

A5290
 FY 2017 Insp

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

A529041333

FACILITY: FERNDAL LABORATORIES INC		SRN / ID: A5290
LOCATION: 780 W EIGHT MILE RD, FERNDAL		DISTRICT: Southeast Michigan
CITY: FERNDAL		COUNTY: OAKLAND
CONTACT:		ACTIVITY DATE: 08/16/2017
STAFF: Iranna Konanahalli	COMPLIANCE STATUS: Compliance	SOURCE CLASS: MINOR
SUBJECT: FY 2017 inspection of Ferndale Laboratories, Inc.		
RESOLVED COMPLAINTS:		

A5290 - SAR - 2017 08 16

Ferndale Laboratories, Inc. (A5290)
 Parent company: Ferndale Pharma Group, Inc.
 780 West Eight Mile Road
 Ferndale, Michigan 48220-2422

Subject to existing Area source NESHAP / MACT ZZZZ / MACT 4Z / RICE MACT, Standards of Performance for Stationary Spark Ignition Internal Combustion Engines and National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines / Final rule (Page 3568, Federal Register / Vol. 73, No. 13 / Friday, January 18, 2008 / Rules and Regulations / Final rule; Page 51570 Federal Register / Vol. 75, No. 161 / Friday, August 20, 2010 / Rules and Regulations / Final rule; Page 12863 Federal Register / Vol. 76, No. 46 / Wednesday, March 9, 2011 / Rules and Regulations / Direct final rule; amendments for August 20, 2010, final rule; Page 6674 Federal Register / Vol. 78, No. 20 / Wednesday, January 30, 2013 / Rules and Regulations / Final rule. Page 48072 Federal Register / Vol. 79, No. 158 / Friday, August 15, 2014 / Rules and Regulations / Notice of final decision on reconsideration. etc.). AQD has no delegation of these standards and therefore no attempt has been made evaluate Ferndale's compliance with NESHAP / MACT 4Z. Besides, SI RICE produces only 20 kW of power. Compliance with NSPS 4J is deemed compliance with MACT 4Z

Emergency generator is subject to (73 FR 3591, January 18, 2008, 76 FR 37972 June 28, 2011, 78 FR 6697 January 30, 2013): NSPS 4J, 40 CFR, Part 60, Subpart JJJJ— Standards of Performance for Stationary Spark Ignition Internal Combustion Engines (natural gas fired Spark Ignition). The provisions of NSPS 4J are applicable to owners and operators and manufacturers. Owners or operators of Emergency SI RICE are subject to this NSPS 4J if engine is manufactured after January 1, 2009, emergency engines greater than 19 kW (25 HP) engine power. GENRAC Guardian Series Model No. 0058751 Serial No. 6833287: Installed in April 2012. 20 kW (> 19 kW / 25 HP) - Natural Gas. This engine is subject to NSPS 4J.

On August 16, 2017, I conducted a level-2 self-initiated FY 2017 inspection of Ferndale Laboratories, Inc. ("Ferndale Labs"), a drug / pharmaceutical manufacturing company, located at 780 West Eight Mile Road, Ferndale, Michigan 48220-2422. The inspection was conducted to determine compliance with the Federal Clean Air Act; Article II, Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994, PA 451; Michigan Department of Environmental Quality, Air Quality Division (MDEQ-AQD) administrative rules.

During the inspection, Ms. Cecile Cruz (Phone: 248-548-0900-ext. 522; Fax: 248-548-0470; E-mail: cCruz@FerndaleLabs.com), Regulatory Affairs Specialist, Ms. Lori Sloane (Phone: 248-548-0900-ext. 628; Fax: 248-548-0470; E-mail: LSloane@FerndaleLabs.com), Associated VP Manufacturing, and Mr. Bill Allen (Phone: 248-548-0900-ext. 628; Fax: 248-548-0470; E-mail: bAllen@FerndaleLabs.com), Facilities Engineering Supervisor, assisted me.

Ms. Sarah Van Hoof (Phone: 248-548-0900-ext. 467), Manager of Regulatory Affairs, was present. Mr. Richard Hamer (Phone: 248-586-8433; E-mail: rhamer@ferndalelabs.com), Director, Regulatory Affairs, did not participate.

Mr. Dave Missovich (Phone: 248-548-0900-ext. 521; E-mail: dmissovich@ferndalelabs.com), Safety Coordinator, separated about February 2014. Mr. Harvey Finzel (Phone: 248-548-0900-ext. 562; E-mail: hfinzel@ferndalelabs.com), Facilities Director, also separated about February 2014.

Ferndale Labs (part of Ferndale Pharma Group, a privately held group of Specialty Health Care Companies), with 100,000 sq. ft. FDA-approved facility manufactures drug products and medical devices, such as creams, lotions, ointments, liquid adhesives (devices), etc. It also performs contract manufacturing. Ferndale Labs has 140 (Aug 2017: reduced from 170 due to 2014 reorganization) employees.

