

DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: Self Initiated Inspection

E223627652

FACILITY: Allegiance Health		SRN / ID: E2236
LOCATION: 205 N East Ave, JACKSON		DISTRICT: Jackson
CITY: JACKSON		COUNTY: JACKSON
CONTACT: Jamie Ferrie , Materials Handling - Plant Engineering		ACTIVITY DATE: 10/07/2014
STAFF: Sersena White	COMPLIANCE STATUS: Compliance	SOURCE CLASS:
SUBJECT: Inspection to determins regulatory status of non-permitted sterilizers and to evaluate compliance with the permitted sterilizers.		
RESOLVED COMPLAINTS:		

SRN: E2236

Facility Name: Allegiance Health

Facility Address: 205 East Avenue, Jackson, MI 49201

Facility Contacts: George J. Gancsos, Jr. Director, Plant Engineering

Jamie Ferrier: Materials Handling – Plant Engineering

Dan Ellenwood: ETO Maintenance

Phil Tilford: CSP Manager (Clean Sterile Processing)

Jacob Bollinger: Boiler Operation & Maintenance

Facility Contact E-mails: George.gancsos@AllegianceHealth.org, Dan.Ellenwood@Allegiancehealth.org,Jamie.Ferrier@AllegianceHealth.org, Philip.Tilford@AllegianceHealth.org,Jacob.Bollinger@AllegianceHealth.org

Introduction: Allegiance Health is a hospital complex with several buildings located in Jackson, Michigan. It was formerly known as Foote Hospital when the permit to install was issued. Allegiance Health is a community-owned, locally-governed health system in Jackson, Michigan.

Purpose of the Inspection: As a result of a FOIA request, it was discovered that a permit to install was issued for two Ethylene Oxide Sterilizers on March 20, 1996. AQD attempted to confirm whether these units were still in operation by phone calls and e-mails. On October 6th, 2014, a site visit was scheduled to evaluate the compliance status of the ethylene oxidizers for the following day. AQD also intends to evaluate the Federal regulatory requirements of the Ethylene Oxide Sterilizers and four boilers in use at the facility.

Previous Inspection: Based upon the last inspection conducted on September 13, 2001, by Rob McLeod, the incinerator which was permitted under 17-811 has been removed. The four boilers are listed as exempt from requiring a permit to install, and the remaining permitted equipment is three ethylene oxide sterilizers under permit 395-95. The permit was originally for 3 units. A handwritten notation was made on the permit to reflect that there are only 2 units based on a letter dated November 9, 1995, stating that the 3M Model No. 400B will be removed from service.

The installation of a 3M Donaldson 50 CFM ethylene oxide abator was completed on June 21, 1996.

The units identified during the inspection were as follows: The model 400B sterilizer was installed in 1983; the model 4XL in July 1990; and the 5XL in September 1992. The dedicated exhaust point is located on top of the hospital's roof at fan #E-2. It was noted that one of the sterilizers had been taken out of operation. The conclusion of the inspection was that the facility was operating in compliance with applicable Air Quality requirements.

Inspection:

On October 7, 2014, I arrived at approximately 10:26 a.m. I had to use an intercom to gain access to the maintenance area. I introduced myself and the person I was to meet with.

As a result of corresponding with Jamie Ferrier, she mentioned that there were other sterilizers in use at the hospital, and they wanted assistance in determining if a permit is needed. I also told her that I would bring the current permit and evaluate compliance with it based on the operation of the remaining ethylene oxide sterilizer. Before beginning the inspection, I gave her an Inspection brochure and she made copies of the permit and a description of the Ethylene Oxide Sterilization Process (from www.eurotherm.com/industires/life-

sciences/applications/eto-sterilization/) which I brought so that I could better understand the process. Other research information on ethylene oxide sterilizers is attached to this inspection report.

Ethylene Oxide Sterilizer (PTI 395-95)

Phil Tilford is the Manager of Clean Sterile Processing (CSP), which is where the emission unit is installed and operated. A gown and hair net is required before entering this secure dedicated area to prevent contamination to materials inside the area.

The only unit left operating in this permit is the 5XL STERI-VAC manufactured by 3M. Instructions for operation are posted on the unit. Dan told me that he changes the filter cartridge (catalytic abatement system) on this unit on a maintenance schedule. The change is made from a roof top location inside a small enclosure they refer to as the dog house/club house. The exhaust point appears to meet the 10 inch diameter and not less than 48 feet above ground level requirements.

