



# Alternate Method to Evaluate Pharmaceutical Waste for the Lethality Characteristic

Waste/Hazardous Waste #4.45b, June 2005

*This fact sheet is intended to help hospitals identify pharmaceuticals that display the hazardous lethality characteristic.*

## Contents:

What is “pharmaceutical waste”? .....	1
What is the “lethality characteristic”? .....	1
How is the alternate evaluation method different?.....	1
Who may use the alternate method?.....	2
When can the alternate method be used? .....	2
What is the alternate method?.....	2
What about other listings and characteristics? .....	3
Disposing of lethal and non-lethal pharmaceuticals ...	3
Infectious pharmaceutical waste .....	3
More Information .....	3
Definitions .....	4

## What is “Pharmaceutical Waste”?

Pharmaceutical waste includes expired drugs, patients’ personal medications, waste materials containing excess drug (syringes, IV bags, tubing, vials, etc.) and drugs that are intended to be discarded. You must evaluate each of these wastes to determine whether it is hazardous and dispose of it accordingly. This fact sheet offers guidance only on evaluating pharmaceutical waste against the lethality characteristic. You must also determine whether each pharmaceutical waste is hazardous because of being listed on the F, P or U lists of hazardous waste or it displaying a hazardous characteristic other than lethality.

For more information about evaluating pharmaceutical waste, see the Minnesota Pollution Control Agency’s (MPCA) fact sheet #4.45a, *Evaluating Pharmaceutical Wastes* available on the Web at: <http://www.pca.state.mn.us/publications/w-hw4-45a.pdf>

## What is the “Lethality Characteristic”?

“Lethality” is a hazardous waste characteristic specific to Minnesota. A waste is determined to be “lethal” if the median lethal dose of a representative sample of the waste exceeds specified limits. (See Minn. Rules 7045.0131 Subp. 6.)

Using this median lethal dose analysis method, pharmaceutical waste which exceeds the specified limits is

considered lethal. If the generator does not have median lethal dose data for a specified pharmaceutical, that pharmaceutical is *presumed* to be lethal and must be disposed of as a hazardous waste. Because the data needed to determine whether a certain pharmaceutical is lethal is not always readily available, performing a thorough evaluation is often challenging.

For this reason, the Minnesota Hospital Association (MHA) petitioned the MPCA to use an alternate method to determine lethality of a pharmaceutical. The petition was approved by the MPCA Commissioner on February 25, 2005.

## How is the alternate evaluation method different?

The alternate evaluation method assumes a pharmaceutical waste is lethal if it is *contained in* or *described by* any of the following seven risk criteria groups\*:

1. Carcinogen
2. Chemotherapy agent
3. Combination U/P-List drug
4. Controlled Substance
5. Endocrine Disruptor
6. NIOSH Hazardous Drug
7. OSHA Hazardous Drug

If a pharmaceutical waste is not contained in or described by any of the risk criteria groups, generators may assume it is not lethal regardless of its median lethal dose.

\*See “Definitions,” page 4, for full definitions.



### Who may use the alternate method?

The alternate evaluation method is currently available only to the generator hospitals represented by the MHA; it is not now available to other healthcare providers.

Generators eligible to use the alternate evaluation method may still choose to use median lethal dose analysis to determine whether or not pharmaceutical wastes are lethal.

### When can the alternate method be used?

The alternate evaluation method can only be used for waste pharmaceuticals. For all other wastes, use the median lethal dose analysis evaluation method.

When evaluating a pharmaceutical waste:

- First, determine whether it is listed on the F, P or U lists of hazardous wastes.
- If it is not listed, evaluate against the hazardous waste characteristic criteria for: ignitability, oxidizers, corrosivity, reactivity and toxicity. (See Minn. Rules 7045.0131.)

If the waste *is* hazardous for any of these reasons, no further evaluation is necessary. Manage the waste as a hazardous waste.

