



Minnesota Pollution Control Agency

PROGRAM MANAGEMENT DECISION MEMO

Issue: Facilitating safe and efficient collection and management of waste pharmaceuticals generated from households

Effective Date: September 9, 2010

DECISION

This Program Management Decision (PMD) allows collection and management of household pharmaceutical waste in accordance with Minn. R. 7045.0310 as modified by the terms and conditions set forth below. It also establishes a pilot project that allows the owner or operator of a solid waste management facility managing household pharmaceutical waste in accordance with Minn. R. 7045.0310 to accept household pharmaceutical waste for disposal by permitted municipal solid waste or medical waste incineration until necessary changes can be made to the Minnesota Rules.

Each household pharmaceutical collector shall report to the Minnesota Pollution Control Agency (MPCA), by February 1, for the preceding calendar year:

- a. the total number of participants in the program,
- b. the total amount of pharmaceuticals collected,
- c. the total amount of controlled substances collected, and
- d. the management/disposal method for pharmaceuticals collected.

In the 80 non-metropolitan counties, a household pharmaceutical collector that does not generate hazardous waste from its own business operations shall comply with the hazardous waste accumulation requirements for Very Small Quantity Generators (VSQG) found in Minn. R. Ch. 7045.0292, subp. 6, regardless of the amount of household pharmaceuticals collected. A household pharmaceutical collector that is a generator of hazardous waste pharmaceuticals from its own business operations shall comply with the applicable hazardous waste accumulation requirements of Minn. R. 7045.0292 consistent with its existing generator size, excluding collected household pharmaceuticals. Collected household pharmaceuticals shall not count toward determining generator size. A household pharmaceutical collector shall not be charged an annual hazardous waste license fee for collected household pharmaceuticals.

In the seven-county metropolitan area (Anoka, Carver, Dakota, Hennepin, Ramsey, Scott and Washington), a household pharmaceutical collector shall comply with all license, fee, and accumulation requirements imposed by the county in which the collection occurs.

The terms and conditions of this PMD apply only to pharmaceutical waste generated by households. No business-generated pharmaceuticals or non-pharmaceutical household hazardous waste shall be managed by collectors under the terms of this PMD. A household pharmaceutical collector must comply with all Drug Enforcement Administration (DEA) and Minnesota Board of Pharmacy regulations.

This PMD replaces the June 26, 2009 PMD addressing household pharmaceutical waste collection and management. Compliance assistance fact sheets and guidance documents will be developed for use by household pharmaceutical collectors, as well as municipal solid waste and medical waste incinerators.

The MPCA will review the effectiveness of this pilot project within two years after the effective date of the PMD to consider whether the terms shall be adopted into State Rule. The MPCA reserves the right to modify or revise the pilot project and or the PMD without notice, if necessary in order to protect human health or the environment.

BACKGROUND

The MPCA estimates that between 5-20% of collected household pharmaceuticals are hazardous wastes due to being listed or possessing hazardous characteristics. Minn. R. 7045.0310 establishes requirements for household hazardous waste collection programs. Minn. R. 7035.2535 prohibits the owner or operator of a solid waste management facility, including municipal solid waste or medical waste incinerators, from accepting hazardous waste.

Household pharmaceutical waste includes all expired, unwanted or unusable prescriptions or over-the-counter medications generated by households. Presently, concerns with disposal of household pharmaceutical waste focus on water quality impacts. The MPCA seeks to encourage collection and controlled incineration of household pharmaceuticals in order to minimize disposal of household pharmaceutical waste by direct discharge to the sewer or placement in a landfill whose leachate may be discharged to the sanitary sewer or land-applied.

The MPCA recognizes the increased interest in collection of household pharmaceuticals and the resulting environmental and human health benefits gained by establishing standards that allow:

- a. entities other than household hazardous waste collection programs to collect this waste stream and
- b. entities other than permitted hazardous waste incinerators to treat this waste stream.

RATIONALE

The accumulation and disposal standards established in Minn. R. 7045.0310 are designed for acceptance of high volumes of numerous waste streams with significant potential for spills, chemical reactions, or adverse impacts to human health and the environment. The rigorous standards of environmental compliance for accumulation and disposal present a significant barrier to targeted collection of household pharmaceuticals.

