Risk Management of Pharmaceuticals Entering POTWs and Municipal Landfills from Routine Hospital Waste Management Practices

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Abstract

Determination of Current Pharmaceutical Waste Management Practices

Over the past three years, PharmEcology® Associates, LLC (Brookfield, WI) has been conducting risk management reviews of healthcare organizations to determine how waste pharmaceuticals are being discarded, both in the pharmacy and in patient care area. While the primary goal of these assessments has been to determine the degree of identification and segregation of hazardous waste as defined by the US EPA's Resource Conservation and Recovery Act (RCRA), a secondary goal has been to determine when and where drugs are being sewered or landfilled as a routine method of waste management. An evaluation of common waste streams has been conducted. New waste streams to alleviate drain disposal and to bring the organization into compliance with RCRA have been developed.

Determination of Hazardous Waste Status of Pharmaceuticals in the US Marketplace

To assist in the identification and segregation of hazardous pharmaceutical waste, a database has been developed of over 114,000 drug products. Each of these items has been reviewed with respect to the criteria set forth by US EPA for hazardous waste under RCRA.

Existing Disconnects Between Drug Development and Regulatory Oversight

The listings of hazardous chemicals identified in RCRA have not been significantly updated since their promulgation in 1976. Therefore, only eight chemotherapy drugs are listed as hazardous wastes and are banned from land disposal by healthcare facilities and other commercial entities. Households are exempt. Approximately 100 chemotherapy agents of similar toxicity are totally unregulated federally. An exclusion in RCRA also allows for the disposal of up to 15 kg of U-listed and characteristic hazardous waste per calendar month with no notification of the local publicly owned treatment works (POTWs), the state, or the US EPA. All amounts of P-listed waste (acutely hazardous) require notification but are not definitively banned, based on the ability of the POTW to handle the effluent.

To assist healthcare organizations in managing to the highest level of practice, we have developed a "Risk Management" category for identifying those pharmaceuticals not listed as hazardous waste in RCRA but which exhibit toxicity characteristics (including endocrine disruption) that warrant management at the highest level of precaution. Included in this "Risk Management" category are those hazardous drugs identified by the National Institute for Occupational Safety and Health (NIOSH) in their recent Hazardous Drug Alert (pre-publication copy posted March 26th, 2004, http://www.cdc.gov/niosh/docs/2004-HazDrugAlert/).

We have reviewed hospital formularies, consisting of several thousand drug products, to determine the percentage of hazardous or "Risk Management" drugs. Studies to determine the frequency of waste disposal of these drugs are ongoing.

Conclusions

RCRA has not kept pace with drug development and therefore does not adequately regulate a significant number of hazardous drugs. The sewer exemption within RCRA enables the introduction of hazardous waste directly to the POTW. Both healthcare organizations and POTWs need to be made aware of current practices and the current inability to ensure deactivation of hazardous drugs that may be sewered or landfilled. Educational campaigns at the state and national level need to be developed to educate healthcare professionals in the proper identification and management of hazardous drug waste.

Risk Management of Pharmaceuticals Entering POTWs and Municipal Landfills from Routine Hospital Waste Management Practices

Challenges in Preventing Sewering and Landfilling of Waste Pharmaceuticals from Hospitals

Pollution prevention should always be the first line of defense against the introduction of hazardous chemicals into POTWs and municipal landfills. Organizational and individual awareness must be developed, however, to ensure pollution prevention practices. Within healthcare systems, there are several challenges to the prevention of sewering and landfilling of waste pharmaceuticals.

The first of these challenges is a lack of awareness of the concept of endocrine disruptors and the subtle but devastating effects these chemicals can have on human development and functioning. Healthcare professionals are trained in the therapeutic usage of powerful pharmaceuticals and are accustomed to thinking in terms of acute toxic effects and dose/response curves. The cumulative effect of drain disposal of these drugs is not on the radar for most healthcare professionals.

A second challenge is the almost universal lack of awareness of the responsibility of healthcare professionals to identify and manage hazardous chemical waste as it is defined by the EPA Resource Conservation and Recovery Act (RCRA)[1] and by state environmental protection agencies. Recent educational and enforcement activity in USEPA Regions 1 and 2, and states including Florida, California, Minnesota and Washing State, have only begun to bring this regulatory responsibility to the attention of healthcare organizations and their employees.

Once awareness has been achieved, the ability to comply with current regulations is hampered by the difficulty in identifying, segregating and managing the drug waste generated at a given facility. There are over 119,000 drugs on the US market. An individual healthcare facility may stock between 2,000 and 4,000 of these on a routine basis. Application of RCRA to drug formulations is a very difficult endeavor. Given the lack of expertise and lack of time to make waste determinations, identification of hazardous waste is difficult at best.

