



Environmental
Protection Agency

John R. Kasich, Governor
Mary Taylor, Lt. Governor
Scott J. Nally, Director

Butler Co.
Health Dept
IW Corr

August 25, 2011

Hand Delivered

Teresa Cramer
Obstetrics & Gynecology Associates, Inc.
3050 Mack Rd #375
Fairfield, Ohio 45014

Re: Obstetrics & Gynecology Associates, Inc., Butler County
Notice of Violation – Large Infectious Waste Generator Inspection

Dear Ms. Cramer:

On August 16, 2011, I representing the Ohio Environmental Protection Agency (Ohio EPA), Southwest District Office (SWDO) met with Jackie Means, Nursing Supervisor and conducted a comprehensive infectious waste large generator inspection of the Obstetrics & Gynecology Associates, Inc. office located at 6770 Cincinnati Dayton Rd#100, Liberty Township, Ohio (Facility).

The purpose of this inspection was to determine compliance with Ohio's Infectious Waste Regulations, Ohio Administrative Code (OAC) 3734-27. I inspected the infectious waste handling areas including patient exam rooms, the procedure room, the laboratory, infectious waste storage areas, spill kit and procedures, conducted a records review, and checked for a valid registration certificate.

The following discussions & observations were made during this inspection:

1. During my inspection Ms. Means indicated that the infectious wastes, including sharps generated at this Facility and the 3050 Mack Rd #375 location, were no longer being picked up by a registered infectious waste transporter for treatment and disposal. She indicated that since 2009, all of the infectious wastes including sharps, have been treated on-site using the Demolizer™ unit and then disposed of in the regular trash. While the Demolizer™ Technology was approved as a statewide alternative method of treatment for infectious waste by the Ohio EPA, this Facility and the Mack Road facility have not requested an amendment to the current infectious waste registration to include treatment using the Demolizer™.

According to the current Ohio EPA infectious waste registration certificate issued for both of your facilities there is neither designation of on-site treatment nor a

waste treatment method indicated. **Therefore, the current registration is not correct and up to date to reflect on-site treatment. The generator's failure to amend the infectious waste certificate to include on-site treatment and the method of treatment is a violation of OAC Rule 3745-27-36(A)(2) which states:**

"Any generator who holds a valid registration certificate under this paragraph shall ensure that all information that is contained on the registration certificate is correct and up to date by submitting an amended registration application form and obtaining an amended registration certificate that reflects any changes to current registrant information, premises information, or treatment method. No additional fee shall be charged to amend a registration certificate. An amended registration shall not alter the expiration date of the original registration certificate."

2. **The generator has been improperly disposing of their treated infectious waste in the regular municipal solid waste stream without proper verification of treatment of waste which is a violation of OAC Rule 3745-27-30(B)(5) and OAC Rule 3745-27-30(B)(7).**

OAC Rule 3745-27-30(B)(5) states:

"A large infectious waste generator shall dispose of the infectious wastes at a solid waste disposal facility holding a license issued under division (A) of section 3734.05 of the Revised Code, after being treated to render them noninfectious by either:

- (a) Treating the infectious waste that is generated at a facility owned or operated by the generator by any of the methods, techniques, or practices prescribed by paragraph (B) of rule 3745-27-32 of the Administrative Code to render them non-infectious; or
- (b) Designating the wastes for treatment off that premises at an infectious waste treatment facility holding a license issued under division (B) of section 3734.05 of the Revised Code, or to a facility that holds a license issued under section 4717.17, and a permit issued under Chapter 3704. of the Revised Code to the extent that the treatment of those wastes is consistent with that permit and its terms and conditions prior to disposal of the wastes, or a facility in another state operating in compliance with state and federal regulations.

OAC Rule 3745-27-30(B)(7) states:

"The generator shall cause all infectious wastes that have not been treated to render them noninfectious in accordance with OAC Rule 3745-27-32 of the Administrative Code to be transported in shipments consisting only of untreated infectious wastes."

3. **Disposal of treated, infectious waste must be accompanied by disposal shipping paperwork. The generator has not maintained disposal shipping paperwork nor have disposal shipping papers accompanied the loads of waste received at the landfill in violation of OAC Rule 3745-27-33(C) which states in part:**

"The disposal shipping paper shall accompany treated infectious waste from the treatment facility to the disposal facility. The disposal shipping paper shall:

- (1) Be produced from a form prescribed by or approved by Ohio EPA;
- (2) Be legible and complete;
- (3) Be kept on file for a minimum of three years;
- (4) Be prepared by:
 - (a) The infectious waste treatment facility responsible for treating the wastes when a shipment of treated wastes is transported to a solid waste disposal facility; and
 - (b) The generator if the infectious waste treatment facility is owned or operated by the generator.
- (5) Be signed, dated, and given to the transporter by the infectious waste treatment facility before the wastes are removed from the premises;
- (6) Contain the following information:
 - (a) The name, address, and telephone number of the generator;
 - (b) The name, address, telephone number, and dated signature of the owner or operator of the infectious waste treatment facility;
 - (c) The name, address, telephone number, and dated signature of the owner or operator of the disposal facility;

- (d) A certification by the owner or operator of the treatment facility where the wastes were treated that the wastes have been treated by any of the methods, techniques, and practices prescribed by paragraph (a) of rule 3745-27-32 of the Administrative Code; and
4. During the inspection Ms. Means was unable to locate an infectious waste spill containment and clean-up procedure or designated infectious waste spill kit for the Facility. **The generator's failure to develop and maintain an infectious waste spill containment and clean-up procedure and spill kit is a violation of OAC Rule 3745-27-30(B)(10) and OAC Rule 3745-27-30(B)(11).**

OAC Rule 3745-27-30(B)(10) states:

"Develop a spill containment and clean-up procedure. A copy of the procedure shall be posted or readily available on the premises to persons likely to handle infectious waste, including janitorial services. The name, address, and telephone number of the infection control manager or infectious waste control manager and their back-up, along with the location of all spill containment and clean-up materials/kits at this facility, shall be listed at the top of the spill containment and clean-up procedure. Copies of the procedure shall be provided at the request of the board of health with jurisdiction or the director of the Ohio EPA or their authorized representative;

[Comment: These procedures can be the same procedures that were developed in response to OSHA's blood borne pathogen regulations.]"

