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September 23, 2013

Submitted Via Email

Environmental Quality Board
P.O. Box 8477
Harrisburg, PA 17105
Submitted electronically: Regcomments@pa.gov

Re: Stericycle, Inc. comments on Proposed Rulemaking, Environmental Quality Board on Regulated Medical and Chemotherapeutic Waste

Thank you for the opportunity to comment on the proposed regulations on the Proposed Rule Making for Regulated Medical and Chemotherapeutic Waste. Stericycle, Inc. takes matters regarding the safe and proper management of medical and chemotherapy wastes very seriously and appreciated the opportunity to work with the Pennsylvania Department of Environmental Protection (PADEP) through this process. Attached you will find our comments to the proposed regulations.

Overall Stericycle is in support of the need for the changes in these regulations and clear direction to healthcare and healthcare waste providers on the proper management of medical and chemotherapy wastes. Attached please find our comments and requests for clarification to the new regulations they will be broken down by section per the proposed rule. Our comments are for your consideration as we have worked with other states such as New Jersey, New York, Florida, Texas, Colorado, California, Washington, as well as the federal level on this very important matter and are confident that these comments will help to further improve these new proposed provisions. We would also be willing to meet with the PADEP to help clarify or explain any comments provided in the attached.

Should you have any further questions or comments please feel free to contact me at 847-943-6685 or via email at shboy@stericycle.com.

Respectfully submitted,

Selin Hoboy
VP Legislative and Regulatory Affairs
Stericycle, Inc.

Enclosures

CC: Phil Hagen, Healthcare Waste Institute, Inc.
Tim Barrett, Onsite Sterilization, LLC
George Weishoff, Med-Flex, Inc.

COMMENTS TO PADEP PROPOSED RULEMAKING ON
REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE
GENERAL COMMENTS AND SECTION BY SECTION REVIEW

**GENERAL COMMENTS:**

- Manifest – The PADEP has done a great job in changing the manifesting requirements. This provides added flexibility and compliance with federal regulations for the shippers (generators), the haulers and processing facilities. There are some sections that still refer to "manifest" or requirements for "properly completed manifest". We would recommend to be consistent that these documents continue to be referred to a "log or shipping document".

**§ 271.1. Definitions.**

*Infectious Waste -*
(i)(B) *Pathological wastes.* Human pathological wastes, including tissues, organs and body parts and body fluids that are removed during surgery, autopsy, other medical procedures or laboratory procedures. The term does not include hair, nails or extracted teeth **or tissues that have been preserved with formaldehyde or other approved preserving agents.**

- Clarification Requested: If these materials are no longer considered pathological waste are they still considered regulated medical waste? Would they be permitted to be placed in autoclaves or in the solid waste? Concern has been raised that while some pathological waste (e.g. prepared slide specimens) may not be of concern, other materials such as full body parts (e.g. legs, arms, etc.) will be more recognizable creating issues at landfills and formalin/formaldehyde preservatives may volatilize during autoclaving which could be harmful to healthcare waste workers. Perhaps there may be a way to better define what types of tissues would be acceptable.

**§ 284.220. Operating requirements**

- Clarification requested: Other sections of the regulations refer to now a consistent 72 hours for holding time of waste. Would transfer stations be permitted to hold waste for 72 hours as well or would there be different requirements as under Chapter 279, Subchapters A and C
- Recommendation: Add **§ 284.230 – Storage time requirements.** This section can specify the 72 hour requirement to be consistent with **§ 284.512. (g) – ". . . Regulated medical waste may be kept in an unrefrigerated transport vehicle for up to 72 hours provided the waste is not putrescent."**

**§ 284.321. (m) An autoclave facility shall comply with all applicable requirements and is prohibited from processing pathological waste or chemotherapeutic waste.**

- Under the definition of pathological waste, those materials which have been in preservatives are no longer considered pathological waste. Does the department intend then that those materials may be autoclaved or would they not be required to be treated at all (see definition Pathological Waste clarification request above)?

**§ 284.321(n)(3) To validate existing systems by _____, (Editor's Note: the plank refers to 6 months after the effective date of adoption of this proposed rulemaking) and at a frequency specified by the manufacturer, but no less than 1 year.**

- It is not typical that autoclave processes are "validated" regularly. They are typically validated at the start up or during process change (such as the desire to increase the weight processed, change in equipment etc.). Is there a specific reference to the need for annual validations of equipment?

