ENVIRONMENTAL HEALTH & ENGINEERING

MANAGING PHARMACEUTICAL HAZARDOUS WASTE IN THE HOSPITAL

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Federal U.S. Environmental Protection Agency (EPA) and state Departments of Environmental Protection (DEP) have recently begun inspecting and citing hospitals for improper disposal of pharmaceutical hazardous waste. This new scrutiny is not the result of changes in regulations but is rather recognition that pharmaceuticals are often overlooked as a source of hazardous waste in hospitals and are typically combined with biohazardous medical waste.

Regulatory Requirements

The primary regulations that apply are the EPA hazardous waste regulations falling under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261–265. These regulations address the definition of hazardous waste, the requirement for hazardous waste generator registration, the establishment of satellite and main accumulation areas for hazardous waste, and the processes for labeling, storage, handling, inspections, training, disposal, and record keeping.

In regulatory terms, a RCRA hazardous waste is a waste that appears on one of the four hazardous wastes lists (F-list, K-list, P-list, or U-list) or exhibits at least one of four characteristics—ignitability, corrosivity, reactivity, or toxicity. The F- and K-lists apply to industrial waste products, and only the P-list and U-list apply to hospital wastes. The P-list is what the EPA considers "acutely hazardous". P-listed materials, their residue, and empty containers which contained those materials that must be disposed as hazardous waste. Some of these materials or certain forms of these materials may be exempt under federal rule, such as nitroglycerin. U-listed materials must also be treated carefully, but in this case only partially filled containers must be disposed as hazardous waste. Empty containers may be disposed as trace chemotherapy waste.

Hazardous waste must be disposed of in a designated container with a special hazardous waste label. It must say hazardous waste, the name of the materials in the container, the type of hazard (e.g., toxic, ignitable, reactive, or corrosive), and

the date the container became full. There must be a sign designating the hazardous waste satellite accumulation area (SAA). The SAA must be inspected weekly for any spills, leaks, or improper closures. An individual knowledgeable in the generation of this waste and applicable rules must be responsible for the SAA. Hazardous waste must be removed to a main accumulation area (MAA) within three days of the container being filled. There may be other specific requirements by your state DEP.

The RCRA hazardous waste must be transported by a licensed contractor to a state licensed EPA permitted Treatment, Storage and Disposal (TSD) facility for hazardous waste incineration. This is a high temperature incineration process that breaks down the chemical structures of the materials, and the ash is put into a lined hazardous waste landfill. This is a different process from medical waste incineration.

As a hazardous waste generator, you are classified as a small quantity generator until you exceed 220 pounds of hazardous waste or 2.2 pounds per month of P-listed waste. If you do, then you must reclassify your generator status as a large quantity generator (LQG). Additional requirements apply to LQGs under RCRA such as shorter time limits on accumulation and storage of waste at your site (90 days); submission of a "biennial report" on hazardous waste tracking; and more comprehensive training for employees managing the hazardous waste program.

Drugs as Hazardous Waste

Some examples of P-listed drugs (acutely hazardous waste) found in hospitals are listed below:

- *P012 - Arsenic trioxide (Trisenox)*
- *P042 - Epinephrine (Adrenalin)****
- *P075 - Nicotine (Nicoderm)*
- *P081 - Nitroglycerine*
- *U129- Lindane (Kwell lotion)*
- *P046 - Phenteramine*

- *P188 - Physostignine salicylate (Antilirium)*
- *P001 - Warfarin >0.3% (Coumadin)*

*** Does **NOT** include epinephrine salts as part of the federal hazardous waste program. Most or all of epinephrine used in healthcare applications is in the form of epinephrine salts. State regulations may be applied differently in this case and the regulated party is encouraged to clarify P042 regulations at the state level.

All expired, unused, or partially filled vials, bottles, bags, and tubing for P-listed drugs **AND** all empty containers for P-listed waste must be disposed of as hazardous waste. Any tubing or container with more than a few milliliters is **NOT** considered empty. This would include moistened clean-up materials. Those items should go into the hazardous waste collection containers.

Examples of U-listed drugs are:

- *U015 - Azaserine*
- *U035 - Chlorambucil (Leukeran)*
- *U034 - Chloral hydrate*
- *U026 - Chlornaphazin*
- *U158 - 2-Chloroaniline*
- *U-058 - Cyclophosphamide (Cytoxan)*
- *U059 - Daunomycin*
- *U089 - Diethylstilbesterol*
- *U116 - Ethylene thiourea*
- *U181 - 5-Nitro-0-Toluidine*
- *U109 - Benzene hexachloride shampoo*
- *U010 - Mitomycin C*
- *U150 - Mephalan (Alkeran)*
- *U206 - Streptozotocin*
- *U237 - Uracil mustard*
- *U248 - Warfarin <0.3% (Coumadin)*

All expired, unused, or partially filled vials, bottles, bags, and tubing for U-listed drugs must be disposed of as hazardous waste.