If the waste pharmaceutical is not hazardous when measured against these criteria, then you, the generator, must determine whether the waste is lethal by using:

- Median lethal dose analysis or
- If yours is a MHA member hospital, the alternate method described in the flowchart.

### What is the alternate method?

The alternate evaluation method for lethality is described in Chart 1. Definitions for the risk criteria groups in Table 1 and additional resources for use with the flowchart are included in the 'Definitions' section following the flowchart.

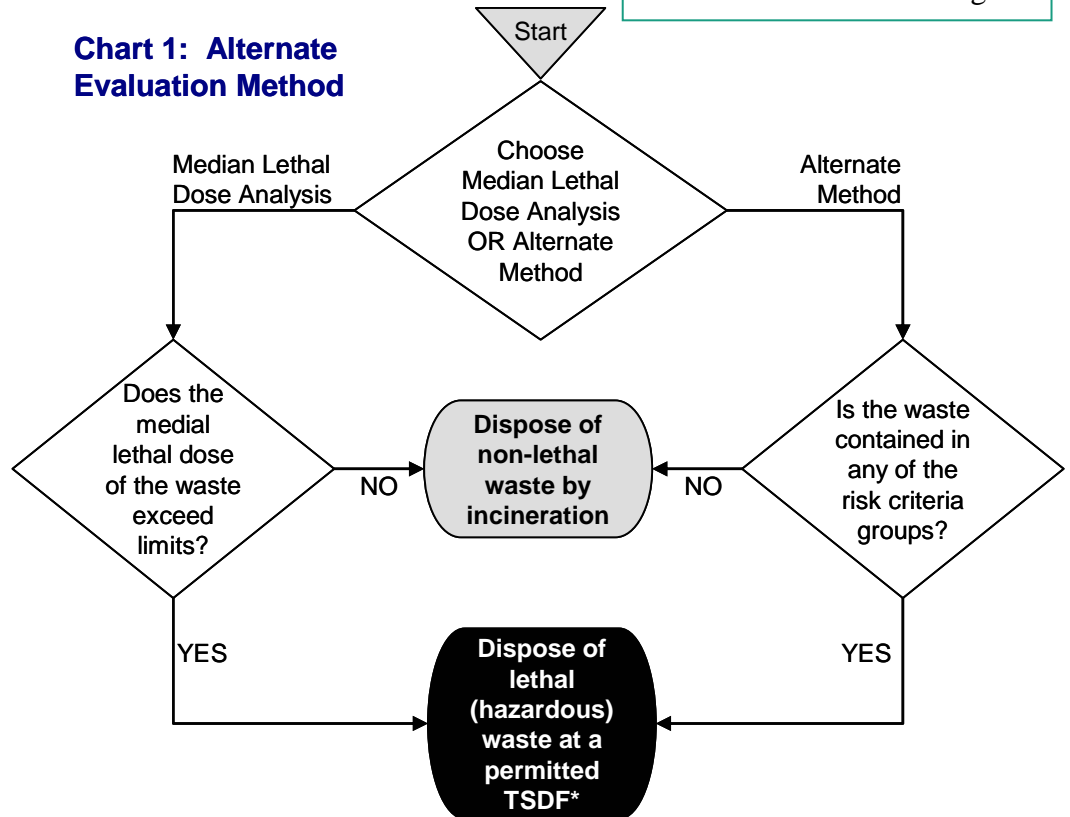
You need only evaluate those pharmaceuticals that are not on the F, P or U lists and do not display a hazardous characteristic other than lethality. Follow the flowchart for each pharmaceutical.

If use of the alternate evaluation method indicates a specific pharmaceutical is lethal, you may still choose to use the median lethal dose analysis method. If the median lethal

**Table 1: 7 Risk Criteria Groups**

1. Carcinogen
2. Chemotherapy agent
3. Combination U/P-List drug
4. Controlled Substance
5. Endocrine Disruptor
6. NIOSH Hazardous Drug
7. OSHA Hazardous Drug

**Chart 1: Alternate Evaluation Method**



\*See 'Definitions,' page 4, for information about disposing of Controlled Substances.



dose analysis method shows a pharmaceutical waste is not lethal, it is considered nonhazardous – no matter what the alternate method indicates.

