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June 27, 2016

Via Electronic and First Class Mail

Michael E. Scott
NCDEQ, Director of Division of Waste Management
1601 Mail Service Center
Raleigh, NC 27699-1601

**Re: Stericycle, Inc. –Information Related to Proposed Petition
for Rulemaking**

Dear Michael:

Thank you for meeting with me on March 7, 2016 regarding Stericycle, Inc.'s ("Stericycle") interest in amending certain elements of the North Carolina transport and storage requirements for medical waste. As you are aware, Stericycle operates regulated medical waste treatment and transfer facilities in Haw River and Concord, North Carolina pursuant to Solid Waste Permit No. 01-02-I and Solid Waste Permit No. 1305TP-TP, respectively. As we discussed on March 7, the purpose of this letter to provide you with additional information regarding Stericycle's proposed rule changes. To support these proposed changes, I have provided below: (i) the proposed amendments; (ii) information supporting the proposed amendments; and (iii) a description of the potential effects of the proposed amendments.

Proposed Amendments

Pursuant to N.C. Gen. Stat. § 130A-309.26, the Environmental Management Commission has the authority to promulgate the proposed revised rules.

The proposed amendments to 15A NCAC 13B §§ .1205(7), (8) are as follow:

**CHAPTER 13. SOLID WASTE MANAGEMENT
SUBCHAPTER 13B. SOLID WASTE MANAGEMENT
SECTION .1200. MEDICAL WASTE MANAGEMENT**

.1205 REQUIREMENTS FOR TRANSPORTERS OF REGULATED MEDICAL WASTE

...

A person who transports Regulated medical waste that has not been treated as the generating facility shall meet the following requirements:

...

(7) Except as allowed by subsection (8) of this rule, Regulated medical waste shall be delivered in a non-putrescent state to a permitted storage or treatment facility within seven fourteen calendar days of the date of shipment from the generator.

(8) Refrigeration at an ambient temperature between 35 and 45 degrees Fahrenheit shall be maintained for Regulated medical waste that will not be delivered for treatment within ~~seven~~ fourteen calendar days.

...

The proposed amendment to 15A NCAC 13B § .1206(4) is as follows:

**CHAPTER 13. SOLID WASTE MANAGEMENT
SUBCHAPTER 13B. SOLID WASTE MANAGEMENT
SECTION .1200. MEDICAL WASTE MANAGEMENT**

.1206 REQUIREMENTS FOR STORAGE OF REGULATED MEDICAL WASTE

...

A person who stores Regulated medical waste that has not been treated at the generating facility shall meet the following requirements:

...

(4) Regulated medical waste shall be stored in a non-putrescent state ~~not be stored and no longer than seven-fourteen~~ calendar days from the date of shipment from the generator unless the Regulated ~~M~~medical ~~W~~waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit. Provided that Regulated medical waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit in a non-putrescent state, such waste shall be stored no longer than sixty calendar days from the date of shipment from the generator.

...

The proposed amendment to 15A NCAC 13B § .1207(1) is as follows:

**CHAPTER 13. SOLID WASTE MANAGEMENT
SUBCHAPTER 13B. SOLID WASTE MANAGEMENT
SECTION .1200. MEDICAL WASTE MANAGEMENT**

.1207 OPERATIONAL REQ/REGULATED MEDICAL WASTE TREATMENT FACILITIES

...

A person who treats Regulated medical waste shall meet the following requirements for each type of treatment in addition to the requirements in Rule .1203 of this Section.

...

(1) General requirements:

~~(a) Refrigeration at an ambient temperature between 35 and 45 degrees Fahrenheit shall be maintained for Regulated medical waste not treated within seven calendar days after shipment.~~

(a) (b) Regulated medical waste shall be stored prior to treatment for treated or placed into refrigerated storage consistent with 15A NCAC § 13B .1206(4) no more than seven calendar days after receipt.

...

Basis for Proposed Amendments

Currently, the North Carolina regulations addressing the storage of Regulated medical waste provide that such waste: (i) shall be delivered to a permitted storage or treatment facility

within seven calendar days of the date of shipment from the generator unless the Regulated medical waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit; (ii) shall not be stored longer than seven calendar days from the date of shipment from the generator unless the Regulated medical waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit; and (iii) shall be stored prior to treatment for no more than seven calendar days after receipt unless the Regulated medical waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit.

Limiting storage of Regulated medical waste to seven days without refrigeration provides no health or environmental benefit and extending the storage time from seven to fourteen days will not harm public health or the environment. In our meeting on March 7, the Division of Waste Management specifically asked what happens to unrefrigerated Regulated medical waste between seven and fourteen days. Based on Stericycle's experience in other states, the most correct answer is "nothing." In almost every case, there is no difference in the characteristics of Regulated medical waste that is not refrigerated during the period of seven to fourteen days when compared to refrigerated. Importantly, unlike in other states, the North Carolina regulations prohibit the transport or storage of Regulated medical waste in a putrescent state. These protections ensure that Stericycle does not at any time transport or store Regulated medical waste that is in a putrescent state.

Stericycle or its competitors operate regulated medical waste incinerators in the following states: North Carolina, Florida, Maryland, Ohio, Illinois, Minnesota, Kansas, and Utah. The storage requirements for each of these states and South Carolina are summarized below.