They keep records of the number of loads per day. They can only process one load per day because each load takes 16 hours to process. They also have to keep records of all equipment sterilized for legal purposes.

The permitted emission rates are 0.01 ounces per hour, nor 5.2 ounces per year based on a 12 month rolling time period. These limits are based upon four loads per day, 365 days per year using two sterilizers.

The Ethylene oxide single dose cartridges are ordered in 100 gram (3.527 ounce) size. When the door is closed on the sterilizer, the cartridge releases the gas at the proper time in the cycle. Since they are only operating one sterilizer, with only one load per day, the emissions are well below the allowed limit. The catalytic abatement system has a control efficiency of 99.9% by weight according to the literature from 3M's website. This unit can operate using a warm cycle which is approximately 5.75 hours or a cool cycle, which is approximately 7.75 hours based upon literature from 3M's website. The time that the ETO gas injection occurs is only part of the 16 hour cycle.

The permit required weekly records of sterilant usage, before the installation and operation of the catalytic abatement system. The permit also required that the catalytic abatement system be installed and operated properly on and after July 1, 1996. Since these events occurred over 17 years ago, no records were requested.

No testing has been required to date.

A bar code system is used by Allegiance to track material usage and maintenance activities. Dan provided me with a copy of the ETO maintenance record for February 6, 2012 at the time of the inspection. The records indicate a minus number from inventory to track the number of cartridges used and a monthly total.

There is a Federal National Emission Standard for Hazardous Air Pollutants (NESHAP) Subpart WWWWWWW which regulates Hospital Sterilizers using Ethylene Oxide. This regulation has not been delegated to the State of Michigan for compliance. A copy of the FACT SHEET information was provided during e-mail communications during inspection follow-up.

The other sterilizers identified by Allegiance's bar code system are: 100-3399 (No. 4), 100-6032 (No. 5) and 100-6031 (No. 6) are located in CSP and use steam as the cleaning agent. There are two more steam sterilizers referred to as the Surgery Flash sterilizers identified as 100-3942 and 100-3941. There is a cart washer in CPS that does not have a bar code and uses a disinfectant as the cleaning agent.

These units are exempt from requiring a permit to install under Rule 281(i) – Sterilization equipment at medical and pharmaceutical facilities using steam, hydrogen peroxide, peracetic acid, or a combination thereof.

Boilers:

There are four natural gas fired boilers at Allegiance Heath which are identified in the table below:

Boiler Number ID	Boiler Manufacturer	Boiler Install Date	Boiler Heat Input
No. 1	Cleaver Brooks	September 19, 1972	14,645,000 Btu per hour
No. 2	Cleaver Brooks	September 20, 1972	14,645,000 Btu per hour
No. 3	Cleaver Brooks	December 3, 1970	14,645,000 Btu per hour
No. 4	Hurst	Late 2005	16,732,500 Btu per hour

Based upon the heat input capacity of the boilers, they are exempt from requiring a permit to install under Rule 282(b)(i) – Fuel-burning equipment which is used for space heating, service water heating, electric power generation, oil and gas production or processing, or indirect heating and which burns only the following fuels: Sweet natural gas, synthetic gas, liquefied petroleum gas, or a combination thereof and the equipment has a rated heat input capacity of not more than 50,000,000 Btu per hour.

Boilers No. 1 through No. 3 use No. 2 fuel oil as a back-up fuel and each one is tested once per day per month on a rotating basis. Per follow-up with Jacob on November 10, 2014, the boilers are operated approximately 30 minutes using fuel oil, and visible emissions observations are concurrent with the operation.

These boilers are not subject to any Federal regulations since Allegiance Health would be categorized as an area source and the boilers only burn natural gas. See attached FACT SHEET – Final Air Toxics Standards for Industrial, Commercial, and Institutional Boilers at Area Source Facilities

These boilers are not subject to 40 CFR 63 National Emission Standards for Hazardous Air Pollutants for Area Sources: Industrial, Commercial, and Institutional Boilers; Final Rule

Based upon my observations and review of the records, Allegiance Health is complying with the requirements of the permit and the permit exemptions.

Attachments: Information about ETO Sterilizers, including Federal FACT SHEET & Summary, Information about Boiler Federal Requirements FACT SHEET, records of ETO maintenance and ETO cartridge usage on a monthly basis.

NAME *Suzanne M. White* DATE *11-10-2014* SUPERVISOR *[Signature]*