The EPA lists do not include many of the new chemotherapy drugs. However, if tested for toxicity, many of the new chemotherapy drugs would meet the characteristic of toxicity. A current list of hazardous drugs has been prepared by the National Institute for Occupational Safety and Health (NIOSH). This list contains approximately 135 hazardous drugs including new antineoplastics, antivirals, and endocrine disruptors. Endocrine disruptors have been of concern due to their possible effects on animal life, particularly aquatic life in the environment. We recommend that hospitals include the drugs on the NIOSH list in their hazardous waste program. It should be noted that NIOSH is not a regulatory or enforcement agency and their list has not been formally adopted by the EPA for hazardous waste regulatory enforcement purposes.

Reverse Distributors

Expired and unopened or unused drugs are typically collected from pharmacies by a "reverse distribution vendor." For those items that are not returnable to the manufacturer and meet the EPA definition of hazardous waste, the "reverse distribution vendor becomes the hazardous waste 'generator' and must dispose of the materials" according to the regulations found in 40 CFR 261–265. Opened and partially dispensed hazardous drugs should not be disposed via the reverse distributor. The regulatory inspectors will not allow the hospital to use the reverse distributor as their drug hazardous waste vendor in this way.

Containers of hazardous drugs that are not accepted by the "reverse distribution vendor" must be disposed of as hazardous waste. The hospital must use a licensed hazardous waste disposal vendor to remove these materials under manifest for destruction at a hazardous waste incinerator. The drugs that must be disposed of as a hazardous waste include all those that meet the EPA definition of hazardous

waste. Hazardous drugs that have been processed or re-packaged by the pharmacy or are not in their original package should be disposed of as hazardous waste.

Possible Exemptions

There are some federal rules that can be applied to minimize collection of drugs as hazardous waste **if your state permits it.**

Exception for Nitroglycerine

In 2001, a revision to the mixture and derived-from rules (66 FF 27286) excluded all P-listed and U-listed wastes listed solely for an ignitability, reactivity, and/or corrosivity characteristic once they no longer exhibit a characteristic. Nitroglycerin, P081, is listed solely for its reactivity characteristic. This action effectively removed medicinal nitroglycerin as a P-listed waste at the federal level since it is a weak, non-reactive formulation that does not exhibit the reactivity characteristic.

Epinephrine Salts

Epinephrine (identified by the chemical abstract number 51-43-4) is a P-listed hazardous waste. The P-list of hazardous wastes applies to unused discarded commercial chemical products. Commercial chemical products are defined as commercially pure grades and technical grades of the listed chemicals or chemical formulations in which the listed chemical is the sole active ingredient, which have not been used for their intended purpose.

The EPA has recently come to understand that the chemical epinephrine typically used in healthcare applications consists of epinephrine salts. In an effort to clarify the scope of the hazardous waste listing, the federal EPA has determined that epinephrine salts were not intended to be within the scope of the P042 listing for epinephrine. Therefore, any chemical or formulation where epinephrine salts are the sole active ingredient is not a P-042 listed hazardous waste when discarded. However, it is important to note, than any formulation that contains epinephrine salts, if that formulation when disposed also meets the criteria of a RCRA

hazardous waste, the material must be disposed of in accordance with those RCRA guidelines.

Some states may have more stringent requirements therefore, you should check with your state regulatory agencies regarding proper disposal of epinephrine salts.

The Two Necessary Conditions Rule, e.g. Flovent

The "two necessary conditions rule" states that a drug waste containing a P- or U-listed constituent of concern must be managed as a hazardous waste if two conditions are satisfied: (1) it contains a sole active ingredient that appears on the P- or U-list, and (2) it has not been used for its intended purpose. To satisfy the definition of sole active ingredient, the listed chemical in the discarded drug must be the only ingredient that performs the intended function of the formulation. Ingredients that serve ancillary functions such as mobilizing or preserving the active ingredient are not considered when determining the sole active ingredient.

Disposal of Chemotherapy Waste

Trace chemotherapy wastes may be disposed of differently from hazardous waste. Trace chemotherapy wastes may be removed by a licensed contractor that transports them to a regulated medical waste incineration facility for destruction. Again this is a different type of incineration process than that used for RCRA hazardous waste.