A fourth challenge to compliance is the lack of understanding among healthcare professionals of the role and function of wastewater treatment plants. Until fairly recently, the preferred method of disposal for pharmacists of unwanted drugs was through the sewer system, to prevent accidental poisoning and diversion. EPA and state environmental agencies are beginning to offer landfilling as a better alternative, yet that only slows the eventual release of the drugs into the environment.

The final challenge to implementation is that in healthcare, as in many sectors of the economy, change is crisis driven. Given the competing demands for resources, the proper identification, segregation and management of hazardous drug disposal will most likely not occur within an organization until a real or perceived regulatory crises raises it to a top priority level.

The Developing Awareness of Endocrine Disruptors

As noted above, the concept and importance of endocrine disruptors within the ecosystem and more specifically with respect to human development is in its infancy with respect to public awareness. A number of pharmaceuticals are known to interfere with the normal function of the endocrine system either by mimicking the hormone, triggering an identical response, or blocking the hormone. These do not follow the normal

[1] http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=064cab4037906fe673efb7ff9aa4b1e5&tpl=/ecfrbrowse/Title40/40cfr261_main_02.tpl

dose/response curve relied upon by pharmacologists, pharmacists, nurses and physicians. The impact of endocrine disruption upon the developing fetus was made painfully obvious by the development of vaginal cancers among teen-aged daughters of mothers who were treated with diethylstilbestrol (DES) during pregnancy, ostensibly to prevent miscarriage.[2]

Reproductive hormones, such as estradiol, progesterone, and testosterone, are in widespread use as birth control agents and hormone replacement therapies and routinely and continuously enter the environment through the sewer system. Drugs such as lindane, a pesticide used to treat lice, are estrogen mimics and can have a devastating impact on a developing fetus if exposed during critical periods of sexual development. As of January 1, 2002, lindane has been banned in California for human use.[3]

One of the most accessible sources of information on the impact of endocrine disruptors is *Our Stolen Future*,[4] a well written summary of research over the past sixty years which demonstrates the impact of endocrine disruption on animal and human development. Findings such as a 50% reduction in sperm counts in multiple countries since 1939, the increase in infertility, genital deformities, and hormonally triggered cancers all illustrate the importance of this phenomenon. Neurological disorders in children, including hyperactivity, attention deficit, lowered IQ and rage reactions, are being linked to endocrine disruption in fetal and perhaps early childhood development. This type of information makes a compelling story for healthcare professionals whose primary goals are healing and disease prevention.

Increasing USEPA Regulatory Activity

One of the primary drivers causing healthcare organizations to focus on more compliant pharmaceutical waste management is the increased educational and enforcement actions within USEPA Regions 1 and 2. In December of 2002 US EPA Region 2, which includes New York, New Jersey, Puerto Rico and the Virgin Islands, sent letters to 480 hospitals in December of 2002 inviting them to self-audit their hazardous waste management programs.[5] Since July of 2003, a number of hospitals have been cited and fined.[6] Fines range from $40,000 to $279,900 and include such prestigious organizations as Memorial Sloan Kettering Cancer Center. This high rate of violations indicates that healthcare organizations in general are not well informed regarding their responsibilities under the Resource Conservation and Recovery Act (RCRA) which defines hazardous waste and determines its proper management.

Jane M. Kenney, Regional Administrator of Region 2, made the following statement regarding the Memorial Sloan Kettering action: "Hospitals and healthcare facilities must consider the proper handling of hazardous waste an integral part of their mandates to protect people's health. Chemotherapy waste is an especially toxic waste produced by many medical facilities. Hazardous waste regulations are in place to help to ensure that facilities like Sloan-Kettering do not release these or other toxic chemicals into the environment."[7]

Based on the findings in Region 2, US EPA Region 1 notified 250 hospitals in New England that it was beginning an educational and enforcement initiative.[8] Two grants to Hospitals for a Healthy Environment (H2E) have also been awarded by Region 1. The first involves developing a blueprint for the compliant and environmentally responsible management of pharmaceutical waste.[9] The second enables H2E to interface more

