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“Hazardous Pharmaceutical Waste – Keeping Things Clean”

July 2014

This lesson focuses on HPW in hospital & community pharmacies. The goal is to increase awareness of the need for proper management. The objectives of this lesson are such that upon completion:

Pharmacists will be able:

1. Review current regulations surrounding hazardous pharmaceutical waste (HPW) management.
2. Describe options for properly managing HPW in hospitals & community pharmacies.
3. Identify opportunities for improving the current HPW stream at a facility.

Technicians will be able to:

1. Comprehend regulations associated with pharmaceutical waste.
2. List ways of managing HPW.



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INTRODUCTION

The management of **hazardous pharmaceutical waste (HPW)** is complicated. Multiple regulatory agencies are involved in the oversight of disposal of these agents, at federal, state and local levels.¹ It is also important to remember that the guidelines for disposal of any hazardous waste were originally designed to address industrial waste concerns, not finished pharmaceutical products. Drugs are complex ionic and hydrophilic compounds that are biologically active.² In addition, 90% of drugs enter the waste-stream through patient use.³ This makes it even more difficult to ensure proper disposal. The Associated Press recently published a report on the safety of our drinking water. This report stated that the drinking water supplied to over 41 million Americans contained traces of anticonvulsants, antibiotics, mood stabilizers, sex hormones and other drugs.²

As a result of the pharmaceuticals appearing in the water supply, the World Health Organization has designated these agents as emerging contaminants of drinking water.⁴ There is mounting concern in the scientific, environmental, and governmental sectors on agents known as endocrine disruptors that may interfere with the normal functioning of the hormone system. Endocrine disruptors that are currently being evaluated include agents that mimic or antagonize estrogen hormones, testosterone or thyroid hormones. Endocrine disruption may result in reproductive problems, behavioral changes, or impaired immune system.

Studies have been conducted that evaluate the effects of these endocrine disrupting agents in the waterways.⁵ Data shows that they can alter physiological function in wildlife and humans. Effluents from wastewater treatment plants are a primary method of endocrine disrupting agents reaching the waterways. Their exposure has been associated with a range of reproductive impacts, particularly in fish, including the induction of intersex, lowered hormone levels, and reduced gamete production and fertilization capability.

Every year US hospitals and nursing homes generate more than 100,000 tons of hazardous pharmaceutical waste.² The Environmental Protection Agency (EPA) requires businesses, including healthcare facilities, to safely manage their hazardous waste from the moment it is generated to when it is appropriately disposed of (e.g. cradle to grave).¹ The EPA has become more aggressive recently about ensuring compliance with hazardous waste regulations. They have fined a number of facilities up to \$280,000 for failure to comply with the HPW disposal requirements. In addition, the EPA has sent out notices of their intent to fully enforce the HPW laws in healthcare facilities. The fines average around \$37,000 per incident per day that a facility is in noncompliance. A major concern is that many hospitals and healthcare facilities are not aware of the regulations and may not be fully compliant with the EPA requirements. Not only are the facilities putting themselves at risk for fines, but pharmacies may be fined as well.

Individual state regulations may be more stringent than the federal requirements.¹ Specifically, California, Minnesota and Washington have stricter policies in place. Florida and Michigan have determined that HPW should be disposed using the Universal Waste Rules for their states. As pharmacy professionals, it is important to understand not only what is classified as HPW, but how is it managed in your state.

EPA DEFINITION

HPW is defined by the EPA as drugs that appear on the Agency's P, U and D lists of hazardous waste or a product with hazardous characteristics.¹ These hazardous characteristics are: **ignitability** – (wastes that can readily catch fire and maintain combustion); **corrosivity**

– (wastes that are acidic or alkaline); **reactivity** – (wastes that readily explode or undergo violent reactions or react by releasing toxic gases or fumes); **toxicity** – (wastes likely to leach dangerous concentrations of toxic chemicals into groundwater).

