



## RESEARCH ARTICLE

### PHARMACEUTICAL WASTE- EFFECT ON ENVIRONMENT AND ITS MANAGEMENT

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#### ABSTRACT

Pharmaceutical waste is type of medical waste, the improper disposal of which is causing the harmful effects on the environment in turn affecting health of all forms of living creatures. If appropriate action is not taken the adverse effects may lead to serious consequences. This paper discusses about generation of pharmaceutical waste from different sources, types of pharmaceutical waste, various regulating bodies, waste treatment and disposal methods and solutions for pharmaceutical waste management. So there is a need for providing better facilities to ensure proper waste management and to reduce the amount of waste generation by bringing awareness and education.

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## INTRODUCTION

Pharmaceutical waste is not one single waste stream, but many distinctive waste streams that can affect the integrity and uniformity of the chemicals that involve pharmaceuticals. Pharmaceutical waste is possibly generated through a wide variety of deeds in a healthcare facility, including but not limited to I.V. preparation, general compounding, breakages, partially used ampoules, needles, and I.V., out-dated, unused preparations, fallow unit doses, personal medications and outdated pharmaceuticals (Shafir, 2013). Recent investigations showed that low concentrations of pharmaceuticals are detectable in municipal waste water, surface water, groundwater and even drinking water. Occurrence of pharmaceuticals in surface waste, drinking water and sediments are not well known except for two preliminary studies that measured levels of pharmaceuticals in the environment (Hignite *et al.*, 1977; Richardson *et al.*, 1985). The worldwide ranges of pharmaceuticals are 12,000 human and 2,500 veterinary pharmaceuticals. Each pharmaceutical consists of an active substance, mixed with a number of auxiliary substances to make it possible to handle and dose the

pharmaceutical. The pharmaceuticals and their metabolites are excreted *via* faeces and urine and end up in the aquatic environment, either by discharge after passage of a sewage water treatment plant, or by run-off from the surface, leaching *via* the soil or drainage to the surface water after spreading of manure on the land. To counter the above shortcoming and to preserve the high quality of the environment new concept so called "*Cleaner Production*" for waste minimization is being introduced, technology designed to prevent waste emission at the source of generation itself (Freitos dos santos *et al.*, 1995). There are a number of different options available for the treatment and management of waste containing dodging, minimization, re-use, reutilizing, energy recovery and disposal (Shafir, 2013). Differently, direct release of veterinary pharmaceuticals in environment may occur *via* application in aquaculture (*i.e.* fish farming), but also indirect release by way of animals topically treated, and mostly *via* run-off and leaching through fields from manure spreading to agricultural fields and livestock wastes (Boxall, 2008; Khan *et al.*, 2007; Kemper 2008). Many other studies identified many products, including analgesics, anti-inflammatories, antibiotics, antiepileptics, beta-blockers, blood lipid regulators, antidepressants, contrast media, oral contraceptives, and cytostatic and bronchodilator drugs in sewage, surface water, groundwater, and drinking waste (Constanzo *et al.*, 2005).

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## Generation of pharmaceutical waste

In the past, much of the pharmaceutical waste occurring at a pharmacy was due to expired pharmaceuticals. The development of reverse distribution companies has enabled pharmacies to ship all outdated drugs as products back through these firms for the purpose of returning them to the manufacturer for credit. Any outdated items that do not meet the manufacturer's return policy become waste at the reverse distributor which becomes the waste generator, since this is where the decision to discard the item is made. This practice has been supported by the Environmental Protection Agency (EPA) through two guidance letters to the industry (Corson, 2002; Lowrance, 1991). The letters make it clear, however, that while EPA will consider an outdated drug to remain a product until the decision is made to discard it, reverse distribution cannot be used solely as a waste management tool. Obviously waste like materials, such as partial vials, compounded I.Vs, and broken or spilled materials, must be considered waste at the pharmacy and managed in compliance with Resource Conservation and Recovery Act (RCRA). Other sources of pharmaceutical waste include undispensed compounded products, discontinued indated items, unused unit dosed items, unused I.Vs, and patients' personal medication.

## Sources of pharmaceutical Waste

Pharmaceutical Waste is potentially generated through a wide variety of activities from health care facility such as syringes and intravenous (I.V.) preparations.

General Pharmaceutical Waste may include the following:

- Expired drugs (Kuspis *et al.*, 1996)
- Patient's discarded personal medications
- Waste materials containing excess drugs (syringes, I.V. bags, tubing, vials *etc.*)
- Open containers of drugs that cannot be used
- Containers that held acute hazardous waste (P-listed) drugs
- Drugs that are discarded
- Contaminated garments, absorbents and spill cleanup material (Heberer, 2002).

