Q&A

With Charlotte A. Smith, RPh, MS, HEM,
President of PharmEcology Associates, LLC

Developing an **EPA-Compliant Waste Management Program**

Photo courtesy of Kendall-LTP

"If you don't use a hazardous waste container for unused chemotherapy agents, you are in violation of RCRA," says Smith.

PP&P: How frequently should a hospital expect an EPA audit of their pharmaceutical waste management practices?
Smith: It depends on the EPA region. There are certain hot spots, such as Regions I and II. Over the last year or so, Regions IV and VII have seen increased auditing activity. In addition to EPA audits, hospitals may be audited by state agencies for compliance with RCRA guidelines for waste management. Minnesota has been the most aggressive, so to speak, over the last few years, but we have also seen RCRA audits in Florida, California, Connecticut, and Alabama. So geographical location has a lot to do with the odds that the EPA will audit your hospital. However, I do believe it is just a matter of time before your hospital is audited. It's a "when" and not an "if" situation.

PP&P: Under what circumstances are hospitals most likely to be audited?
Smith: The inappropriate disposal of waste could certainly trigger an audit, even if it isn't pharmacy-related. Once the EPA is in the hospital, they will most likely inspect how drugs are being disposed of in the pharmacy and throughout the organization.

PP&P: Would you say a majority of hospitals are currently in compliance with EPA guidelines?
Smith: I would say about 15% to 20% of hospitals are reasonably compliant right now. I hope that most hospitals will start moving toward compliance before being audited and subsequently cited.

PP&P: How would you recommend hospitals respond to an enforcement action?
Smith: First, you should respond as quickly and appropriately as possible. Demonstrating progress is extremely important. Begin by immediately analyzing your inventory to identify drugs that classify as hazardous waste. That kind of activity goes a long way in demonstrating a hospital's intent to achieve full EPA compliance as quickly as possible. Hospitals need to be very proactive. A self-disclosure audit is also a great way to identify violations before the EPA shows up. Of course, you have to fix any problems you find, but you won't be fined for them. The main thing is to be very focused on responding to any citations.

PP&P: How can hospitals limit the financial risks associated with EPA audits?
Smith: It all comes back to moving in the direction of compliance. Taking the necessary actions now will mitigate risk, but it has to be real action. It can't just be lip service. You have to actually identify, segregate, and manage your pharmaceutical waste appropriately.

PP&P: What specific practices can pharmacies examine to determine their EPA and RCRA compliance? Are certain aspects of waste management more error-prone than others?
Smith: Chemotherapy waste is the low-hanging fruit for auditors. The EPA lists nine chemotherapy agents as hazardous waste, and over the years, many hospitals have disposed of them in yellow chemo containers, because they say "chemotherapy waste" on them. However, we didn't understand that those were going to a regulated medical waste (infectious waste) incinerator, which is not the appropriate disposal site for RCRA-listed hazardous waste. Rather, unused listed chemotherapy waste must go to a higher-level incinerator with

cradle-to-grave tracking. Waste vendors need to be very clear with their customers as to what their permits allow. A regulated medical waste incinerator is not permitted to dispose of hazardous waste, which must be transferred to a treatment, storage, and disposal facility (TSDF) permitted by EPA. Some hazardous waste vendors are now permitted to accept regulated medical waste as a service to their customers. The only way to be sure of a vendor's status is to require copies of their EPA and state permits.

One of the easiest things for a regulator to spot is an inappropriately used yellow chemotherapy container. Only RCRA-empty containers and trace contaminated items should be placed in a yellow chemotherapy container. If you don't use a hazardous waste container for unused listed chemotherapy agents, you are in violation of RCRA. Also, because the laws haven't been updated, in addition to the nine listed by the EPA, there are over 100 chemotherapy drugs that really should be disposed of as hazardous waste. As a best management practice, all remaining chemotherapy in the pharmacy and on the nursing units should be managed as hazardous waste.

