

[Organization logo]

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GUIDELINE FOR PHARMACEUTICAL WASTE MANAGEMENT

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Change history

Date	Version	Created by	Description of change
	0.1	14001Academy	Basic document outline

Table of contents

1. PURPOSE, SCOPE AND USERS	3
2. REFERENCE DOCUMENTS	3
3. PHARMACEUTICAL WASTE MANAGEMENT	3
3.1. CLASSIFICATION OF PHARMACEUTICAL WASTE	4
3.2. COLLECTION OF PHARMACEUTICAL WASTE ON PLACE OF GENERATION	4
3.3. MOVEMENT OF WASTE WITHIN HEALTHCARE INSTITUTION	4
3.4. TEMPORARY WAREHOUSING OF HAZARDOUS PHARMACEUTICAL WASTE	5
3.5. MARKING AND LABELING PHARMACEUTICAL WASTE	5
3.6. PHARMACEUTICAL WASTE DEPLOYMENT TO THE AUTHORIZED ORGANIZATION FOR TAKING OVER	5
4. MANAGING RECORDS KEPT ON THE BASIS OF THIS DOCUMENT	5

1. Purpose, scope and users

The purpose of this document is to define the process of managing pharmaceutical waste at the place of its generation, except in households.

This document applies to all activities and processes of [organization name] in which pharmaceutical waste is generated.

Users of this document are all employees of [organization name].

2. Reference documents

- ISO 14001:2015 standard, clause 8.1
- Environmental Manual
- Environmental Policy
- Procedure for Identification and Evaluation of Environmental Aspects
- Procedure for Operational Control of Significant Environmental Aspects
- List of Interested Parties, Legal and Other Requirements

3. Pharmaceutical waste management

Pharmaceutical waste, as a special category of medical waste, is drugs, including primary packaging, as well as all accessories used for application of such products.

Pharmaceutical waste can be:

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Hazardous pharmaceutical waste:

- **Disinfectant drugs waste** that contains heavy metals, as well as drugs which composition can't be defined, which because of their composition require special methods of treatment.

- *[Faint, illegible text]*
- *[Faint, illegible text]*

- **Primary packaging** where medication is packed or where an expired drug was packed.

- *[Faint, illegible text]*

used for preparation and use of such products. Cytotoxic and cytostatic drugs are toxic compounds that have cancerous, mutagenic, and/or teratogenic effect.

- **Waste pressurized bottles** are waste of full or empty bottles which contain inert gasses under pressure with antibiotics, disinfectants, or insecticides, which are applied as aerosols, and which when exposed to high temperatures may explode.

- **Sharp objects** – needles, broken glass, etc.

3.1. Classification of Pharmaceutical waste

[Job title] is responsible for sorting and collection of waste that occurs at the facilities where pharmaceutical waste is generated, by type of waste.

3.2. Collection of Pharmaceutical waste on place of generation

- Medicines with an expired shelf life, which in their original packaging are stored in labeled cardboard boxes separately from other drugs

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- Primary packaging of unusable and/or drugs with expired shelf life are disposed of in red bags

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- The bags may be filled up to ¾ of volume
- The cytotoxic and cytostatic waste is packed in purple bags, up to a maximum ¾ of volume, kept in a leak-proof container

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- Waste bottles under pressure are disposed in purple containers
- Waste bottles under pressure should not be drilled by force and/or deactivated
- Waste bottles under pressure should be kept out of the heat and do not expose them to sunlight

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- Hazardous pharmaceutical waste must not be treated (incineration, etc.) within the institution
- Chemical, pharmaceutical and cytotoxic waste is treated by physico-chemical methods or by incineration in plants that have a permit for hazardous waste treatment

3.3. Movement of waste within healthcare institution

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[organization name]

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All labels on waste package must remain intact.

3.4. Temporary warehousing of hazardous pharmaceutical waste

[job title] ensures that the room for temporary warehousing is:

- Clearly identified
- With enough capacity for reception of waste

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3.5. Marking and labeling pharmaceutical waste

On classified and packed hazardous pharmaceutical waste, [job title] places a label with information on hazardous waste with minimum dimensions of 50 mm x 75 mm, which contains the following:

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- Symbol for labeling of waste;
- Date of waste creation;
- Name and signature of the responsible person who fills in the label

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3.6. Pharmaceutical waste deployment to the authorized organization for taking over

[Job title] is responsible for deployment of hazardous pharmaceutical waste to the organization authorized for taking over and/or waste treatment and thereby creates the necessary documentation.

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4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Deployed Waste Report	PR.08.13	2 years	[office of [job title]]	[job title]

Commented [14A20]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Only [job title] can grant other employees the right to access records.