- Empty containers of chemo drugs that are not on the EPA P-list or the NIOSH list may be disposed as trace chemotherapy waste including:
  - Tubing
  - Empty IV bags
  - Empty vials and containers
  - Gloves

Typically a rule of thumb is that any tubing or container with more than a few milliliters is **NOT** considered empty. This would include moistened clean-up

materials. Those items should go into the hazardous waste collection containers. Contaminated needles of chemotherapy drugs may be disposed into trace chemotherapy sharps waste containers.

Review of Hospital Waste Streams

Figure 1 shows the four typical solid waste streams in a hospital. From left to right in the figure they are:

1. Garbage
2. Medical waste and sharps
3. Chemotherapy (and some pathology) waste
4. Hazardous waste

Typical garbage goes to a municipal landfill or a local incinerator. Medical waste and sharps are treated by autoclave, microwave, or some other means to render the material non-infectious, and it is then shredded and put to a landfill. This waste could go to a medical waste incinerator but typically it does not. Trace chemotherapy and some pathology waste are sent to a regulated medical waste incinerator (low temperature incineration). Hazardous waste goes to a Treatment Storage and Disposal facility under manifest and is treated by high temperature incineration. Air emissions from these incinerators are tightly regulated.

The cost of disposal increases from left to right in the figure as well.

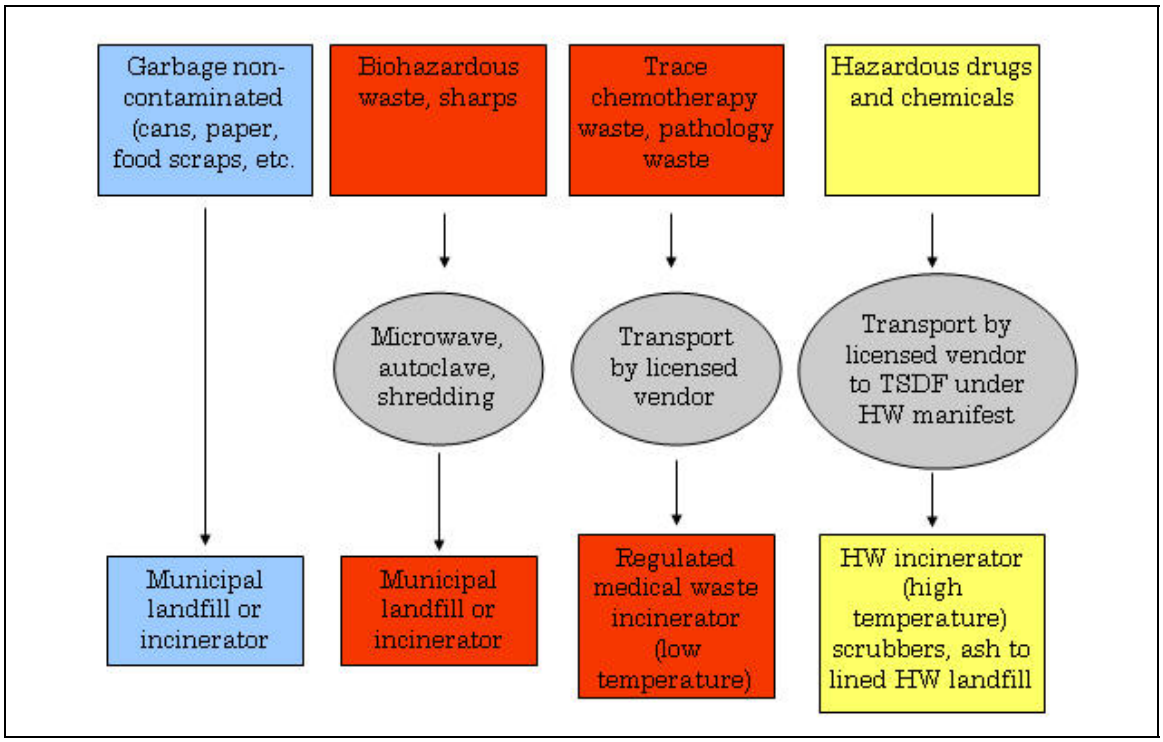

Figure 1 Four typical solid waste streams in a hospital. The cost of disposal increases from left to right in the flow chart.

Implementing a Hazardous Drug Waste Program

There are six essential components to any hazardous drug waste program. The development and implementation of these components will vary from hospital to hospital depending on the current state of the hazardous waste program. A medical research institution will typically have a well-developed hazardous waste program in effect, and the addition of drug waste will be relatively straightforward. A small hospital may be required to invest more time and effort.

