

	Office of Waste Management and Radiological Protection POLICY AND PROCEDURE		DEPARTMENT OF ENVIRONMENTAL QUALITY
Original Effective Date: March 6, 2015 Revised Date: September 22, 2016 Reformatted Date:	Subject: Medical Waste Statute and Rules Interpretation	Program Name: OWMRP-Medical Waste Regulatory Program	Category: <input type="checkbox"/> Internal/Administrative <input type="checkbox"/> External/Non-Interpretive <input checked="" type="checkbox"/> External/Interpretive Type: <input checked="" type="checkbox"/> Policy <input type="checkbox"/> Procedure <input type="checkbox"/> Policy and Procedure
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A Department of Environmental Quality (DEQ) Policy and Procedure cannot establish regulatory requirements for parties outside of the DEQ. This document provides direction to DEQ staff regarding the implementation of rules and laws administered by the DEQ. It is merely explanatory; does not affect the rights of or procedures and practices available to the public; and does not have the force and effect of law. DEQ staff shall follow the directions contained in this document.

PURPOSE:

This policy and procedure was developed to accompany the associated reference document, entitled “Frequently Asked Questions Regarding Medical Waste,” that was revised to provide more accurate, current information and to ensure proper interpretive clarification on specific questions relative to the Medical Waste Regulatory Program.

AUTHORITY:

Medical Waste Regulatory Act, Part 138, Medical Waste, of the Public Health Code, 1978 PA 368, as amended, and associated Administrative Rules

STAKEHOLDER INVOLVEMENT:

The reference document was developed to respond to frequently asked questions and has been shared with the following stakeholders for comment:

1.	<i>Michigan Society for Infection Prevention & Control</i>
2.	<i>University of Michigan’s Environmental Health and Safety Department</i>
3.	<i>Michigan Dental Association</i>
4.	<i>Michigan Veterinary Association</i>
5.	<i>Michigan Pharmacists Association</i>
6.	<i>Michigan Health & Hospital Association</i>
7.	<i>Elite Trauma Clean-Up</i>
8.	<i>Splash of Color Tattoo</i>
9.	<i>Michigan Funeral Directors Association</i>
10.	<i>Michigan Podiatry Association</i>
11.	<i>Hospital Network Health Services</i>

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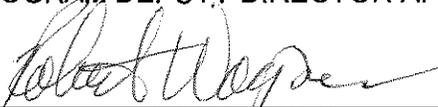
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FREQUENTLY ASKED QUESTIONS REGARDING MEDICAL WASTE

Introduction: A Brief Summary of the Medical Waste Regulatory Act (MWRA), Rules, and Associated Functions of the Program

Regulations and Rules: The Medical Waste Regulatory Act (MWRA), Part 138, Medical Waste, of the Public Health Code, 1978 PA 368, as amended, regulates the generation, storage, treatment, and disposal of medical waste in Michigan. The MWRA was enacted in 1990 in response to incidents of medical waste washing up on the shores of Lake Michigan and Lake Erie, as well as other bodies of water in Michigan. The purpose of the MWRA is to prevent potential public health risks associated with exposure to untreated medical waste and to preserve Michigan's environment through pollution prevention.

Categories of Medical Waste in Michigan: The MWRA defines specifically what is considered to be medical waste and subject to the regulations and rules. These include the following waste items when generated, stored, treated, or disposed of by a "producing facility," *which is also specifically defined under Section 1 of this document:*

- Cultures and stocks of infectious agents.
- Human and animal blood and body fluids.
- Sharps.
- Pathological waste (organs, tissues, etc.).
- Contaminated animal waste infectious to humans.

Primary Staff: The Medical Waste Regulatory Program (MWRP) consists of one Program Specialist, who oversees and implements program priorities, creates technical and regulatory guidance available on the MWRP Web site, creates materials for distribution to the regulated community or the public, responds to and mitigates reported incidents of MWRA violations, and improves or mitigates compliance issues among regulated medical waste producing facilities throughout the state of Michigan, including the administration and enforcement of the MWRA.

Program Support: Routine administrative duties, primarily dealing with the registration of facilities, are handled by the Department of Environmental Quality (DEQ), Office of Waste Management and Radiological Protection, Solid Waste Section's Registration Technician.