OAC Rule 3745-27-30(B)(11) states:

"The generator shall ensure that clean-up materials / kits are available in those areas designated in the spill containment and clean-up procedures. Materials utilized in the clean-up of a spill of infectious wastes shall include, but are not limited to:

- (a) Materials designed to absorb spilled liquids;
- (b) An U.S. EPA registered hospital disinfectant that is also tuberculocidal, for a contact time as specified by the manufacturer, a unexpired dated stablized bleach product that is an U.S. EPA registered hospital disinfectant that is also tuberculocidal, for a contact time as specified by the manufacturer, or materials necessary to prepare a minimum ten per cent sodium hypochlorite solution prepared immediately prior to use with a minimum of thirty minutes of contact time with the waste;

- (c) Red or biohazard labeled bag(s) as specified in paragraph (a) of rule 3745-27-34 of the Administrative Code;
- (d) Latex gloves, or equivalent type of glove, and any other personal protective equipment necessary to implement the spill containment and clean-up procedure; and
- (e) A first aid kit, unless emergency medical care is available on the premises, boundary tape, and other appropriate safety equipment.

Please develop a spill containment and clean-up procedure and put together an infectious waste spill kit for the Facility.

5. During this inspection, Ms. Means indicated that the Facility did not have an infectious waste storage area. However, I did observe storage of sealed and in-use containers in the laboratory. One specialized sharps container was completely full and placed on top of the Demolizer™ unit in the laboratory waiting to be treated. The laboratory was not equipped with a door or an international biohazard symbol at all points of access.

The improper handling of infectious waste is a violation of OAC Rule 3745-27-35 which states in part:

“A generator shall handle all infectious wastes in accordance with rule 3745-27-35 of the Administrative Code.”

The Facility needs to designate a storage area for the collection of infectious waste containers that are sealed and/or closed sharp containers prior to treatment in accordance with OAC Rule 3745-27-35(A). The infectious waste storage area needs to not be readily accessible to the general public and those storage areas that are not locked, shall be visibly labeled with a sign stating "warning: infectious waste" and/or displaying the international biohazard symbol at all points of access.

6. The Facility has been operating the Demolizer™ unit without first conducting the required validation testing or performing the necessary quality assurance testing to ensure spore reduction to demonstrate proper treatment prior to disposal which is a violation of the Director's approval letter dated November 28, 2007 and a violation of OAC Rule 3745-27-32. You must conduct this testing before you may legally dispose of waste treated in this unit in the solid waste dumpster.
7. As discussed during a conference call with Ms. Cramer on August 17, 2011, before resuming use of the Demolizer™ unit to treat infectious wastes the Facility shall do the following:

- amend their infectious waste registration to include treatment and designate a treatment method; and
 - operate the Demolizer™ unit in accordance with the conditions outlined in the director's approval letter of the Demolizer™ Technology, dated November 28, 2007; the manufacturer's specifications and all applicable infectious waste regulations; and
 - follow the requirements for treatment of infectious waste using an alternative treatment method outlined in OAC Rule 3745-27-32(A)(6) and OAC Rule 3745-27-32(I); and
 - conduct on-site validation testing of the Demolizer™ unit in accordance with the manufacturer's specifications
 - perform quality assurance testing to ensure that the dry heat encapsulation system is capable of achieving the performance standard of a minimum four log₁₀ reduction of Bacillus subtilis spores;
 - develop and maintain quality assurance records and the daily log of operations on-site; and
 - operate the treatment unit using only the specifically designed containers; and
 - develop and maintain a Facility Management Plan for each site; and
 - develop and maintain disposal shipping papers to accompany the solid waste dumpster containing the treated infectious waste to the landfill; and
 - comply with all applicable infectious waste treatment rules in OAC Rule 3745-27-32.
8. If the registrant's facilities wish to resume to treat infectious waste generated on-site then the registrant will need to amend the infectious waste registration certificate by completing and submitting the amendment form to Ohio EPA, the form can be found at:

http://www.epa.state.oh.us/portals/34/document/guidance/gd_079.pdf

Compliance with the requirements outlined in this letter shall not relieve you of your obligation to comply with other legal obligations, including, but not limited to, Chapters 3704, 3714, 3734, or 6111 of the Ohio Revised Code or under the Federal Clean Water Act, Clean Air Act, Comprehensive Environmental Response, Compensation, and Liability Act, or Resource Conservation and Recovery Act remedying conditions resulting from any release of contaminants to the environment.

Correction of the aforementioned violations is expected to begin immediately upon receipt of this letter. If you have any questions or need any additional information or assistance, please call me at (937) 285-6046.

Sincerely,



Maria Lammers, R.S.
Environmental Specialist
Division of Materials and Waste Management

cc: Chief Environmental Services, Butler County Health Department
Sara Anderson, Ohio EPA, DMWM-Central Office

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