[2] http://www.cdc.gov/DES/
[3] http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=111001-112000&file=111225-111246
[4] Colburn, Theo, Dumanoski, Diana, Peterson Myers, John, March 1, 1996, *Our Stolen Future*: Penquin, USA.
[5] http://www.epa.gov/region02/capp/hospital.pdf
[6] http://www.epa.gov/Region2/news/2003/03066.htm; http://www.epa.gov/region2/news/2003/03127.htm; http://www.epa.gov/Region2/news/2003/03139.htm; http://www.epa.gov/region02/news/2004/04008.htm; http://www.epa.gov/region02/news/2004/04081.htm .
[7] http://www.epa.gov/region02/news/2004/04008.htm
[8] http://www.epa.gov/NE/pr/2004/apr/040407.html
[9] http://www.epa.gov/oswer/docs/iwg/2004_h2e_pharmaceuticals_draft3.pdf

closely with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[10] on pollution prevention and waste management compliance issues.[11]

These educational and enforcement efforts are causing real change in the management of waste pharmaceuticals. Related actions by other USEPA regions would have a comparable impact.

Increasing State Regulatory Activity

At the state level, Florida,[12] Washington State,[13] California,[14] New Hampshire,[15] and Minnesota[16] are among states that have become very active in both educational programs and enforcement efforts with respect to pharmaceutical waste. For example, Minnesota initiated educational programs last year which are continuing, and began active enforcement July 1, 2004. As understanding of the issues spreads among state regulators, it is again reasonable to expect other states to take a more active enforcement role.

Point of Entry of Waste Pharmaceuticals

There are a variety of mechanisms by which pharmaceuticals may enter the waste stream. These include the following:

- Wastage of raw materials from the manufacturing process
- Wastage at drug distributors and wholesalers, pharmacies and healthcare facilities
- Wastage at long term care facilities, assisted living facilities, and other residential treatment facilities, including the prison system
- Expired pharmaceuticals
- Wastage at the consumer level
- Metabolites entering wastewater

This discussion will focus on wastage occurring within healthcare facilities.

Common Pharmaceutical Waste Streams

The most common waste streams found in healthcare facilities that may contain waste pharmaceuticals are illustrated below in Diagram 1.

Reviewing them briefly, it is very common for unused IVs to be sewered, either in the nursing units or in the pharmacy. The exception to this is chemotherapy waste, which is usually placed into a yellow or white sharps container labeled “chemotherapy waste.” While this keeps the hazardous chemotherapy drugs from being sewered, this container is shipped to a regulated medical waste incinerator, which causes the organization to violate RCRA. Eight chemotherapy drugs are P or U listed as hazardous waste, and must be shipped to a permitted RCRA incinerator which operates at higher temperatures and with more emissions controls. This is a prime area of enforcement at this time.

[10] The Joint Commission on the Accreditation of Healthcare Organizations audits hospitals every three years to assure quality care. Their website can be accessed at http://www.jcaho.org/.
[11] http://www.epa.gov/oswer/docs/iwg/Hospitals_6_25_03_final.pdf
[12] http://www.floridacenter.org/brochures_bulletins/pharmacies.htm
[13] http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/pages/exclusions.html
[14] http://www.dhs.ca.gov/ps/ddwem/environmental/Med_Waste/PDFs/MangtPharmsMW_101502.pdf
[15] http://www.des.nh.gov/nhppp/healthcare_p2/default.asp?link=letter
[16] http://www.pca.state.mn.us/publications/w-hw4-03.pdf

Regarding municipal solid waste, some creams, ointments, liquids, tablets, capsules and other non-injectable dosage forms may be disposed in this waste stream. While this is preferable to sewering, the drugs have the potential to leach into ground water at some future date. There are also safety and security concerns regarding this method of disposal.

As noted above, the containers traditionally labeled as "chemotherapy waste" are actually for trace chemotherapy contaminated items only, such as empty vials, syringes and IVs. Gowns, gloves, goggles, tubing and other accessories can also be disposed in these containers, which are incinerated at a regulated medical waste incinerator.