Registrant Data: The registrant pool consists of approximately 15,550 active facilities, which include but are not limited to medical facilities, dental offices, nursing homes, mortuaries, veterinary practices, tattoo/body art facilities, among others as defined in the MWRA.



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Section 1: Common Questions on Registration and Certificate Requirements

1.1 Is my business required to register as a medical waste producing facility?

If you meet the definition of a “producing facility” as indicated in Section 13807(4) of the MWRA as well as in Section 2.1 of this document, you are required to be registered in the state of Michigan. A producing facility includes any facility that generates, stores, or decontaminates medical waste prior to disposal.

Examples of producing facilities include, but are not limited to, hospitals, private practice offices (MD, DO, DDS, DVM, etc.), tattoo/body art facilities, mortuaries (not including funeral homes where embalming is not performed), pharmacies offering flu shots or generating needles with syringes in compounding medications, health departments, clinics, etc. There are a few entities specifically exempted from any of the MWRA regulations and rules, including the following:

- Personal residences (apartments, homes, condominiums, etc.) not performing any business or commercial activities within the residence regulated under the MWRA, including services related to generation, storage, treatment, or disposal of medical waste.
- Homes for the aged and assisted living facilities.
- Agricultural businesses (dairy farms, orchards, etc.).

1.2 I generate a very small amount of medical waste. Am I still required to register?

Yes. Regardless of the volume of waste or frequency at which the waste is collected, there are no exemptions contained in the MWRA that would allow these producing facilities to waive obtaining a registration and following all other requirements and rules in the MWRA.

For example, a facility location that is generating, storing, decontaminating, or disposing of medical waste in any capacity is required to register the physical location of the producing facility, even if it only generates a very small volume of medical waste. If you independently own multiple facilities, you must obtain a registration for each facility that is a producer and subject to the MWRA rules and regulations if not located on contiguous property or at the same physical location.

1.3 How can I find out if my facility is already registered?

You may check the Michigan Department of Licensing and Regulatory Affairs (LARA), Bureau of Health Care Services, Health Professions Division, Web site and use the “[Verify a License or Registration](#)” search tool to determine if your facility is already registered. You may also use the “[Registration and Fee Payment Portal](#)” link to see if you are currently registered (not expired) and up for renewal. Inquiries may also be sent via e-mail to medicalwaste@michigan.gov.

1.4 If I am not registered, how do I register my facility?

If you are a new registrant, you can conveniently register online by using the “Registration and Fee Payment Portal” link on the program Web site at www.michigan.gov/degmedwaste. By using this method, you will receive an e-mail confirming receipt of your registration form within 24 hours and, if all of the required information has been provided, you will receive your certificate within approximately one week via postal mail.

If you do not have access to the Internet, you may contact program staff at 517-230-2980 or 517-230-9800 to request that a form be sent to you. Please be advised that this process takes significantly longer than registering online.

1.5 How long are registration certificates valid?

Certificates of registration are valid for a three-year period. At the end of each three-year cycle, you will be notified approximately two months prior to your expiration date to renew your certificate online or via postal mail and your new certificate will be issued.

1.6 I lease a suite in an office building owned by a separate business entity (large hospital system, etc.). Can my facility be included under their registration certificate?

No. If you own an independent business and simply lease an office suite from a separate entity, you are required to obtain a separate registration for each facility that generates medical waste, including multiple locations at separate addresses.

A “mobile” operation, however, that does not own or lease any of the multiple business locations that they visit to perform contracted services, such as a traveling nurse group providing flu shots or an ambulance operation, are not required to register these unaffiliated locations. Only the physical location at which the business performing flu shots on contract collects, transports, stores, or decontaminates the collected sharps containers, etc., prior to disposal would need a registration at the same physical location where the medical waste is stored.

1.7 Are school districts required to register?

If any school building or other district facility generates medical waste, other than student or staff-generated sharps from self-injection, they are required to register. Each facility is not required to register; the school system may register as a district.

1.8 Our facility has recently moved. Is a new registration required?

No. Using your current facility registration number, you can use the “Registration and Fee Payment Portal” link on the MWRP Web site at www.michigan.gov/degmedwaste to change your information. You must enter your number in the format “MW000Reg#.” Seven digits must follow the “MW,” and leading “0s” would be used until you have the seven-digit format. For example, if your number were 4329, you would enter it as “MW0004329.”

