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Guideline for disposal of medical product waste

Medical Device Section
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1. Introduction

In accordance with Section 47.5 of the Waste Prevention and Management Regulation 2012, the Medical Product Division of the Bhutan Food and Drug Authority is mandated to monitor and provide guidelines for the effective management of waste derived from medical products and their sale. The proper disposal of pharmaceutical and medical waste is crucial for both healthcare management and environmental conservation.

Given the substantial volume of waste generated by the healthcare industry, including expired medications, used medical devices, and other materials, there exists a potential risk to public health and the environment if these are not handled and disposed of correctly. This guideline serves to outline the procedure for the appropriate disposal of both hazardous and non-hazardous wastes originating from healthcare facilities, encompassing private premises engaged in the sale and distribution of medical products. This framework is designed to ensure compliance with regulations while promoting responsible waste management practices within the healthcare sector including the private premises engaged in the sale and distribution of medical products.

2. Scope

This guideline shall apply to the disposal of following category of wastes generated from:

2.1. Pharmaceuticals including vaccines and biologics

2.2. Medical devices

3. Objectives

3.1. This guideline is developed to guide the applicant on proper disposal of medical product waste

4. Normative References

4.1. The Medicines Act of the the Kingdom of Bhutan 2003

4.2. Bhutan Medicines Rules and Regulation 2019

5. Definitions

5.1. Authority: It refers to refers to Bhutan Food and Drug Authority

5.2. Chemical waste: It refers to laboratory reagents, X-ray film developer, disinfectants and others like Deltamethrin etc

5.3. General waste: It refers to the waste free of pathogenic microorganisms or hazardous substances. Therefore waste is harmless and does not need special handling or treatment

5.4. Genotoxic waste: It refers to cytotoxic drugs, highly toxic and may contain mutagenic, teratogenic or carcinogenic properties

5.5. **Heavy metals:** It refers to Mercury from broken thermometers and mercury sphygmomanometer, dental amalgam, cadmium from batteries, tube lights and bulbs

5.6. **Infectious waste:** It refers to live or attenuated vaccines, wastes from production of biologicals and devices used for transfer of cultures, used syringes and contaminated materials.

5.7. **Pharmaceutical waste:** It refers to medicines, biological products (blood, serum, vaccine) which are expired, incompletely used, damaged, spilled, rejected medicinal products, and recalled medicinal products

5.8. **Pressurized containers**: Gas cylinders (anesthetic gas, oxygen, compressed air in health facilities) stored in pressurized cylinders, cartridges, aerosols and cans

5.9. **Sharps:** It refers to the needles, syringes, scalpels, blades, broken vials, ampoules and other glass articles, or any other items used or unused that may cause an injury

5.10. **Radioactive waste**: It refers to radioactive substances used for diagnostic or therapeutic purposes. Blood, urine and feces of patients on treatment or tested with radionuclide

5.11. **Medical product waste**: It refers to wastes generated from pharmaceutical including vaccines and biologics and medical devices

6. Acronyms

6.1.1. **BFDA:** Bhutan Food and Drug Authority

6.1.2. **MPD**: Medical Product Division

6.1.3. **NEC**: National Environment Commission

7. General Principles

7.1. Categorization of medical product waste

7.1.1. **Hazardous waste:** Infectious waste, sharps, pathological waste, hazardous pharmaceutical waste, chemical waste, radioactive waste and genotoxic waste.

7.1.2. **Non-hazardous waste:** Waste free of pathogenic microorganisms or hazardous substances such as non-hazardous pharmaceutical wastes and general waste.

7.2. Roles of MPD, BFDA

7.2.1. Guide the applicants on proper disposal methods and regulatory requirements of medical product wastes**.**

7.2.2. Facilitate the disposal of medical product wastes by identifying the disposal sites

7.2.3. Monitor premises in effective management of medical product wastes.

7.2.4. Continuously evaluate and approve the use of new and environmentally friendly technology for medical product wastes disposal.