The drugs listed on the **P-list are considered acutely hazardous**.¹ Their oral lethal dose is < 50 mg/kg. The drugs listed on the EPA's **U-list are included because of their chronic toxicity**. Chemical waste shown on the **D-list has at least one of the hazardous characteristics** discussed above. All products on the P, U and D lists must be handled as hazardous waste. There are no concentration limits or dilution exclusions on either the P or U lists. It is important to note that agents listed on the D-list may not be the primary drug in a final product.

P-List Drugs¹

P Code	Drug	P-Code	Drug
P012	Arsenic trioxide	P188	Physostigmine salicylate
P042	Epinephrine	P046	Phentermine
P075	Nicotine	P001	Warfarin >0.3%
P204	Physostigmine		

U-List Drugs¹

U Code	Drug	U-Code	Drug
U034	Chloral hydrate	U010	Mitomycin C
U035	Chlorambucil	U182	Paraldehyde
U044	Chloroform	U188	Phenol
U059	Daunomycin	U200	Reserpine
U075	Dichlorodifluoromethane	U201	Resorcinol
U089	Diethylstilbestrol	U202	Saccharine
U122	Formaldehyde	U205	Selenium
U129	Lindane	U206	Streptozocin
U150	Melphalan	U237	Uracil mustard
U151	Mercury	U248	Warfarin < 0.3%

D-Listed Chemicals¹

D Code	Drug name	Concentration	Type
D004	Arsenic	5 mg/L	Dual
D005	Barium	100 mg/L	Oral
D007	Chromium	5 mg/L	TPN
D024	M-cresol	200 mg/L	Insulin
D013	Lindane	0.04 mg/L	Liquid
D009	Mercury	0.2 mg/L	Vaccine
D101	Selenium	1 ml/L	TPN
D011	Silver	5 mg/L	Creams

These lists were originally developed in 1980 by the EPA and have not changed significantly since that time.⁶ The Agency has recently come under fire by their own Office of Inspector General (OIG) for not establishing a method for regular identification and updating of these lists as new drug products are approved for use. The OIG report stated that they had identified

8 chemicals that should be added to the P-list due to acute hazardous waste, and over 100 agents that should be included on the U-list.

The OIG commented that the National Institute for Occupational Safety and Health (NIOSH) is the federal agency responsible for making recommendations for the prevention of work-related hazardous exposures.⁶ NIOSH publishes the NIOSH Drug Alert list which contains drugs that should be handled as hazardous agents. The Occupational Safety and Health Administration (OSHA) requires healthcare facilities to identify hazardous drugs that must be handled by employees using special precautions. OSHA developed a hazardous drug list in the early 1990s and updates the list regularly. OSHA lists 61 pharmaceuticals on its hazardous drug list, and the latest version of the NIOSH list published in 2010 includes 157 drugs. These lists are substantially more comprehensive than the EPA P and U lists and are often used when developing hazardous waste policies at healthcare facilities.

Test your understanding

In the hospital pharmacists 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 empty, does it need to be handled and disposed of as hazardous waste?

This trace element product is an additive that contains chromium, selenium and other micronutrients. This product contains 10mg/ml of chromium and would be above the amount listed on the D-list table. It would be classified as a hazardous waste if it was NOT empty. The vial has to be emptied and not contain more than 3% by weight of the waste or no more than 1 inch of material remains in the container. If that is done, it can be disposed as nonhazardous waste.

NIOSH DEFINITION

NIOSH defines hazardous drugs as oncology agents, antivirals, hormones, certain bioengineered drugs and a category of miscellaneous drugs.⁷ These drugs possess a minimum of 1 of 6 characteristics: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, or new drugs that have same characteristics of drugs previously determined to be hazardous

A current listing of these agents is available in the NIOSH Drug Alert which can be found at www.cdc.gov/niosh/topics/hazdrug/. The information available through NIOSH is designed to ensure that hazardous drugs are handled safely by healthcare workers. NIOSH also recognizes that institutions should not rely on a printed list of hazardous drugs. This list can be quickly outdated as new drugs become available. NIOSH recommends that each institution make a determination of the hazard risks for each drug, using the NIOSH Alert and other resources as guidance.