You will be directed to a page that has the option for you to change your address. Once you have changed the address, the system is prompted to send you a revised certificate free of charge. Please allow one to two weeks for receipt of a revised certificate.

1.9 Our facility no longer requires a certificate of registration as our circumstances have changed (owner retired, deceased, etc.). How do we inactivate our registration?

If you have the renewal application for the facility, you may simply mark the option that best applies to your situation as to why you are not renewing, and send the form (no fee included) to the address located at the bottom of the application. If you check "Registered Under Another Facility," indicate the name and registration number of the facility you are registered under. If you do not have your renewal application, registration number, or would like to receive a response, inquiries as to your status may also be sent via e-mail to medicalwaste@michigan.gov.

1.10 Our facility will be undergoing a change of ownership. Can we continue to be covered under the registration obtained by the original owner?

No. The registration under the original owner should be inactivated unless the original owner moved to another location and wishes to transfer the registration to the new location. The new owner may conveniently register online by using the "Registration and Fee Payment Portal" link on the program Web site at www.michigan.gov/deqmedwaste. By using this method, they will receive an e-mail confirming receipt of your registration form within 24 hours and, if all of the required information has been provided, they will receive their certificate within approximately one week via postal mail.

If you do not have access to the Internet, you may contact program staff at 517-230-2980 or 517-230-9800 to request that a form be sent to you. Please be advised that this process takes significantly longer than registering online.

If you receive a renewal notice for the previous owner, please return it indicating there has been a change of ownership.

Alternatively, the previous owner may send an e-mail message to medicalwaste@michigan.gov to report that the registration should be inactivated or transferred to a new location if the owner remains in practice at another site.

1.11 Does an adult foster care facility caring for individuals with physical or mental disabilities need to register?

No, based on the fact that these facilities are residential in nature, do not employ medical professionals to provide invasive treatment that generates medical waste, and the primary function of these facilities is to assist disabled individuals in performing basic routine "life functions" they are unable to perform on their own such as dressing, showering, practicing good oral hygiene, preparing meals, and other related functions typically performed in a residential setting.

1.12 Are tattoo/body art facilities required to register?

If the facility generates regulated medical waste (disposable sharps, blood saturated gauze, etc.), registration as a medical waste producing facility and compliance with the MWRA are required. Please refer to Section 1.4 for information on registration. Body art facilities are also subject to 2007 PA 149, Body Art Facilities Act, MCL 333.13101 *et seq.*, which requires permitting and other regulatory requirements for tattoo/body art establishments. This information can be accessed at www.michigan.gov/bodyart. The facility is also subject to the requirements of the Blood Borne Infectious Diseases Standard, which can be accessed at www.michigan.gov/lara and selecting on the left navigation bar "MI Occupational Safety & Health Administration," "A to Z Topic Index," scrolling down to "Bloodborne Pathogens," and selecting the information wanted. You can also go directly to the index by using the following link: http://www.michigan.gov/lara/0,4601,7-154-11407_52824---,00.html, scroll down to "Bloodborne Pathogens," and select the information wanted.

1.13 Our business ceased operations before the registration expired. Are we entitled to a "prorated" refund for the remaining two years we will not be generating medical waste?

No. There is no provision in the MWRA that allows for refunding a prorated fee amount in such situations. Please contact the MWRP by e-mail at medicalwaste@michigan.gov to provide the closure notification, or fax notification information to 517-373-4051.

Once your notification is received, the registration will be inactivated in our database as a producing facility.

Section 2: Questions About Medical Waste Identification, Handling, Separation, Treatment, and Disposal

2.1 What is medical waste and what types of medical waste are subject to regulation in Michigan?

Under the MWRA, the following items are considered “medical waste”:

- Cultures, stocks, and biologicals that may be infectious to humans.
- Liquid human and animal waste, excluding urine.
- Pathological waste (organs, tissues, etc.) of human origin that are not fixed in formaldehyde.
- Sharps (whether used or unused), including needles, syringes, scalpels, and syringes or tubing with needles attached. *The Michigan Occupational Safety and Health Administration has additional items regulated as sharps, however, such as lancets, broken capillary tubes, and exposed ends of dental wire.* These items must be treated appropriately and comply with the MWRA.
- Contaminated wastes from research animals that may be infectious to humans.