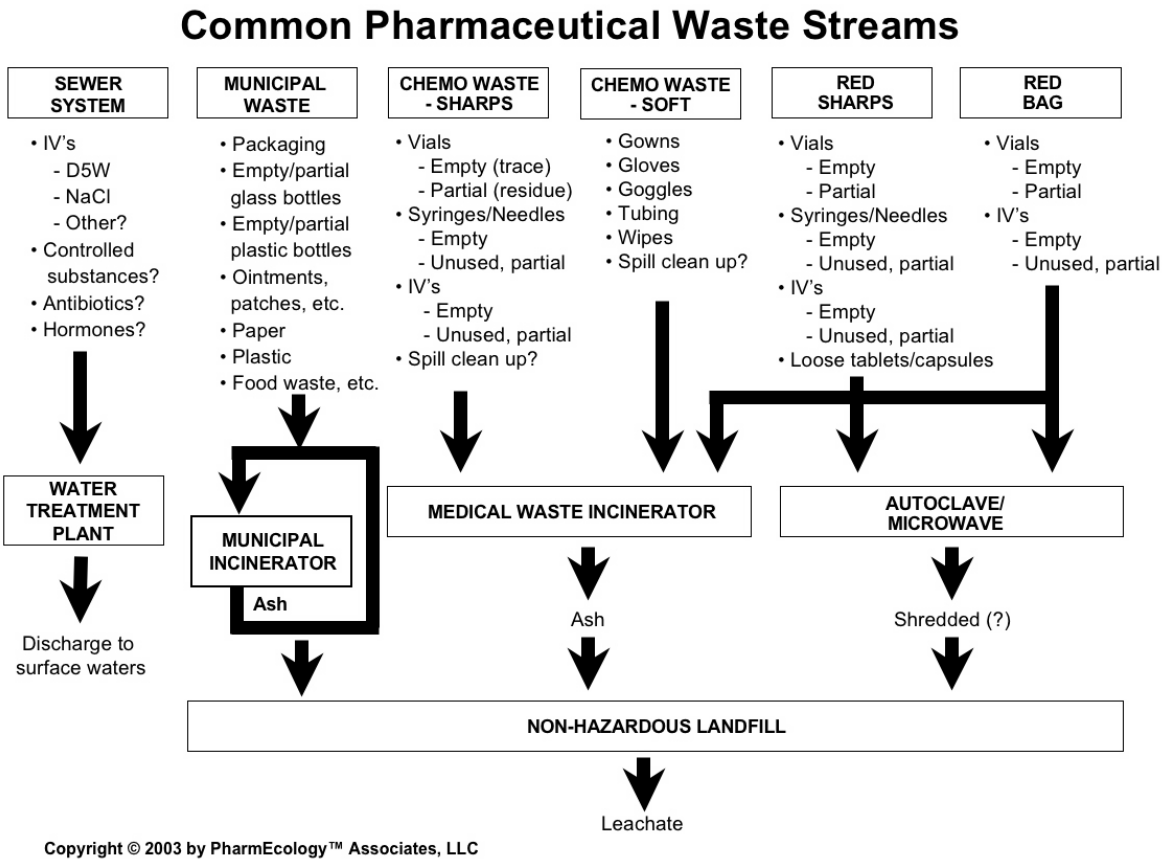

Diagram 1

Finally, it is common for partial vials and syringes to be disposed in red sharps containers, which are most often autoclaved or microwaved and then landfilled. It is important to recognize the primary purpose of regulated medical waste disposal, which is sterilization and employee protection. Driven by the concern over AIDS and other blood borne illnesses, modalities for sterilization include incineration, autoclaving, microwaving, treatment with bleach, and several other methods. The tremendous decrease in local and regional regulated medical waste incinerators, due to the more stringent regulations of the Clean Air Act, have made autoclaving and microwaving the primary treatment methods. These methods do not destroy hazardous organic molecules.

The Resource Conservation and Recovery Act

Compliant management of waste pharmaceuticals is being driven by the Resource Conservation and Recovery Act (RCRA). Enacted in 1976 and enforced by the USEPA and state authorized programs, RCRA addresses the

disposal of solid waste (including gases and liquids) and encourages the minimization of waste generation. It defines hazardous waste very specifically and requires "cradle to grave" tracking of hazardous waste. Households are exempt from regulation under RCRA.

The Resource Conservation and Recovery Act hazardous waste definitions which apply to waste pharmaceuticals include the P and U lists of chemicals, some of which are pharmaceuticals, and the four characteristics of hazardous waste: ignitability, toxicity, corrosivity, and reactivity. All of these definitions must be considered when discarding a drug.

P and U-listed Drugs[17]

If a drug is the sole active ingredient of the waste and is on the P or U list, it is automatically hazardous waste. Table 1 includes all the pharmaceuticals in the P list and Table 2 includes a representative list of U-listed drugs.