STATE REGULATIONS

Various states decided to have more restrictive rules on the disposal of HPW than the EPA. In those states it is important to understand what professional responsibility may be. For example, in 2001, the federal EPA exempted oral nitroglycerin from their P and U lists, and in 2007 epinephrine salts were exempted. Michigan has chosen to be more restrictive and has not adopted these exclusions. In addition, Nebraska requires aerosol can segregation which is more restrictive than federal EPA guidelines.

REGULATION OF HPW

Environmental Protection Agency

Although several regulatory agencies have oversight for the management of pharmaceutical agents, the EPA is the lead agency that establishes proper management of hazardous and non-hazardous waste.¹ The EPA established the Resource Conservation and Recovery Act (RCRA), the Clean Water Act, and the Safe Drinking Water Act. The EPA established a mechanism in RCRA Subtitle D for states to develop plans to manage hazardous waste and prohibits the open dumping of solid waste. Subtitle C of RCRA establishes a system for controlling hazardous waste from the time it is generated, until its final disposal.

Currently household generated hazardous waste is exempt from RCRA regulations.¹ This allows for consumers to dispose of household hazardous waste (including pharmaceuticals) in their trash. This exemption not only applies to waste generated in the home, but also waste generated by residents of long-term care facilities (LTCF). Most LTCFs generate 2 types of waste: that generated through their management of the pharmaceuticals used in the facility; and that generated directly by the residents from drugs under their own control. It is critical for pharmacies supplying medications to nursing homes to understand the regulations related to RCRA waste.

Department of Transportation (DOT)

The DOT is responsible for ensuring that waste haulers and employees preparing waste for transportation have completed the appropriate 6 hours of education related to safe transportation of pharmaceutical waste.⁸ The DOT conducts audits of waste haulers and waste generators to verify that proper processes are in place.

Drug Enforcement Administration (DEA)

When disposing of controlled substances, the DEA requires that the controlled substances be "beyond reclamation".⁹ Although the DEA has not directed healthcare providers to use the drain or toilet to dispose of these drugs, it is common practice. In addition, the FDA-approved package inserts for approximately 13 drugs, including fentanyl, instruct users to dispose of product by using the toilet. There was never any discussion between the FDA and EPA before approving this language in the package insert.

At this time, agencies and healthcare facilities are still waiting on statutory changes by the DEA to fully define a process for the proper destruction of controlled substances. Until that time, healthcare facilities have very few options, and the sink remains one option to render controlled medications irrecoverable. The practice of disposing of pharmaceutical waste in toilets or sinks is one that must be modified.

Pharmacies may dispose of any expired, excess, or unwanted controlled substances by contacting and utilizing the services of a reverse distributor as defined by the DEA.⁹ Reverse distributors must hold a valid Certificate of Registration Number issued by the DEA.

Occupational Safety and Health Administration (OSHA)

Under the OSHA Hazard Communication Standard, all healthcare employees have the right to know if they are handling hazardous agents.¹⁰ They should also expect that their

employer has provided them with necessary protection. All employees handling HPW should undergo training and education to ensure they understand how to properly handle this type of hazardous waste disposal.

The Joint Commission (TJC)

The Environment of Care standards have been expanded to include specific standards on the handling of pharmaceutical wastes.¹¹ Facilities can expect surveyors to ask for DOT manifests for the past 6 months, question employees about the HPW policy or other related topics. If a surveyor finds any violations, they have the right to report a hospital to the EPA as being noncompliant with regard to federal or state regulations.