**§ 284.412. (a)(4) Maintains the waste in a non-putrescent state, using refrigeration (<=°C or <=45°F) or freezing (<=—18°C or <=0°F) when necessary.**

- The temperature for C needs to be included <=7C.

**§ 284.412.**
**(b) Enclosures at a waste generating or processing facility that are used for the storage of regulated medical or chemotherapeutic waste must be constructed of finish materials that are impermeable and capable of being readily maintained in a sanitary condition. Exhaust air from storage areas must be ventilated to minimize human exposure.**

- Ventilation requirements are too generic or broad. Would recommend that the department consider deleting last sentence and replacing it with the requirement that containers should be maintained closed when not in use in the storage areas to minimize exposure and vectors.
- ".. . Containers in enclosures must be maintained in a closed upright position when not in use in the storage areas to minimize exposure and vectors."

**(c) Regulated medical and chemotherapeutic waste may not be commingled with other waste.**

- Confusing. Recommend "Regulated medical and chemotherapeutic waste may not be commingled with other waste in the same container". This would clarify what we understand may be the intention of the department based on the Summary of Regulatory Requirements. The distinction is that other wastes may be stored together or near each other so long as they are not comingled In the same container. Is this correct?

**(d) The generator may store regulated medical and municipal waste that has been sorted and separately containerized on the same cart for movement to an onsite processing or disposal facility. Chemotherapeutic waste may also be stored on the cart with municipal and regulated medical waste if it is sorted and separately containerized and if it is moved to an onsite incinerator.**

- There are several on site treatment facilities in the state but there are not many on site incinerators. It may be better stated for the generators if they are intending to treat on site or are bringing waste to a centralized storage area to prepare waste for segregation and proper packaging for off site treatment.

**§ 284.413 Storage Containers (a)(1) Leakproof.**

- Federal DOT requires that the final container for shipping be leakproof, however a new regulation passed in 2012 and implemented spring of 2013 allows for the transport of sharps containers which are not themselves leakproof to be transported in racks which maintain them upright for transport.
- Most sharps containers are not leakproof, however are closed and overpacked prior to transport.
- The language in the OSHA Bloodborne Pathogens 1910.1030(d)(4(iii)(A)(1)(ill) regulations states that containers must be leakproof on sides and bottom.
- We would recommend that the section be modified to read "Leakproof on sides and bottom and maintained upright."

**§ 284.414 Marking of Containers (a) (2) and (3) relating to change from "infectious waste" to "regulated medical waste".**

- Will it be a violation if both regulated medical waste and infectious waste are noted on the container – meaning wording would be added to reusable or single use containers in order to ensure compliance?
- Would the department be willing to extend the time frame for coming into compliance with rule to 2 years? This would ensure all inventory of single use containers (cardboard boxes) are completed and that all reusable containers which are rotating through the inventory of generators. Based on the fact that generators will be able to hold waste on site longer (30 days after the container is full

or closed to be shipped versus 30 days after the first time waste was put into the container) we want to make sure that the containers are fully rotated through the operating facilities to change appropriate markings.

**§ 284.414 (a)(5) Marking of Containers – Date**

- This is difficult to control for transporters or processing facilities which take waste from generators. We would like to request that it be clear that this is a generator responsibility. Under 284.724(a)(2) specifies that transporters may not accept or transport regulated medical waste if the waste is not properly labeled per this section. If there are customer loaded trailers this may make it impossible for transporters to know that all containers have the date.
- Would recommend that either this section make it clear this is a generator requirement or that the requirement for the transporter or facility operator be exempt from this specific labeling provision.

**§ 284.416. Duration of storage of regulated medical waste for processors. (1)**

- Clarification requested: This section specifies that the processing facility can maintain the waste on site for 72 hours without refrigeration for waste over 77F. Does this mean once the waste is accepted on site. Most processing facilities do not necessarily have air conditioning for the processing floor. Processing facility temperatures can fluctuate. Under the current rule there is no temperature requirement to maintain waste on site. Is this for waste that is being "stored" or would the department consider waste which is being off loaded "in process"???
- Recommendation: Modify (1) to read: **Seventy-two hours at ambient temperature. Should the waste become putrescent or create a concern for vectors, it must be refrigerated immediately and then must be maintained as specified under §284.416(2) or (3).**

**§ 284.512.(e) Comingling of waste. Regulated medical or chemotherapeutic waste may not be commingled with municipal waste or transported in the same vehicle as residual waste.**

- Clarification requested: Does this mean in the same container or could you have for example non-RCRA pharmaceutical waste (which is currently municipal waste) in separate containers but on the same vehicle? Is the idea that you could not have a roll off that had all the waste together?