## Endocrine Disruptors

As if violating the law weren't enough to get our attention, being a generally law-abiding group of professionals, there are other compelling reasons to take a hard look at the final resting place of any drug waste we generate. Growing evidence indicates that "endocrine disruptors," those chemicals that mimic natural hormones, trigger an identical response, or block natural hormones are having a dramatic negative impact on critical developmental stages in the fetus and newborn. The book *Our Stolen Future* (Colborn *et al.*, 1997) documents the research of pharmacist, Theo Colburn, who identified this phenomenon among wildlife populations. In addition to the obvious impacts of the estradiols, testosterone and progesterone related drugs, pesticides such as Lindane (an estrogen mimic) can cause significant damage if they enter the environment inappropriately. Lindane was recently banned for all use both human and pesticide in California and Canada. With human male sperm counts dropping 50% on average world-wide since 1939, an increase in infertility, genital deformities, hormonally triggered cancers such as breast

cancer and prostate cancer, and an upswing in neurological disorders in children, we have an even greater responsibility as health care professionals to ensure that our activities as pharmacists "do no harm" through inadvertent secondary exposure.

## Pharmaceuticals in Surface Waters

In March of 2002, the United States Geological Society released the results of the first nationwide reconnaissance of the occurrence of pharmaceuticals, hormones and other organic wastewater contaminants (OWCs) in surface waters. USGS surveyed 139 streams across the country, including three in Wisconsin, looking for 95 different OWCs. One or more contaminants were found in 80% of the samples, and included common pharmaceuticals. Water treatment plants to date are designed to filter out sediment, bacteria and viruses. They have not in the past been designed to identify and remove organic molecules. Due to the extensive use of antibiotics in aquaculture, veterinarian medicine, animals, and human medicine, extensive literature exists on their environmental effects, the studies show that up to 95% of antibiotic compounds can be released unaltered into the sewage system. Hormones (particularly estrogen compounds) are some of the earliest medicines reported in sewage, and they have been found in significant concentrations (Shore *et al.*, 1993; Tabak *et al.*, 1981) are shown in the Figure 1 ([www.the-scientist.com](http://www.the-scientist.com)).



Fig. 1. Pharmaceutical Waste in Water

High concentrations of antibiotics can lead to alterations in microbial community structure and affect food chains. Antibiotics such as Sulfamethoxazole, Trimethoprim, Erythromycin and Keflex can get into the water and create antibiotic resistance. Antibiotics are turning up in surface and ground waters, and are of concern due to the fact that antibiotics in the environment select for drug-resistant strains of bacteria. This is of concern to people because there are 14,000 deaths annually due to antibiotic resistance (Reckhow and Anastas, 2007).

## Types of pharmaceutical waste

Pharmaceutical Waste is classified in 3 different categories:-

- Hazardous Pharmaceutical waste
- Non-hazardous Pharmaceutical waste
- Chemo waste

## Hazardous Pharmaceutical Waste

A starting point for determining which pharmaceutical waste is hazardous, RCRA definitions must be considered. Drugs deemed hazardous by federal EPA regulations are categorized as "P- list," "U- list," or "chemical (D-list) characteristic."

### P-listed Wastes

P-listed items are reflected acutely toxic (*e.g.*, Epinephrine, Phentermine, Physostigmine, Nicotine, Nitroglycerin and Warfarin >3%); both the drug and the container that held the drug are considered hazardous and must be disposed of in an RCRA-approved container.

### U-listed Wastes

U-listed items are considered toxic (*e.g.*, Phenol, Lindane, Choralhydrate and selected anti- neoplastic waste). Items on the chemical characteristic list are pharmaceuticals that cause wastes.

## Characteristics of Hazardous waste

### A. Ignitability

The aspect of the ignitability characteristic is to identify wastes that either present a fire hazard under routine storage, disposal, and transportation or are capable of exacerbating a fire once it has started. There are several ways that a drug formulation can exhibit the ignitability character. Many of the hazardous wastes that pharmacies handle are hazardous because they are ignitable. These wastes are easily combustible or flammable which poses the greatest managing problems for pharmacies (40 CFR Part 261.21).