HOSPITAL MANAGEMENT OF HPW

As stated earlier, state and federal agencies are taking a more aggressive stance in enforcing the EPA regulations for HPW management at healthcare facilities. Hospital pharmacy managers and staff need to understand the impact of HPW and how it should be managed. The EPA has not developed a specific health-system survey that can be used to determine compliance. There is a 10-step blueprint document that hospitals can use to review their current practices.¹

A survey of Directors of Pharmacy (DOP) that was conducted in 2012 reported that 61% indicated the complexity and often conflicting regulations for HPW made it difficult to be fully compliant with the EPA requirements.¹² In addition, about one third of the DOPs reported that there is a lack of in-house expertise about hazardous waste. Hazardous waste can be a complicated problem. There are many types of hazardous and non-hazardous waste. The first step is to determine the various waste streams at the hospital.

Waste Streams

Medical waste is what is typically called "red bag" waste.¹ Medical waste would include any infectious waste, biomedical waste or materials that have come into contact with body fluid. Common items that are medical waste include sharps containers, bandages, surgical gloves, and IV tubing that has been contaminated with blood. Medical waste must be collected and transported by approved waste haulers. Many states have regulations requiring medical waste treatment technologies to be certified, licensed, or regulated. Over 90% of medical waste is incinerated at approved medical waste incinerators.

Nonhazardous pharmaceutical waste consists of pharmaceutical product packaging that has been opened (cardboard and plastic containers), medication that is unused or returned to the pharmacy, partially used IV bags with drug in them, and empty ampules or vials.¹ There is no clear indication of the risk to the environment or the general public from these items. For products in this category that are not regulated by RCRA or state regulations, hospital pharmacies can dispose of them as general waste and send them to a landfill. One exception is the disposal of inhaler medications. Individual states have stricter regulations for these devices and may require them to be segregated or punctured and rinsed before being placed in the nonhazardous pharmaceutical waste stream.

Hazardous pharmaceutical waste includes all drugs with RCRA characteristics as described above or any drugs that are on the P or U-lists.¹ It is important to note when developing

the waste stream management program that all containers that come into contact with these hazardous drugs must also be handled as RCRA waste and be disposed of in an RCRA approved container. Each hospital must create their own list of hazardous pharmaceutical agents and should evaluate drugs that meet the RCRA definition as well as any agent that may appear on NIOSH or OSHA lists. Only about 5% of the drugs used in the hospital qualify as RCRA hazardous waste, but many more have the characteristics of RCRA hazardous agents. The problem is that the RCRA list has not been updated since 1980.

Test your understanding

Medication remaining in an IV bag, is it considered "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). 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.

Many facilities have established a process to determine the appropriate waste stream of a drug when it is added to the formulary.¹³ By reviewing each new drug, the pharmacy can determine how the product should be disposed of and create a process for proper disposal. Many facilities will label the product in such a way to alert staff of how to dispose of the product (nonhazardous pharmaceutical waste, hazardous pharmaceutical waste).

PHARMACEUTICAL WASTE MANAGEMENT PROGRAM

When implementing or updating a pharmaceutical waste management program, the hospital should take a multidisciplinary approach to the problem.¹³ It is important to consider where HPW is generated within the healthcare facility. Not only is it created in the hospital pharmacy, but waste from these agents is created on the nursing unit, in patient rooms, in clinics, and specialty units such as infusion centers, MRI suites and operating rooms.

Think of a typical 300 bed hospital. If you consider all the areas a drug is handled, there could be over 400 potential hazardous drug contact points.

Example: where are hazardous drug contact points in a 300 bed hospital?

Hospital Loading Dock--- hazardous drugs are received.

Pharmacy--- hazardous drugs are delivered from the dock; storage of hazardous drugs (Inventory area); compounding of hazardous drugs (IV room).

Medication delivery---individual is delivering hazardous drugs to patient care area.

Oncology Unit--- hazardous drugs are delivered.

Intensive Care Unit--- agents are infused.

Operating Room or interventional radiology unit--- waste is created during infusion process.

Housekeeping--- cleans areas where hazardous drugs are used or stored.

Patient room---hazardous drugs may be administered

Medical office building--- infusion suite.

