



REVIEW ON: WASTE MATERIAL MANAGEMENT IN PHARMACEUTICAL INDUSTRY

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Accepted on: 21-04-2012; Finalized on: 30-09-2012.

ABSTRACT

Pharmaceutical waste is a form of medical waste that includes unused medications, over-the-counter personal care products, and sometimes accessories such as sharps, used test strips, and other supplies. It is a cause for concern because it poses a threat to human and environmental health. Because of the dangers, pharmaceutical waste cannot be disposed of like conventional waste and requires special handling, whether it comes from a hospital, clinic, pharmacy, or private household. There are several concerns with the management of pharmaceutical waste. In this paper we included types of waste, regulatory bodies involved in management of waste material and waste management strategy. Some drugs contain heavy metals, endocrine disruptors, and other compounds that are dangerous for animals and the environment. There is also a risk that poorly controlled waste could end up in the hands of people who misuse the medications. In order to safely handle and dispose of waste it is necessary to understand the specific hazards of the waste product, and the ability of a given disposal technique to manage them.

Keywords: Pharmaceutical waste, biomedical waste, chemo waste, P & U listed waste.

INTRODUCTION

Waste includes all items that people no longer have any use for, which they either intend to get rid of or have already discarded. Additionally, wastes are such items which people are required to discard, for example by law because of their hazardous properties. Many items can be considered as waste e.g., household rubbish, sewage, sludge, wastes from manufacturing activities, packaging items, discarded cars, old televisions, garden waste, old paint containers etc. Thus all our daily activities can give rise to a large variety of different wastes arising from different sources. This is mainly made up of waste coming from households, commercial activities (e.g., shops, restaurants, hospitals etc.), industry (e.g., pharmaceutical companies, clothes manufacturers etc.), agriculture (e.g., slurry), construction and demolition projects, mining and quarrying activities and from the generation of energy. With such vast quantities of waste being produced, it is of vital importance that it is managed in such a way that it does not cause any harm to either human health or to the environment. There are a number of different options available for the treatment and management of waste including prevention, minimization, re-use, recycling, energy recovery and disposal.

OVERVIEW OF BIOMEDICAL WASTE

Biomedical waste is broadly defined as any solid or liquid waste that is generated in the diagnosis, treatment of immunization of human beings or animals in research pertaining thereto, or in the production or testing of biological material. According to World Health Organization (WHO) estimates 85% of hospital waste is actually non-hazardous and around 10% is infectious while the remaining 5% is non-infectious but consists of hazardous chemicals like methyl chloride and formaldehyde. Here, the main concern of infectious

hospital waste is the transmission of HIV and Hepatitis B or C viruses. In this context, Syringes and needles have the highest disease transmission potential.¹

Hospital waste, till recently was not being managed but it was simply 'disposed off'. The disposal of hospital waste can be very hazardous particularly when it gets mixed with municipal solid waste and is dumped in uncontrolled or illegal landfills such as vacant lots in neighboring residential areas and slums. This can lead to a higher degree of environmental pollution, apart from posing serious public health risks such as AIDS, Hepatitis, plague, cholera, etc. The waste produced in the course of health care activities carries a higher potential for infection and injury than any other type of waste.²

Overview of the types of health care wastes according to whom

1. Communal waste: Also known as "general health care wastes"

It is defined as solid wastes that are not infectious, chemical, or radioactive. E.g. Cardboard boxes, paper, food waste, plastic and glass bottles

2. Biomedical wastes: Also known as "hazardous health care wastes," or "health care risk wastes," or "special wastes". It is further classified as:-

- Infectious waste: It is defined as wastes suspected of Cultures, tissues, dressings, swabs, and other blood-soaked items; waste containing pathogens from isolation wards.
- Anatomical waste: It includes recognizable body parts, sharps, needles, scalpels, knives, blades, broken glass.
- Pharmaceutical waste: It includes expired or no longer needed medicines or pharmaceuticals.