### B. Corrosivity

Corrosive wastes corrode metals or other materials or burn the skin. These liquids have a pH of 2 or lower or 12.5 or higher. Examples of acids that exhibit a pH of 2 or lower include Glacial acetic acid. Examples of bases that show a pH of 12.5 or higher include Potassium hydroxide and Sodium hydroxide. Generation of corrosive pharmaceutical wastes is generally limited to compounding chemicals in the pharmacy (40 CFR Part 261.22).

### C. Reactivity

Reactive wastes are unstable under "normal" conditions. They can cause explosions, toxic fumes, gases, or vapors when heated, compressed, or mixed with water. Examples include Clinatest (a test tablet to determine sugar in urine). When Nitroglycerin is in pure form, it is reactive. Pharmaceuticals holding Nitroglycerin are too weak to react and have been omitted from the reactive classification federally and in Florida (40 CFR Part 261.23).

### D. Toxicity

Wastes are toxic if they contain toxic organic chemicals or certain heavy metals, such as Chromium, Lead, Mercury, or Cadmium. Approximately 40 chemicals meet specific leaching concentrations which classify them as toxic. Toxic D-listed chemicals used in drug formulation. Forty chemicals have been

included in RCRA as a concern in a solid waste landfill environment above certain concentrations. Wastes that exceed these concentrations must be managed as hazardous waste (40 CFR Part 261.24). U-listed chemicals include a broader range of pharmaceuticals and again must be the sole active ingredient to come under regulation. From the scientific perspective of a pharmacist, the sole active ingredient criterion is suspect. For example, the topical anesthetics Fluori-Methane® and Aerofreeze® both contain two U-listed chemicals, Dichlorodifluoromethane and Trichloromonofluoromethane (Table 1). Technically, these items would not be regulated as hazardous waste when discarded since neither U-listed ingredient is the sole active ingredient. Common sense and professional knowledge, however, should lead us to manage these as hazardous waste.

**Table 1. U-Listed Pharmaceuticals**

Name	Hazardous waste number
Chloral hydrate	U034
Chlorambucil (Chemo)	U035
Chloroform	U044
Cyclophosphamide (Chemo)	U058
Daunomycin (Chemo)	U059
Dichlorodifluoromethane	U075
Diethylstilbestrol	U089
Formaldehyde	U122
Phenol	U188
Reserpine	U200
Resorcinol	U201
Saccharin	U202
Selenium Sulfide	U205
Streptozotocin (Chemo)	U206
Trichloromonofluoromethane	U121
Uracil mustard (Chemo)	U237
Warfarin <0.3%	U248

P-listed chemicals are considered "acutely hazardous" by EPA the worst of the worst (Table - 2). If a chemical on the P list is the sole active ingredient of a discarded product, it causes the entire product, including the solvent and container, to be contaminated and must be treated as a hazardous waste is shown in the Figure 2 ([www.life-pharmadegrade.arhel.com](http://www.life-pharmadegrade.arhel.com)). Pharmaceuticals on the P list include:

**Table 2. P-Listed Pharmaceuticals**

Name	Hazardous waste number
Arsenic trioxide	P012
Epinephrine	P042
Nicotine	P075
Nitroglycerin	P081
Physostigmine	P204
Physostigmine Salicylate	P188
Warfarin >0.3%	P001
Physostigmine Salicylate	P188
Warfarin >0.3%	P001

## Nonhazardous Pharmaceutical Waste

Some have considered that once the manufacturer's packaging is opened, any unused or partially used product is nonhazardous pharmaceutical waste. Examples include unused or partially used vials, ampules, or bottles; unused or partially used I.V. bags and tubing containing drugs; discontinued medications that are not suitable for reuse; and tablets and capsules that have been dropped or spit out by a patient. Outdated drugs being discarded may be also be included in this category. Discontinued medications that patients have brought

from home and left are also considered pharmaceutical waste that should be disposed of in accordance with EPA, state, and Drug Enforcement Administration regulations. The impact of these types of pharmaceutical waste on public health and the environment is unclear. When permitted by both state regulations and RCRA, this waste can be solidified and placed in a landfill. However, a better management practice is to have nonhazardous pharmaceutical waste processed by a medical waste incinerator or a properly permitted municipal waste incinerator. An exception to this is I.V. solutions without drug additives; these can be placed in sewer systems. Disposal of

devices used to administer nonhazardous medications, such as inhalers that use propellants, is another consideration. In addition to RCRA requirements, some states have regulations specific to the device and propellant used to deliver drugs; these must be considered in establishing waste streams. In Nebraska, for example, hospitals are required to either segregate inhaler devices from the normal waste stream or puncture and triple rinse the container before disposal in the nonhazardous waste stream (Smith, 2002). The other pharmaceutical waste streams are presented in Figure 3 (www.slidesharecdn.com).