Arsenic trioxide	P012
Epinephrine	P042
Nicotine	P075
Nitroglycerin	P081
Phentermine (CIV)	P046
Physostigmine	P204
Physostigmine salicylate	P188
Warfarin >0.3%	P001

Table 1: P-listed pharmaceuticals

Chloral hydrate (CIV)	U034	*Streptozotocin*	U206
Chlorambucil	U035	Lindane	U129
Cyclophosphamide	U058	Saccharin	U202
Daunomycin	U059	Selenium Sulfide	U205
Melphalan	U150	*Uracil mustard*	U237
Mitomycin C	U010	Warfarin<0.3%	U248

Table 2: Partial list of U-listed pharmaceuticals

Because the lists were developed in the late 1970's and have not been substantially updated since, they have not kept up with drug development. Only one chemotherapy agent, arsenic trioxide, is P listed and only seven are U-listed. These are indicated in italics in Tables 1 and 2. Common and equally hazardous chemotherapy drugs which are not listed as hazardous waste federally include: Cisplatin, Thiotepa, Fluorouracil, Methotrexate, Lupron, Tamoxifen, and Taxol. This discrepancy illustrates another very serious challenge to ensuring proper disposal of over 100 of these non-listed chemotherapy agents. Best management practices would encourage management of any amounts of these drugs and other chemotherapy agents greater than trace as hazardous wastes.

One P-listed drug, phentermine, used for weight loss, and one U-listed drug, chloral hydrate, a sedative, are also controlled substances defined as drugs of abuse by the Drug Enforcement Administration (DEA). This makes their disposal that much more difficult since the destruction of controlled substances must be witnessed by two healthcare professionals. Drain disposal has traditionally been the accepted method since the demise of local hospital incinerators. Alternative technologies for rendering the drugs unrecoverable need to be developed by the waste disposal industry. These must be approved by DEA and could reduce the amount of controlled substances being sewered.

Characteristic Hazardous Waste

There are four characteristics of hazardous waste: ignitability, corrosivity, toxicity, and reactivity. Of these, ignitability and toxicity apply most often to waste pharmaceuticals. Of these two, toxicity is the greater concern from a ground water perspective.

[17] For a complete listing of all P and U listed chemicals, refer to http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=064cab4037906fe673efb7ff9aa4b1e5&rgn=div8&view=text&node=40:24.0.1.1.2.4.1.4&idno=40

Ignitability has several definitions,[18] but the one most applicable to waste pharmaceuticals is an alcohol content of 24% or more and a flashpoint of less than 140 degrees F (60 degrees C.) A number of drugs are relatively insoluble in water and alcohol is used to solubilize them. Common examples include antiobiotic skin preparations and other topical preparations. Less commonly known are injectable drugs, such as paclitaxel, a chemotherapy drug which is almost 50% alcohol before dilution into an IV. At the time it is administered, the alcohol content is below 24% and any waste would be managed as a chemotherapy drug. This example illustrates the complexity, however, of determining not only the initial hazardous waste classification of a product, but also the final status of the waste as it is generated. Hazardous waste exhibiting the characteristic of ignitability is identified as waste code D001.

Corrosivity is defined as a pH of equal to or less than 2 and equal to or greater than 12.5.[19] These parameters would apply primarily to bulk compounding chemicals stored within the pharmacy. Pharmacists should be encouraged to examine these stocks annually and have any discontinued items lab-packed by a hazardous waste vendor for proper disposal. Hazardous waste exhibiting the characteristic of corrosivity is identified as waste code D002.

Only one drug, nitroglycerin, exhibits the characteristic of reactivity, which includes being normally unstable, reacting violently with water, forming potentially explosive mixtures with water, or emitting toxic fumes when mixed with water. While nitroglycerin is reactive in its pure state, it is so dilute in finished dosage forms, such as tablets, capsules, patches, ointments, IVs, and aerosols, that it is no longer reactive. As of August 14, 2001, under the Hazardous Waste Identification Rule (HWIR), any waste containing a P or U listed chemical which was listed for ignitability, corrosivity, or reactivity and which does not exhibit the characteristic for which it was listed, is no longer regulated as a hazardous waste.[20] Therefore, nitroglycerin in finished dosage forms is no longer regulated as a P-listed waste. Formulations must be evaluated for other characteristics, however, and nitroglycerin aerosols and IVs may be ignitable. Under HWIR, chemicals listed for toxicity remain as hazardous waste regardless of concentration if they are the sole active ingredient of the waste.

The toxicity characteristic is much more difficult to identify and manage, and poses a greater threat to the environment than ignitability and corrosivity. EPA has listed 40 chemicals[21] which it considers a threat for leaching into ground water above certain concentrations. Each chemical has its own concentration limit above which the waste must be managed as hazardous waste. The following table indicates ten chemicals, which are D-listed, that may be found in pharmaceuticals.