**What about other listings and characteristics?**

Whether or not the alternate evaluation method to determine lethality is used, a generator must still evaluate the pharmaceutical waste to determine whether it is hazardous because it is listed or displays another hazardous waste characteristic.

**Disposing of Lethal & Non-lethal Waste Pharmaceuticals**

Dispose of lethal pharmaceutical waste at a permitted hazardous waste treatment, storage or disposal facility (TSDF).

For pharmaceuticals determined to be non-lethal, the MPCA and the Metropolitan County Solid Waste Management Coordinating Board (SWMCB) strongly recommend disposal by incineration

**Infectious Pharmaceutical Waste**

Pharmaceutical waste that is infectious or potentially infectious must also be evaluated to determine whether it is hazardous. Dispose of pharmaceutical waste that is classified as infectious, but *not* hazardous, by incineration in a medical waste incinerator. Remember to manage and dispose of hazardous-infectious pharmaceutical waste, (referred to as “dual waste” by the MPCA) in accordance with *all* applicable regulations, not just the hazardous waste regulations.

**More Information**

**Waste Management** - The MPCA and your county have waste management staff available to assist you with your waste management questions. Contact your county or the MPCA office nearest you for help.

For information about and assistance reducing the amount of hazardous waste you generate (which can lower your disposal costs), contact the Minnesota Technical Assistance Program.

**Sewering** - If your facility is in the Twin Cities Metropolitan Area, be sure to get approval from Metropolitan Council Environmental Services Industrial Waste Section before discharging any pharmaceutical waste. If your facility is in Greater Minnesota, contact your local wastewater treatment plant operator or the MPCA office nearest you.

**Fact Sheets** - The MPCA has fact sheets that provide detailed information about hazardous waste requirements. Find them on the MPCA Web page at: <http://www.pca.state.mn.us/waste/pubs/business.html>

**Web Links** - Find Web links and more information for the health care provider on the MPCA web site at: <http://www.pca.state.mn.us/industry/healthcare.html>

**Metro County Hazardous Waste Offices**

- Anoka County ..... 763-422-7093
- Carver County ..... 952-361-1800
- Dakota County..... 952-891-7557
- Hennepin County ..... 612-348-8100
- Ramsey County ..... 651-773-4466
- Scott County ..... 952-496-8475
- Washington County ..... 651-430-6655
- Web Sites: [http://www.co.\[county name\].mn.us](http://www.co.[county name].mn.us)

**Minnesota Pollution Control Agency**

- Toll free (*all locations*) ..... 800-657-3864
- Brainerd..... 218-828-2492
- Detroit Lakes ..... 218-847-1519
- Duluth..... 218-723-4660
- Mankato..... 507-389-5977
- Marshall ..... 507-537-7146
- Rochester ..... 507-285-7343
- St. Paul ..... 651-297-2274
- Willmar ..... 320-214-3786
- Web Site: ..... <http://www.pca.state.mn.us>

**Minnesota Technical Assistance Program**

- Toll free ..... 800-247-0015
- Metro ..... 612-624-1300
- Web Site: ..... <http://www.mntap.umn.edu>

**Metropolitan Council Environmental Services**

- Twin Cities Metropolitan Area..... 651-602-4703
- Web Site: <http://www.metrocouncil.org/environment/>



## Definitions for Terms Used in Alternate Evaluation Method

**Carcinogen** - Drug listed as known to be a human carcinogen in Part A of Section II of the 11th Report on Carcinogens, 2004, published by the U.S. National Toxicology Program (NTP), or as reasonably anticipated to be a human carcinogen in Part B of Section II of the 11th Report. The 11<sup>th</sup> Report is available on the NTP's Web site at:

