a bin. This disposal method could allow hazardous materials to combine.
 - Containers of hazardous waste in pharmacy and front end (retail) – Some were empty; some had labeling and dating issues. The plastic bag, considered a “container” by store, had no marking or dating.
 - Store needs to designate separate bins for incompatibles.
 3. **Inspection of Storage Areas:** Definite lack of organized inspections. Employees were either not conducting inspections at all or not inspecting the amount RCRA requires. There were no well-delineated inspections for hazardous waste regarding keeping a schedule and log.
 4. **Training:** There was a failure to train and/or employees not trained to degree of requirements. If training had occurred, there were gaps regarding type and frequency. Employee job descriptions were lacking.
 5. **Contingency Plan:** Store had plan on site, but elements were either missing or inadequate. Emergency response procedures were lacking. There were problems identifying the Emergency Coordinator; home phone numbers and addresses were missing. Lot of turnover in the stores. Arrangements and distribution to local authorities were lacking. Required equipment list was not present or minimal.

6. **State Regulatory Issues:** State recycling concerns were observed, such as bottles in trash and cardboard in trash dumpster.
7. **Reverse Distribution:** There was inadequate documentation of claims.
8. **Recordkeeping:** Not available on site for inspection.
9. **Hazardous Waste Determination:** Stores have a software program called “Work System” to determine if material is hazardous waste – CT DEEP will be following up on this system. The stores use a scanner gun that designates various waste codes that determines how to manage the waste. It is unsure how the store handles certain disposal methods, i.e., drain disposal.

More on the results of the inspections:

- Of the 7 Rite-Aid stores inspected, 6 had already notified as an LQG.
- Six corporate Rite-Aid personnel met CT DEEP at a store. They explained that employees can’t show proof of their training on site, because the computer only allows the employee to complete the training program in order to view it. However, corporate can bring up proof of training; they will have to train employees to do so.
- When the retail (front) part of the store generates nicotine waste (when it has reached its shelf life), this waste goes to the pharmacy.
- CT DEEP considers the container in the front section as 90-day. Corporate compares this to the “California system”.
- Stores need to have separate containers for different waste characteristics.
- Storage of ignitable waste is in question. The stores CT DEEP inspected were ok, since they were surrounded by asphalt pavement and stores were “separate” (e.g., not in a strip mall).
- There are still questions about storage for pesticides and bulbs. At least one store is serviced by an electrical contractor for waste lamps. Universal waste (UW) is collected with all other wastes in store and at the time of pickup, the transporter separates out the UW.
- Rite-Aid sees bags in storage bins as containers – CT DEEP disagrees.

Comments from EPA HQs:

- A nicotine-reclaim facility in Ohio (Knightshade) is taking discarded nicotine-containing products (e.g., patches), reclaiming the nicotine, and selling it to another company that purifies the nicotine (up to 78 percent). This company then sells the purified nicotine to manufacturers to make new nicotine products. Knightshade provides collection boxes to retailers for the discarded nicotine “waste”. The company also provided supporting documentation to EPA for the reclamation process. Related EPA memos from May 8, 2015 are #14850 (e-cigarettes) and #14851 (nicotine reclaim).
- There are questions on incompatibles, especially in the front part of store with retailer-related waste (e.g., acetone in nail polish remover, drain cleaner, peroxide).
- Compounding pharmacies are part of EPA’s proposed pharmaceutical rule; FDA urged EPA to include these pharmacies as part of new rule.

Vermont

VT conducted 5 percent of LQG pharmacy universe = one inspection; will also be conducting one inspection during FY 2016. VT DEC’s inspection found:

- VT echoed CT regarding violations and observations
- Issued NOAV on 8/7/2015, with alleged violations and corporate responses being:

1. **Contingency Plan:** Plan was not on site but was provided post-inspection– still issues of no arrangements being made with local authorities was in plan; no emergency coordinator information.
 - A revised contingency plan has been submitted to local authorities and is on site at stores
 2. **Training:** No training records available for review on site – training records sent post-inspection not adequate (e.g., no dates of training, no training elements specified).
 - Rite-Aid has revised its training plan and will forward copies of employee records upon completion of training
 3. **Arrangements with Local Authorities:** No documentation of required arrangements with local authorities.
 4. **Short-Term Storage Area:** Labeling/markings issues on containers.
 - Store placed correct label on container
 5. **Inventory:** No STSA inventory was provided on site.
 - Rite-Aid feels that the need to maintain a detailed inventory is excessive
 6. **Inspection of STSA:** No records of inspections were provided; Rite-Aid stated that only weekly inspections are being conducted, not daily (VT requires daily).
 - Corporate stated that the STSA inspections occur weekly
- Additional Items of Concern noted during inspection:
 1. Lack of manifests pre-dating notification of LQG status (June 26, 2014).
 - Prior to initiation of its Hazardous Waste Program, Rite-Aid stated that all items were returned through reverse distribution
 2. Illegible manifests
 - Rite-Aid's hazardous waste vendor is working to increase font size for better legibility – could this be a transporter issue and/or maybe problem with recopying the manifests?
 3. Potential for storage of incompatible wastes, since plastic bags can break or become unsealed within the container
 - Corporate stated that since Rite-Aid is a retail pharmacy, using heavy-gauge plastic bags to separate hazardous waste items seems reasonable and appropriate
 4. In the contingency plan, store had wrong number of days for written report of an incident to be submitted to our office; plan stated within 15 days, VT requirement is within 10 days
 - Rite-Aid has modified plan for 10 day notification.
 - Since Rite-Aid has not responded to all of the alleged violations, VT has referred this case for formal enforcement.
 - Considers storage bin in pharmacy as satellite accumulation container and front (retail) bin as <90 day storage area.
 - Discussion about scanner gun used to determine if waste is hazardous – using the scanner came about due to a Wal-Mart enforcement case; Rite-Aid uses “The WERCs” program for determination of hazardous wastes; the program uses manually-fed information for waste determinations. Someone stated that “The WERCs” includes state waste codes; CT DEEP confirmed this by saying that after their inspections, they got a lot of questions from manufacturers about waste determinations.

New Hampshire

Briefly discussed how Pharmacy Flex inspections came about from June, 2014 meeting and a request to EPA. NH conducted full CEI inspections at two Retail Pharmacies (one Rite-Aid and one Costco) in FY 2015; since there has been a large increase in LQG notifications, four pharmacies will be inspected in FY 2016. All inspections were conducted in May 2015, with enforcement being near complete on both – enforcement still needs to go through administration route. NH DES's inspection found:

- Issues found during Rite-Aid inspections:
 1. **Hazardous Waste Determination:** There are questions as to how store managed waste prior to 2014, when it notified as an LQG
 2. **Training:** NH does not have all the information yet regarding the training for store handlers of hazardous waste; managers of both stores inspected have previously attended the NH Retail Self-Certification module
 3. **Contingency Plan:** Store had plan on site but wasn't complete – emergency requirements were missing; NH is requesting more information
 4. **Universal Waste:** Waste lamp boxes were not marked nor closed
 5. **Incompatibles:** NH considers plastic bags used to store wastes as containers; no incompatibles observed during inspection; NH wants to ensure that Rite-Aid knows regulations
- Costco was in slightly better shape than Rite-Aid
- NH will share information with other states once results of inspections are final

Plans for FFY 2016

Maine, Massachusetts, and Rhode Island plan on conducting pharmacy inspections in 2016.