



State of Ohio Environmental Protection Agency

Southwest District

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August 7, 2008

Mr. John McKinney
Director Facilities Mgmt Services
Atrium Medical Center
P.O. Box 8810
Middletown, Ohio 45042

**Re: Atrium Medical Center (IW REG# 09-G-00022), Butler County
Notice of Violation – Large Generator Inspection Correspondence**

Dear Mr. McKinney:

On July 24, 2008, Tracy Buchanan and I with the Ohio Environmental Protection Agency (Ohio EPA) met with you to conduct a comprehensive infectious waste large generator inspection of the newly opened Atrium Medical Center, Premier Health Partners (Facility), (prior operations were conducted at Middletown Regional Hospital) located in Middletown, Ohio. Darlene Fletcher, Environmental Services Manager and Charlene Kurtz, Infection Control Practitioner from Atrium Medical Center accompanied us during the inspection.

The purpose of this inspection was to determine compliance with Ohio's Infectious Waste Regulations. I inspected the infectious waste handling areas, infectious waste storage areas, spill kit and procedures, conducted a records review including treatment shipping paperwork, and checked for a valid registration certificate. The following areas of the hospital observed during this inspection were: Pathology storage, Central Service, Atrium Heart Center, Atrium Surgical Services, Emergency Trauma Center, Family Birth Center, Atrium Laboratory Patient Services, Outpatient EEG/EMG/EKG Medical Imaging/X-Ray, and Outpatient Lab Pre-Admission Testing Pulmonary Function.

1. Registration/Shipping Papers

Mr. McKinney and Ms. Fletcher assisted Ohio EPA during the review portion of the infectious waste treatment shipping paperwork and registration for the Facility during this inspection. A valid amended Ohio EPA Generator of Infectious Waste Certificate of Registration (Registration), generator registration number 09-G-00022 was on file, dated June 9, 2008. The Registration for this Facility was granted October 19, 2007; the Facility opened for patients on December 9, 2007, and the treatment shipping papers were on file from this date forward. Stericycle, Inc (Stericycle), transporter registration number 00-T-00199, was identified as the



Facility's Infectious Waste Transporter. The Facility is currently using the Biosystem™ for the management of sharps, and recently switched to the interlocking gray infectious waste totes for the handling of all additional red biohazard bagged waste. Ms. Fletcher informed us that a second amendment to the registration would be submitted in early September with the move of Atrium's comprehensive sports medicine and athletic training services from Middletown Regional Hospital to the new Atrium YMCA building on the Premier Health Campus-Middletown.

Upon review of the infectious waste treatment shipping papers for the Facility, I observed several white (original) copies had not been returned to the generator within the forty-five (45) day period as required by OAC Rule 3745-27-33(B)(6). In the files I found two (2) letters dated July 22, 2008 and July 23, 2008, that were sent to Stericycle from the Facility in attempt to obtain the documentation verifying treatment of waste picked up from the Facility on several different dates. These letters specifically identified several infectious waste treatment shipping papers that had not been returned to the Facility. Also, during my review I noted that three (3) white copies of the infectious waste treatment shipping papers had exceeded the forty-five (45) day return requirement. These manifest numbers were #5I6F, #5IJM, and #5EDY, however, proper documentation by the Facility was found in the file outlining the generator's efforts to locate the waste treatment information. The Facility informed us during this inspection that they have been having problems receiving the original shipping paper back from the treatment facility within the forty-five (45) day time period from the date of treatment as prescribed by OAC Rule 3745-27-33(B)(6), and as such a meeting was being held with Stericycle on Friday, July 25th to discuss these issues.

As discussed during the inspection, I also will be contacting Stericycle for their failure to return the original shipping papers within forty-five (45) days of treatment to the generator which is a violation of OAC Rule 3745-27-33(B)(6), (see attached letter to Stericycle). Please continue to document when the treatment shipping paperwork is not being properly returned to the Facility and notify Ohio EPA accordingly.

2. **Atrium Medical Center-Unit Inspections**

During the unit inspections, representatives from Ohio EPA were accompanied by John McKinney, Darlene Fletcher and Charlene Kurtz. In each of the specialized units of the Facility, the infectious waste handling areas, infectious waste storage areas, spill kit and procedures were inspected.



The primary storage area for the infectious waste from the Facility currently resides in a semi-trailer provided by Stericycle. This trailer is stationed at the loading dock as a means of final storage for infectious waste containers and the rolling racks containing the Biosystem™ sharps (see Figure 2). The Facility indicated that Stericycle conducts daily pick-ups of infectious waste, as the trailer is not a refrigerated unit (see Figure 1) no violations were observed in the storage trailers.

