

A Review on Managing of Pharmaceutical Waste in Industry

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Abstract: Pharmaceutical waste is a form of medical waste that includes unused medications, and occasionally frills such as used test strips, and other supplies. It is not a less important issue to consider because of the dangers, pharmaceutical waste cannot be disposed of like conventional waste and requires special handling. There are several concerns with the management of pharmaceutical waste. In this paper we discussed various forms of waste, regulatory managements involved in the management of waste material and waste management approach. Some drugs include metals, endocrine disruptors, and various compounds that are dangerous for animals and the environment. There is also a risk that inadequately pharmaceutical waste could end up in the hands of people who misuse the medications. In order to safely hold and dispose of waste it is crucial to understand the specific hazards of the waste matter, and the facility of a given disposal technique to control them.

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

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partially used ampoules, needles, and IVs, out-dated, unused preparations, fallow unit doses, personal medications and outdated pharmaceuticals. 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.^[1]

Overview of Biomedical Waste:

Biomedical Waste is mostly considered as any solid or liquid waste that is engendered in the diagnosis, treatment of immunization of human beings or animals in research concerning thereto, or in the production or testing of biological substantial. Conferring to World Health Organization (WHO) approximates 85% of hospital waste is actually non-toxic and around 10% is infectious while the remaining 5% is non-infectious but contains of hazardous chemicals like methyl chloride and formaldehyde. Here, the main apprehension of the hospital waste is the infectious transmission disease like, Hepatitis B or C viruses. In this situation, Syringes and needles have the highest risk on the health potential.

Now a days the hospital waste was not being managed but it was simply 'disposed off'. When the hospital waste is disposed it can be very hazardous because, when it gets mixed with municipal solid waste and

is discarded in uncontrolled or illegal landfills such as neighboring residential areas and slums. This can lead to endanger the human health by various diseases like AIDS, Hepatitis, plague, cholera, etc. The waste which is produced in the health care facilities carries a higher hazard potential for infection and injury than any other type of waste.^[2]

Overview of the types of health care wastes according to whom:

1. Mutual waste : Also known as “universal health care wastes”

It states that, solid wastes which are not harmful to living beings. E.g. Cardboard boxes, newspaper, foodstuff waste, plastic and glass bottles

2. Biomedical wastes: It affects the health of the humans or animals called “Dangerous waste”. It can be classified as:-

- **Infectious waste:** It is defined as wastes that are included in the Cultures, tissues, dressings, swabs, and other blood- soaked items; waste holding pathogens from isolation wards.
- **Anatomical waste:** It includes detectable body parts, sharps, spines, switchblades, knife blade, and glassware.
- **Medical waste:** It involves outdated or no longer needed medicines or pharmaceuticals.
- **Genotoxic waste:** Wastes containing genotoxic drugs and chemicals (used in cancer therapy).
- **Chemical waste:** It contains research laboratory reagents, solvents, expired or no longer desirable disinfectants, and organic chemical wastes (for example, HcHO, phenol contained washing solutions).
- **Heavy metal waste:** Batteries, pressure gauges of blood, Pressurized bottles, Aerosol cans, gas cylinders (that is, anesthetic gases such as NO₂) 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 administer pharmaceutical waste management

- I. Environmental Protection Agency (EPA)
- II. Department of Transportation (DOT)
- III. Drug Enforcement Administration (DEA)
- IV. Occupational Safety and Health Administration (OSHA)
- V. State Environmental Protection Agencies
- VI. State Pharmacy Boards
- VII. 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 previous 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 and achieve your program. MTFs can build 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 determination of these guidelines is:

- a. 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.
- b. 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 modified twice in 2000, are based on the principle of separation of communal waste from BMWs, followed by control, treatment, and disposal of different classifications of BMW

The rules categorize BMWs into 10 categories and require detailed treatment and controlmain Structures of India's Biomedical Waste Rules of 1998 (amended twice in 2000)