State	Storage Requirements	Cite
Florida	30-day limit for storage of biomedical waste at the generating facility and in a place other than the generating facility.	FLA. ADMIN. CODE § 64E-16.004(a)
Maryland	Except under the supervision of the Department during an emergency, a special medical waste hauler may not store special medical waste except in an approved facility. Storage in a special medical waste vehicle does not include periods of stoppage. Stoppage is a period of time not to exceed 72 hours during which a special medical waste vehicle is at rest. The cumulative period of stoppage may not exceed 5 days for a particular shipment of special medical waste within the State. Any stoppage in excess of 12 hours shall be at an authorized facility or other suitable site. Pursuant to a permit condition, there is a 10-day	CODE OF MD. REGS. § 26.13.13.01(E); Permit conditions

	storage limit for non-refrigerated special medical waste from the date of receipt at the treatment facility.	
South Carolina	Infectious waste must be maintained in a non-putrescent state, and storage of infectious waste shall not exceed twenty-eight (28) days without refrigeration or sixty (60) days if maintained at or below 42 degrees Fahrenheit.	S.C. Code Ann. § 61-105(K)(5)
Ohio	14-day time limit to process regulated medical waste as long as it is not putrescent. If waste becomes putrescent, then the waste must be immediately refrigerated or frozen and shall be treated and disposed of as soon as possible regardless of any storage time frame.	OHIO ADMIN. CODE § 3745-27-35
Illinois	Unless otherwise permitted, 3-day time limit for storage at storage or transfer operation with no refrigeration. 30-day time limit regardless of temperature.	35 IL. ADMIN. CODE § 1422.111
Minnesota	No time restrictions. Infectious waste must not be allowed to become putrescent during transportation. A person who stores, incinerates, or decontaminates infectious or pathological waste, other than at the facility where the waste was generated, or a person who incinerates infectious or pathological waste on site, must submit a copy of a management plan to the commissioner of the Pollution Control Agency.	MINN. ADMIN. CODE §§ 7035.9120.2, 7035.9120.4 MINN. GEN. STAT. § 116.79(4)
Kansas	No time restrictions. All medical services waste shall be stored in a manner and in a container that will prevent the transmission of disease or the causing of injury. Medical services wastes shall be collected at least daily from the point of origin for transport to a storage or disposal area or a processing facility. All medical services wastes transported off-site shall be transported in a manner that will prevent the spread of disease or the causing of injury to persons.	KAN. ADMIN. CODE 28-29-27
Utah	7-day time limit without refrigeration and no longer than 60 days.	UTAH ADMIN. CODE § 315-316-3(9), (10)

Other states in the Southeast generally provide for periods longer than seven (7) days for storage of Regulated medical waste. *See, e.g.*, Fla. Admin. Code § 64E-16.004(a) (providing 30-day limit for storage of biomedical waste at the generating facility and in a place other than the generating facility); Ga. Comp. R. & Regs. § 391-3-4-.15(4) (containment of biomedical waste shall be in manner that minimizes exposure to the public); *but see* 9 Va.

Admin. Code §§ 10-120-360, 20-120-430 (providing that Regulated medical waste stored for more than seven days must be refrigerated, and no Regulated medical waste shall be stored for more than fifteen days at the site of generation). Thus, other states in which medical waste incinerators are located generally provide for periods longer than seven days for storage of regulated medical waste.

With respect to the transporter requirements set forth in 15A NCAC § 13B .1205, transporters often use consolidation facilities. However, the current regulation requires shipment or refrigeration within seven days of shipment from the generator and does not provide for additional time if consolidation facilities are used. Delivery or refrigeration of Regulated medical waste within seven days of shipment from the generator without consolidation is impracticable and unworkable. For example, Stericycle has determined that in a typical year this requires an additional sixty-nine (69) refrigerated trailers resulting in significant, unnecessary costs to Stericycle.

Limiting storage of Regulated medical waste to seven days without refrigeration has significant economic impacts on the regulated community with no corresponding benefits to public health or the environment. Stericycle estimates that such a restriction results in economic losses of at least \$675,000 per year to Stericycle. This amount is based upon the costs associated with leasing additional refrigerated trailers and/or diverting waste to other facilities to avoid the burdensome restrictions in North Carolina. Further, limiting the use of diesel engines to provide power to refrigerated trailers will result in a decrease in criteria pollutant emissions and benefit public health and the environment.

There have been no spills of regulated medical waste at Stericycle's Haw River facility in the last five years. In addition, Stericycle has received no odor complaints related to the Haw River facility in the last five years.

Effect of the Proposed Rule

The effect of these proposed amendments on existing rules would be to extend the time for delivery of unrefrigerated Regulated medical waste by transporters to a permitted storage or treatment facility from seven to fourteen calendar days provided that such waste is in a non-putrescent state. The proposed amendments would allow Regulated medical waste to remain unrefrigerated in a non-putrescent state for a maximum of 21 days after shipment from the generator (14 days during shipment plus 7 days after receipt at the treatment facility). In addition, the proposed amendments clarify that there is a 60-day time limit on the refrigerated storage of Regulated medical waste at an ambient temperature between 35 and 45 degrees Fahrenheit provided that it remains in a non-putrescent state.

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Effect of the Proposed Rule on Existing Practices

The proposed rule changes would have a significant beneficial effect on Regulated medical waste transporters, storage facilities, and treatment facilities. First, the proposed rule changes would allow Regulated medical waste transporters to continue the practice of using consolidation facilities without incurring substantial and unnecessary costs of purchasing additional refrigerated trailers. Second, the proposed rule changes would allow Regulated medical waste transporters, storage facilities, and treatment facilities operational flexibility to store such waste for an additional seven days without refrigeration. The proposed rule changes would also harmonize North Carolina regulations with the majority of Southeastern states. These proposed rule changes would provide operational flexibility while at the same time protecting the public health and environment.

We look forward to hearing back from you regarding Stericycle's proposed petition for rulemaking, and thank you for your assistance with this matter. If you need additional information or would like to discuss, please do not hesitate to contact me.

Sincerely,



Alan H. McConnell
Counsel for Stericycle, Inc.

cc: Don Nuss
Ellen Lorscheider