**§ 284.513 Transportation of regulated medical and chemotherapeutic waste; additional provisions. (b)(2)A placard or decal containing the phrase "regulated medical wste" or "chemotherapeutic waste" or both as applicable and the universal biohazard symbol that conforms to the design shown in the United States Occupational Safety and Health Administrator's regulations at 29 CFR 1910.10130(g)(1)(i)(B)(relating to bloodborne pathogens).**

- Clarification and exception requested: Would like to request a transition period similar to the container labeling to be able to change the marking of transport vehicles. Most vehicles have "infectious waste" today and would be required to be changed which may take some time. Would it be permitted to provide the same 1 year transition period or potentially 2 years (as requested in the comments above). Also would it be improper or considered a violation if both markings were on the vehicle?

**(d) The surface of vehicles that have not been in direct physical contact with regulated medical or chemotherapeutic waste shall be cleaned weekly. Drainage from the cleaning shall be discharged directly through a holding tank to a sanitary sewer system or treatment facility.**

- Clarification requested: why would all surfaces of vehicles which HAVE NOT been in contact with contamination be required to be cleaned weekly? Also is it the intent of this regulation that all surfaces would be required to be cleaned? Could there be language included to be clear about the

cargo area or interior area of the trucks? Not all trucks may be cleaned on all surfaces weekly (roof or undercarriage especially in the winter months).

**§ 284.623. Condition of licenses. (c)". . .Leased or subcontracted drivers and drivers who provide equipment, have no authority to operate under the licensee's license without prior written approval from the Department."**

- Clarification requested: Some transporters use subcontracted or contracted drivers (meaning they are temporary drivers hired from temporary labor agencies for example) and they would be working under the authority of the waste company. Would it be more clear to specify that "Leased or subcontracted haulers, and haulers who provide equipment . . . "so that it is not an individual driver who is a temporary employee but rather another company that license cannot be transferred.

**§ 284.634. Annual report. (b)(2) The weight or volume of each type of regulated medical or chemotherapeutic waste transported.**

- Comment/Clarification: The requirements for tracking the "type" of regulated medical waste will be eliminated by the change in manifesting. It would be recommended that the annual report identify the total amount of waste incinerated versus what was treated by alternative technologies. Not clear what the department is trying to achieve. If the goal is to ensure wastes which must be incinerated are being properly identified and diverted to incineration then there must be some way to identify that. The manifest will not longer provide that information.
- Recommendation: "The weight or volume of regulated medical waste, pathological waste or chemotherapeutic waste transported"

**§ 284.724 Transportation limitations (a)(2) The waste is not labeled or identified as required by § 284.414 (relating to marking of containers).**

- Please see comments in section **§ 284.414.**

**§ 284.732. Use of manifest. (b)(3) Provide the transporter with dated, handwritten signature from an authorized representative of the facility acknowledging that it has been accepted the waste from the transporter on that date.**

- Clarification requested: Would the department be willing to accept a stamp of the signature from the authorized representative at the facility?

**§ 284.734. Significant discrepancies. (b) If there is a significant discrepancy in the logs or shipping papers, the operator shall attempt to reconcile the discrepancy before the waste is processed or disposed of at the facility or before the waste is accepted at a transfer facility. If the discrepancy is not resolved within 3 business days of receipt of the waste, the operator shall immediately notify the appropriate regional office of the Department by telephone. . Within 7 business days of receipt of the waste the operator shall also send a letter to the regional office describing the discrepancy and attempts to reconcile it.**

- Comment and Recommendation: This is a very difficult section. For operators who are transporting the waste they may not know that there is a discrepancy until it reaches a processing facility. The processing facility is often offloading at the same time that it is processing the waste through. This would mean that under certain circumstances the waste will have already been processed before the discrepancy was clearly identified. The processing facility should make every attempt to identify with the generator what happened (especially because the generator loaded trailers can be off considerably by piece count just due to improper loading procedures). Would not recommend that the waste be held from processing.
- We would offer the following language change/addition:

- **If there is a significant discrepancy in the logs or shipping papers the operator shall:**
  **(i) notify the generator within 3 business days if the waste was a customer loaded trailer;**
  **(ii) notify the transporter within 3 business days to identify to the transporter of the discrepancy when the waste is from multiple generators or a single generator in a load.**
  **(iii) the transporter is required to ensure reconciliation of the load and must report any unresolved discrepancies to the department within 7 business days of being notified of the discrepancy.**