Division of Environmental Response and Revitalization
March 2018

The Disposal of Hazardous Pharmaceutical Waste FAQs

THIS POLICY DOES NOT HAVE THE FORCE OF LAW **Hazardous Waste Program**

Frequently Asked Questions

1. **If we are not doing anything to address the proper disposal of pharmaceutical wastes, are we out of compliance? Can we wait for the finalization of the proposed Universal Waste Rule for pharmaceutical wastes?**

   If a facility who generates pharmaceutical wastes is not evaluating their wastes, they could very well be out of compliance and in violation of the hazardous waste rules for improperly managing and disposing of hazardous waste. This would be a violation of Ohio Administrative Code (OAC) rule ***3745-52-11*** and Ohio Revised Code 3734.02. Such a violation could result in the facility receiving a penalty of up $10,000 dollars a day per violation for illegal disposal of hazardous waste.

   You can't wait for the finalization of the ***universal waste rules*** to change to include pharmaceutical wastes. This is because pharmaceutical wastes are presently regulated as either a hazardous, solid or infectious waste and subject to certain management and disposal rules.

2. **Medication remaining in an IV bag, is it used or unused for the purposes of making a hazardous waste determination?**

   Medication remaining in an IV bag (or other container) is unused for the purposes of making a hazardous waste determination. This is true even if a portion of the medication was administered (i.e., used) and the remaining medication is prohibited from being administered to another patient. This is an important concept because the P and U hazardous waste listings only apply to unused commercial chemical products. So, if medication remaining in a container is discarded, that portion is unused and must be evaluated to determine if it is a listed or characteristic hazardous waste.

3. **How should hazardous pharmaceutical wastes be destroyed or otherwise properly removed from the facility for destruction?**

   There are two common options available to facilities with regard to managing hazardous pharmaceutical wastes. The facility may:

   A. Segregate the hazardous pharmaceutical wastes by waste code and treat each waste code in accordance with the specified treatment standard provided in the Land Disposal Restrictions (LDR) rules for that waste code. The LDR rules, ***OAC chapter 3745-270***, dictate to what level a hazardous waste must be treated. The treatment of the wastes may be done on-site by the generator or be sent off-site to a permitted hazardous waste treatment facility for appropriate treatment; or

   B. Create a lab pack. A lab pack is a collection of different types of hazardous wastes (in small volume containers) that are placed in one large container for storage, transportation, and treatment. Please be aware that incompatible wastes cannot be placed in the same lab pack, see OAC rule ***3745-68-16***. Per the LDR rules, lab packs must be treated by incineration unless the lab pack is disassembled by the hazardous waste transporter or permitted facility into the individual waste groups and sent on for further treatment.

   Hazardous wastes must be managed onsite in accordance with the applicable generator management standards found in the ***Hazardous Waste Generator Handbook***. This handbook will answers you questions like; what requirements apply to hazardous waste that I accumulate on site, what are my container management standards, what am I required to do before I ship my hazardous waste off-site, and do I need to manifest my waste to an off-site disposal site. As a small and large quantity generator you must prepare a manifest before shipping hazardous waste off-site. CESQGs are

not required to prepare a manifest. Manifests are multiple copied tracking documents that accompany hazardous waste shipments. The manifest acts as a chain of custody for the waste from the point it leaves your business until it reaches its final destination.

Generators can only treat their hazardous waste in a tank, container or containment building unless they obtain a hazardous waste permit. Please see our guidance about ***generator treatment***.

Furthermore, hazardous wastes can only be treated or stored off-site at a facility that is permitted under Ohio EPA's or U.S. EPA's hazardous waste program. An incineration facility whether on-site or off-site that is permitted by Ohio EPA to burn solid waste and/or infectious waste cannot burn hazardous waste unless it also holds a hazardous waste permit.

4. **Do facilities need to be concerned with how much P-listed and U-listed waste is generated per month and large quantity waste generator status?**

   Yes. If a facility generates more than 2.2 pounds (1 kg) of an acute hazardous waste in a calendar month or 2200 pounds (1000 kg.) of any other hazardous waste, the facility as a whole is a large quantity hazardous waste generator for that calendar month. An acute hazardous waste carries the P- waste code or is followed by an (H) hazard code in its listing. There are a number of requirements a large quantity generator must follow; please see chapter seven of the ***Generator Handbook*** for a summary of these requirements.

5. **How should a facility determine the total weight of hazardous wastes it generates per month?**

   A facility must determine the amount of hazardous waste it generates, in an individual calendar month, by adding together the amounts of hazardous wastes and the amounts of acutely hazardous wastes generated by each department located on-site at the facility. Hazardous wastes generated at off-site associated facilities may not be included in the facility's monthly hazardous waste generation rate. Off-site facilities must determine the amount of hazardous waste they generate. The hazardous waste rules are site-specific so, each hazardous waste generator, by site, must account for the hazardous wastes generated at their facility. Please see our ***Autumn Notifier 2007 article*** on counting our hazardous waste.