Name	Haz Waste No.	Reg Level (mg/L)	Name	Haz Waste No.	Reg Level (mg/L)
Arsenic	D004	5.0	M-cresol	D024	200.0
Barium	D005	100.0	Lindane	D013	0.4
Cadmium	D006	1.0	Mercury	D009	0.2
Chloroform	D022	6.0	Selenium	D010	1.0
Chromium	D007	5.0	Silver	D011	5.0

Table 3: D-listed chemicals used in drug formulations

[18] http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=064cab4037906fe673efb7ff9aa4b1e5&rgn=div8&view=text&node=40:24.0.1.1.2.3.1.2&idno=40
[19] http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=064cab4037906fe673efb7ff9aa4b1e5&rgn=div8&view=text&node=40:24.0.1.1.2.3.1.3&idno=40
[20] See 40 CFR 261.3(g). http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=064cab4037906fe673efb7ff9aa4b1e5&rgn=div8&view=text&node=40:24.0.1.1.2.1.1.3&idno=40
[21] http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=064cab4037906fe673efb7ff9aa4b1e5&rgn=div8&view=text&node=40:24.0.1.1.2.3.1.5&idno=40

Identifying and Segregating Hazardous Pharmaceutical Waste

The categorization of approximately 120,000 drug products, with the addition of on average 175 new entries every week, is a task which lends itself to private enterprise. To expect every pharmacy and healthcare organization to have the time and expertise to review even 2,000 to 4,000 products is not realistic. PharmEcology® Associates, LLC has marketed the only commercially available categorization system to assist healthcare organizations in reviewing their drug waste.

The PharmEcology® Wizard is an online search engine which enables subscribers to query any drug product in the marketplace and receive two levels of disposal information. For example, if the product Readi-Cat were entered into the search screen, the initial response would indicate the product is regulated as federal hazardous waste with a waste code of D005 for barium. An additional information screen would provide the following calculation:

Barium sulfate ($BaSO_4$) mol.wt. 233.39:

Ba	58.84%
S	13.74%
O	27.42%

Preparations of barium sulfate for radiographic examination of the GI tract come in varying concentrations, the **lowest** being 1.2% (Readi-Cat Suspension by E-Z-EM):

$$1.2\% = \frac{1.2\text{gm}}{100\text{ml}} = \frac{12\text{gm}}{1000\text{ml}}$$

Since barium is 58.84% of barium sulfate, 12 gm x .5884 = 7.06 gm of barium

$$\frac{7.06\text{ gm}}{1000\text{ml}} = \frac{7060\text{mg}}{1\text{ L}}$$

The RCRA D list regulatory limit for barium is 100mg/L, therefore even dilute solutions of barium sulfate exceed the toxicity characteristics for barium.

In addition to identifying P, U and D-listed hazardous wastes, the PharmEcology® Wizard also identifies a "Risk Management" category of drugs, such as over 100 chemotherapy drugs not regulated under RCRA but bearing the same hazard potential. Drugs listed in Appendix A of the recently released NIOSH Hazardous Drug Alert[22] are included in this category.

Adding a Hazardous Pharmaceutical Waste Stream

To properly manage hazardous pharmaceutical waste and divert it from sewering and landfilling, a new waste stream must be set up throughout the healthcare organization. Both a toxic hazardous waste and ignitable hazardous waste containment system should be available. Analysis of which drug formulations are discarded in various units and the pharmacy will determine if both toxic and ignitable containers are necessary in all units. Diagram 2 illustrates the addition of these two waste streams and consideration of how to dispose of non-hazardous drugs, which may still include hormonal agents and antibiotics. Best management practices would recommend incineration at either a municipal incinerator or a regulated medical waste incinerator permitted to handle non-hazardous drug waste.