Minn. R. 7035.2535 was intended to prevent solid waste management facilities from accepting wastes they were not designed or operated to manage. However, the rule does not make allowances for emerging waste streams like household pharmaceutical waste - for which municipal solid waste or medical waste incineration may be the best available disposal method.

Content of collected pharmaceutical waste

In July 2010, the MPCA analyzed the waste collected over the course of three months by the Chisago County Sheriff's Department through a continuous household pharmaceutical collection located in Center City. Table 1 lists the different types of waste collected, the weight of each waste type, and the percentage of the total weight each waste type represented.

Table 1. Waste composition data from Chisago County Sheriff's Department household pharmaceutical collection.

Waste Type	Weight (units in pounds unless otherwise indicated)	Percent of total (by weight)
Total weight	292	100%
Total volume	~255 gallons	NA
Hazardous waste pharmaceuticals	17*	5.8%
Hazardous waste aerosols	4*	1.4%
Nonhazardous controlled substance pharmaceuticals	11*	3.8%
Nonhazardous non-controlled substance pharmaceuticals	158	54.1%
Unused sharps	8*	2.7%
Glass	2	0.7%
Cardboard/Paper	10.5	3.6%
Metal caps	0.2	0.1%
Unit dose packaging (foil/paper/plastic)	9.8	3.3%
Plastic bags	3	1.0%
Plastic caps	12.5	4.3%
Plastic bottles (#1)	8.5	2.9%
Plastic bottles (#2)	14	4.8%
Plastic bottles (#4)	0.1	0.1%
Plastic bottles (#5)	15	5.1%
Plastic bottles (#6)	0.1	0.1%
Plastic bottles (other)	18.4	6.3%

* The weights for these waste types include packaging/containers.

Hazardous waste pharmaceuticals accounted for just 5.8% of the total weight of collected waste. That figure is inflated to some extent because it includes packaging weight. Hazardous waste pharmaceuticals were among the waste types not removed from their packaging for safety reasons. The ratio of pharmaceutical weight to packaging weight for the nonhazardous non-controlled substance pharmaceuticals was approximately 1.7:1 (158 pounds to 94 pounds). Hazardous waste pharmaceuticals would likely demonstrate a similar pharmaceutical weight to packaging weight ratio. Pharmaceutical waste that was evaluated and found to be hazardous waste was hazardous due to P-Listing, the ignitability characteristic, the toxicity characteristic, or the lethality characteristic. Waste aerosols, which accounted for 1.2% of the total weight of collected waste, were hazardous waste due to the ignitability characteristic. This figure is substantially inflated because, like the figure for hazardous waste pharmaceuticals, it includes packaging weight.

A study conducted in Florida indicated that about half of unused medications of all types (over the counter and prescription) are disposed of in the solid waste system¹. A follow-up study estimated that the U.S. municipal solid waste contains between 1259 and 7555 tons of active pharmaceutical ingredient (API), the range due to the assumption of how much of each original medication goes unused (10% to 60%). If it is assumed that 30% of each medication goes unused, the amount of API in the U.S. municipal solid waste is 3778 tons. The calculations account for the active ingredients of the medications and do not account for the salts and other materials in the formulations².

Minnesota disposed of 3.6 million tons of municipal solid waste in 2007, about 1.2 million tons being incinerated in municipal solid waste incinerators. Assuming the API content of Minnesota's waste stream is equal to the U.S. rate, Minnesota is currently incinerating about 63 tons per year of API. If all of Minnesota's unused household pharmaceuticals were disposed of via the solid waste system, about 126 tons per year of API would be incinerated. The increase of 63 tons represents about 0.005% of Minnesota's currently incinerated municipal solid waste.

The packaging of the pharmaceuticals would provide additional fuel value due to the plastic containers. If the characteristics of this waste stream is presumed to have the same characteristics as the waste stream at the Mayo medical waste incinerator (26% paper, 36% plastics, the remainder organics), the fuel value would be about 9,630 Btu/lb³. This fuel value level would provide sufficient fuel to allow for incineration.