The six components (or phases) required to implement a hazardous drug waste program are:

1. Develop Working Group
2. Classify Formulary
3. Prepare Written Plan
4. Coordinate Implementation Logistics
5. Conduct Training
6. Monitor Process

Each component will be addressed briefly along with some suggestions and tips based on EH&E staff field experience in a variety of hospitals.

Step 1: Working Group

Implementing a hazardous drug waste program involves many functions and departments within a hospital and very serious decisions need to be made regarding responsibilities and costs. The program must be viewed in the "big picture" as it will have an impact on many clinical and support staff. At a minimum, the group should include representatives from Pharmacy, Information Technology, Environmental Services, Nursing, Environmental Health & Safety, Employee Health, Cancer Care, and any other group that may be impacted such as Facilities or even Security. The involvement (input) from all these groups can ultimately save the hospital a great deal of time and money in program implementation and waste disposal costs.

Step 2: Classification of the Formulary

The first step is to perform a cross reference of your hospital drug formulary to EPA U-list, P-list, and NIOSH hazardous drug list. The Pharmacy will often have tracking software that can help to minimize this task. Once completed, the process should be repeated regularly to classify new drugs, and your Information Technology department may have suggestions for ways to make this easier. Figure 2 shows an example of a drug inventory database developed by EH&E to capture Microsoft® Excel® formulary lists found in some hospitals and cross-reference the list to the EPA U-list, P-list, and NIOSH listed drugs. Quantities, locations, etc., can also be tracked if desired, and new drugs are automatically cross-referenced.

You will also need to consider drugs that contain heavy metals such as mercury which are considered toxic waste. Thimerosol, a mercury containing preservative, is sometimes found in vaccines and would therefore be considered hazardous waste.

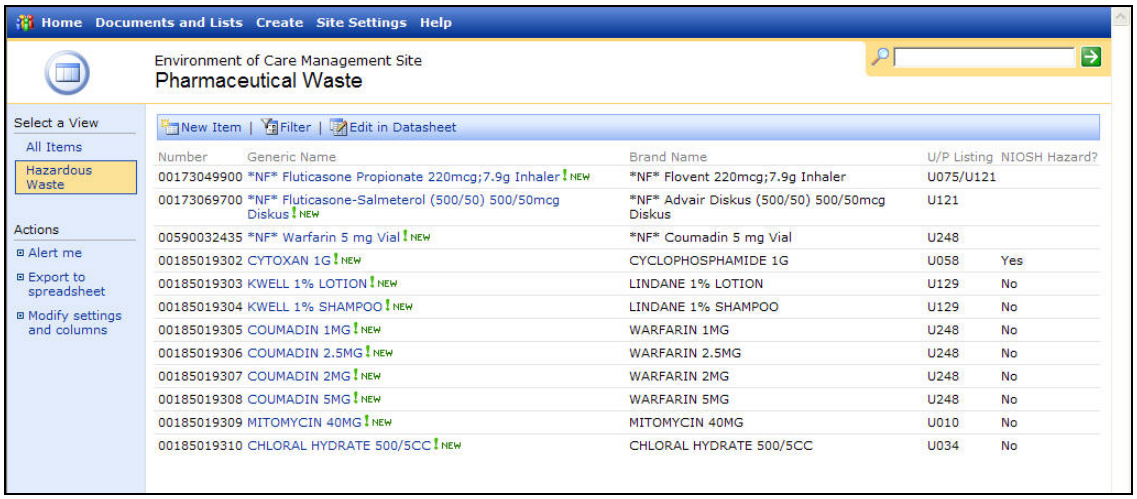

Figure 2 Example of a drug inventory database developed by EH&E that can assist in cross-referencing a hospital's drug inventory to the EPA U-list, P-list, and NIOSH listed drugs.

The next step is to apply any of the exemptions available under federal rule if your state allows it in order to come up with a short list of those drugs that must be handled as a hazardous waste. It is also useful to identify which departments in the hospital administer the various hazardous drugs in order to minimize the number of drugs that staff must be trained to segregate.

Step 3: Prepare a Written Plan

It is important to have your plan in writing. This is the first item that a regulator would typically request during an inspection. It also serves to clarify responsibilities and procedures. The plan should contain these elements at a minimum:

- Purpose and scope
- Responsibilities
- Classification of hazardous drugs
- Exceptions that apply
- Segregation and disposal procedures
- Collection and transportation of waste
- Expired or unused medication disposal policies
- Spill response plan
- Documentation

Step 4: Implementing the Plan

The greatest challenges lay in the area of logistics (i.e., rolling out the plan). Experience has shown the importance of rolling out the program in one area of the hospital at a time, using the experiences gained in one area to help with the next. It is typically best to begin the program in the Pharmacy, and then extend the program to cancer care areas and then general nursing areas.