7.3. Responsibility of private stakeholders

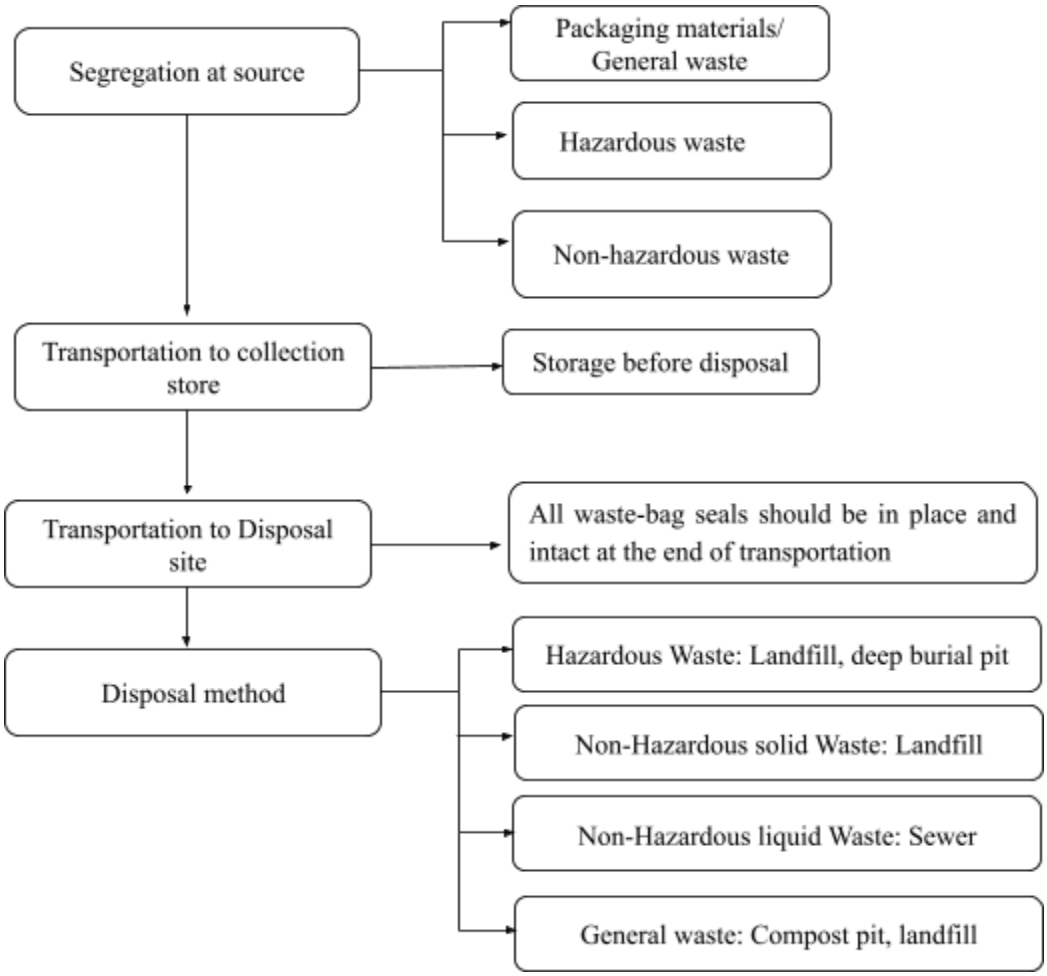
7.3.1. Ensure compliance with the guideline for disposal of medical product waste.

7.3.2. Ensure waste prevention and management of medical product wastes which include segregation, collection, treatment, storage and disposal.

7.3.3. Bear the cost for disposal of medical product wastes.

7.3.4. Maintain records related to generation, collection, storage, treatment, disposal of medical product wastes.

8. Process flow chart



9. Procedure

9.1. Segregation at Source

9.1.1. Packaging materials

9.1.1.1. The secondary packaging should be removed and disposed of as general waste. The contaminated packaging materials with medical products should be treated as Pharmaceutical waste.

9.1.2. Hazardous Waste

9.1.2.1. Segregate the hazardous waste including Pharmaceutical Hazardous waste as per the Annexure I, in leak proof and double layered plastic bags or containers and label as "Hazardous waste" along with name of place where it is produced.

9.1.2.2. Segregate sharps in puncture proof containers/boxes with biohazard symbol labeled as 'SHARPS'

9.1.2.3. Segregate radioactive waste in lead containers with a radioactive symbol labeled as 'BIOHAZARD'

9.1.2.4. If mixing of non-hazardous and hazardous waste occurs, all waste contained together in, should be classified and treated as hazardous waste

9.1.3. Non-Hazardous Waste

9.1.3.1. Pharmaceuticals not listed on the hazardous list should be considered as non- hazardous and should be further segregated into liquid and solid /semi solid dosage forms.

9.1.3.2. The non-hazardous Pharmaceuticals waste should be discarded into the green plastic bags or containers and labeled as "Non-Hazardous Pharmaceuticals waste: Liquid waste OR Non-Hazardous Pharmaceuticals waste: Solid waste" along with the name of place where it is produced.

9.1.4. Biological and vaccines should be treated as infectious waste and disposed accordingly.

9.2. Transportation to Collection Store

9.2.1. The medical product wastes should be stored separately prior to disposal

9.2.2. Genotoxic waste must be stored separately from other medical waste in a secure and designated area and should be under lock and key.

9.2.3. Radioactive wastes should be stored in lead containers. During radioactive decay, it should be labeled with the type of radionuclide, dated and taken back by the concerned dealers.