6. **Virtually all insulin vials contain a concentration of M-Cresol (D024) greater than the regulatory level of 200mg/L. But this is clearly not the sole active ingredient in the insulin vial. In a hospital, do empty or partially used vials of insulin need to be managed as hazardous waste?**

   In short, yes, unless the container meets the criteria for being classified as empty according to Ohio Administrative Code (OAC) rule ***3745-51-07***.

   M-cresol is a chemical that appears on the list of hazardous constituents that can cause a waste to be classified as a toxic characteristic hazardous waste (i.e., characteristic hazardous waste), OAC rule 3745-51-24. Based on the information provided - that insulin contains greater than 200 mg/L of m-cresol - the insulin would be classified as a toxic characteristic hazardous waste when disposed. Therefore, partially used vials or vials which contain residual insulin that does not meet the definition of empty in OAC rule 3745-51-07 would contain a hazardous waste and be required to be managed and disposed of according to the hazardous waste rules.

   Insulin vials which meet the criteria for being defined as empty are not classified as hazardous waste and may be disposed of into the regular trash.

   In addition, as was stated, m-cresol is not an active ingredient in insulin in this case. It is used as a preservative and is not a chemically active component for the function of insulin. Therefore, residual insulin in a vial would not be defined as a listed hazardous waste when disposed. Whether a chemical is the sole active ingredient is only important when determining if a discarded unused commercial chemical product is classified as a P or U listed hazardous waste, see OAC rule ***3745-51-33***.

7. **In the hospital we use a "Trace Elements" single dose vial that is 1 ml in size and contains chromium 10mg/1ml (D007). This exceeds the regulatory concentration. Once the vial has been used and is effectively empty, must it still be handled and disposed of as hazardous waste? (We have no intention or ability to "triple rinse" these vials.)**

   "Trace Elements" is a nutrient additive that can contain chromium, selenium and other micronutrients.

   A nutrient additive solution containing 10mg/ml of chromium would fail the toxicity characteristic due to its chromium content and be classified as a hazardous waste when disposed. Therefore, vials containing residuals that do not meet the criteria for being empty, OAC rule ***3745-51-07*** would be classified as a hazardous waste, D007, and subject to regulation under the hazardous waste rules.

   Since the solution would only be hazardous waste due to a hazardous waste characteristic, the vial does not need to be triple rinsed in order to meet the criteria for being empty. The vial has to be emptied by common means to the extent possible and not contain more than 3% by weight of the waste or no more than 1 inch of material remains in the container. Please be aware, the triple rinse criteria only applies to containers that hold residues of a chemical that is classified as an acute hazardous waste (i.e., P-listed hazardous waste) when disposed.

8. **Am I correct in assuming that the empty or partially used vials of lidocaine + epinephrine, or bupivacaine + epinephrine that we use in the hospital would NOT be considered hazardous pharmaceutical waste because the epinephrine (P042) is not the sole active ingredient?**

   Correct. The empty or partially used vials would not be listed hazardous waste, P042, because the solutions contain two active ingredients. However, you do need to determine if the residual in non-empty vials meet the definition of a characteristic hazardous waste. Please note: Epinephrine salts do not meet the listing description for the P042 waste listing description and therefore, would not be a listed hazardous waste. Common forms of epinephrine are hydrochloride, bitartrate or borate salts. Please see, US EPA's ***memo***.

9. **Do empty dose wrappers or soufflé cups (that once contained individual warfarin tablets, a P001 substance) need to be handled as hazardous waste?**

   If the dose wrappers or soufflé cups contain visible residues from the tablet, then you need to follow the criteria in OAC rule ***3745-51-07*** to render the container empty. In this case, the wrapper must be triple rinsed or managed as a listed hazardous waste. However, if no residue is visible, then no determination needs to be made on whether the wrapper contains a hazardous waste because there is no waste present in the wrapper. Such a wrapper may be disposed of into the regular trash.

   If you determine that the dose wrapper or soufflé cup must be managed as a hazardous waste, you will need to decide which hazardous waste listing for warfarin applies to the waste. Hazardous waste listing, U248, applies to medication with warfarin concentrations of less than 0.3 percent and hazardous waste listing, P001, applies to medication with warfarin concentrations of greater than 0.3 percent.

10. **Are expired epinephrine pens and tablets listed hazardous waste P042?**

    If the epinephrine used in the pharmaceutical is a salt then the pharmaceutical does not meet the listing description for epinephrine and is not listed hazardous waste P042. The P042 listing only applies to epinephrine CAS # 51-43-4 which does not include epinephrine salts. So, if the epinephrine in the pharmaceutical waste is not a salt then the waste is hazardous waste, P042.

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11. Are discarded nitroglycerin tablets, capsules and sprays listed hazardous waste P081?