2.2 Are there some specific examples of what is and what is not medical waste?

Yes, there is a link on the MWRP Web site (www.michigan.gov/deqmedwaste), entitled “*Medical Waste Directory*,” which gives an extensive listing of items by profession and indicates whether they are medical waste or general solid waste.

2.3 How do we find a medical waste disposal company?

A listing of medical waste disposal companies is available on the MWRP Web site. The list may not reflect all disposal companies currently available, but is comprehensive and provides many options to find a company that can provide this service to your business.

2.4 I cannot locate a medical waste disposal/treatment facility close to my area. Does this mean I cannot get service?

No. Many of the medical waste disposal services on the listing have multiple nationwide locations from which they operate. It is suggested that you call several services to get the best service and cost that meets the needs of your facility.

2.5 Do we need to dispose of urine specimen cups as medical waste?

No, urine is specifically exempted from the definition of medical waste in the regulations. They can be placed in the regular trash, assuming no visible blood that can be released from the receptacle during disposal is observed.

2.6 Are sanitary napkins/tampons regulated if generated in a registered producing facility?

No. They are like diabetic self-injection needles, considered an extension of home-generated waste, and are not regulated by our program.

2.7 Are band-aids, pieces of gauze, or wound dressings considered medical waste?

These items are only considered a regulated medical waste if human or animal blood or body fluids are capable of being released from the containing material. Gauze, wraps, and bandages usually will not release blood or body fluid unless copious amounts of body fluid are contained in a small volume of absorbent material.

This only applies when the material is “supersaturated” to the point that it will drip fluids on the floor if gently squeezed or in instances when dried, caked blood is not contained and is capable of “flaking off” and releasing fluids from the material or surface.

Section 3: Questions About Compliance and Facility Inspections

3.1 Why is my facility being inspected?

Your facility may be inspected following the receipt by the DEQ of an alleged disposal violation/complaint or as part of a random compliance outreach effort in your area.

Although it can vary based upon the nature of the facility, here are some situations that may prompt either an announced or an unannounced inspection:

- Incident report alleging improper disposal by the facility is occurring.
- The facility is not registered as required under the MWRA.
- Other potential administrative violations or imminent threats to public health or the environment due to improper treatment/handling/disposal of the waste has been reported to the DEQ.
- The facility has never been inspected before and, as such, may benefit from educational outreach efforts or compliance assistance.
- Any other random or routine compliance activity that is not due to a complaint or potential incident.

3.2 What should I expect during an inspection of my facility?

As a general rule of thumb, you should expect the following if an inspector arrives at your facility:

- You can expect a brief walk-through of your facility, focusing on areas in which medical waste is generated, stored, treated, or disposed of.
- You will be asked to provide a copy of your current medical waste registration certificate (which should be kept on file at each registered facility).
- You will be asked for records verifying that any employees have been trained appropriately in safety and infection control risks when handling or packaging medical waste.

3.3 Who is authorized to inspect our facility?

Any DEQ staff or other State of Michigan staff with overlapping requirements, such as Michigan Occupational Safety and Health Administration, Body Art Permitting Program, X-Ray Permitting Inspectors, or you may also be contacted or visited by your local health department that is under contract with the DEQ.

3.4 I am concerned that I may be out of compliance. How do I verify our business is compliant?

Although it is ultimately the responsibility of the facility owner to ensure compliance with any regulations applicable to the services they provide, the MWRA and associated Administrative Rules are available under the "Laws and Rules" heading at www.michigan.gov/degmedwaste. If you have questions, either contact the program specialist at 517-230-9800 or send an e-mail to medicalwaste@michigan.gov.

3.5 How do we respond to violations that were discovered during an inspection of our facility?

If violations are discovered during the inspection, MWRP staff or staff authorized by the DEQ will inform you verbally during or at the conclusion of the inspection and, following the inspection, will memorialize the inspection findings in a letter to the facility owner/operator. This letter will be called a compliance communication or violation notice depending on the nature of the violation(s) observed. Corrective actions taken before the conclusion of the inspection will be identified in the letter. Facilities are expected to correct violations as soon as possible to protect human health, safety, welfare, and the environment. The inspector may ask for documentation (photos, shipping records, invoices, training documents, etc.) that demonstrate the violations have been resolved.