PP&P: It costs more to dispose of hazardous waste. Do you have any suggestions for managing those costs?
Smith: Yes, the cost per pound is higher. The best way to manage costs is to first properly segregate the waste so only those items that need to be discarded as hazardous waste enter that waste stream. The next phase is to examine why a drug that becomes hazardous waste needed to be wasted and see if changes in purchasing or practices can reduce the amount of waste generated.

PP&P: What red flags will cause inspectors to dig deeper into a facility's waste management practices?
Smith: Let's say the inspectors start with the safety department – not pharmacy. A lack of drugs on the hazardous waste manifest is a red flag. Also, a lack of hazardous waste containers in the pharmacy or on the nursing units is a pretty good indicator

for inspectors that proper waste management isn't happening. So those are some high-profile, easy-to-spot indicators that auditors will look for.

PP&P: Where else should pharmacy focus its waste management efforts?
Smith: About 5% of pharmacy's inventory classifies as hazardous waste, including epinephrine and nicotine. All hazardous waste in your inventory needs to identified, and then you need to develop a system for segregating that waste. H2E's "Managing Pharmaceutical Waste" blueprint (www.h2e-online.org/docs/h2epharmablueprint41506.pdf) identifies five different models for waste management, each offering a different level of sophistication. A hospital can choose the most logical mode for its operations and implement it to achieve proper disposal of hazardous agents.

Bar code-driven systems like Vestara's EcoRex can simplify waste stream segregation.

Photo courtesy of Vestara

After identifying all hazardous waste in your inventory, you need to develop a system for segregating that waste.

Photo courtesy of Stericycle

PP&P: What is pharmacy's responsibility in a hospital's overall waste management plan?
Smith: Pharmacy is responsible for identifying drugs that become hazardous waste, and also needs to be knowledgeable about the rules that apply to waste management. The safety department can't be expected to understand 3,000 to 4,000 different pharmaceuticals; it's not their job, and they haven't been trained to do it. So pharmacy should take the lead on the identification piece, but the participation of safety, environmental services, and nursing is absolutely critical to making a waste management plan work. Safety will be highly involved in storing, manifesting, and labeling waste. Environmental services is often involved in transporting waste from satellite locations to the storage accumulation location. And nurses discard many of the drugs that become hazardous waste, making it incumbent upon them to understand the proper disposal methods. It is important to involve all of these departments in the development of your waste management plan, and ideally, purchasing, administration, infection control, and risk management will also be involved, at least peripherally.

We have found the "champion" of the process may be from pharmacy, safety, or environmental services. Most often, it is the safety department that leads the process through their knowledge of the hazardous waste regulations. They often chair the Joint Commission Environment of Care committee, which is a good place to start. The membership may need to be expanded to include pharmacy and nursing.

PP&P: What kind of waste management training does pharmacy need?
Smith: Ideally, we should begin teaching these practices in schools of pharmacy. Each pharmacist needs to understand the basics. But

in the field, we need additional continuing education programs for waste management that evolve with changing state regulations. Also, pharmacists can stay informed through organizations like Hospitals for a Healthy Environment (www.h2e online.org). This is not a static issue, so it is very important for pharmacists to stay up-to-date, particularly in terms of what state inspectors are looking for.

PP&P: **How often should a pharmacy evaluate their inventory to identify hazardous drugs?**

Smith: Ideally, every pharmacy should do an initial total inventory analysis of every drug purchased over the last 12 months – not just a formulary analysis, as all off-formulary purchases must also be included in the analysis. Involve other departments like radiology and respiratory therapy, as they also may have purchased hazardous materials. Next, a process for continuous evaluation should be established. PharmEcology recommends the creation of a spreadsheet that pharmacy can update when new items are added to the inventory. In addition to the inventory-analysis system, a labeling system for hazardous drugs needs to be established. Like any other system, your hazardous waste policy needs to become a routine standard operating procedure. This is a fairly labor-intensive process, which is why I think bar code-driven devices will become more popular in the future as hospitals to seek to replace manual waste management processes with more efficient automation.

