



Environmental
Protection Agency

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

December 7, 2011

Mr. Jim VandenEynden
Director of Environmental Services Department
McCullough-Hyde Memorial Hospital
110 North Poplar Street
Oxford, Ohio 45056

**Re: McCullough-Hyde Memorial Hospital, Butler County,
Quarterly Autoclave Inspection Notice of Violation/Notice of Return to
Compliance Correspondence**

Dear Mr. VandenEynden:

On November 29, 2011, Maria Lammers and I, representing Ohio EPA, Southwest District Office (SWDO), met with Mark Rapier, Environmental Supervisor, McCullough-Hyde Memorial Hospital, in order to conduct a comprehensive quarterly autoclave treatment facility inspection, including the associated record keeping, at McCullough-Hyde Memorial Hospital (Facility) located in Butler County, Ohio.

The purpose of this inspection was to determine compliance with Ohio's Infectious Waste Regulations. The autoclaving unit and records were inspected for compliance with Ohio Administrative Code (OAC) Rule 3745-27-32, Standards for the Operation of Infectious Waste Treatment Facilities. The Facility also operates as a large generator of infectious waste and also must comply with Ohio Administrative Code (OAC) Rule 3745-27-30, 33, 34, 35 and 36.

We inspected the autoclave treatment unit, the infectious waste handling areas, infectious waste storage areas, spill kit and procedures and conducted a complete records review including treatment shipping paperwork, disposal papers, temperature recording charts, quality assurance logs, daily logs, and maintenance and calibration records.

Violations and Return to Compliance

The Facility Management Plan (FMP) was also reviewed as a follow up to the technical assistance provided during the September 13, 2011 inspection. The following violations were noted and corrected during the November 29, 2011 inspection:

A current set of solid waste regulations was not in the FMP.

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This violation of OAC Rule 3745-27-32 (l)(2)(a)(i) which states in part:

The facility management plan shall contain copies of...applicable environmental regulations regarding...solid wastes...

During the November 29, 2011 inspection, the operator corrected this violation by printing and replacing the outdated version with the current rules.

A copy of the current registration was not available in the FMP.

This violation of OAC Rule 3745-27-32 (l)(2)(a)(ii) which states in part:

The facility management plan shall contain copies of...applicable...registrations for the treatment facility...

The operator corrected this violation by locating a copy of the current registration and placed it in the FMP.

According to daily log records the autoclave unit at the Facility was inoperable during the time period of November 23, 2011 through November 25, 2011. The Facility's contingency plan found within the FMP indicates if the autoclave unit is down for a period greater than 24 hours then Stericycle will be contacted to transport all of the infectious waste for treatment. However, according to Mr. Rapier the Facility packaged the infectious waste into the Stericycle containers and simply interlocked the cardboard lids instead of taping them shut. Once the autoclave unit was up and running on 10/26, the Facility re-opened these containers and treated the infectious waste in the autoclave unit.

The Facility's failure to follow their FMP and contingency procedures is a violation of OAC Rule 3745-27-32(l) and OAC Rule 3745-27-32(l)(2)(a)(vii).

During the inspection, the operator stated that it's understood the Facility is to follow their FMP and contingency procedures and will do so going forward.

Recommendations

The Facility's policy number 5.04 titled Operating Autoclave indicates that the unit will be cleaned each Friday, however, it doesn't contain details as to how this procedure will be accomplished.

The Ohio EPA recommends putting cleaning details into this section.

The Ohio EPA recommends putting tabs in the FMP binder in order to better organize the FMP. Tabs corresponding to the table of contents will make the FMP a more user friendly reference for the Facility.

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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.

Ohio EPA is available to provide any training requests that you and your staff may need regarding Ohio EPA's Infectious Waste Rules and Regulations.

If you have any questions or need additional information, please contact me at (937) 285-6647.

Sincerely,



Monte Bluebaum, R.S.
Environmental Specialist II
Division of Materials and Waste Management



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

MB/tf

cc: Butler County Health Department, Chief of Environmental Services