Nitroglycerin was listed as a hazardous waste solely due to its reactivity (i.e., ability to explode). However, medicinal nitroglycerin does not exhibit the characteristic of reactivity and therefore, is not classified as listed hazardous waste P075 but it may exhibit another hazardous waste characteristic.

12. What is meant by "sole active ingredient?"

Sole active ingredient means the ingredient (that potentially may be a P or U listed hazardous waste) is the only chemically active component in the pharmaceutical that performs the function of the pharmaceutical.

13. Are non-empty vials of vaccines containing the preservative thimerosal classified as a characteristic hazardous waste when disposed?

Yes, it is likely that discarded vaccines containing thimerosal will be classified as a toxic characteristic hazardous waste due to the presence of mercury.

Thimerosal is a preservative that has been used in some vaccines since the 1930's. It is 49.6% mercury by weight and is metabolized or degraded into ethylmercury and thiosalicylate.[1]

As a vaccine preservative, thimerosal is used in concentrations of 0.003% to 0.01%. A vaccine containing 0.01% thimerosal as a preservative contains 50 micrograms of thimerosal per 0.5 ml dose or approximately 25 micrograms of mercury per 0.5 ml dose.[1]

Using the information above about the amount of thimerosal and mercury in some vaccines, a vaccine containing 0.01% of thimerosal contains 50 mg of mercury per liter of vaccine (50 mg/L). A vaccine containing 0.003% thimerosal contains 15 mg of mercury/L. The regulatory level for classifying a waste as a hazardous waste due to the presence of mercury is 0.20 mg of mercury/L. Therefore, such vaccines would be classified as a characteristic hazardous waste due to the presence of mercury.

14. Where can I find Ohio EPA's hazardous waste rules?

You can find Ohio EPA's laws and rules on the Division of Response and Revitalization's Hazardous Waste Program's ***webpage.*** Also, our ***Generator Handbook*** further explains the hazardous waste rules for generators.

15. How do I classify a waste stream that has both a hazardous and an infectious waste component? For example, an IV bag containing 50 ml of mitomycin C chemotherapeutic agent, listed hazardous waste U010, that is contaminated with blood.

In Ohio, an infectious waste that is also a listed or characteristic hazardous waste must be managed, stored, transported, treated and disposed according to Ohio's hazardous waste rules.

The infectious waste rule that states the requirement is OAC rule ***3745-27-30(C)(7***):

"Any infectious waste or infectious waste mixture that meets the definition of hazardous waste as specified in rule 3745-51-03 of the Administrative Code shall be managed as a hazardous waste in accordance with Chapters 3745-50 to 3745-69 of the Administrative Code. No generator of infectious waste shall transport, or cause to be transported, wastes

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[1] Federal Food and Drug Administration: Thimerosal in Vaccines http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228

deemed hazardous in accordance with rule 3745-51-03 of the Administrative Code to an infectious waste treatment facility licensed in accordance with section 3734.05 of the Revised Code;"

16. **A medication I am administering by injection would be classified as a P-listed hazardous waste if disposed. Therefore, in order to dispose of the syringe as infectious waste, must the syringe be triple rinsed to render the syringe empty and no longer containing a P-listed hazardous waste?**

    If the medication has been fully dispensed from the syringe**,** the remaining residual medication in the needle and syringe is considered used for its intended purpose and no longer classified as a P-listed hazardous waste. Such a syringe does not need to be triple rinsed prior to disposing of it as infectious waste. This approach of not triple rinsing syringes was instituted due to needle stick risks incurred with additional handling - it does not apply to other containers or other delivery devices. However, the syringe, itself, must be evaluated to determine if it is a characteristic hazardous waste.

17. **Do I Ever Need to Manage These Materials as Wastes?**

    When there is reasonable expectation on the part of the manufacturer, distributor or supplier that the material will be recycled, it may be shipped to a third party contractor for handling as a product. For the purposes of this fact sheet, reasonable expectation means that unless an unexpected event occurs, it is believed that the materials will be reclaimed, reformulated or repackaged. When there is no reasonable expectation that the CCPs will be recycled (i.e., the products will be discarded), then the materials must be managed as wastes. They must be evaluated in accordance with OAC rule ***3745-52-11*** to determine if they are hazardous wastes. If the materials are hazardous wastes and will not be recycled, then they must be managed in accordance with the applicable hazardous waste regulations; including manifesting, storing and transporting. Be aware that the waste must be managed as hazardous from the point of generation if it will not be recycled. This means that if a particular product is consistently unusable and must be treated and disposed, it cannot be handled as a non-waste under a reverse distribution system. For more information on the requirements of managing a hazardous waste, please refer to ***the Hazardous Waste Generator Handbook***.

Contact

If you have questions that aren't answered in this guidance, please contact the Hazardous Waste Compliance and Inspection Support Unit of the ***Division of Environmental Response and Revitalization*** at 614-644-2924. For more information about pharmaceutical waste, please review the DEFA web site regarding ***Pharmaceutical waste.***