Section 4: Questions About Waste Generated in the Home

4.1 I use needles at home for self-injection as part of my diabetic treatment. How can I dispose of my used needles?

The DEQ publication, "The Point is...Needles Hurt!" located under the "MWRP Information" heading at www.michigan.gov/deqmedwaste provides tips and guidance regarding the disposal of home-generated needles. You may also access a listing of residential disposal programs by county by clicking the "Sharps Collection Programs for Michigan Residents" link under the same heading and scroll down until you see your county.

If your county is not currently listed as having a program, we recommend you contact your physician, local pharmacy, hospital environmental services staff, or your local health department and inquire as to why a program has not yet been integrated into their household hazardous waste or clean sweep collection events. Emphasize the importance these programs serve to the protection of public health and the environment.

4.2 Our facility would like to accept sharps containers for disposal from our patients and/or local residents as part of a community service initiative. Are we allowed to do this? How do we start?

Outreach efforts by DEQ staff have encouraged these programs for over ten years, and we would like to emphasize the importance of such public service efforts in preventing needle stick injuries or other exposure to potentially infectious waste to community members, landfill operators, etc.

Over the last decade, by working in conjunction with environmental stewardship organizations and volunteers from local health departments, hospitals, pharmacies, fire departments, and community action groups, we are proud to say most counties in Michigan developed programs to accept properly contained sharps from local residents.

To date, we have not received any reports that offering these programs has caused an undue burden on these facilities through expenditures or staff resources, and overall, the comments we have received have been very positive. It is a valuable service to the community and a good public relations tool for both public and private operations that offer these programs.

If your facility would be willing and able to accept used needles from community residents for disposal, or if you have any questions, please contact us at medicalwaste@michigan.gov. We will add the name and contact information for your facility to our community sharps collection listing on our Web site, including specific instructions as to how they may bring in the containers for disposal. We would appreciate the assistance of more participants as it helps to protect public health and the environment. We can remove the listing at any time should you no longer wish to be on the list.

Section 5: Additional Documentation Required for Compliance

5.1 What other documents should I have on file to comply with the MWRA and associated Administrative Rules?

In addition to maintaining a current medical waste producing facility certificate of registration on file, you must also develop a site-specific Medical Waste Management Plan that reflects current operational practices, shipping records, and/or decontamination and disposal documentation to verify that your medical waste is being handled, stored, decontaminated, and disposed of properly in accordance with the regulations, as well as evidence in the form of electronic or paper records indicating employee training has occurred on how medical waste is handled, packaged, segregated, and stored at the producing facility.

5.2 What is a Medical Waste Management Plan?

A Medical Waste Management Plan, which is completed and kept on file at each registered facility, contains information relating to the handling of all medical waste generated, stored, decontaminated, or incinerated at each location, or transported from the producing facility for handling by another facility prior to disposal. See Section 13817 of the MWRA for specific requirements. A sample Medical Waste Management Plan is available on the MWRP Web site at www.michigan.gov/deqmedwaste.

5.3 Our facility has multiple sites. Can we use one Medical Waste Management Plan to cover all of our sites?

Yes. In accordance with Section 13817(1) of the MWRA, *“A professional corporation may identify and prepare a common medical waste management plan for all producing facilities owned and operated by the corporation.”*

A copy of the common Medical Waste Management Plan should be kept on file at each facility and should list the respective types of medical waste handled by each facility.

5.4 We train our employees annually on the Blood Borne Infectious Diseases Standard as required by the Michigan Occupational Safety and Health Administration. Does this training satisfy the employee training required under the MWRA?

We accept Blood Borne Pathogens training records as long as the training covers the procedures outlined in the facility’s Medical Waste Management Plan. The documentation of the training must be presented upon request.

Section 6: Questions About Alternative Treatment Technologies

6.1 What is the definition of an “alternative treatment technology” under the MWRA?

An alternative treatment technology is any method or device used for the treatment of medical waste this is not specifically approved in the regulations and is not an autoclave or incinerator. Examples would include processes such as alkaline hydrolysis, plasma arc treatment, dry heat ovens, etc.

6.2 I am developing a new treatment method for medical waste and hope to market the product in Michigan. Is there an approval process for this?