MANUAL SORTING OF REGULATED WASTE

Some hospitals have determined that manual sorting of regulated waste is most appropriate for managing their HPW.¹³ In these cases, drugs are dispensed in colored overwrap bags that correlate with the type of waste container that should be used for disposal. For example, chemotherapy can be dispensed in a yellow bag and that indicates it should be disposed of as hazardous waste in a yellow container. RCRA waste can have a black overwrap indicating it should be disposed of in a black waste container for RCRA waste. Biomedical hazardous waste should be disposed of in a red container. Each of these containers needs to be available wherever HPW may occur.

ELECTRONIC WASTE DEVICES

Another method of managing HPW in the hospital is the use of electronic devices. One such device is the Pyxis ECOstation which identifies, sorts and segregates HPW and provides tracking reports.¹⁴ The clinician scans the used product and then places the waste into the EcoStation. It is automatically sorted and placed into the correct receptacle. By automating the identification and sorting of residual drugs, empty containers and IV admixtures, this system can reduce errors inherent in the manual sorting of pharmaceutical waste.

CONTROLLED SUBSTANCE WASTE

The Smart Sink is a small container with three openings to dispose of medications: one for solids, one for liquids, and one for patches. The openings are configured so that sharps cannot be placed into the unit.¹⁵ Each opening is associated with a separate container that has compounds that render the drugs unrecoverable and unusable.

The Smart Sink can be securely mounted to a wall or countertop at the nursing unit.¹⁵ The nurse places the waste into the appropriate opening. When a container is full, there is an audible alarm and a blinking red light. Custom locks and security keys are supplied with every unit, allowing only authorized staff to open them.

Another form of narcotic waste removal is the MedSorb ContraPatch device.¹⁶ This product is designed specifically for use with transdermal narcotic systems (Fentanyl). The device deactivates the residual drug that is found in used transdermal patches. To use this device, the release liners from the ContraPatch are placed on the drug side of the patch, and then the product is placed under warm water for 15 seconds. The product is then placed into a ziploc bag and disposed of as nonhazardous trash.

COST OF WASTE REMOVAL

The primary types of waste streams used in the hospital for HPW are municipal incineration and medical waste incineration for chemotherapy related waste.¹⁷ Both of these waste streams eventually end up in a landfill. RCRA specified hazardous waste requires incineration by an approved facility that will create EPA-safe RCRA waste. The hospital's vendor who incinerates chemotherapy may not be approved for RCRA waste incineration so it is important to verify their status.

It is critical to educate healthcare workers about the cost of HPW disposal.¹⁷ Many times it seems just easier for the nurse to throw everything in the same container. If the cost of each

type of waste is reviewed, it is easy to visualize the impact of these costs on the hospital's finances. This is why some institutions have moved to electronic methods of sorting RCRA waste, to prevent unnecessary overuse or misuse of the RCRA waste stream.

Cost of Hospital Waste Removal¹⁷

Type of waste	Examples	Cost per pound
Biohazardous Medical Waste	Blood products, sharps, material contaminated with blood.	\$0.01
Hazardous and non-hazardous waste	Empty chemotherapy vials, syringes, IV, tubing, gowns, packaging, gloves.	\$0.10
RCRA Waste	Bulk chemotherapy in vials, unused IV's, P,U toxic and ignitable. Overtly contaminated gowns, glove, chemo spill cleanup material.	\$1.20

ELECTRONIC WASTE DEVICES

A number of large community pharmacy chains have been fined by the EPA and its state regulators for violation of hazardous waste disposal laws.¹⁸ One chain must pay \$81.6 million after pleading guilty to criminal charges of mismanagement of hazardous waste.¹⁹ Others who have been fined in the past 2 years include penalties of \$13.75 million & \$16.6 million. One lawsuit claimed that employees were illegally dumping pharmaceutical and biohazardous waste into regular trash bins rather than sending the waste to authorized disposal sites.