Fig. 2. Hazardous waste

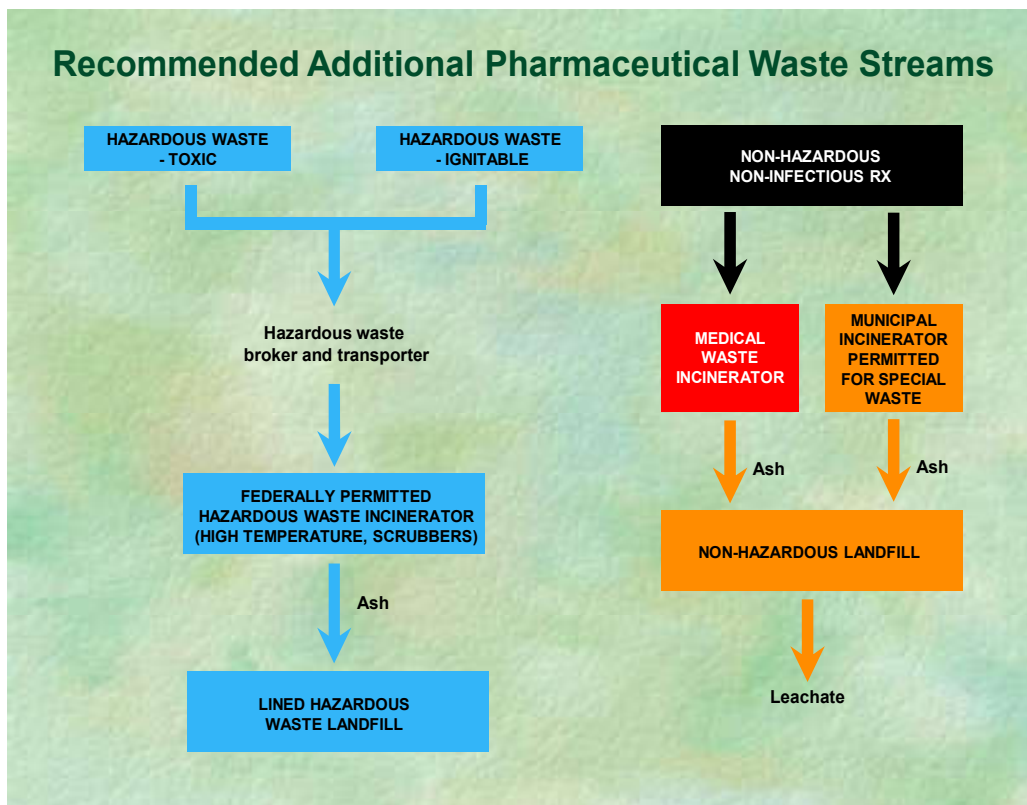


Fig. 3. Other Pharmaceutical Waste Streams

## Chemo Waste

Chemo wastes are further classified as

- Trace chemotherapy waste
- Bulk chemotherapy waste

### Trace Chemotherapy Waste

The federal RCRA regulations do not address trace chemotherapy waste. There is no recognized distinction between bulk and trace chemotherapy contamination for P and U-listed hazardous wastes since there is not a lower concentration limit under which these wastes can exit the regulatory system. Most state regulated medical waste regulations are either silent or not specific on the definition of trace chemotherapy waste. The unique orientation to set apart trace chemotherapy waste is found in an article written in 1984 by pharmacy personnel at the National Institutes of Health who pioneered applying the RCRA regulations to antineoplastic wastes. California's Medical Waste Management Act and Wisconsin's Medical Waste Rules identify trace chemotherapy waste and require incineration at a regulated medical waste facility or other approved treatment method. All chemotherapy paraphernalia should be managed as trace chemotherapy waste if there has been the potential for exposure to chemotherapy contamination.

### Substances that are applicable for management as trace chemotherapy waste include:

- “RCRA empty” ampoules, injects, IV bags, and tubing.
- Gowns, gloves, wipes and other paraphernalia associated with medical preparations.
- Wipes and other materials used during routine cleaning and decontamination of a Biological system.
- Safety Cabinet or glove box.