- Genotoxic waste: Wastes containing genotoxic drugs and chemicals (used in cancer therapy).
- Chemical waste: It includes laboratory reagents, film developer, solvents, expired or no longer needed disinfectants, and organic chemical wastes (for example, formaldehyde, phenol-based cleaning solutions).
- Heavy metal waste: Batteries, broken thermometers, blood pressure gauges Pressurized containers Aerosol cans, gas cylinders (that is, anesthetic gases such as nitrous oxide, halothane, enflurane, and ethylene oxide; oxygen, compressed air) comes under heavy metal waste
- Radioactive waste: It includes unused liquids from radiotherapy; waste materials from patients treated or tested with unsealed radionuclides.³

Regulatory bodies that oversee pharmaceutical waste management

- Environmental Protection Agency (EPA)
- Department of Transportation (DOT)
- Drug Enforcement Administration (DEA)
- Occupational Safety and Health Administration (OSHA)
- State Environmental Protection Agencies,
- State Pharmacy Boards, and
- Local Publicly Owned Treatment Works (POTW)

Background

The Resource Conservation and Recovery Act (RCRA) were enacted in 1976 and govern the management of solid and hazardous waste generated within the United States. In the past several years, the Environmental Protection Agency (EPA) and state environmental protection inspectors have determined that healthcare facilities have not been managing hazardous waste in compliance with RCRA. A number of pharmaceuticals and formulations of pharmaceuticals meet the definition of hazardous waste under RCRA. EPA and some state environmental agencies are now requiring healthcare facilities to identify, segregate, contain, and appropriately label, store, transport, and dispose of these hazardous wastes in compliance with RCRA regulations. As a result of this focus on the part of regulators, surveyors for the Joint Commission (JC) are also including pharmaceutical waste management in their survey questions.⁴

Purpose

These guidelines discuss categorizing pharmaceutical waste, maintaining and updating an inventory of pharmaceutical waste streams, managing waste storage sites throughout the military treatment facility (MTF), and disposing of waste material. The guidelines provide suggestions on how to manage your program. MTFs can make the final decisions on the best way to develop and

maintain the requirements set forth. Pharmaceutical waste that meet the requirements delineated in 40 CFR 261.33(e) (P list) or 40 CFR 261.33(f) (U list), or exhibits a characteristic of hazardous as defined in the 40 CFR 261 must be managed and disposed of in accordance to Federal, State, and local regulations. Therefore, the purpose of these guidelines is:

- To provide policy and guidelines for MTFs generating pharmaceutical waste and to ensure the implementation of Reference (a), 40 CFR 260-279, EPA Hazardous Waste Management Regulations.
- To provide Best Management Practice (BMP) guidelines for the management of other non-RCRA Pharmaceutical waste included in these guidelines.⁵

THE BIOMEDICAL WASTE RULES OF 1998

India's Biomedical Waste Rules of 1998, which were amended twice in 2000, are based on the principle of segregation of communal waste from BMWs, followed by containment, treatment, and disposal of different categories of BMW. The rules classify BMWs into 10 categories and require specific containment, treatment,

Main Features of India's Biomedical Waste Rules of 1998 (amended twice in 2000)

In 1998, India's Ministry of Environment and Forests prepared and issued the Biomedical Waste (Handling and Management) Rules. The main features of the current rules are summarized here and in the below:

- **Definition of biomedical waste:** Any waste that is generated during the diagnosis, treatment, or immunization of human beings or animals, or in research activities pertaining to or in the production or testing of biological.
- **Application of the Biomedical Waste Rules:** The rules apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle BMWs in any form.
- **Duty of occupier (operator):** It is the duty of the occupier (operator) of a health care facility that is, hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank to ensure that BMWs are handled without any adverse effect to human health and the environment, and according to the prescribed treatment and disposal requirements in the Biomedical Waste Rules.
- **Prescribed authority:** State Pollution Control Boards (SPCBs) in states and Pollution Control Committees in territories are responsible for permitting and enforcing the requirements of the Biomedical Waste Rules.
- **Permitting:** Each occupier (operator) handling BMWs and providing services to 1,000 or more patients per month are required to obtain a permit from the prescribed authority.
- **Recordkeeping:** Each occupier (operator) is required to maintain records on the generation, collection, reception,



storage, transportation, treatment, and disposal of BMWs. All records are subject to inspection and verification by the prescribed authority at any time.

