

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

P083642750

<b>FACILITY:</b> Orchid Orthopedic Solutions		<b>SRN / ID:</b> P0836
<b>LOCATION:</b> 23149 Commerce Drive, FARMINGTN HLS		<b>DISTRICT:</b> Southeast Michigan
<b>CITY:</b> FARMINGTN HLS		<b>COUNTY:</b> OAKLAND
<b>CONTACT:</b> Jim Diroff , Director		<b>ACTIVITY DATE:</b> 11/15/2017
<b>STAFF:</b> Robert Joseph	<b>COMPLIANCE STATUS:</b> Compliance	<b>SOURCE CLASS:</b> MINOR
<b>SUBJECT:</b> Self-Initiated Inspection		
<b>RESOLVED COMPLAINTS:</b>		

On Wednesday, November 15, 2017, I, Michigan Department of Environmental Quality-Air Quality Division staff Robert Joseph, conducted an unannounced inspection of Orchid Orthopedic Solutions located at 23149 Commerce Drive, Farmington Hills, Michigan. The purpose of the inspection was to determine the facility's compliance with the requirements of the Federal Clean Air Act; Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 Public Act 451, as amended (Act 451); Michigan Department of Environmentally Quality-Air Quality Division (MDEQ-AQD) Administrative Rules.

Upon arrival at approximately 10:30am I met with the facility director, Jim Diroff, and the plant manager, Walt. I introduced myself and presented my identification and credentials and stated the purpose of my visit. Jim and Walt led me into the facility and I toured the facility's operations. I last visited the facility in July 2017 due to an odor complaint. An investigation of the odor resulted in the facility receiving a violation notice regarding Rule 901 (Air Contaminant) and Rule 910 (Air Cleaning Devices).

Jim is the new director of the facility and took over for Mark Olsen who transferred to another Orchid facility. Jim gave me a tour of the facility and explained the facility's processes. Both Jim and Walt indicated they were still getting more familiar with the facility's operations. The facility coats metal orthopedic implants used for patient surgery, and operates 20 hours a day at 7 days a week with approximately 150 employees.

Once the facility receives shipment of the orthopedic implants they are sanitized and recorded for measurement and usage. There are approximately 20 stations in which the medical implants are sterilized with a combination of isopropyl alcohol and deionized water, and then its dimensions are measured by employees at individual work stations. Once this process is completed the parts are then coated with Titanium powder. The facility has two Titanium Plasma Spray (TPS1 and TPS2) units which spray heated Titanium powder onto the orthopedic metal parts to provide a coating.

The powder is injected into the unit after being subject to a very high temperature plasma flame with the assistance of Argon gas as a facilitator. Argon gas is inert and is used to create the heat source. The heated powder immediately coats the metal implant. Part type and size determine the number of parts that can be sprayed at once. The Argon gas is housed outside the facility in a large storage tank and is filled via a pump when the gas supply decreases. The TPS1 unit was not operating due to maintenance issues. The TPS1 unit previously had a damaged filter causing an odor disturbance within the residential neighborhood. As previously mentioned, an odor investigation was conducted and the facility received a violation notice. In their response, the facility indicated the odor was due to a damaged filter. They also voluntarily agreed to install a secondary oil mist filter as a precautionary measure to prevent against a future odor incident.

A cartridge filter is connected to each unit and is changed approximately monthly. Prior to installing a this secondary filter, the facility was unable to detect if a filter was damaged during the process due to its enclosure within the unit. The filter is designed to capture particulates and smoke associated with the process. If the filter is damaged, the process then emits a plume of white smoke through the stack

resulting into an odor nuisance. Therefore, installing this secondary filter should prevent this from occurring. I also suggested to Jim that frequent inspections be made into the filter housing in-between filter changes.

The facility also has one robotic plasma spray unit which vents into the general plant environment. This unit connects to a dust collector. This dust collector was previously located outside the facility and caused a noise disturbance in the residential area. The dust collector has now been relocated inside the facility and captures the residual powder from the process. The dust collector shakes the residual powder from the process into the base of the unit onto the filters. The filters are changed periodically with no set time interval. As the filters become clogged the residual powder exits the dust collector and begins to collect around the unit on the floor of the facility. I witnessed some visible matter around the unit and suggested more frequent filter changes.

This concluded my inspection of the facility. I thanked both Jim and Walt for their time and I left the facility.

The plasma coating spray process is an exempt process per R 336.1285 Permit to install exemptions; miscellaneous. The rule in-part states;

Rule 285. (1) This rule does not apply if prohibited by R 336.1278 and unless the requirements of R 336.1278a have been met.

(2) The requirement of R 336.1201(1) to obtain a permit to install does not apply any of the following:

(i) Brazing, soldering, welding, or plasma coating equipment.

The sterilization of the medical implants with the use of isopropyl alcohol is exempt per R 336.1290 Permit to install exemptions; emission units with limited emissions. The rule in-part states;

Rule 290. (1) This rule does not apply if prohibited by R 336.1278 and unless the requirements of R 336.1278a have been met.

(2) The requirement of R 336.1201(1) to obtain a permit to install does not apply to any of the emission units listed in subdivision (a) of this subrule, if the conditions listed in subdivisions (b), (c), (d), and (e) of this subrule are met. Notwithstanding the definition in R 336.1121(a), for the purpose of this rule, uncontrolled emissions are the emissions from an emission unit based on actual operation, not taking into account any emission control equipment. Controlled emissions are the emissions from an emission unit based on actual operation, taking into account the control equipment. (a) An emission unit which meets any of the following criteria:

(i) Any emission unit that emits only non-carcinogenic volatile organic compounds or non-carcinogenic materials that are listed in R 336.1122(f) as not contributing appreciably to the formation of ozone, if the total uncontrolled or controlled emissions of air contaminants are not more than 1,000 or 500 pounds per month, respectively.

Based on the facility's usage of 300 gal/mo. with a material density of 6.56 lb/gal (786 kg/m<sup>3</sup>), it was calculated that the facility uses 652 lbs/mo. per coating spray for each of the 3 emission units (totaling 1,956 lbs/mo). This is less than the 1,000 lb. limit for uncontrolled emissions of air contaminants.

NAME Robert Joseph DATE 12/20/17 SUPERVISOR SK