### Bulk Chemotherapy Waste

Trace chemotherapy containers have long been used to discard listed chemotherapy drug waste that should be managed as hazardous waste. The trace chemotherapy waste is incinerated at an RMW incinerator, hazardous waste incinerator. RMW incinerators have less restrictive emissions limits and permit requirements. Discarding “bulk” P- or U- listed chemotherapy agents as trace chemotherapy waste has been the cause of substantial enforcement actions and fines and should be one of the first changes you implement in your pharmaceutical waste management program (Kolpin *et al.*, 2002).

## Regulatory bodies

### The Resource Conservation and Recovery Act

The RCRA Act was enacted in 1976 as a response to national environmental disasters, the purpose of RCRA is to encourage waste minimization, define hazardous waste, and provide for a system of “cradle to grave” tracking of hazardous waste. Since the word “hazardous” is used in multiple contexts with in health care, it is important to recognize that we are not talking about biohazardous, infectious waste, Occupational Safety and Health Administration (OSHA) hazardous materials as featured in employee right to know programs, or Department Of Transportation (DOT) hazardous substances. EPA has an

entirely different set of criteria for defining hazardous chemical waste as it impacts human health and the environment when discarded. In case the compelling evidence surrounding species viability is not sufficient to encourage compliance, EPA has provided for more prosaic motivators, such as personal and corporate liability. Corporate fines may be levied at a rate of \$27,500 per violation per day and responsibility extends from the manager level up through the CEO of the organization. Personal liability carries no statute of limitations and, in criminal cases of knowing, willful violation, can involve prison sentences.

### Compliance challenges

Fully complying with RCRA regulations will present both

- Operational challenges
- Financial challenges for institutions.

### Operational challenges

Processes that require manual sorting of pharmaceutical waste are time consuming, potentially dangerous to the sorter, and labor intensive (for data entry and database management as well as the actual sorting), and they may not be in compliance with regulations. Direct care provider's general lack of knowledge or misunderstanding of state and federal regulations is a potential contributor to noncompliance (Smith, 2007). Pharmacies need uniform guidelines for the safe disposal of expired medications, and pharmacists should include this information in routine patient education. A survey of consumers and pharmacies about medication disposal habits revealed a variety of disposal methods (Kuspi *et al.*, 1996). It was apparent that the patients had not been properly educated about pharmaceutical waste disposal. Pharmacies had specific policies for expired or undispensed pharmaceuticals but lacked uniform guidelines on disposal. Only 5% of the 100 pharmacies surveyed had consistent recommendations for their patients on drug disposal. Pharmacist's lack of awareness or understanding of the cumulative effect of improperly disposed pharmaceutical waste on human health and the environment is an important challenge to be overcome (Smith, 2007). Educating health care professionals about the issue, the relevant state and federal regulations, and the consequences of noncompliance will go a long way toward promoting more effective pharmaceutical waste management. Each health care institution will need to make changes in its processes for drug dispensing, administration, wastage, return, and disposal.

### Financial challenges

Complying with RCRA regulations may place an additional financial burden on health systems. For example, newer, more toxic pharmaceuticals may require more intensive waste management. Changes in prescribing practices may place additional financial burden on an institution due to additional wastes generated from these changes. Also, institutions may face fines for noncompliance. A facility that is not in compliance with regulations for managing its listed waste could be fined \$32,500 per day. In addition, failure to institute guidelines for proper segregation of waste and to educate staff about them can be expensive, because processing costs vary significantly by type of waste. Medical waste (red sharps containers) costs 18 cents to 35 cents per pound; chemotherapy waste (yellow containers), \$4 per pound; RCRA hazardous

waste, \$2 to \$4 per pound; and infectious hazardous waste, \$4 to \$8 per pound.

### Pharmaceutical waste treatment & disposal

Pharmaceutical Waste Treatment and Disposal Technologies Specified in India's Pharmaceutical Waste Rules:

- Incineration
- Autoclaving
- Microwaving
- Chemical Disinfection
- Deep Burial



**Fig. 4. Disposal of Waste**

#### Incineration

Incineration is a disposal method in which solid organic wastes are subjected to combustion so as to convert them into residue and gaseous products. This method is useful for disposal of residue of both solid waste management and solid residue from waste water management is shown in the figure 4 ([www.securewaste.com](http://www.securewaste.com)). This process reduces the volumes of solid waste to 20 to 30 percent of the original volume. Incineration and other high temperature waste treatment systems are sometimes described as "thermal treatment". It is recognized as a practical method of disposing of certain hazardous waste materials (such as biological medical waste).