- **Accident reporting:** Each occupier (operator) is required to report any accident related to the management of BMWs.

- **Annual reporting:** Each occupier is required to submit an annual report to the prescribed authority to provide information about categories and amounts of wastes generated and treated, and modes of treatment.

- **Common disposal/incineration sites:** Local public entities are required to provide common disposal/incineration sites, and the occupiers (operators) of such sites are required to comply with the Biomedical Waste Rules.

- **Segregation, packaging, transportation, and storage:** BMWs are not to be mixed with other waste. According to the Rules, BMWs are to be segregated into labeled bags/containers. Transportation of BMWs is to be conducted in authorized vehicles. No untreated waste is to be stored more than 48 hours, unless special permission is obtained from the regulatory authorities.

- **Standards:** Technology and discharge standards for incineration, autoclaving, microwaving, liquid waste discharges, and deep burial are prescribed in the Biomedical Waste Rules.⁶

PHARMACEUTICAL WASTE

Pharmaceutical waste is potentially generated through a wide variety of activities in a health care facility, including syringes, and not limited to intravenous (IV) preparation, general Pharmaceutical waste may include, but is not limited to:

- Expired drugs;
- Patients' discarded personal medications;
- Waste materials containing excess drugs (syringes, IV bags, tubing, vials, etc.);
- Waste materials containing chemotherapy drug residues;
- Open containers of drugs that cannot be used;
- Containers that held acute hazardous waste (p-listed) drugs;
- Drugs that are discarded; and
- Contaminated garments, absorbents and spill cleanup material.

Pharmaceutical waste is further classified in 3 categories:-

1. Hazardous waste ,
2. Non-hazardous waste,
3. Chemo waste.

HAZARDOUS WASTE

Waste that is dangerous or potentially harmful to human health or the environment is called as hazardous waste. It can be liquids, solids, contained gases, or sludges. Hazardous wastes are divided into two categories:

- (1) Listed wastes, and
- (2) Characteristic wastes.

Listed wastes appear on one of four lists of hazardous waste (F, K, P and U). Pharmaceuticals are found on two of these lists, the P and U lists which both contain commercial chemical products. Characteristic wastes are regulated because they exhibit certain hazardous properties – ignitability, corrosivity, reactivity and toxicity. Wastes that are not listed and do not exhibit a characteristic are considered solid waste. Solid wastes should be discarded according to state and/or local regulations, including regulated medical waste requirements.⁷

Listed hazardous waste

P-Listed Pharmaceutical waste

P-listed wastes are commercial chemical products that are categorized as acutely hazardous under RCRA as shown in table no.1. One of the primary criteria for including a drug on the P-list as acutely hazardous is an oral lethal dose of 50 mg/kg (LD50) or less. LD50 is the amount of a material, given all at once, which causes the death of 50% of a group of test animals. They are toxic and can cause death or irreversible illness at low dose.

When a drug waste containing a P-listed constituent of concern is discarded or intended to be discarded, it must be managed as hazardous waste if two conditions are satisfied:

- (1) The discarded drug waste contains a sole active ingredient (54 FR 31335) that appears on the P list, and it has not been used for its intended purpose (54 FR 31336).
- (2) Empty Containers of P-Listed Wastes (40 CFR Part 261.7(b)(3)):-A container that has held a P-listed waste is not considered "RCRA empty" unless it has been:
 - (a) Triple rinsed, and
 - (b) The rinsate is managed as hazardous waste.