There are smaller temporary holding areas on each floor for infectious waste containers and sharps containers that are filled and need replaced. Depending upon the storage area size, clean containers may also be stored in the utility closet. According to the Facility, spill kits/procedures should also be located in the dirty utility room in every pod within each unit of the Facility, with the exception of the kits wall mounted in the inpatient lab and outpatient lab.



Figure 1: IW non-refrigerated outdoor Stericycle Trailer



Figure 2: Biosystem™ –reusable sharp containers

3. During the site inspection we met with Phyllis Costello, Manager of Laboratory Services and discussed the storage and disposal schedule of pathological waste. The proactive approach utilizing secondary containment of specimens (see Figure 3) created a fume free environment in the storage room and aided in the prevention of formalin spills within the storage room. Ms. Costello also indicated that the Facility is currently recycling and reusing the formalin for specimen preservation. The storage room was locked and was labeled with an international biohazard symbol (see Figure 4). There were no violations observed in this area.





Figure 3: Secondary containment of Pathological Specimens



Figure 4: Biohazard symbol /secured door

4. We conducted an inspection of the Atrium Heart Center. We observed a patient treatment room, infectious waste handling areas and we inspected the spill kit/procedures. There were no violations observed within this area.
5. We met with Connley Garrett, Manager of Central Services to observe the handling of infectious waste & equipment in Central Services. Through a system of clean/dirty elevators infectious waste and equipment is transported from the Family Birth Center, Operating Rooms, and LDR instead of transporting this material throughout the main walkways of the Facility. The dirty carts and equipment are washed and sterilized along with the wheel bases then returned for reuse, and the infectious waste is properly containerized for disposal. (See Figures 5, 6, 7, and 8). No violations were observed in this unit.



Figure 5: Equipment wash



Figure 6: Containerized infectious waste





Figure 7: Central Service area



Figure 8: Rolling wheel bases cleaned for reuse

6. We met with Becki Payne, R.N. of the Inpatient Surgical Center, and conducted an inspection of the patient treatment areas including the inpatient holding areas and operating room (OR) OR#1 where a procedure had just finished. In OR#1, sharps containers and infectious waste biohazard containers were in use and properly labeled, there was no unauthorized materials in the regular waste receptacles. There were no violations observed in OR#1.

Operating Room #1

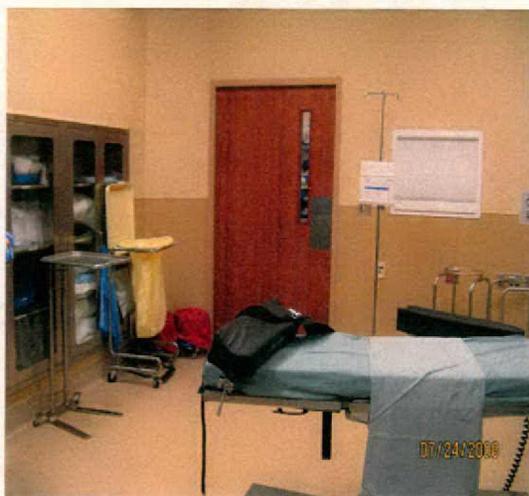


Figure 9: Kick buckets with red biohaz bags in OR1



Figure 10: OR1 in use sharps/biohaz containers





Figure 11: Neptune™ - fluid suction equipment in OR



Figure 12: Fluid container from OR



Figure 13: In use sharps container in OR

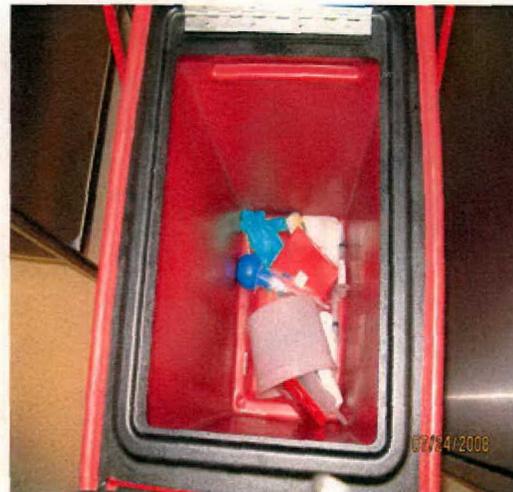


Figure 14: Materials in the OR sharps container

INPATIENT HOLDING AREA

I observed an eight (8) gallon step-on biohazard container in use without proper labeling (see Figure 15) in room number three (3) in the Inpatient Holding Area (see Figure 15, 16, and 17). As discussed failure to have the proper international biohazard symbol label on two (2) opposing sides of the infectious waste container is a violation of OAC Rule 3745-27-34(4)(a). The Facility indicated that labeling would be corrected on all of these containers throughout the Facility.