The EPA is currently developing a proposed rule that would subject retail pharmacies and others to healthcare facility specific hazardous waste pharmaceutical management standards.¹⁸ The proposed rule is scheduled to be released in August 2014. The agency issued a "Notice of Data Availability" (NODA), a report that summarizes the recent history of retail hazardous waste disposal, and has called for a public comment period to help inform its decision-making. The comment period ended April 15, 2014.

There are a number of actions the EPA may take from this NODA. It could be a memo offering industry guidance to new federal retail hazardous waste disposal regulations, and a number of other possibilities within that spectrum. Regardless of the outcome, this has brought increased attention to the industry. Community pharmacists should pay close attention as these decisions are enacted to ensure rapid compliance. Combined with state-issued fines, retail pharmacies could face substantial penalties daily for even routine violations such as mislabeled, misidentified or improperly stored hazardous waste. The financial and legal implications of noncompliance are significant, but negative publicity attached to federal or state violations against a pharmacy can impact the reputation of the pharmacy.

The EPA will focus on the identified vulnerabilities of retail pharmacies. The EPA has been inspecting these businesses and has identified areas of noncompliance that should be addressed.¹⁸ One area of vulnerability is how to manage returned or otherwise expired or unusable consumer products in accordance with the hazardous waste laws.

Your pharmacy should ensure that all staff knows: Is a product considered hazardous waste; how should the product be shipped off site for waste disposal; and what are the record-keeping requirements?

Training of pharmacy staff is critical to meet the regulatory requirements. All staff handling prescription drugs as well as consumer products must be properly trained on the proper disposal of returned and expired materials to meet the hazardous material requirements.

Some specific examples provided by the EPA after their inspections included: improper employee training; incorrect or missing hazardous waste identification system; spill evidence and improper clean-up/disposal; materials poured down the drain; no procedure for dropped pills; incorrect waste manifests.

Test your understanding

Do empty unit dose blisterpacks that contained individual warfarin tablets need to be handled as hazardous waste?

If no residue is visible, then no determination needs to be made on whether the blisterpack contained a hazardous waste because there is no waste present in the blisterpack. It may be disposed of into the regular trash.

Community pharmacies may want to consult organizations or companies with experience in this area to assist in the development of a plan for managing hazardous waste.¹⁸ Reverse distributors can be used to handle processing unused or expired medications for credit. This process is in compliance with EPA regulations. Of course, certain items would never be returned for credit (compounded products, patient containers, liquid spills). These items would be handled by the pharmacy HPW program and state regulations.

As mentioned earlier, aerosol spray containers may be listed as HPW in some states (such as Nebraska). Many inhalers contain chlorofluorocarbons (CFCs), a propellant that may have effects on the protective ozone layer. However, CFCs have been phased out of inhalers and have been replaced with more environmentally friendly inhalers. Examples of medical aerosol containers include Cetacaine spray or ethyl chloride spray.

Read handling instructions on the labeling of inhalers and aerosol products because they could be dangerous if thrown into a fire or incinerator.¹ To ensure safe disposal that complies with local regulations and laws, contact your state regulatory agency and local trash and recycling facility. Some states offer specific guidance on how aerosol cans may be disposed of. These include California, Ohio, Colorado, Minnesota and Kansas. Some states require puncturing of the container prior to incineration, or triple rinsing of the container.

CONCLUSION

Both hospital and community pharmacies have identified managing HPW as a priority. In part this may be due to the increased environmental concerns; however, the fines with noncompliance are significant. A recent survey suggests that 60% of DOPs have not been able to be fully compliant with the regulations because of the complexity and confusion associated with the regulations. The EPA has also identified the need to be more aggressive with inspecting health systems as well as community pharmacies for noncompliance with HPW disposal. Pharmacy professionals can have an active role both at the institution and in the community pharmacy in reducing drug waste and improving compliance with EPA guidelines.

CASE STUDIES

Scenario 1

The Joint Commission is scheduled to come to the hospital in the next 12 months for an inspection. As the DOP, you are concerned that the hospital may not be in compliance with disposal of HPW. You meet with the Director of Nursing to discuss your concerns and she agrees that the hospital needs to look closely at how HPW is discarded. What are the first steps that you take as a DOP?