Since triple rinsing is not practical in healthcare settings, all vials, IVs, and other containers that have held a P-listed drug must be managed as hazardous waste, regardless of whether or not all of the contents have been removed. Some states have chosen to interpret "used" less stringently in the case of solid dosage forms (tablets, capsules) and are not regulating "empty" warfarin stock bottles or unit-dose packaging.



Table 1: P-listed drugs with waste code

P-listed pharmaceutical	waste code
Arsenic trioxide	P012
Epinephrine	P042
Nicotine	P075
Nitroglycerin	P081
Physostigmine	P204
Physostigmine salicylate	P188
Warfarin	>0.3% P001

U-Listed Pharmaceutical Wastes

U-listed chemicals include a broader range of pharmaceuticals and again must be the sole active ingredient to come under regulation. Technically, these items would not be regulated as hazardous waste when discarded since neither U-listed ingredient is the sole active ingredient. There are 21 drugs on the U-list some of them are shown in table 2. These chemicals are listed primarily for their toxicity. Similar to a P-listed waste, when a drug waste containing one of these chemicals is discarded, it must be managed as hazardous waste if two conditions are satisfied:

- (1) The discarded drug waste contains a sole active ingredient that appears on the U list, and It has not been used for its intended purpose.
- (2) Empty Containers of U-Listed Wastes (40 CFR Part 261.7(b)(1)):- A container that has held a U-listed waste is considered "RCRA empty" if two conditions are met:
 - All the contents have been removed that can be removed using normal means, such as drawing liquid out with a syringe
 - No more than 3% by weight remains.

If both of these criteria are not met, the container must be managed as hazardous waste. Any residues removed from the empty container must be managed as hazardous waste.

Table 2: U-Listed drugs with waste code

U-listed pharmaceutical	Waste code
Chloral hydrate	U034
Paraldehyde	U182
Chlorambucil	U035
Phenol	U188
Cyclophosphamide	U058
Reserpine	U200
Daunomycin	U059
Resorcinol	U201
Dichlorodifluoromethane	U075
Saccharin	U202
Diethylstilbestrol	U089
Selenium sulfide	U205
Hexachlorophene	U132
Streptozotocin	U206
Lindane	U129
Trichloromonofluoromethane	U121
Melphalan	U150

NOTE:

1 Nitroglycerin in finished dosage forms has been exempted federally based on a Federal Register Notice dated May 16, 2001 (Volume 66, Number 95)(Page 27266-27297). Since every state except Iowa and Alaska have mirroring regulations, check with the Wisconsin Department of Natural Resources to determine the status of waste nitroglycerin dosage forms in Wisconsin.

2 Chloral hydrate and paraldehyde are controlled substances regulated by the Drug Enforcement Administration in schedule IV as an indication of moderate abuse potential. Since controlled substances must be destroyed through a witnessed destruction process, their status as a RCRA hazardous waste makes disposal difficult.⁸

CHARACTERISTICS OF WASTE

The EPA defines four characteristics of hazardous waste:

- Ignitability (D001)
- Toxicity (D number specific to the chemical)
- Corrosivity (D002)
- Reactivity (D003)

Table 3: Drug formulation exhibiting ignitability characteristic

IGNITABLE PROPERTY	RESOURCES	IGNITABLE FORMULATION
Aqueous drug formulation containing 24 % or more alcohol by volume and having a flashpoint of less than 140°F or 60°C (261.21(a)(1))	a) Material Safety Data Sheet b) Common pharmacy references such as Facts and Comparisons or their on-line database, E-Facts	1. Erythromycin Gel 2% 2. Texacort Solution 1% 3. Taxol Injection
Liquid drug formulations, other than aqueous solutions containing less than 24 % alcohol, with a flashpoint of less than 140°F or 60°C	Standard laboratory test procedure for measuring flashpoint	Flexible collodion used as a base in wart removers is not an aqueous solution and has a flashpoint = 45 degrees
Oxidizers or materials that readily supply oxygen to a reaction in the absence of air as defined by the DOT	a) 40 CFR 264 Appendix V Examples of Potentially Incompatible Waste Group 6-A Oxidizers b) Possible ORM-D Consumer Commodity exclusion in 49 CFR173.151 for small	Bulk chemicals found in the compounding section of the pharmacy such as potassium permanganate
Flammable aerosol propellants meeting the DOT definition of compressed gas (261.21(a)(3))	Possible ORM-D Consumer Commodity exclusion in 49 CFR173.306	Primatene aerosol



i. Ignitability: D001 (40 CFR 261.21)

