

DEPARTMENT OF ENVIRONMENTAL QUALITY  
AIR QUALITY DIVISION  
ACTIVITY REPORT: Scheduled Inspection

N077531913

FACILITY: TERUMO CARDIOVASCULAR SYS.	SRN / ID: N0775
LOCATION: 6200 JACKSON RD, ANN ARBOR	DISTRICT: Jackson
CITY: ANN ARBOR	COUNTY: WASHTENAW
CONTACT: Steven Carter, Facility Engineering Manager	ACTIVITY DATE: 10/22/2015
STAFF: Zachary Durham	COMPLIANCE STATUS: Compliance
SUBJECT: Scheduled, unannounced inspection of permit exempt processes.	SOURCE CLASS: MINOR
RESOLVED COMPLAINTS:	

### Contacts

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### Purpose

This was a scheduled inspection of permit exempt sources located on site at Terumo in Ann Arbor, MI. I arrived at about 9:30am on 10/22/15. I met with Steven Carter and Dave Cotton after signing in at the front desk. The previous contact, Greg Dubiel, is now in a different position within the company.

### Background

The facility houses processes that manufacture and repair critical life support systems used in hospitals around the world. This facility was last inspected in 2010 by Glen Erickson and was determined to be in compliance. They have since removed all processes that would have potential air emissions, except for a small paint booth, which is used to coat metal casing components of their instruments. They do also use a small steam heating boiler not previously commented on in past inspection reports.

Steve informed me that they have not been in production for about 4 years due to a consent decree they have entered into with the FDA. The only production operations they are currently running are electromechanical, which includes assembly of ~40 new units per month as well as refurbishing and routine maintenance of others. He indicated that their main product is a blood gas monitor used during surgeries.

To clarify any uncertainty, the processes and equipment outlined in the 9/19/2008 inspection report that are no longer installed include the flow soldering operation, blood access clean room, Heprin coating process, and the X Coating process. These have all been removed.

### Compliance Evaluation

The only processes now left on site that are a concern of the Air Quality Division are the small paint booth and the steam heating boiler. The paint booth appeared to be well maintained with filters installed and changed as needed. Steve showed me the two part epoxy paint they use at less than 10 gallons per month. They purchase the Polane HAPs Free Reducer and polyurethane enamel in one gallon buckets. They are well below the 200gal/month limit described under Rule 287(c). The coating is still applied via a HPLV spray gun.

The steam heat boiler had a boiler nameplate heat input capacity of 6,277,000 BTU/hr (~6.3 mmbtu/hr). This is well below the 50 mmbtu/hr described in permit exemption rule 282(b)(i). I provided Steven and Dave with a copy of the boiler MACT card for help with any future questions they should have on the subject.

### Summary

After the facility tour and discussions with Steven and Dave about the company's current operational status, I have determined they are in compliance with air regulations.

Terumo is in a limited production capacity at the moment, and unless that changes I recommend that this facility remain on a long intermittent inspection schedule.

NAME Jack Durbin

DATE 10/23/15

SUPERVISOR [Signature]