#### Autoclaving

Autoclaving uses saturated steam in direct contact with the Bio Medical Waste (BMW) in a pressure vessel at time lengths and temperatures sufficient to kill the pathogens. The Biomedical Waste Rules specify the minimum temperature, pressure, and residence time for autoclaves for safe disinfection. Autoclaving is not suitable for human anatomical, animal, chemical, or pharmaceutical waste. Autoclaving produces a waste that can be land filled with municipal waste. Autoclave operation requires qualified technicians, and medium investment and operating cost.

#### Microwaving

Application of an electromagnetic field over the BMW provokes the liquid in the waste to oscillate and heat up, destroying the infectious components by conduction. This technology is effective if the ultraviolet radiation reaches the waste material. Before microwaving, BMWs require shredding to an acceptable size and humidification. Microwaving is not

suitable for human anatomical, animal, chemical, or pharmaceutical wastes, or for large metal parts. Microwaving produces a waste that can be land filled with municipal waste. The advantages of this treatment technology are its small electrical energy needs and no steam requirement. The disadvantages include the need for qualified technicians and frequent breakdown of shredders. This technology requires medium investment and operating costs.

#### Chemical Disinfection

Chemical disinfection is most suitable for treating liquid wastes such as blood, urine, stools, or health care facility sewage. Addition of strong oxidants like chlorine compounds, ammonium salts, aldehydes, or phenol compounds kills or inactivates pathogens in the BMW. Disinfection efficiency depends on such factors as the type and amount of chemical used, and the extent and duration of contact between the disinfectant and the BMW.

#### Deep Burial

The Biomedical Waste rules require that human anatomical and animal wastes in cities with population less than 500,000 and in rural areas be disposed of by deep burial. Accordingly, the deep burial site should be prepared by digging a pit or trench of about 2 meters deep in an area that is not prone to flooding or erosion, and where the soil is relatively impermeable, there are no inhabitants or shallow wells in the vicinity, and the risk to surface water contamination is remote (Pratyusha *et al.*, 2012).

#### Sewer

Some liquid pharmaceuticals, *e.g.* syrups and intravenous (I.V.) fluids, can be diluted with water and flushed into sewers in small quantities over a period of time without serious public health or environment (Green S 2003-2007). Current Pharmaceutical Waste Streams and their treatments are shown in Figure 5 ([www.slidesharecdn.com](http://www.slidesharecdn.com)).

### Potential solutions for Pharmaceutical Waste management

#### New waste streams

For proper handling of hazardous pharmaceutical waste, health care organizations most likely will need to create additional waste streams (Smith, 2007). All facilities must review their current policies and procedures to ensure compliance with state and federal pharmaceutical waste management and environmental regulations (Saljoughian, 2004). Computerization, automation, and bar-code scanning technology may be useful in the development of safe and effective pharmaceutical waste management streams. Smith has used diagrams to illustrate current and potential waste streams. New pharmaceutical waste management streams would include P, U, and D-listed wastes; bulk and residue chemotherapy; chemotherapy spill clean-up materials; toxic hazardous waste; ignitable hazardous waste; and nonhazardous pharmaceutical waste. In addition, infectious hazardous and compressed gas aerosols should be considered as separate waste streams. Ignitable hazardous waste should be segregated, properly labeled, stored, transported, and disposed of by a specialized broker and a federally permitted RCRA incineration firm.