PP&P: **What are pharmacy's documentation responsibilities surrounding waste management?**

Smith: It is very important that pharmacy document the process for determining which pharmaceuticals become hazardous waste. This documentation must include the references used during their analysis. If they are using an outside firm, the third-party should have that documentation available. In terms of documenting the amount of generated waste, pharmacy typically coordinates with the safety department. If you generate more than 2.2 pounds of P-listed waste within a calendar month, your organization will be designated a large waste generator (LQG). So

the safety department may ask pharmacy and nursing to document how much P-listed hazardous waste they are generating per month. Small waste generators have significant documentation burdens, because they must continue to document P-listed waste generation monthly to be sure they retain their small quantity status. If the monthly amount exceeds the 2.2-pound limit, they become a large quantity generator for that month. Once they have met those requirements, it makes more sense to remain an LQG. Except for this issue, the pharmacy doesn't have too many documentation requirements beyond the initial development of the waste management plan.

PP&P: What hazardous waste storage issues should pharmacy keep in mind when seeking EPA compliance?

Smith: It's important to have satellite accumulation in the pharmacy. Some pharmacies are designated as storage accumulation areas, but there are a lot of additional rules for a storage accumulation area, which is typically in the basement in a locked, restricted-entry, fire-safe room. So, ideally, pharmacy is a satellite accumulation area, equipped with the right containers. To ensure proper storage of waste, pharmacy should also inspect their containers for leakage on a weekly basis.

PP&P: What kind of hazardous drug spill-management policy should pharmacy put in place?

Smith: A maximum spill amount, such as 5, 10, or 30 mL, that pharmacy is expected to clean up should be established. Furthermore, spill kits that include personal protective equipment should be available in the pharmacy, and the entire pharmacy staff should be actively trained on the spill procedure. I recommend training demonstrations using water. Pour out an amount of water equaling your established maximum spill so that everyone can see what it looks like. Your hazardous material response team should also be trained on your procedure. In addition, define the spill quantity at which it is prudent to call in the facility hazardous material response team or the fire department's hazmat team. Keep in mind that fire department intervention is expensive and disruptive. So be sure to set the respective limits at appropriate levels.

PP&P: What immediate steps should pharmacy take to ensure the proper handling of hazardous waste?

Smith: I think the first step is to manage chemotherapy properly, since improper management is very obvious to EPA auditors. Secondly, you should begin to identify the rest of your hazardous pharmaceuticals and start moving toward a compliant plan. It can take an organization more than 12 months to get into compliance. So this is not a trivial process. Third-party service providers and consultants can likely provide thorough inventory analyses in a much shorter timeframe. It is most important to apply the necessary time and resources to compliance before you are audited. Compliance requires a lot of coordination and is much easier to do if you don't have a 60-day notice of violation hanging over your head. ■

Charlotte A. Smith, RPh, MS, HEM, is president of PharmEcology Associates, LLC, an information management and consulting company specializing in the cost-effective, compliant management of hazardous pharmaceutical waste. She can be reached at csmith@pharmecology.com or 262-814-2635.

WHERE TO FIND Waste Management Products and Services:

Vendor	Reader Service Number
Attentus Medical Sales, Inc.	23
Clean Harbors Environmental Services	24
Hospitec, Inc.	25
Kendall-LTP	26
Stericycle Inc.	27
Strong Pharmaceutical Services	28
Veolia Environnement	43
Vestara	44

Web Resources:

EPA Enforcement & Compliance History Online: www.epa.gov/echo

Hospitals for a Healthy Environment: www.h2e-online.com

PharmEcology Associates, LLC: www.pharmecology.com

RCRA Online: www.epa.gov/rcraonline