



**Guideline for Disposal of Pharmaceutical waste (1st
Edition, 2014)**

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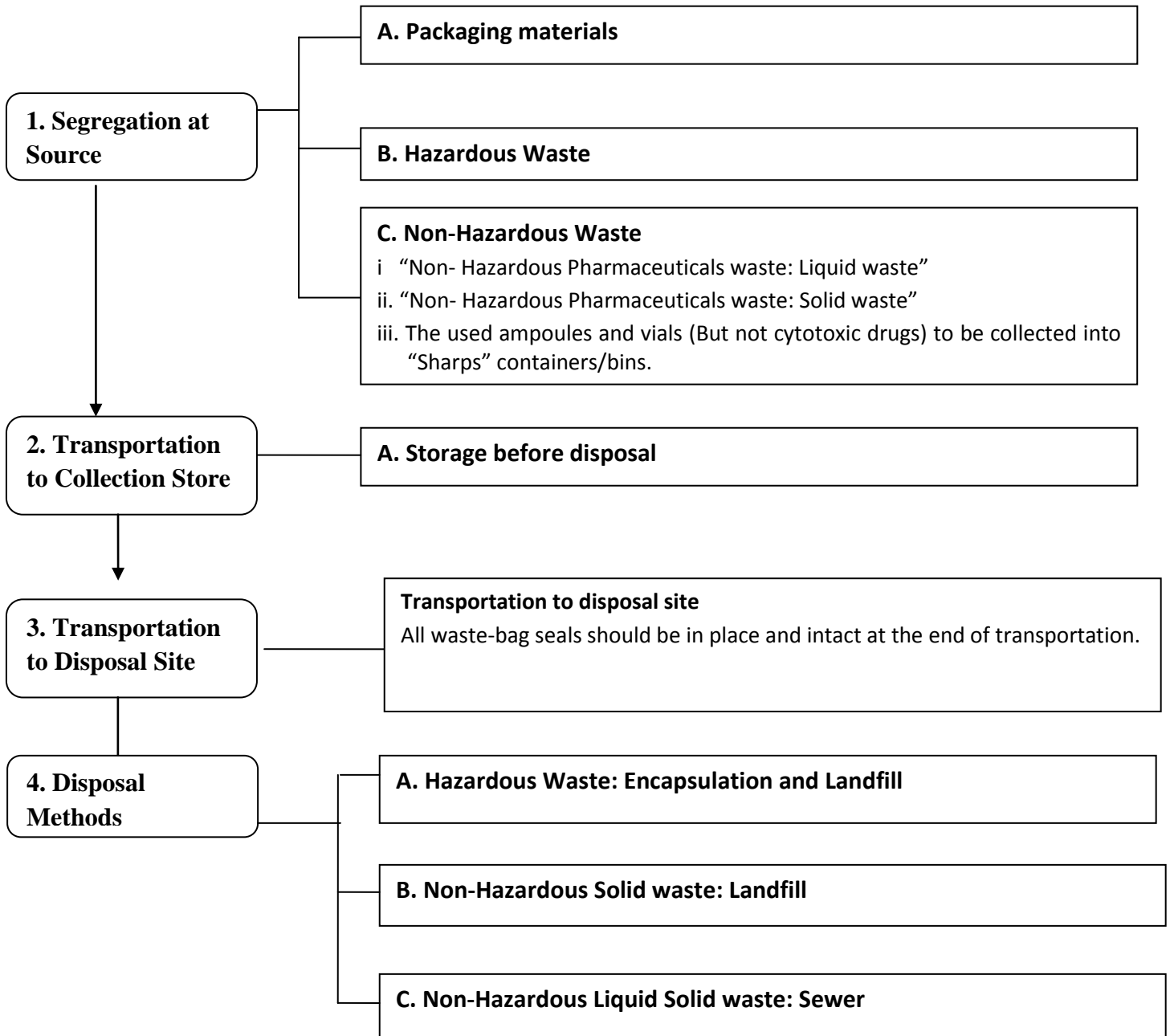
1. Definition

In accordance to the Section 47.5 of Waste Prevention and Management Regulation 2012, Pharmaceutical waste includes medicines, biological products (blood, serum, vaccine) which are expired, incompletely used, damaged, spilled, rejected medicinal products, and recalled medicinal products.

2. Principle and General Requirements

- i. Regardless of the quantity, proper treatment and disposal is necessary owing to wide range of chemicals present which have inherent health risk and environmental hazards.
- ii. Persons handling the hazardous Pharmaceutical waste right from segregation to disposal should be equipped with protective gears such as hand gloves, mask.

3. Process flow chart



4. Procedure

1. Segregation at Source

A. Packaging materials

The secondary packaging should be removed and disposed as general dry waste as per the method under the Medical Waste guideline. The contaminated packaging materials with medicinal products should be treated as Pharmaceutical waste.

B. Hazardous Waste

- i. Segregate the pharmaceuticals waste into Hazardous according to the Hazardous list as per the Table i.(Hazardous List).
- ii. Discard Hazardous waste into the leak –proof (double layered) **purple plastic bags or containers** and labelled as “Hazardous Pharmaceuticals waste” with the name of place where produced (e.g. ward).
- iii. Biological and vaccines should be treated as infectious waste and disposed accordingly.

