



State of Ohio Environmental Protection Agency

Southwest District Office

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Chris Korleski, Director

November 20, 2008

Ms. Amy Houpey
Director of Hospitality Services
McCullough-Hyde Memorial Hospital
110 North Poplar Street
Oxford, Ohio 45056

**Re: McCullough-Hyde Memorial Hospital, Butler County
Notice of Violation- Quarterly Autoclave Inspection**

Dear Ms. Houpey:

On November 12, 2008, Maria Lammers and I representing Ohio EPA, Southwest District Office (SWDO) met with Dan Chaney 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) 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, conducted a complete records review including treatment shipping paperwork, disposal papers, temperature recording charts, quality assurance logs, daily logs, and maintenance and calibration records, along with a review of the facility management plan (FMP) and checked for a valid registration certificate.

The following observations were made during our inspection:

1. There were containers of untreated infectious waste stored in front of the autoclave treatment room door (See Figures 1 & 2). The untreated bags of infectious waste and containers were located in a room that is not the designated infectious waste storage area. "Storage area" as defined in OAC Rule 3745-27-



35(A) is an area used to collect containers that are sealed, and/or bags that are sealed or otherwise closed, and tied, and/or closed sharps containers prior to transportation or treatment.



Figure 1: IW stored outside the treatment room Figure 2: IW containers stored along the wall outside of the autoclave room

The Facility's failure to store the infectious waste in the designated infectious waste storage area restricting infectious waste handling areas to authorized personnel, utilizing a locking mechanism or visibly labeling all access points with an international biohazard symbol is a violation of OAC Rule 3745-27-32(I)(14) and OAC Rule 3745-27-35(A)(3).

OAC Rule 3745-27-32(I)(14) states in part:

"Restrict infectious waste handling areas to authorized personnel, utilizing signs or a locking mechanism"

OAC Rule 3745-27-35(A)(3) states in part:

"Designate infectious waste storage areas. Those storage areas that are not locked, shall be visibly with a sign displaying the international biohazard symbol at all points of access"

Also generators, transporters, and treatment facilities, as defined under chapter 3734 of the Revised Code, shall adhere and follow the handling requirements for all in-use and stored containers of infectious waste in accordance with OAC Rule 3745-27-35, Standards for handling infectious waste. The Facility is both an infectious waste large quantity generator and a treatment facility, and is required to designate infectious waste storage areas and they shall be locked or visibly labeled with an international biohazard symbol at all points of access.



Please ensure that in the future, all infectious waste bags and/or containers that are being held for transportation or treatment are properly stored in the designated storage areas.

2. In the infectious waste storage area there was a box that had been cut, another box that was over packed and the lid was bulging and other boxes that had slight crushing damage to their corners. The boxes were stacked to the ceiling which may have resulted in some of the crushing (See Figures 3, 4, & 5).



Figure 3: Damaged IW container in storage area



Figure 4: IW Storage area boxes stacked to ceiling



Figure 5: Over packed IW boxes in storage area

The Facility's failure to maintain the integrity of the packaging is a violation of OAC Rule 3745-27-35(A)(1) which states in part:

"Handle infectious waste containers in a manner and location that maintains the integrity of the packaging".

3. We met with Dr. Svrbely and Robin Sutter, the Microbiology Laboratory Manager and conducted an inspection of the infectious waste and sharps handling areas, storage areas, and the infectious waste spill kit/procedure in the lab. We also discussed the



quality assurance and validation of the *Bacillus stearothermophilus* spores utilized in the autoclave treatment unit.

There were no violations observed in the laboratory.

4. Upon review of the FMP, we were unable to locate a copy of the municipal solid waste regulations. As a reminder, OAC Rule 3745-27-32(l)(a)(i) requires that applicable environmental regulations regarding infectious wastes, solid wastes, surface water and air pollution control be maintained within the FMP. **Please place a copy of all applicable environmental regulations in the FMP.**
5. On the treatment shipping paper manifest MDMN006759, dated October 1, 2008, the Stericycle driver did not sign the shipping paper. A notice of violation letter will be issued to the transporter, Stericycle by Maria Lammers. **As a reminder, please verify that the applicable sections of the treatment shipping papers are completed prior to signing as this the Facility's only proof that the waste has been sent for proper treatment and disposal until an original white copy is returned from the treatment facility.**
6. The current sign on the door of the designated storage area has a list of contacts on it that is not current (See Figure 3).

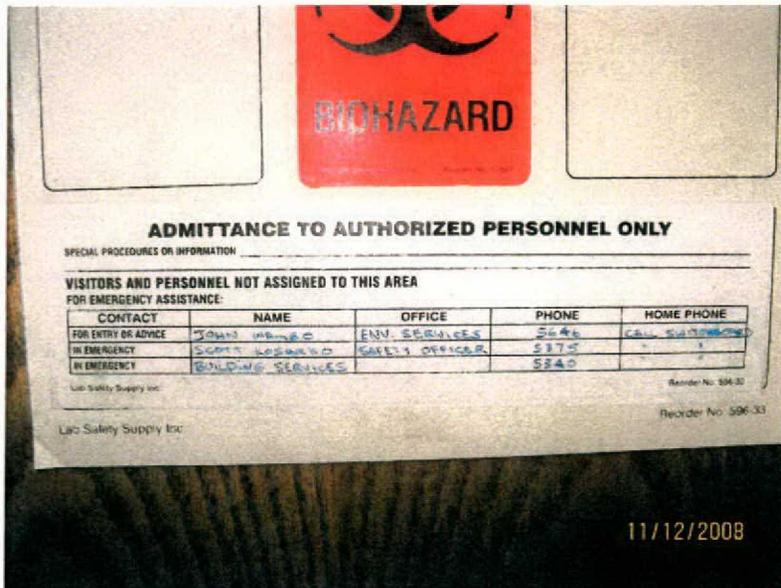


Figure 3: Label on the designated infectious waste storage room

Please either remove or update this contact list to include your name as the new Environmental Services contact, since Mr. Wambo has retired from the Facility.

In addition, please update all documents pertaining to the autoclave and the infectious waste program with your current legal name as we were notified by your staff during the inspection that this has recently changed. Also, please ensure that personnel are available to accompany and retrieve records during



random Ohio EPA inspections. It is understood, and appreciated, that personnel, emergent, situations may arise and staff member(s) may have to leave work early. However, Ohio EPA inspections must be made on a random basis.

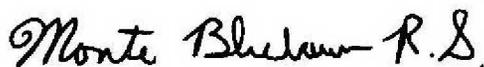
Compliance with the requirements outlined in this letter shall not relieve you of your obligation to comply with other legal obligations, including, but not limited to, Chapters 3704, 3714, 3734 or 6111 of the Ohio Revised Code or under the Federal Clean Water Act, Clean Air Act, Comprehensive Environmental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

As such, corrections of the violations cited herein are expected to begin immediately. Please respond in writing within fourteen days of receipt of this correspondence regarding your remedy and implementation schedule in regards to the aforementioned violations. **A re-inspection will then be scheduled to verify and document your return to compliance with Ohio law. I would like to thank your staff for cooperating in this inspection.**

Ohio EPA is available to provide any training needs 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 Solid and Infectious Waste Management

Cc: Butler County Health Department -Chief of Environmental Services
Maria Lammers, Ohio EPA, SWDO-DSIWM

MB/plh