[22] http://www.cdc.gov/niosh/docs/2004-HazDrugAlert/

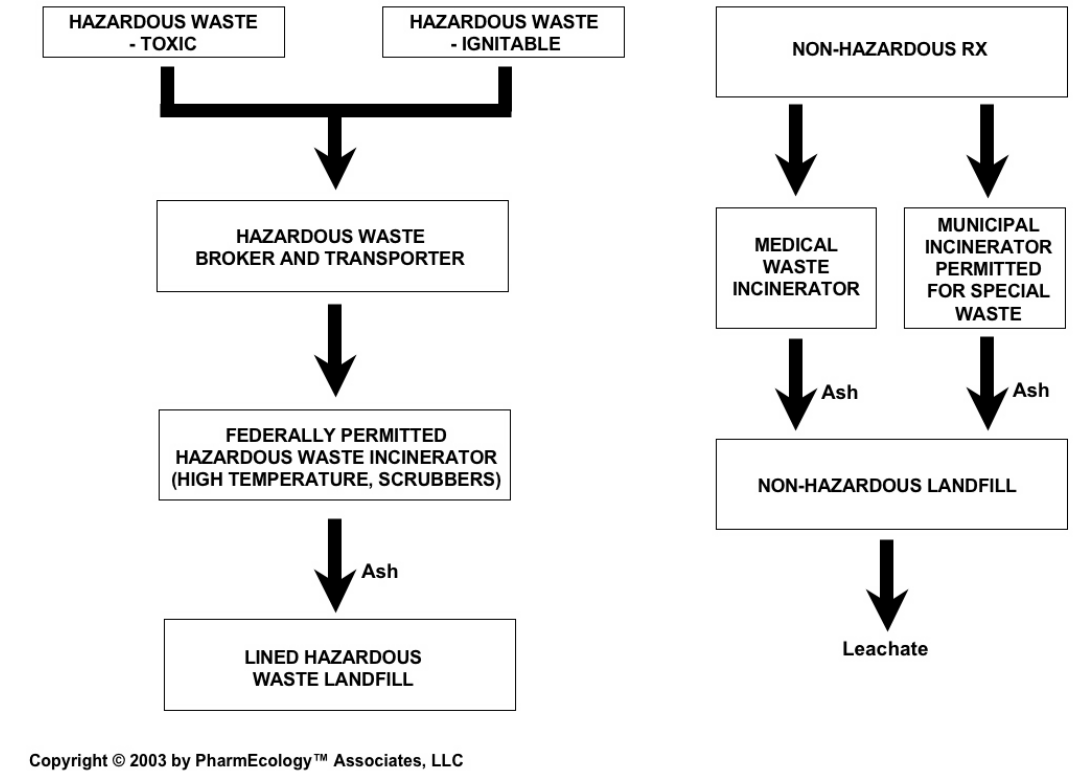

Diagram 2

Inserting these hazardous and non-hazardous pharmaceutical waste streams into the waste stream designations represented in Diagram 1, Diagram 3 illustrates how pharmaceutical waste can be managed to reduce sewer and landfill disposal to a minimum.