Yes. In order to market your product or device for use as an alternative method for treatment of medical waste in Michigan, you must first obtain an approval from the DEQ. Contact our office at medicalwaste@michigan.gov for information on the requirements for these approvals.

6.3 I want to treat my own medical waste and am considering a new product I saw advertised. Am I allowed to use this product?

You must first check the listing of alternative treatment technologies that have been approved in Michigan for the treatment of medical waste. Before treating medical waste generated at your facility or using a product that advertises use as a medical waste treatment device, you must first verify that the product or equipment is approved in Michigan for this purpose.

A list of currently approved alternative treatment devices is available on the MWRP Web site, www.michigan.gov/degmedwaste under “Approved Alternative Treatment Technologies for Medical Waste.”

Section 7: Miscellaneous Questions

7.1 Does the MWRP regulate transport of medical waste?

No. While not specifically required under the MWRA, DEQ staff may ask to view shipping records to verify that the MWRA's 90-day storage limitation is met. Transport of medical waste is regulated by other federal and state agencies, as noted below:

Transportation of medical waste is primarily addressed in the Federal Code of Regulations, Section 173, and classified as a hazardous material when transported on public roads by the United States Department of Transportation (USDOT). You may visit the USDOT Web site by visiting www.dot.gov. Search for "medical waste" for a listing of applicable Web sites and interpretive documents.

The Michigan State Police, Commercial Vehicle Enforcement Division, Hazardous Materials Transportation Information Unit and Investigative Unit, enforce the USDOT regulations as well. You may contact the Commercial Vehicle Enforcement Division at 517-284-3250, or the Hazardous Materials Unit and/or the Investigative Unit at 517-206-2312 with questions. Packaging, shipping, and transport of medical waste is required by Michigan's Motor Carrier Safety Act, 1963 PA 181, as amended, being Sections 480.11 to 480.25 of the Michigan Compiled Laws.

7.2 If we return an organ/limb/placenta to a patient who requests it, is our facility in violation if we allow them to take these? Isn't it "pathological waste"?

No. The removed body part/organ/surgical specimen may be released to the patient for cultural, religious, or other personal reasons because it is not considered a "waste," but rather an item of value to the patient requesting the material. The only exception to this would be if the material requested by the patient is known or highly expected to contain a pathogen that may cause disease to the patient or pose risks to public health.

A facility may choose to prepare a waiver statement to be signed by the patient if necessary to release any legal obligations to the facility once the material is released to the patient, although this is not a requirement.

7.3 Am I required to write both the "START" and "END" date of storage on each medical waste disposal container to ensure compliance with the 90-day storage limitation?

No, but it is strongly recommended that either this or another comparable method be used in order to assure the waste is not being stored at the facility in excess of 90 days. It is up to the discretion of the facility as to how they choose to track this storage period to assure compliance with the MWRA.

7.4 When does the storage period for medical waste begin?

The 90-day storage limit begins when the use of the container is initiated. It does not begin when the container is placed in storage for removal from the facility.

7.5 Are empty vaccine vials always considered medical waste?

No. They are only to be disposed of as medical waste if they contain waste that may be considered infectious to humans.

7.6 Are needles that have never been used (sterile) considered as medical waste?

Yes. Any sharp regulated under the MWRA must be treated as a medical waste whether it has been used or not. This includes needles used for “practice” in medical assistant and/or phlebotomy training schools or if the lot has expired according to the manufacturer’s packaging.

7.7 Our company or facility provides sharps containers for public or employee use in restrooms. Does the MWRA and registration requirement apply?

No. You would not be considered to be a medical waste producing facility nor be subject to the requirements of the MWRA. Facilities are encouraged to provide sharps containers for the public or employees that must self-inject medications. This is an extension of waste that would normally be generated in a household, which is exempt from the requirements of the MWRA.

If you need a listing of services that can properly dispose of these containers when they become full, there is a listing of “Medical Waste Disposal Services” on the MWRP Web site at www.michigan.gov/deqmedwaste under the “MWRP Information” heading. If the facility contacted states that you must sign a contract for removal at least quarterly and register as a producer with the State of Michigan, inform them that you have already consulted with the information on the MWRP Web site and that you are not subject to the registration or compliance requirements under the MWRA for this reason. You may refer them to send a message to medicalwaste@michigan.gov should they require confirmation.