The first step is to form a multidisciplinary committee to review the current process of HPW and identify areas of potential noncompliance. It is important to include not only individuals from the pharmacy, but other stakeholders including hospital administration, nursing, physicians and environmental services. Next, your committee may want to investigate how HPW is disposed of currently. This can be done simply by walking around the nursing units and pharmacy to determine how people dispose of these products.

The committee has met and identified areas for improvement. A new plan has been implemented and has been in place for 5 months. What if anything do you need to do to prepare for the Joint Commission visit?

Since hospitals can expect surveyors to ask for DOT manifests for the past 6 months, it would be useful to have a "mock mini-survey" and question staff about the HPW policy. You might have some of the committee members go to the nursing units and patient rooms to determine if hazardous waste is being disposed of properly and question the staff. If a surveyor finds any violations, they have the right to report a hospital to the EPA as being noncompliant with regard to federal or state regulations. This "mini-survey" can help you identify areas that continue to need to be addressed and provides an adequate amount of time for changes to take place prior to the Joint Commission visit.

Scenario 2

You are the pharmacist in charge at Community Pharmacy, a local independent pharmacy in your town. Your pharmacy provides drugs to the local nursing home. When processing returns, you notice that the pharmacy technician is tossing used aerosols and inhalers into the regular trash containers. What do you do?

First it is important to determine what the state regulations are that pertain to disposal of aerosols. After determining the proper method of disposal of aerosols, you should educate the pharmacy technician as well as the rest of the staff on the proper disposal procedures.

Scenario 3

You are a pharmacist filling in for a friend at another pharmacy. The pharmacy technician is cleaning out the storage area and comes across a box of broken thermometers. There is some mercury at the bottom of the drawer. What do you say to the technician about disposing of this material?

Mercury is a U-list chemical on the EPA list. Disposal of mercury should be done following RCRA waste guidelines. You check the pharmacy policy manual to determine what their policy is for disposal of RCRA waste. All material that has been contaminated with mercury while the technician cleaned up the broken thermometers is considered RCRA waste and should be handled as such.

REFERENCES

1. Managing pharmaceutical waste: a 10-step blueprint for healthcare facilities In the United States. <http://www.hercenter.org/hazmat/tenstepblueprint.pdf>. Updated August 2008. Accessed June 4, 2013.
2. Donn J. Medical facilities making uncontrolled releases of controlled drugs into water. AP website. http://hosted.ap.org/specials/interactives/pharmawater_site/sept14b.html. Accessed June 4, 2013.
3. Silverman E. Gulp: The medicines in your drinking water. National Health Federation website. <http://www.thenhf.com/article.php?id=506>. Accessed March 15, 2014.
4. Pharmaceuticals in drinking water.: Public health and environment water, sanitation, hygiene and health. World Health Organization. 2011.
5. Filby A, Neuparth T, Thorpe K, Owen R, Galloway T, Tyler C. Health impacts of estrogens in the environment, considering complex mixture effects. *Environ Health Perspect*. 2007;115(12):1704-1710.
6. U.S. Environmental Protection Agency, Office of the Inspector General. 12-P-0508. EPA inaction in identifying hazardous waste pharmaceuticals may result in unsafe disposal. epa.gov/oig/reports/2012/20120525-12-P-0508.pdf. Accessed March 20, 2014.
7. Department of Health and Human Services. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012. <http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf>. Accessed March 21, 2014
8. Department of Transportation. How to comply with federal hazardous material regulations. <http://www.fmcsa.dot.gov/safety-security/hazmat/complyhmregs.htm>. Accessed March 28, 2014.
9. US Department of Justice, Office of Diversion Control. Pharmacist Manual Sect I-VIII. http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.htm#4. Accessed March 28, 2014.
10. Occupational Safety and Health Administration. Pharmacy etool. <https://www.osha.gov/SLTC/etools/hospital/pharmacy/pharmacy.html>. Accessed March 28, 2014.
11. The Joint Commission. Standards BoosterPaks. A quality improvement tool. http://www.jointcommission.org/standards_booster_paks/. Accessed March 28, 2014.
12. Halvorson D. Embracing responsibility. *Pharm Purch Prod*. 2012; 12:S1-S5.
13. Managing pharmaceutical waste: a discussion guide for health-system pharmacists. American Society of Health-System Pharmacists website. <http://ashpadvantage.com/docs/PharmaWaste-Discussion-Guide.pdf>. Accessed March 28, 2014.
14. Carefusion. Pyxis ECOSation. <http://www.carefusion.com/medical-products/medication-management/medication-technologies/pyxis-ecostation/>. Accessed March 23, 2014.
15. Cactus. What is the SmartSink? <http://www.cactusllc.net/what-is-smart-sink.cfm>. Accessed March 23, 2014.
16. Medsaway. MedSorb Contrapatch. <http://contrapatch.com/product-description/>. Accessed March 23, 2014.
17. Masoomi F. Pharmaceutical waste. Is your facility at risk?<http://www.psqh.com/september-october-2012/1408-pharmaceutical-waste-is-your-facility-at-risk.html>. Accessed March 21, 2014.
18. Environmental Protection Agency. Hazardous waste management and the retail sector: Providing and seeking information on practice to enhance effectiveness to the RCRA program. http://www.epa.gov/waste/hazard/generation/retl_noda_fnl_020414.pdf. Accessed March 21, 2014.
19. California Environmental Enforcement Agency. Enforcement orders and judgments. <http://www.calepa.ca.gov/Enforcement/Orders/>. Accessed March 21, 2014.