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

- **Meaning of biomedical waste:** The waste which is generated during the diagnosis, or immunization of human beings or animals, or in research deeds or in the manufacture or testing or analysis of biological.
- **Duty of occupier (operator):** The operator regarding to any medical facilities, animal facilities ensure that BMWs are handled without any opposing effect to human health and the environment.
- **Recommended authority:** State Pollution Control Boards (SPCBs) in states and Pollution Control Committees in territories are in charge for allowing and imposing the requirements of the Biomedical Waste Rules.
- **Permitting:** Each operator handling BMWs should provide facilities to 1,000 or more patients per month in order to obtain a license from the prescribed authority.
- **Recordkeeping:** Each operator is necessary to maintain records on the waste disposal of BMWs. And the records are to be inspected and verified by the approved authority at any time.
- **Accident reporting:** Each operator is essential to report any misfortunelinked to the management of BMWs.
- **Annual reporting:** The operators are essential to submit an annual report to the approved authority to deliver information about amount of wastes produced, and ways 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:** According to the rules, BMWs not to be mixed with the other wastes .These should be segregated into labeled bags/containers. Transportation of BMWs is to be piloted in permitted vehicles. There should be no waste to be stored, unless special authorization is obtained from the regulatory experts.^[6]

Pharmaceutical Waste

Pharmaceutical Waste is potentially generated thorough a wide variety of activities is a health care facility, including syringes, and not limited to intravenous (IV) preparation, general Pharmaceutical Waste may include the following:

1. Expired drugs;^[7]
2. Patient's discarded personal medications;
3. Waste materials containing excess drugs (syringes, IV bags, tubing, vials, etc.);
4. Open containers of drugs that cannot be used;

5. Containers that held acute hazardous waste (p-listed) drugs;
6. Drugs that are discarded; and
7. Contaminated garments, absorbents and spill cleanup material.^[8]

Pharmaceutical Waste is classified in 3 different categories:-

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

Hazardous 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 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 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 with any of the following characteristics

i. Ignitability: D001 (40 CFR 261.21)

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.

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 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.

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). 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.

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. 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.

Determining the appropriate waste stream:

As new drugs are added to formularies, it is the responsibility of each hospital to determine the appropriate waste stream for each new item. Clearly, not all pharmaceutical waste is considered hazardous according to RCRA definitions. However, RCRA does not adequately regulate a number of hazardous drugs. Even if not classified as hazardous, some pharmaceutical wastes are dangerous to the environment. For example, if a chemotherapy i.v. bag has been hung but not completely used, and if it can be separated from the patient-exposed sharp without exposure of the employee, it should be removed and disposed of as RCRA hazardous waste. If chemotherapy residue cannot be removed safely from the i.v. bag, it should be disposed of in a trace chemotherapy container as infectious chemotherapeutic waste.

Pharmaceutical waste is considered dangerous if it contains any of the following:

- More than one P- or U-listed drug,
- Chemotherapy agents,
- Drugs meeting National Institute for Occupational Safety and Health (NIOSH) or Occupational Safety and Health Administration (OSHA) criteria,
- Drugs with LD50 (lethal dose in 50% of test animals) less than or equal to 50 mg/kg,
- Endocrine disrupters,
- Immunosuppressant's,
- Vitamins and mineral preparations with potential toxicity due to chromium, selenium, or cadmium.

When hazardous drug waste is infectious, a double hazard exists. Some states may require a separate waste stream for infectious hazardous pharmaceutical waste. With the extra time and caution required, this may be one of the most expensive waste streams to manage. This waste must be separated for proper handling by a RCRA-permitted incinerator.^[9]

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 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.^[10]

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 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. substance that are applicable for management as trace chemotherapy waste include:

- a. "RCRA empty" ampoules, injects, IV bags, and tubing;
- b. Gowns, gloves, wipes and other paraphernalia associated with medical preparations.

- c. Wipes and other materials used during routine cleaning and decontamination of a Biological
- d. 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.^[11]

Pharmaceutical Waste Treatment & 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". It is recognized as a practical method of disposing of certain hazardous waste materials (such as biological medical waste).

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 waste. Autoclaving produces a waste that can be land filled with municipal waste. 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. 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.

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.^[12]

6. 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.^[13]

Discussion

Potential Solution for Pharmaceutical Waste:

For proper handling of hazardous pharmaceutical waste, health care organizations most likely will need to create additional waste streams. All facilities must review their current policies and procedures to ensure compliance with state and federal pharmaceutical waste management and environmental regulations. Computerization, automation, and bar-code scanning technology may be useful in the development of safe and effective pharmaceutical waste management streams.

1. 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.

2. Inventory management:

To help control the amount of hazardous pharmaceutical waste generated, minimum inventory levels should be maintained. 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.

3. 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 practice, EPA has decided 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 managed through contrary distribution does not count toward a facility's hazardous waste generator status.

4. 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.^[14]

Implementing a Plan:

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

The key points for the implementing a plan 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.^[15]

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;
- Using pharmaceutical waste management as a stepping-stone to a facility-wide^[16]

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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