OAC Rule 3745-27-34(4)(a) states in part:

“Containers for infectious waste shall be at a minimum labeled with the international biohazard symbol on two opposite sides”.

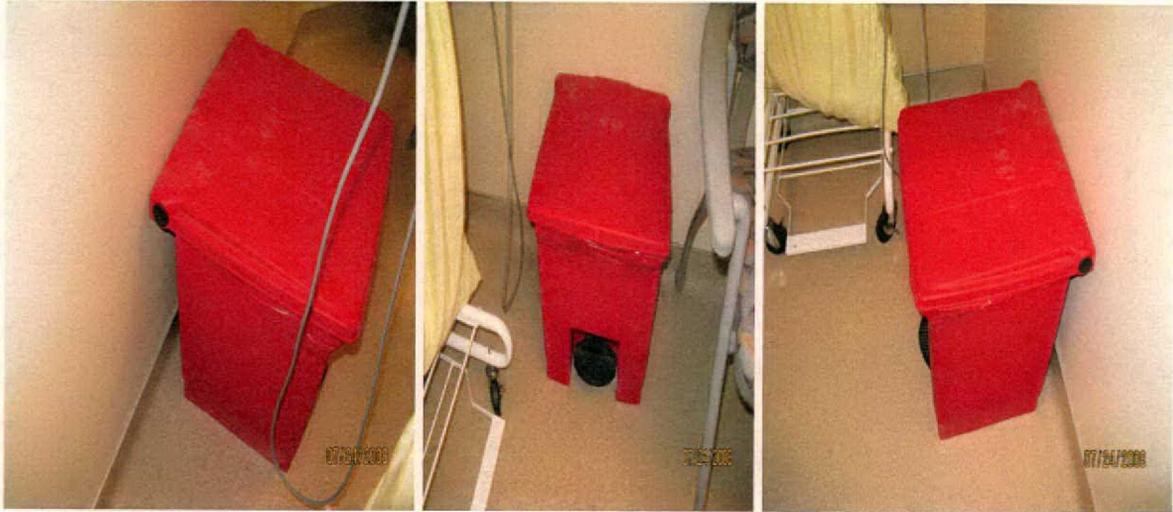


Figure 15(left), 16(center) & 17(right): 8-gal red step-on biohazard container in Inpatient Holding Room #3

7. We met with Lynda Fultz, Clinical Manager of the Family Birth Center and conducted an inspection of the spill kit/procedure and inspected patient care areas: a labor and delivery room, a recovery room and a triage room. Sharps containers and infectious waste biohazard containers were available in each room. The recovery bathroom was equipped with a red biohazard bag in an 8-gallon step on box for the management of peripads (see Figure 18). There were no violations observed in the labor/delivery/recovery rooms.



Figure 18: Infectious Waste container in the post-delivery recovery room bathroom



In Triage Room 3, the red step-on container for infectious waste was missing the red biohazard bag (see Figure 20). The Facility corrected this violation during our inspection.



Figure 19: Triage Room 3 sign



Figure 20: Missing red biohaz bag in Triage Rm#3

8. We met with Cynthia Griffith, Manager of the Inpatient Lab and conducted an inspection of the infectious waste and sharps handling areas, storage areas, and the infectious waste spill kit/procedure. During this inspection I observed fluorescent lamps in a sharps container (see Figure 21). During the inspection Cynthia Griffith, Manager of the Inpatient Laboratory indicated that this practice of placing bulbs in the sharp containers was due to the potential for the bulbs to become cross-contaminated by infectious waste (see Figure 21). As discussed during our inspection I consulted with the Division of Hazardous Waste Management on this issue and was provided the following comments.



Figure 21: Fluorescent bulbs from equipment in the lab in the sharps container



Division of Hazardous Waste Management's General Comment:

Atrium Medical Center should immediately stop disposing of lamps from medical equipment in their sharps containers. These lamps may exhibit a characteristic of hazardous waste (see OAC Rule 3745-52-11). Because the waste was generated by a business, you must comply with Ohio Administrative Code (OAC) Rule 3745-52-11.

OAC Rule 3745-52-11 states in part:

"Any person who generates a waste, as defined in 3745-51-02 of the Administrative Code, must determine if that waste is a hazardous waste."