C. Non-Hazardous Waste

- i. 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.**
- ii. The non-hazardous Pharmaceuticals waste should be discarded into the green plastic bags or containers and labelled as “**Non- Hazardous Pharmaceuticals waste: Liquid waste OR Non- Hazardous Pharmaceuticals waste: Solid waste**” and name of place where produced.
- iii. The used **Ampoules or vials** ampoules which contained Non-hazardous Pharmaceutical wastes should be crushed on a hard, impermeable surface and disposed off as “Sharps”.

2. Transportation to Collection Store

A. Storage before disposal

- i. In the health facilities, pharmaceuticals waste in hospital wards or departments should be returned to the pharmacy store for disposal with a duly filled **waste generation record**
- ii. For the private pharmacies, the pharmaceutical waste should be stored separately prior to disposal.

3. Transportation to Disposal Site

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

4. Disposal Methods

A. Hazardous Waste: Encapsulation and Landfill

i. It should be immobilized or encapsulated prior to disposal into landfill as per the **encapsulation method** below:

- a. If the waste is with their secondary packages, remove materials from their package but not from the primary packaging (strips/blisters/bottles/sachets).
- b. Fill a steel/plastic drum up to 75% capacity with pharmaceutical waste
- c. Fill the remaining space with the following at approximate ratios by weight:
 - Cement 15%
 - Lime 15%
 - Water 5% or more to obtain required consistency
- d. Close the lids of the drum and place the drums at the base of the land fill and cover with soil.
- e. Once the wastes are encapsulated, it may be disposed off with the municipal wastes or ordinary landfill.

ii. Incineration of hazardous pharmaceutical waste is an option.

Incinerators

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

- c. Pressurized containers should not be incinerated as it may explode during incineration and cause damage to the equipment.
- d. Wastes with high heavy-metal content (e.g. lead, cadmium, mercury) should not be incinerated as it will cause emission of toxic metals into the atmosphere.
- e. 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.

- f. The wastes should be mixed with cardboard, and possibly with other combustible material for incineration.
- g. The residues of incineration should be land filled.

B. Non-Hazardous Solid waste: Landfill

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

C. Non-Hazardous Liquid Solid waste: Sewer

- i. 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.
- ii. Fast flowing water sources should be used to flush the diluted liquid pharmaceutical wastes.
- iii. Do not discharge even small quantities of pharmaceutical waste into slow-moving or stagnant water bodies.
- iv. 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.

5. Recording and reporting of Medical waste

Recording and reporting of medical 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.

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

1. Weighing of waste:

i. Equipments:

- Appropriate personnel protective equipments
- Appropriate weighing machine

ii. Methods to weigh waste:

- The total waste generated from the facility should be weighed at the common storage site and recorded on the register/Form.
- The wastes should be weighed without opening the plastic bags

2. Responsible persons

- i. The designated personal for the intended purpose should be responsible for weighing and recording.

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

3. Frequency of reporting

- i. Every Private Pharmaceutical dealers should submit their annual compliance and monitoring status report to the DRA yearly.
- ii. The **annual compliance and monitoring status report** should contain 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).

Table 1: Hazardous Waste List

i.	All chemotherapy drugs
ii.	Immunosuppressant drugs
iii.	Other Category of drugs: <i>Epinephrine</i> <i>Phentermine</i> <i>Physiostigmine</i> <i>Nitroglycerine</i> <i>Warfarin</i> <i>Coumarol</i> Adrenalin Disulfiram
iv.	Chemicals: <i>Phenol</i> <i>Lindane</i> <i>Choral Hydrate</i> <i>Chloroform</i> <i>Ethyl Ether</i> <i>Fluori- methane</i> <i>Formaldehyde</i> <i>Naphthalene</i> <i>Selenium</i> <i>Pharmaceuticals containing heavy metals(Barium, mercury, cadmium, Thiomersal)</i>
Note: This list is not comprehensive; it is subject to revision as and when notified by National Environment Commission.	

Table 3. Waste Generation Record

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)
	<i>a. General Waste</i>		
	<i>b. Infectious Waste</i>		
	<i>c. Pathological Waste</i>		
	<i>d. Sharps</i>		
	<i>e. Chemical waste</i>	<i>List the chemical names:</i> <i>H:</i> <i>NH:</i>	<i>H:</i> <i>NH:</i>
	<i>f. Pharmaceutical waste</i>	<i>List the Pharmaceuticals:</i> <i>H:</i> <i>NH:</i>	

Table 4: 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 (<i>where disposal is done by a different party other than the In-charge/competent Person</i>)	
DISPOSAL METHOD	

References:

1. WHO Guidelines for safe disposal of unwanted Pharmaceuticals in and after emergencies.
2. USA, Hazardous Waste Characterization, Framework for Resource Conservation and Recovery Act.
3. USA, Florida Department of Environment Protection: List of Pharmaceuticals that are potentially hazardous waste when discarded.
4. Vestara, Managing Pharmaceutical Waste; A discussion Guide for Health –System Pharmacists
5. Tanzania Food and Drug Administration
6. Waste Prevention and Management Regulation 2012