The hospital's hazardous waste vendor should be relied on to help develop a chemical waste profile and with the selection of proper waste containers in each area. Seemingly simple issues (e.g., the size and shape of the containers and whether to bag and keep the container stationary or to dispose of the container) are important to consider in order to minimize the disruption to work flow in each of the areas impacted and to manage costs.

The hospital will have to identify hazardous waste container accumulation area locations and collection processes and create additional space in their main accumulation area. Label templates may have to be created as well as accompanying signs or training posters. A single hospital department should be responsible for maintaining all manifest-related documentation.

Proper waste segregation is also an important issue. The easiest method to ensure proper segregation is to have the hazardous drugs given a special colored label before it leaves the Pharmacy. This may be done by Pharmacy staff or through the current Information Technology drug labeling system. An excellent solution is one in which a color or code on each hazardous drug container matches with the properly colored or coded waste container. If that is not possible, then a note should be entered via the drug dispensing system which states "special disposal required." The clinician can then check the drug waste segregation chart to identify the proper waste container to use. If the drugs cannot be labeled in this way for disposal, then staff must be fully trained in proper segregation. This can be accomplished by live and on-line training as well as posters and signs. Figure 3 shows a sample poster.

There may be alternatives available that may not require hazardous waste disposal. You may also wish to remove certain infrequently used drugs from the formulary with physician approval. Think through segregation strategies carefully before finalizing. For example, we encountered one plan that proposed hazardous waste be segregated in the main accumulation area after disposal of all waste materials in a single bin in the clinical areas. We strongly discourage this practice as it could pose significant occupational and safety hazards for the personnel involved with sorting, as well as additional cost to the institution due to the labor cost of ongoing sorting and segregating, typically by an outside vendor.

Figure 3 Posters and signs are useful tools, in addition to live and on-line training, to inform staff of hazardous drug disposal procedures.

Finally, a careful review of purchasing practices, and drug packaging and dispensing procedures for P-list drugs should be performed to minimize the waste being generated. Any packaging that has been in contact with the drug would be considered an empty container and have to be disposed as hazardous waste. Small changes to packaging that eliminate extra waste can quickly save hundreds of thousands of dollars in a large hospital.

Step 5: Training of Personnel

Ensure that training is conducted for all affected groups and all shifts. Be prepared to accept feedback from the staff concerning ideas to improve workflow and minimize disruptions. No one system will work for all areas or all hospitals. One solution we've adopted for refresher training, or to make sure new employees are well informed, is the use of on-line training modules. Employees like the ability to complete the training on their schedule, and experience has shown us that the effectiveness is not compromised. It also ensures that night shift and per diem staff have access to the training information.

Step 6: Monitoring

Finally, it is important to monitor the process in order to determine where problems are being encountered or specific training needs must be addressed. Consider adding a few questions to your Joint Commission Hazard Surveillance surveys (environmental rounds), and you can use the information as a Performance Indicator for Joint Commission compliance. Most importantly, this will help you to continually improve the process.

In our experience, it can typically take several months or more to complete the development of a hazardous drug waste program within a hospital, so don't expect an overnight solution. A methodical approach that incorporates the program components listed above and takes feedback from all areas of the hospital as the program develops will have the best chance of success.

EH&E is an environmental health & safety consulting firm that specializes in offering solutions within "critical" environments including hospitals and research

laboratories. Our staff currently maintains EH&S oversight of over 5 million square feet of research space. We offer affordable web-based Environment of Care support solutions for hospitals of all sizes that draw on the expertise of our experienced staff. You can find out more about these solutions at http://www.eheinc.com/compliance_calendars.htm.

Notice – 3/16/10: Since EH&E first published this white paper, the U.S. Environmental Protection Agency (EPA) has proposed to add hazardous pharmaceutical wastes to the Universal Waste Rule in order to provide a system for disposing hazardous pharmaceutical wastes that is protective of public health and the environment. The proposed addition may make it easier for generators to collect and properly dispose of these items as hazardous wastes, resulting in a simpler and more streamlined waste management system. EPA has not published a final rule yet. EH&E recommends checking the EPA website periodically, as changes under this proposal may simplify your hospital's hazardous waste program.

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