The objective 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 characteristic as mentioned in table 3. Many of the hazardous wastes that pharmacies handle are hazardous because they are ignitable. These wastes often pose the greatest management problems for pharmacies. Ignitable wastes are easily combustible or flammable.

ii. Corrosivity: D002 (40 CFR Part 261.22)

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 exhibit 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.

iii. Reactivity: D003 (40 CFR Part 261.23)

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). While nitroglycerin in its pure form is reactive; pharmaceuticals containing nitroglycerin are too weak to react and have been excluded from the reactive classification federally and in Florida.

iv. Toxicity: Multiple D Codes (40 CFR Part 261.24)

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 12 concentrations which classify them as toxic. Toxic D-listed chemicals used in drug formulation are shown in table 4. 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.^{8,9}

Table 4: Toxic D-listed Chemicals Used in Drug Formulations

Ingredient Waste	Code	Regulatory Level (mg/l)	Drugs Formulations Containing These Ingredients
Arsenic	D004	5.0	Arsenic trioxide
Barium	D005	100.0	Used in radiology
Cadmium	D006	1.0	Multiple mineral preparations
Chloroform	D022	6.0	No longer used
Lindane	D013	0.4	Treatment of lice, scabies
Mercury	D009	0.2	Vaccines of thiomersal, eye, ear preparation
Selenium	D010	1.0	Dandruff shampoo, multiple mineral preparation
Silver	D011	5.0	Silver sulphadiazine creams

NON-HAZARDOUS WASTE

Materials in this category are considered to present no significant hazardous properties. It is worth noting, however, that this is not an indication that there are no hazardous components present, only that any such components are below the threshold for causing harm to human health. Importantly, this non-hazardous state is subject to change and the addition or removal of specific items from the waste stream may significantly alter the management options available.

Pharmaceutically inert: Certain medicinal products have no pharmaceutical properties but are still controlled and administered by medical staff (examples include sodium chloride or dextrose solutions). Through use, however, these products may become contaminated, or mixed with other compounds and therefore require assessment for hazardous properties prior to disposal.

CHEMO WASTE

Chemo wastes are further classified as trace chemotherapy and 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 isn't 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 original reference to segregating 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.¹³ 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. Items that are appropriate for management as trace chemotherapy waste include:

- "RCRA empty" vials, syringes, IV bags, and tubing;
- Gowns, gloves, wipes and other paraphernalia associated with routine handling, preparation, and administration of chemotherapy; and,
- Wipes and other materials used during routine cleaning and decontamination of a Biological
- Safety Cabinet or glove box (unless alcohols, phenols or other hazardous materials are used).

Bulk Chemotherapy Waste

One chemotherapy agent is a P-listed constituent of concern and eight chemotherapy agents are U-listed.



Trace chemotherapy containers have long been used to discard listed chemotherapy drug waste that should be managed as hazardous waste. This is not only illegal but also inappropriate since 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.

PHARMACEUTICAL WASTE TREATMENT AND DISPOSAL

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

1. 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. 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". Incinerators convert waste materials into heat, gas, steam and ash. Incineration is carried out both on a small scale by individuals and on a large scale by industry. It is used to dispose of solid, liquid and gaseous waste. It is recognized as a practical method of disposing of certain hazardous waste materials (such as biological medical waste). Incineration is a controversial method of waste disposal, due to issues such as emission of gaseous pollutants. Incineration is not suitable for such health care wastes as pressurized gas containers, large amounts of reactive chemical wastes, wastes treated with halogenated chemicals, halogenated plastics such as polyvinyl chloride, wastes with mercury or cadmium (such as broken thermometers, used lead or mercury batteries), or radiographic wastes. Incinerators that meet the CPCB draft incineration regulations must have a sophisticated (for example, double- chamber) design and include a scrubber as the air pollution control equipment. Ash from these incinerators must be disposed of in a secure landfill. Such incinerators are associated with high investment and operating costs and require highly skilled operating personnel.