Pursuant to OAC Rule 3745-50-10(A)(64), **"Lamp" or "universal waste lamp" means the bulb or tube portion of an electric lighting device. A lamp is specifically designed to produce radiant energy, most often in the ultraviolet, visible, and infra-red regions of the electromagnetic spectrum. Examples of common universal waste electric lamps include, but are not limited to, fluorescent, high intensity discharge, neon, mercury vapor, high pressure sodium, and metal halide lamps. Lamps that have been used and are being discarded are "spent materials" as defined in rule 3745-51-01 of the Administrative Code.**

To evaluate waste lamps, either you must have them tested at a laboratory or use knowledge based on information provided by the manufacturer or materials safety data sheets- known as an MSDS. The waste will need to be properly characterized in accordance with OAC Rule 3745-52-11, and if the waste is determined to be hazardous, it must be managed and disposed in accordance with applicable hazardous waste generator requirements found in OAC Chapter 3745-52.

If the lamps are hazardous and you don't manage them in your facility's current lamp recycling program as universal waste they must be managed under Ohio's Hazardous Waste Rules which can include storage requirements, manifesting, land disposal restrictions (LDR) determination and use of a hazardous waste transporter to ensure delivery to a permitted hazardous waste facility. If you have knowledge that the lamps are non-hazardous, then those lamps can either be recycled or disposed of with the business' regular trash. However, Ohio EPA prefers that the all lamps be recycled through your current lamp recycling system.

For additional information on the Universal Waste Rules, please find attached the following guidance documents: **"Fluorescent Lamps: What You Should Know"** and **"Universal Waste Rules for Handlers of Lamps"**.



Please note if an infectious waste is also considered a hazardous waste or is mixed with a hazardous waste, it must be managed according to Ohio's Hazardous Waste Rules and cannot be sent to an infectious waste treatment facility pursuant to OAC Rule 3745-27-30(C)(7).

Generators of infectious waste shall comply with OAC Rule 3745-27-30(C)(7) which states in part:

"Any infectious waste or infectious waste mixture that meets the definition of hazardous waste as specified in rule 3745-51-03 of the Administrative Code shall be managed as a hazardous waste in accordance with Chapters 3745-50 to 3745-69 of the Administrative Code. No generator of infectious waste shall transport, or cause to be transported, wastes deemed hazardous in accordance with rule 3745-51-03 of the Administrative Code to an infectious waste treatment facility licensed in accordance with section 3734.05 of the Revised Code".

Should you have any further questions regarding DHWM's comments on the Universal Waste Rules or Hazardous Waste Regulations and management please contact Jeff Smith at (937) 285-6070.

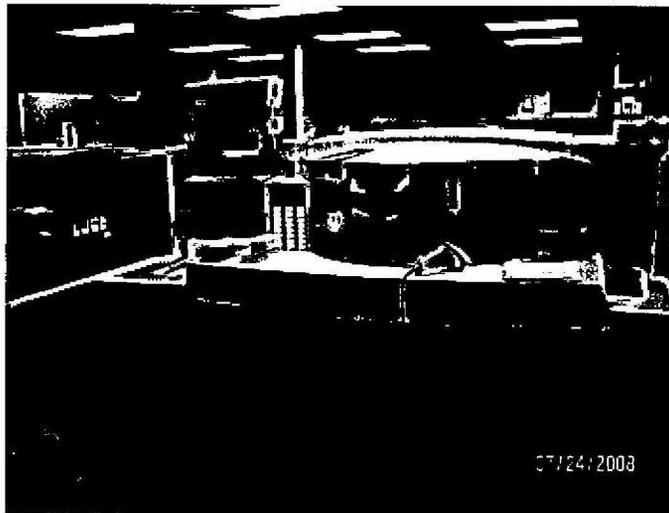


Figure 22: Infectious Waste bag/container in use next to Stream Lab™

Ms. Griffith indicated that the Inpatient Lab maintained a separate spill procedure which differed from the Facility's standard spill kit/procedure in both the material list and spill containment and cleanup procedures. The Inpatient Lab spill kit was missing the U.S. EPA Registered hospital disinfectant that is also a tuberculocidal (see Figure 23) as



prescribed in the Facility spill procedures. **This is a violation of OAC Rule 3745-27-30 (B)(11)(b).**

However, Ms. Kurtz indicated that this would be corrected and the missing materials and procedures would be placed in the spill kits within this laboratory. Please ensure that copies of the spill procedures are available with the spill kits along with all other required materials.