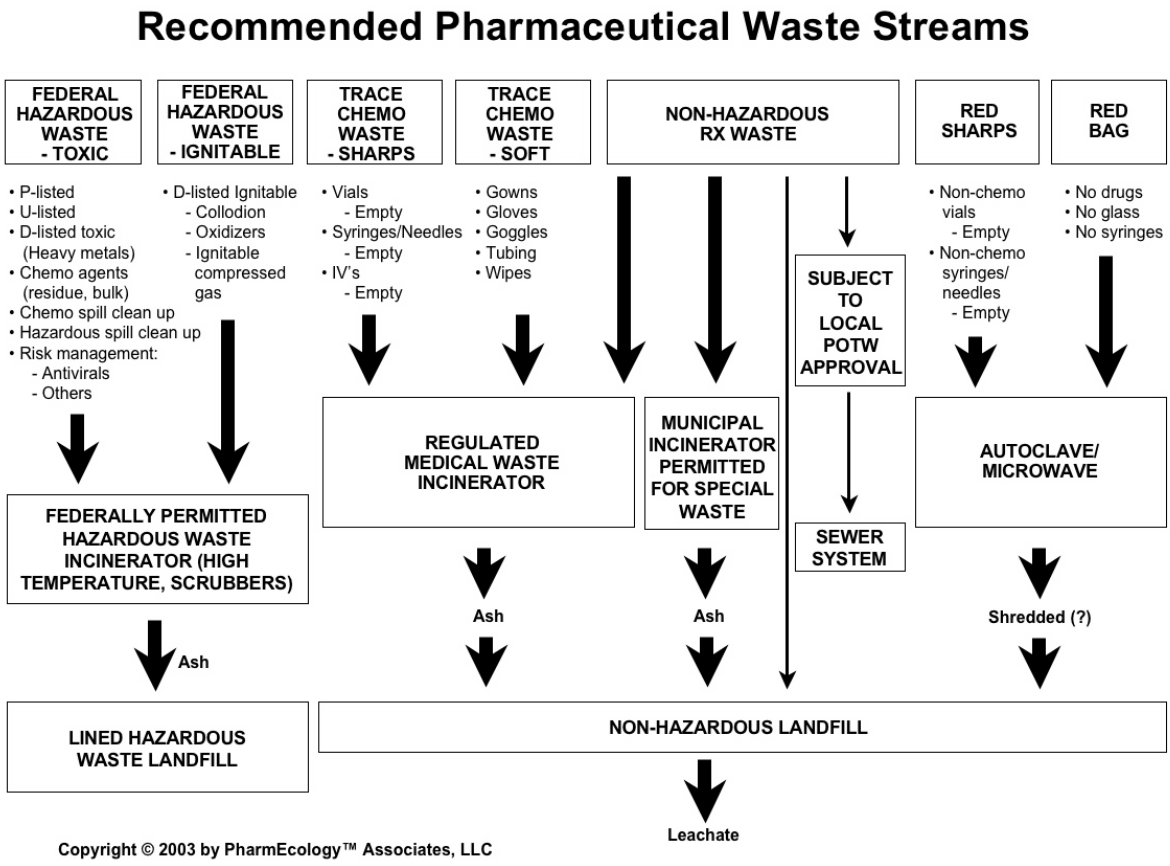

Diagram 3

Development of Hazardous Waste Containment Systems

To meet the growing demand for appropriate containment of this evolving hazardous waste stream, two companies have developed containers appropriate for healthcare settings. The Hospitec[23] company offered a dark blue container in three sizes in 2003. The Kendall Co.[24] has just released its offering, a black container, in Fall of 2004. Both of these containers meet Dept. of Transportation (DOT) requirements and can be used to ship hazardous waste in interstate commerce. The hazardous waste industry continues to offer 5 gallon, 20 gallon and 55 gallon pails and barrels which are less attractive in clinical settings.

The importance of the availability of dedicated containers cannot be over-emphasized, as these market entries reinforce the reality of this waste stream to healthcare professionals and make compliance somewhat easier to implement.

Sewering Hazardous Waste: A Legal Loophole

A little known loophole exists for healthcare facilities to sewer hazardous waste. Under RCRA, up to 15 kg. (33lbs) of U-listed and characteristic hazardous waste can be sewered per calendar month without notification

[23] For more information, contact Christopher Hahn, Hospitec, Inc., (561) 833-2296, chris@hospitecinc.com.
[24] For more information, contact Mike Liscio, Kendall Sharps Division, (508) 261-8493, mike.liscio@tycohealthcare.com.

of the POTW.[25] Sewering of any amount of P-listed hazardous waste and over 15kg of other hazardous waste per calendar month requires notification of the POTW, the EPA Regional Waste Management Director, and the State environmental protection agency. States and local water districts may have stricter rules, as is the case in California, Washington State, and Minnesota. However, it does leave a large opportunity available for healthcare organizations to continue to sewer hazardous pharmaceutical waste with relative impunity.

Compliant Hazardous Pharmaceutical Waste Disposal

Once hazardous pharmaceutical waste has been identified and segregated, it must be properly stored, labeled, manifested, shipped and disposed of at a permitted treatment, storage and disposal facility (TSDF) through incineration. These heavy duty incinerators are continuously monitored by EPA. Through very high temperature incineration, the molecular bonds of the organic molecules are broken. Potential pollutants are scrubbed from the emitted gases and residual ash is stored in a lined hazardous waste landfill. At this time, this is the most effective method of destruction. Plasma arc technology is gaining attention as a more environmentally sound method of destruction, but has not yet proved commercially viable.

Summary

Significant quantities of waste pharmaceuticals that are now being sewered and landfilled can be diverted into more environmentally sound disposal options. To accomplish this, healthcare professionals must be educated about the environmental risks inherent in the current system. Awareness of endocrine disruption and other health hazards associated with contaminated water supplies must be increased. Regulatory restrictions on sewering must be tightened at the POTW, state, and federal levels. Federal hazardous waste regulations must be updated and enforced uniformly.

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Charlotte A. Smith is President of PharmEcology® Associates, LLC, which she founded in 2000 to assist healthcare facilities in reducing and managing pharmaceutical waste. She co-founded Capital Returns, Inc., a nationally known pharmaceutical reverse distributor and served for 10 years as President and Chief Regulatory Advisor. In those positions, Ms. Smith pioneered the application of the EPA's Resource Conservation and Recovery Act regulations to pharmaceutical waste streams within the reverse distribution industry and developed management systems to assist healthcare facilities in managing and reducing pharmaceutical waste. Ms. Smith is a Registered Pharmacist who received her BS in Pharmacy and MS in Continuing and Vocational Education from the University of Wisconsin. Ms. Smith may be reached at PharmEcology® Associates, LLC, 200 S. Executive Drive, Suite 101, Brookfield, WI 53005, phone 262-814-2635, fax 414-479-9941, csmith@pharmecology.com.

[25] See 40 CFR 403.12 (p)(2) at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=f817659cff13756e4588d9537451b36f&rgn=div8&view=text&node=40:27.0.1.1.4.0.1.12&idno=40