Environmental impacts of the destruction of pharmaceuticals in waste to energy facilities

In Minnesota, because the final ash product from municipal solid waste and medical waste incinerators is already disposed in landfills constructed equivalent to federal hazardous waste landfills (subtitle D), this assessment focuses on potential impacts to air emissions.

¹ S.E. Musson, T.G. Townsend, Seabury, K. Mousa, J. A Continuous Collection System for Household Pharmaceutical Wastes: A Pilot Project. J. Air and Waste Manage. Assoc. 57(2007) 828-835.

² S.E. Musson, T.G. Townsend. Pharmaceutical compound content of Municipal Solid Waste. Journal of Hazardous materials. 162 (2009) 730-735.

³ Pinnacle Engineering, Inc. Waste Composition Study, Mayo Clinic Rochester, Minnesota, January 29, 2010.

The incineration process

Incineration facilities destroy waste through thermal decomposition, meaning that the components of waste, including pharmaceuticals, decompose in the presence of high temperatures and oxygen. Depending on the design of the municipal solid waste or medical waste incineration unit, combustion chamber temperatures will range from 1400°F in modular units to 2000°F in waterwall massburn units. Operating temperatures of the combustion system ensure the application of “good combustion controls”, that is, the control of the combustion process to maximize the consumption of the fuel (waste) and the destruction of pollutants that might be formed in the combustion process.

Air pollution controls and air emissions

Federal and state regulations limit the amount or concentrations of pollutants in stack gases released from incinerators. Standards of performance are set to control classes of air pollutants: hydrogen chloride standards are in place to control acid gases; dioxin and mercury limits address emissions of volatile metals and semi-volatile organics, particulate matter standards limit emissions of condensable pollutants including non-volatile metals. The Clean Air Act directs EPA to establish emission limits specifically for dioxins, lead, mercury and cadmium.

In Minnesota, municipal waste combustors must meet both federal and state air emission limits. The MPCA reviewed the air emission tests of several of Minnesota’s municipal solid waste and medical incinerators, and compared the results to federal standards for hazardous waste combustors. The review shows that some Minnesota municipal solid waste incinerators measured air emissions that meet the air emission limits applicable to a hazardous waste combustor. In addition, during the permitting process for the recent expansion of the Olmsted County municipal solid waste incinerator, permitted emission limits were used to conduct a multi-pathway risk assessment. The emission limits resulted in the facility meeting all risk thresholds.

Municipal solid waste incinerators are designed, operated, and monitored with the expectation that some household hazardous waste is already present in the fuel feed stream. Municipal solid waste incinerators in Minnesota are capable of meeting hazardous waste incinerator emission limits on a routine basis. Based on the expected quantities and characteristics of the household pharmaceutical waste stream, the MPCA believes that there is no evidence to suggest that directing the collected household pharmaceutical waste would measurably change current environmental performance of existing municipal solid waste or medical waste incinerators.

Selection of municipal solid waste and medical waste incineration facilities

The discussion above demonstrates that municipal solid waste and medical waste incinerators in Minnesota possess robust combustion and air pollution controls that appear to minimize environmental impacts. In order to participate in this pilot project, a municipal solid waste or medical waste incinerator must demonstrate substantial compliance with environmental regulatory requirements and carefully follow applicable operating practices.

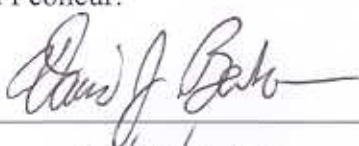
Summary


The MPCA is acting on its authority to allow management of this household waste stream at a level of regulation appropriate to its relative hazard potential. The MPCA intends to incorporate the decision in this PMD that includes reduced accumulation and management requirements for collected household waste into Minnesota Rules at a future date. This PMD for collected household pharmaceuticals allows disposal in a fair and reasonable manner until changes can be made to the Minnesota Rules.

APPROVAL

I have reviewed this program management decision and I concur:

Signed: 
Date: 9/10/10
Jeff J. Smith, Director
Industrial Division

Signed: 
Date: 9/9/2010
David J. Benke, Director
Prevention and Assistance Division

Signed: 
Date: 9/9/10
Steve Giddings, Manager
Prevention and Assistance Section