Fill in the information below, answer questions and return **Quiz Only** for certification of participation to: CE PRN®, 400 Lake Cook Road, Suite 207, Deerfield, IL 60015.

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?
 Review HPW regulations YES NO
 Describe options to manage HPW YES NO
 Identify opportunities to improve HPW management YES NO
2. Was the program independent & non-commercial YES NO
Low Relevance Very Relevant
3. Relevance of topic 1 2 3 4 5 6 7
4. What did you like most about this lesson? _____
5. What did you like least about this lesson? _____

Please Mark the Correct Answer(s)

- | | |
|---|---|
| <p>1. Which of these is NOT considered an endocrine disruptor?
 A. Synthroid
 B. Estrace
 C. Prozac
 D. Humatrope</p> <p>2. The amount of HPW produced by US hospitals & nursing homes is:
 A. 250,000 tons B. Over 100,000 tons
 C. 45,000 tons D. 150,000 tons</p> <p>3. The EPA P-list drugs are:
 A. Acutely hazardous because of low LD50
 B. Cause chronic toxicity
 C. Have specific concentration limits
 D. None of these</p> <p>4. The EPA's P, U & D lists have been updated quarterly since 1980.
 A. True B. False</p> <p>5. How many hours of education regarding safe transportation of hazardous agents are required for waste haulers & employees preparing waste for transportation?
 A. 4 B. 6
 C. 8 D. 16</p> | <p>6. Which of these are examples of nonhazardous pharmaceutical waste?
 A. Empty vials
 B. Cardboard containers
 C. Syringe with 5 ml of vincristine
 D. A & B</p> <p>7. Which of these are examples of medical waste?
 A. Sharps containers
 B. Bandages with blood
 C. Used surgical gloves
 D. All of these</p> <p>8. Each violation of the RCRA results in a fine of:
 A. \$37,000 per day
 B. \$5,000 per day
 C. \$50,000 per day
 D. \$15,000 per day</p> <p>9. The cost of disposing of RCRA waste is:
 A. \$0.01 per pound
 B. \$1.20 per pound
 C. \$0.1 per pound
 D. \$0.90 per pound</p> <p>10. Which agency is the primary one regarding HPW management?
 A. OSHA B. NIOSH
 C. DEA D. EPA</p> |
|---|---|

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