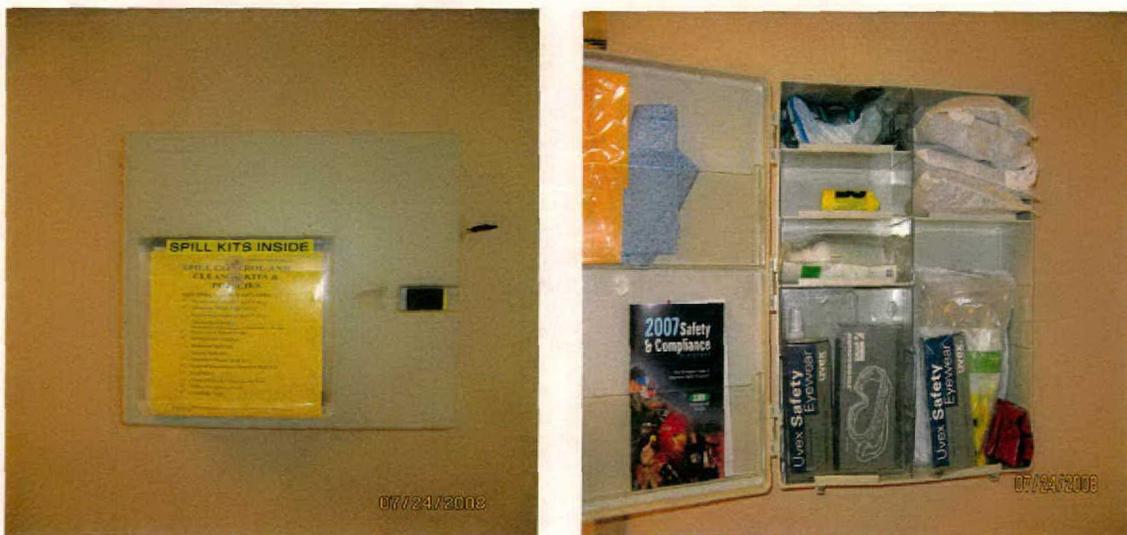


Figure 23: Spill kit in the Inpatient Lab

9. We met with Jim Kern, Clinic Nurse Manager of the Emergency Trauma Center and conducted an inspection of the patient treatment rooms for the management of infectious waste and sharps along with infectious waste storage area and infectious waste spill kit/procedures for the unit located in the clean work/meds room. The spill kit was missing the infectious waste cleanup materials packet as prescribed by the Facility's infectious waste spill clean-up procedure. The Facility corrected this violation during our inspection. We also discussed the Facility's procedure for management of sharps from incoming emergency responders. The Facility is accepting and managing these sharps as part of their own infectious sharp waste. No other violations were observed in this unit during this inspection.



10. We met with Sharon Baker, Director of Medical Imaging and conducted an inspection of the EEG/EMG/EKG Medical Imaging/X-Ray rooms for infectious waste and sharps management/storage. We also inspected the infectious waste spill kit/procedure for the unit. During our inspection no violations were observed.
11. We conducted an inspection of the Outpatient Lab, which included observing patient treatment rooms for the management of infectious waste and sharps along with infectious waste storage areas and infectious waste spill kit/procedures for the unit. The spill kit was missing a copy of the current infectious waste spill containment and clean-up procedure, which is a violation of OAC Rule 3745-27-30(B)(10). The Facility corrected the violation during our inspection as Mr. McKinney had a new spill kit and procedure installed in the Outpatient Lab during our inspection (see Figures 25 and 26).



Figures 25(Left) & 26(Right): Spill procedure & new spill kit installed in the Outpatient lab

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.

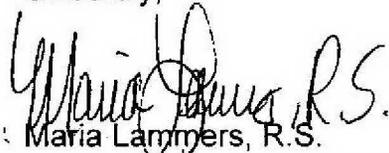
As such, corrections of the violations cited herein are expected to begin immediately. Please respond in writing within fourteen days of receipt of this correspondence regarding your remedy and implementation schedule in regards to the aforementioned



Atrium Medical Center, Butler County
Notice of Violation
Page 13 of 13

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 their time and cooperating during this inspection. If you have any questions, please contact me at (937) 285-6046.

Sincerely,



1 Maria Lammers, R.S.
Environmental Specialist II
Division of Solid and Infectious Waste Management

Enclosures: DHWM Guidance Documents: Fluorescent Lamps-What You Should Know
DHWM Guidance Document-Universal Waste Rules for Handlers of Lamps
Copy of the NOV issued by Ohio EPA to Stericycle Letter dated 8/1/08

CC: Darlene Fletcher, Environmental Services Manager, Atrium Medical Center
Charlene Kurtz, Infection Control Practitioner, Atrium Medical Center

ML/plh



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