9.3. Transportation to Disposal Site

9.3.1. All waste-bag seals should be in place and intact at the end of transportation.

9.4. Treatment and Disposal Methods for Hazardous Waste

9.4.1. Hazardous waste must be treated before final disposal

9.4.2. Encapsulation and Landfill

9.4.2.1. This treatment and disposal method is used for chemical, pharmaceutical and genotoxic wastes.

9.4.2.2. If the waste is with their secondary packages, remove materials from their package but not from the primary packaging (strips/blisters/bottles/sachets).

9.4.2.3. Fill a steel/plastic drum up to 75% capacity with hazardous waste

9.4.2.4. Fill the remaining space with the following at approximate ratios by weight:

- Cement 15%
- Lime 15%
- Water 5% or more to obtain required consistency

9.4.2.5. Close the lids of the drum and place the drums at the base of the land fill and cover with soil.

9.4.2.6. Once the wastes are encapsulated, it may be disposed off with the municipal wastes or ordinary landfill.

9.4.3. Incineration and Landfill

9.4.3.1. This treatment and disposal method is used for Hazardous pharmaceutical wastes, including wastes containing more than 1% halogenated compounds.

9.4.3.2. The incinerators should be set according to the environment control strategies of the National Environment Commission (NEC).

9.4.3.3. The incinerators should have the following specifications:

Type:	Rotary kiln incinerators
Chambers:	Two
Minimum Temperature	1100 degree Celsius
Capacity Range	Depending on the waste generated data.

9.4.3.4. Pressurized containers should not be incinerated as it may explode during incineration and cause damage to the equipment.

9.4.3.5. Wastes with high heavy-metal content (e.g. lead, cadmium, mercury), wastes with large amount of reactive chemicals, radiographic waste, plastic wastes containing chlorine (eg. polyvinyl chloride), high mercury or cadmium content waste (eg. broken thermometers, used batteries, lead), sealed ampoules etc., should not be incinerated

9.4.3.6. Hazardous pharmaceutical wastes, including wastes containing more than 1% halogenated compounds, should be incinerated in rotary kiln incinerators with a minimum temperature of 1100 °C.

9.4.3.7. The wastes should be mixed with cardboard, and possibly with other combustible material for incineration.

9.4.3.8. The residues of incineration should be land filled or buried in concrete waste pits.

9.4.4. Disinfection and deep burial pit

9.4.4.1. This treatment and disposal method is used for solid infectious and genotoxic wastes

9.4.4.2. Disinfection should be carried out using following various methods:

9.4.4.2.1. Chemical disinfection using chlorine dioxide, sodium hypochlorite, peracetic acid, ozone, alkaline hydrolysis

9.4.4.2.2. Thermal disinfection at low temperatures (100° to 180°C)

9.4.4.2.3. Disinfection using vapor (autoclave, micro-waves) or hot air (convection, combustion, infrared heat)

9.4.4.2.4. Disinfection at high temperatures (200° to over 1000°C)

9.4.4.2.5. Disinfection by irradiation (UV rays, electron beams)

9.4.4.3. The disinfected wastes are buried on pit with following standard;

9.4.4.3.1. The deep burial pits should be at least 50 meters away from habitation, residential areas and water sources.

9.4.4.3.2. The area should not be prone to flooding or erosion.

9.4.4.3.3. The bottom of the pit should be at least 1.5 meters above ground water level to prevent pollution of groundwater.

9.4.4.3.4. The entire pit should be lined with a 30 cm layer of compacted clay or any other suitable low permeability material.

9.4.4.3.5. The pit should be 2-3m deep and approximately 2x2m wide (larger size for bigger hospitals.

9.4.4.3.6. After every load of wastes, it should be fully covered with soil.

9.4.4.3.7. The top portion of the pit should be slightly elevated and properly sloped to keep surface waters from entering the pit.

9.4.4.3.8. The pit should be covered with a simple, but sturdy removable cover.

9.4.4.3.9. The entire pit area should be properly fenced in order to keep unauthorized personnel or animals from entering into the area.

9.4.4.3.10. Burial must be performed under close and dedicated supervision.

9.4.4.3.11. Once the pit is full, the top opening should be sealed with soil or with cement and the area clearly labeled.

9.4.4.3.12. A new pit must be built before the old one is sealed off

permanently

9.4.5. Autoclaving & shredding and deep burial pit

9.4.5.1. This treatment and disposal method is used for sharps.

9.4.5.2. The needles should be separated from syringe using onsite mechanical needle cutters

9.4.5.3. The needles should be decontaminated and sterilized in an autoclave and the sharps should be buried in sharps pits.