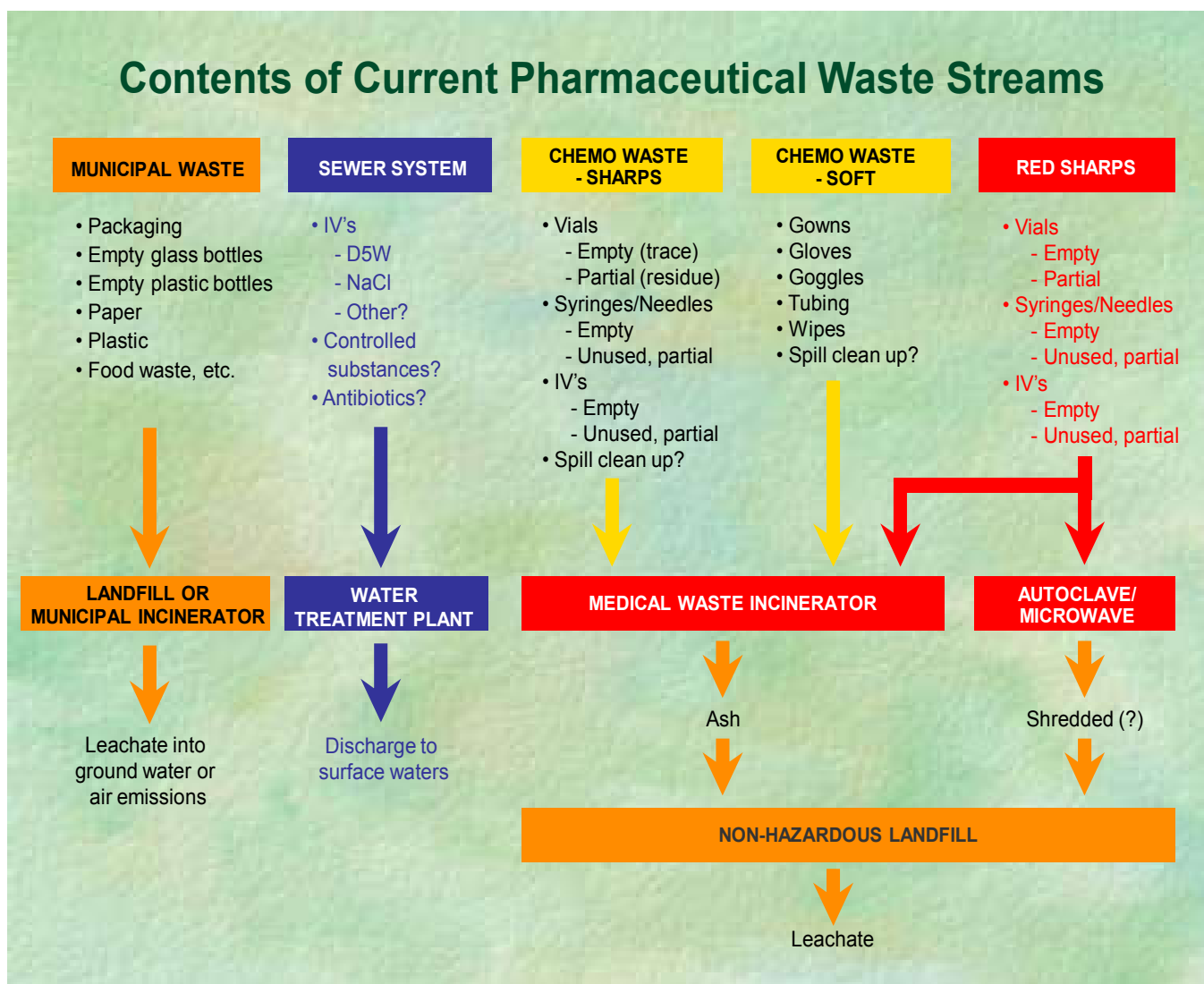


Fig. 5. Pharmaceutical Waste streams & Management

### Waste management team

An interdepartmental, multidisciplinary team could be formed to be accountable for maintaining compliance with RCRA and state regulations. By evaluating current practices for compliance and potential harm, the team could identify gaps in pharmaceutical waste stream management and work quickly to resolve them. The team could serve as the facility's liaison with the regional EPA office and possibly with the state environmental or sanitary office and outside consultants.

### Online Tools

Waste management companies have made resources available on the internet to assist pharmacies in cost-effective and compliant segregation of waste streams. However, more comprehensive tools must be developed to meet the needs of health care facilities across the nation. Pharmaceuticals requiring special disposal can be identified through online databases that enable searches by National Development Council (NDC) number and product or generic name (Smith, 2002). Also available online are recommendations citing federal regulations and recommended waste streams, state regulation alerts where the state regulation is more stringent than the federal, and risk management alerts based on professional knowledge and experience.

### Inventory management

To help control the amount of hazardous pharmaceutical waste generated, minimum inventory levels should be maintained (Shafir, 2004). Health care facilities should rotate inventory and use the oldest stock first, minimize amounts of unwanted or expired medications (original and repacked containers), use multidose vials, prepare patient-specific oral syringes instead of prepacks, centralize disposal of physician's samples, and avoid unnecessary prescriptions (especially antibiotics). Items that do not require special handling can go into the municipal trash or sewer system (e.g., unit dose packaging for non-P-listed items, empty medication vials that contained non-P-listed items, partially used nonhazardous items). Empty containers of nonhazardous items can also go in the trash.