<http://ntp.niehs.nih.gov/ntp/roc/toc11.html>

**Chemotherapy agent** - Drug approved by the U.S. Food and Drug Administration (FDA) for drug treatment of cancer, or used by the healthcare facility for off-label treatment of cancer, and which acts by causing cell death or by significantly decreasing cell growth or reproduction. A list of drugs approved for treatment of cancer by the FDA is available on the FDA's Web site at: <http://www.fda.gov/cder/cancer/druglistframe.htm>

**Combination U/P-Listed drug** - Drug with more than one active ingredient containing at least one ingredient included on the P-List, defined in Minn. R. 7045.0135, Subp. 4, Item E, or containing at least one ingredient included on the U-List, defined in Minn. R. 7045.0135, Subp. F. Drugs which have been used for their intended purpose are not subject to this definition. Hazardous Waste fact sheets #2.02 and #2.03, containing the P-List and the U-List, respectively, are available on the MPCA's Web site at:

<http://www.pca.state.mn.us/publications/w-hw2-02.pdf> and <http://www.pca.state.mn.us/publications/w-hw2-03.pdf>

**Controlled Substance** - Drug defined as a Schedule I-V Controlled Substance by the U.S. Drug Enforcement Agency (DEA) as defined in 21 CFR 1308, as amended, or by the Minnesota Board of Pharmacy as defined in Minn. R. 6800.4200-4250, as amended.

\*Until alternate disposal is approved by DEA, Controlled Substances may be disposed of by discharging to the sanitary sewer system if allowed by sewer authority. Disposal must be included in hazardous waste generation volume calculations and reported to the MPCA or Metropolitan County. A list of Controlled Substances is available on the DEA's Web site at: [http://www.dea.gov/divisions/office\\_of\\_public\\_affairs/schedules/schedules.htm](http://www.dea.gov/divisions/office_of_public_affairs/schedules/schedules.htm)

**Endocrine Disruptor** - Drug that meets the general description of an endocrine disruptor as contained in Chapter 3, Section II of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) Final Report, 1998, published by the U.S. Environmental Protection Agency (EPA). The general description of an endocrine disruptor is available on the EPA's Web site at: <http://www.epa.gov/scipoly/oscpendo/docs/edstac/chap3v14.pdf>

**Incineration** - Destruction by incineration at a facility (other than a Permitted Hazardous Waste TSDF) that is permitted by the MPCA, the EPA or another delegated state to incinerate municipal solid waste, industrial waste, infectious waste or other non-hazardous special waste. For the purposes of incineration, "non-hazardous pharmaceuticals" does not include unused electrolyte, nutritive or volume-expansion solutions. Disposal of non-hazardous pharmaceuticals via incineration is strongly recommended by the MHA, the MPCA and the SWMCB to prevent potential discharge of pharmaceuticals into surface or underground waters. A list of permitted incineration facilities in Minnesota may be found in MPCA's Cleanup fact sheet #4.03, *Spill Debris Disposal Options*, available on the Web at:

<http://www.pca.state.mn.us/publications/c-er4-03.pdf>

**NIOSH Hazardous Drug** - A drug listed in Appendix A of the NIOSH Alert: *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings*, NIOSH Publication 2004-165, published by the U.S. National Institute for Occupational Safety and Health (NIOSH), or that meets one or more of the hazardous drug criteria contained in Appendix A of the NIOSH Alert. The Alert is available on the NIOSH Web site at:

<http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html>

**OSHA Hazardous Drug** - A drug listed in Appendix VI:2-1 of the OSHA Technical Manual, *OSHA Directive TED 01-00-015*, as amended, published by the U.S. Occupational Safety & Health Administration (OSHA), or that meets one or more of the hazardous drug criteria contained in Section VI, Chapter 2, Section II, of the Manual. The Manual is available on OSHA's Web site at: [http://www.osha.gov/dts/osta/otm/otm\\_vi/otm\\_vi\\_2.html](http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html)