2. Autoclaving

Autoclaving uses saturated steam in direct contact with the 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

wastes. Before autoclaving, BMWs require shredding to an acceptable size, an operation that would involve frequent breakdown. Autoclaving produces a waste that can be land filled with municipal waste. A wastewater stream is generated that needs to be disposed of with appropriate controls. Autoclave operation requires qualified technicians, and medium investment and operating cost.

3. 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.

4. 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. However, microbiological cultures, mutilated sharps, or shredded solids can also be treated by chemical disinfection. 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. As chemical disinfectants have hazardous (in particular, toxic) properties, users should wear protective clothes. Chemical disinfectants should not be discharged to surface waters, and no large quantities should be allowed into sewers.¹¹

5. 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. The pit should be half-filled with the BMW, and then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil. On each occasion when BMW is added to the pit, a layer of 10 cm of soil should be added to cover the waste.



6. Secure land filling

Secure land filling involves disposal of solid BMWs at a landfill designed and operated to receive hazardous wastes. The Biomedical Waste Rules require disposal of discarded medicines, cytotoxic drugs, solid chemical wastes, and incineration ash in secured landfills.

Disposing of waste in a landfill involves burying the waste, and this remains a common practice in most countries. Landfills were often established in abandoned or unused quarries, mining voids or borrow pits. A properly designed and well-managed landfill can be a hygienic and relatively inexpensive method of disposing of waste materials. Older, poorly designed or poorly managed landfills can create a number of adverse environmental impacts such as wind-blown litter, attraction of vermin, and generation of liquid leachate. Another common byproduct of landfills is gas (mostly composed of methane and carbon dioxide), which is produced as organic waste breaks down anaerobically. This gas can create odour problems, kill surface vegetation, and is a greenhouse gas. Design characteristics of a modern landfill include methods to contain leachate such as clay or plastic lining material. Deposited waste is normally compacted to increase its density and stability, and covered to prevent attracting vermin (such as mice or rats). Many landfills also have landfill gas extraction systems installed to extract the landfill gas. Gas is pumped out of the landfill using perforated pipes and flared off or burnt in a gas engine to generate electricity.

7. Waste immobilization: encapsulation

Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. Drums should be cleaned prior to use and should not have contained explosive or hazardous materials previously. They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam or bituminous sand. For ease and speed of filling, the drum lids should be cut open and bent back. Care should be taken to avoid cuts to hands when placing pharmaceuticals in the drums. Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15:5 (by weight) is added and the drum filled to capacity. A larger quantity of water may be required sometimes to attain a satisfactory liquid consistency. Steel drum lids should then be bent back and sealed, ideally by seam or spot welding. The sealed drums should be placed at the base of a landfill and covered with fresh municipal solid waste. For ease of movement, the drums may be placed on pallets which can then be put on a pallet transporter.

8. Waste immobilization: Inertization

Inertization is a variant of encapsulation and involves removing the packaging materials, paper, cardboard and plastic, from the pharmaceuticals. Pills need to be removed from their blister packs. The pharmaceuticals

are then ground and a mix of water, cement and lime added to form a homogenous paste. Worker protection in the form of protective clothing and masks is required as there may be a dust hazard. The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste. The paste then sets as a solid mass dispersed within the municipal solid waste. The process is relatively inexpensive and can be carried out with unsophisticated equipment. The main requirements are a grinder or road roller to crush the pharmaceuticals, a concrete mixer, and supplies of cement, lime and water.