### Reverse Distribution

Pharmacies can also minimize the amount of pharmaceutical waste by using reverse distribution, in which unused but potentially usable pharmaceuticals are returned to the manufacturer for credit. To facilitate this process, EPA has determined that health care facilities do not have to consider returned pharmaceuticals as "discarded materials" and therefore do not have to treat them as hazardous waste. The burden for proper disposal thus shifts to the reverse distributor,

which must comply with Return Industry Association (RIA) Standards. Pharmaceutical waste processed through reverse distribution does not count towards a facility's hazardous waste generator status.

### State and county activity

Many states and some counties have specific regulations that are much more stringent than the federal RCRA regulations. Facilities should contact their state EPA or regulatory body to learn what requirements apply.

### EPA Initiatives

EPA has at least four current pharmaceutical waste initiatives. Two will specifically address pharmaceuticals that cannot be disposed of in sewers.

### Implementing a Plan for minimization of Pharmaceutical Waste

Organizations that implement a comprehensive pharmaceutical waste management plan can realize several benefits.

### The key points for the implementing plans are as follows:

1. Hazardous waste storage accumulation sites should be in the same locked area that houses Mercury, Xylene, Formaldehyde and other laboratory chemicals.
2. The maximum storage time should be 90 or 180 days, as determined by the facility's waste generator status.
3. Institutions should either contract with a hazardous waste broker or develop internal expertise in manifest preparation and land ban preparation (preparing those agents that cannot be disposed of in the landfill). The hazardous waste manifest is a form that has both EPA and Department of Transportation (DOT) components. A land disposal restrictions form must accompany the manifest. This document indicates what wastes are being disposed of and how they will be treated prior to application to the land; it also ensures compliance with RCRA. The hazardous waste vendor can prepare this for all of these services; facilities have the option of contracting with a federally permitted RCRA hazardous waste incineration facility or TDSF (treatment, storage, and disposal facility).
4. Nonhazardous drugs should be segregated into non-red and non-yellow containers that are labeled "Nonhazardous Pharmaceutical Waste-Incinerate only" and are disposed of at a regular medical waste or municipal incinerator that is permitted to accept nonhazardous pharmaceutical waste.
5. For the disposal of controlled substances, the practice of two health care professionals witnessing the waste should continue unchanged (Sharma, 2010).

### Minimizing Pharmaceutical Waste

As design and implement your pharmaceutical waste management program, there are inherent limitations on the substitution of a less hazardous drug since the hazardous nature of the chemical often provides the therapeutic effect. However, waste reduction can minimize compliance hassles, costs and risks.

The following section provides a number of minimization opportunities to consider and explore:

- Considering lifecycle impacts in the purchasing process.
- Maximizing the use of opened chemotherapy vials.
- Implementing a samples policy.
- Labeling drugs for home use.
- Priming and flushing I.V. Lines with saline solution.
- Examining the size of containers relative to use.
- Replacing prepackaged unit dose liquids with patient-specific oral syringes.
- Controlled substances.
- Delivering chemotherapy drugs.
- Monitoring dating on emergency syringes.
- Reviewing inventory controls to minimize outdates.
- Considering the management options.
- Getting ready for implementation.
- Locating your satellite accumulation areas
- Evaluating your storage accumulation area
- Conducting a pilot program
- Policies and Procedures

At a minimum pharmaceutical waste management policies and procedures should be:

- Developed to detail the organization's approach to identifying drugs that must be managed as hazardous waste.
- Determining which non-regulated drugs will be managed as hazardous waste.
- Labeling drugs to facilitate segregation of hazardous waste.
- Segregating waste streams.
- Training staff (*e.g.*, which staff, what information and how often).
- Setting up and managing satellite accumulation and storage accumulation areas.
- Preparing and maintaining hazardous waste manifests.
- Determining their hazardous waste generation status.
- What criteria are used for hazardous waste selection?
- Scheduling regular program reviews.
- Keeping management informed.
- Using Pharmaceutical Waste Management as a stepping-stone to a facility-wide.

### Conclusion

Pharmaceutical waste continues to be a new frontier in environmental management for health care facilities. The management of Pharmaceutical wastes poses a great challenge to the policy planners, city administrators, medical personnel and workers in the recycling industry. It is interdisciplinary in nature, involving pharmacy, nursing, environment services, infection control, quality assurance, risk management, *etc.* The management of waste is an increasingly complex task with new waste classifications and disposal techniques being developed and released on a continual basis. Thus there is a need for adopting cost-effective system for providing better medical treatment facilities and also require the implementation of new system to insure proper waste management and to reduce the amount of waste generation by awareness and education of all concerned. Pharmacist can play



a significant role in reducing medication waste and solving the pharmaceutical waste disposal problem.

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