9.4.5.4. The treated plastic parts should be shredded and remelted for recycling.

9.4.6. Decontamination and disposal in sewage

9.4.6.1. This treatment and disposal method is used for liquid infectious waste

9.4.6.2. The liquid infectious waste should be decontaminated with 0.5% bleaching solution in equal proportions (1:1) for 10 minutes

9.4.6.3. The waste should be disposed off in sewage system with plenty of water

9.5. Disposal Methods for Non-Hazardous Waste

9.5.1. Non-Hazardous Solid waste: Landfill

9.5.1.1. Non-hazardous pharmaceutical wastes should be disposed off in a solid landfill, as identified by the local Health Administration Head or Local municipality.

9.5.2. Non-Hazardous Liquid waste: Sewer

9.5.2.1. Non-hazardous pharmaceutical liquid dosage form waste such as large volume parenteral fluids (salts, amino acids, lipids, glucose), vitamins and eye drops (but not antibiotics or cytotoxic drugs can be diluted (dilution factor - water in 1:3 Ratio) and flushed into the sewers in small quantities.

9.5.2.2. Fast flowing water sources should be used to flush the diluted liquid pharmaceutical wastes.

9.5.2.3. Do not discharge even small quantities of pharmaceutical waste into slow-moving or stagnant water bodies.

9.5.2.4. Non hazardous liquid waste other than large volume parenteral fluids (salts, amino acids, lipids, and glucose), vitamins and eye drops should be land filled as it is.

9.6. Disposal method for general waste

9.6.1. The general waste should be segregated into biodegradable and non-biodegradable wastes.

9.6.2. Biodegradable waste should be disposed in compost pit and non-biodegradable waste can be recycled or reused or disposed in landfill

10. Recording and reporting of Medical waste

10.1. Recording and reporting of medical product wastes is important for the future planning on infrastructure, logistics and manpower. It will also serve the purpose of monitoring the compliance to the Medical waste management guideline.

10.2. Waste generated from all units and taken to the storage facility should be individually weighed and reported as per the recording and reporting form

10.3. Weighing of waste

10.3.1. Equipments:

10.3.1.1. Appropriate personal protective equipments

10.3.1.2. Appropriate weighing machine

10.3.2. Methods to weigh waste:

10.3.2.1. The total waste generated from the facility should be weighed at the common storage site and recorded on the register/Form.

10.3.2.2. The wastes should be weighed without opening the plastic bags

10.4. Responsible persons:

10.4.1. The designated personnel for the intended purpose should be responsible for weighing and recording.

10.4.2. The Focal Person for infection control and medical waste management or the competent person should compile the total waste generated and report to the relevant committee or agency.

10.5. Frequency of reporting

10.5.1. Every private stakeholder should submit their annual compliance and monitoring status report to the MPD, BFDA annually.

10.5.2. The annual compliance and monitoring status report should contain the amount of waste generated in that particular year, disposal methods adopted and challenges in implementing the guideline or comments made by the monitoring committee(if any).

11. Reference

11.1. National guideline on Infection control and medical waste management

11.2. Waste Prevention and Management Regulation 2012

11.3. Guideline for Decommissioning and Disposal of Medical Devices, Ethiopian Food and Drug Authority 2022

12. Annexure I: List of Hazardous drugs

i.	**All chemotherapy drugs**
ii.	**Immunosuppressant drugs**
iii.	**Antibiotics**
iv..	**Other category of drug**s: *Epinephrine* *Phentermine* *Physostigmine* *Nitroglycerine* *Warfarin* *Coumarol* *Adrenalin* Disulfiram
v.	**Chemicals:** *Phenol* *Lindane* *Chloral Hydrate* *Chloroform* *Ethyl Ether* *Fluori- methane* *Formaldehyde* *Naphthalene* *Selenium* *Pharmaceuticals containing heavy metals(Barium, mercury, cadmium, Thiomersal)*
Note: This list is not comprehensive; it is subject to revision as and when notified by NEC.	

13. Annexure II: Waste Generation Record sheet

Name of the Premise/source of generation:
Reported by:
Verified by:
Date of reporting:

Sl. No	**Type of Waste (Circle the appropriate category of waste)**	**Hazardous/ Non-Hazardous (Put H for Hazardous, NH for Non- Hazardous)**	**Qty (kg)**
1	General Waste		
2	Infectious waste		
3	Pathological waste		
4	Sharps		
5	Chemical waste		
6	Pharmaceutical waste		

14. Annexure III: Hazardous Waste Tracking Sheet

Reported by (Name & Signature):
Verified by (Name & Signature):
Date of reporting:

Waste consignment no. (Ref no./Dispatch no. from the register)	
Category of Waste:	
Name of health facility/Unit/Pharmacy premises	
Approximate Quantity:	
Date of Dispatch: (Date when the waste is being transported to the disposal waste)	
Signature of the Focal person/in-charge/Competent Person)	
Name and Signature of the person receiving the waste for disposal *(where disposal is done by a different party other than the In-charge/competent Person)*	
Disposal method	

Medical Product Division

Promoting availability of quality, safe and efficacious medicinal products for consumers

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