9. Sewer

Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental affect. Fast flowing watercourses may likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics. The assistance of a hydrogeologist or sanitary engineer may be required in situations where sewers are in disrepair or have been war damaged.

HAZARDOUS WASTE MANAGEMENT STRATEGY

Waste minimization

An important method of waste management is the prevention of waste material being created, also known as waste reduction. Methods of avoidance include reuse of second-hand products, repairing broken items instead of buying new, designing products to be refillable or reusable (such as cotton instead of plastic shopping bags), encouraging consumers to avoid using disposable products (such as disposable cutlery), removing any food/liquid remains from cans, packaging, and designing products that use less material to achieve the same purpose (for example, light-weighting of beverage cans).

Reuse

Re-use means the use of a product on more than one occasion, either for the same purpose or for a different purpose, without the need for reprocessing. Re-use avoids discarding a material to a waste stream when its initial use has concluded. It is preferable that a product be re-used in the same state e.g., returnable plastic pallets, using an empty glass jar for storing items and using second hand clothes. Reuse is normally preferable to recycling as there isn't the same requirement for the material to have gone through a detailed treatment process thus helping to save on energy and material usage.¹²

Recycling

Recycling involves the treatment or reprocessing of a discarded waste material to make it suitable for subsequent re-use either for its original form or for other purposes. It includes recycling of organic wastes but excludes energy recovery. Recycling benefits the environment by reducing the use of virgin materials.



Many different materials can be recycled. Waste materials can either be recycled for use in products similar to their original use (e.g., paper recycling) or can be recycled into a product which is different than the original use (e.g., recycling plastic bottles into fleece jackets or using construction and demolition waste as road aggregate. In the EU up to 13% of municipal waste is recycled.

Energy recovery

The energy content of waste products can be harnessed directly by using them as a direct combustion fuel, or indirectly by processing them into another type of fuel. Thermal treatment ranges from using waste as a fuel source for cooking or heating and the use of the gas fuel (see above), to fuel for boilers to generate steam and electricity in a turbine. Pyrolysis and gasification are two related forms of thermal treatment where waste materials are heated to high temperatures with limited oxygen availability. The process usually occurs in a sealed vessel under high pressure. Pyrolysis of solid waste converts the material into solid, liquid and gas products. The liquid and gas can be burnt to produce energy or refined into other chemical products (chemical refinery). The solid residue (char) can be further refined into products such as activated carbon. Gasification and advanced Plasma arc gasification are used to convert organic materials directly into a synthetic gas (syngas) composed of carbon monoxide and hydrogen. The gas is then burnt to produce electricity and steam. An alternative to pyrolysis is high temperature and pressure supercritical water decomposition (hydrothermal monophasic oxidation).¹⁰

Steps that should be followed to manage pharmaceutical wastes:

Step 1:- establish a pharmacy management plan

Step 2:- identify your hazardous and non-hazardous wastes

Step 3:- implement best management practices

Step 4:- determine your waste generator status

Step 5:- comply with guidelines for transport and disposal

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.

1. Considering Lifecycle Impacts in the Purchasing Process
2. Maximizing the Use of Opened Chemotherapy Vials
3. Implementing a Samples Policy

4. Labeling Drugs for Home Use
5. Priming and Flushing IV Lines with Saline Solution
6. Examining the Size of Containers Relative to Use
7. Replacing Prepackaged Unit Dose Liquids with Patient-Specific Oral Syringes
8. Controlled Substances
9. Delivering Chemotherapy Drugs
10. Monitoring Dating on Emergency Syringes
11. Reviewing Inventory Controls to Minimize Outdates
12. Considering the Management Options
13. Getting Ready for Implementation
 - Locating Your Satellite Accumulation Areas
 - Evaluating Your Storage Accumulation Area
 - Conducting a Pilot Program
14. 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; and,
- using pharmaceutical waste management as a stepping-stone to a facility-wide;
- environmental management system.¹³

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.

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