Bottle filling and packaging lines (Room 126, HEPA #1)

One bottle filling line for liquid adhesives devices is present. Two product-filling machines to fill into the tubes --creams, lotions and ointments-- are present. One carton-filling machine to package products is present. One automated tube-filling machine with cartoning system for creams, lotions and ointments is present. All these machines use the building ventilation with HEPA filter (HEPA #1); i.e., there is no dedicated ventilation system. The HEPA filters are replaced once in five years. FDA regulated clean room conditions are maintained using HEPA filters.

Weighing room (Room 118, HEPA #3)

One weighing room is present. Solids, liquids are weighed and sent to the manufacturing area. The room is equipped with HEPA Filter (HEPA #3) to control dust. The filter system is equipped with a Magnehelic Pressure Monitoring Device. Filtered air is recycled into the room. The HEPA filters are replaced once in five years. The room is exempt from Rule 336.1201 (Permit-to-Install) pursuant to Rule 336.1285.

Raw materials staging room and mixers (Room Nos. 119, 123, 134, 135, 136, HEPA #2 & HEPA #3)

One raw materials staging room (Room 119: manual compounding room) is present. One 150-gallon (Room 136), one 400-gallon (Room 135) and one 40-gallon (Room 134) mixers are present. Mixers are used to make creams, ointments and lotions. 40-gallon mixer is hardly used.

The rooms are equipped with HEPA Filter (HEPA # 2 & 3) to control dust. Rooms 134, 135 and 136 are covered by HEPA #2. The filter system is equipped with a Magnehelic Pressure Monitoring Device. Filtered air is recycled into the room. The HEPA filters are replaced once in five years. The room is exempt from Rule 336.1201 (Permit-to-Install) pursuant to Rule 336.1285.

Raw materials staging room (Room 111, HEPA #3)

One raw materials staging room is present. Also, it is equipped with Donaldson Torit HEPA filter (idle on Aug 16, 2017). The filter system is equipped with Magnehelic pressure monitoring device. The filters are replaced once in five years.

The rooms are equipped with HEPA Filter (HEPA #3) to control dust. The filter system is equipped with a Magnehelic Pressure Monitoring Device. Filtered air is recycled into the room. The filters are replaced once in five years. The room is exempt from Rule 336.1201 (Permit-to-Install) pursuant to Rule 336.1285.

Tank storage room (Room 122, HEPA #2)

One tank storage room is present.

The room is equipped with HEPA Filter (HEPA #2) to control dust. The filter system is equipped with a Magnehelic Pressure Monitoring Device. Filtered air is recycled into the room. The HEPA filters are replaced once in five years. The room is exempt from Rule 336.1201 (Permit-to-Install) pursuant to Rule 336.1285.

Ultra-pure water

One RO / CDI system (US Filter Co.) for ultra-pure water is present.

Because topical drugs are manufactured clean room standards are applied to the manufacturing areas. FDA frequently inspects Ferndale Labs.

Roof-top HEPA filters

Three banks (Nos. 1, 2 & 3) of HEPA filters are present on the roof-top. These filter systems provide dust control services to all process areas. Each filter system is equipped with a Magnehelic Pressure Monitoring Device. The HEPA filters are replaced once in five years. After filtration of dust using HEPA filters, cleaned air is recycled into the plant in both heating (winter) and cooling (summer) seasons. Outside ambient air as fresh make-up air is introduced into the process areas upon cleaning with HEPA filters. Ferndale Labs maintains FDA clean room standard. Hence, the building air purged, in order to prevent sick building syndrome, is cleaner than outside ambient air.

In order to save costs on expensive HEPA filters, two layers of pre-filters that are progressively finer are installed. While the pre-filters (two layers) are replaced once in 6 months, the HEPA filters, as stated before, are replaced once in five years.

Emergency generator (NG fired SI ICE)

On roof top one natural gas fired emergency generator (20 kW) is present. This is natural gas fired spark ignition (SI) reciprocating internal combustion engine (RICE). SI RICE was installed about April 2012 (Manufacture date NA).

- GENRAC Guardian Series Model No. 0058751 Serial No. 6833287
- Rated capacity: 20 kW

- Non-resettable hours meter is present. Oct 07, 2014 reading: 69.1 hours. Aug 16, 2017 reading: 103.4 hours.
- Maintenance schedule (1/yr.) for oil and filter change is present.

The NG fired SI RICE is subject to NSPS 4I, 40 CFR, Part 60, Subpart JJJJ—Standards of Performance for Stationary Spark Ignition (SI) Internal Combustion Engines (ICE) for engines of power greater than 19 kW (25 hp) manufactured after January 1, 2009.

Pursuant to 40 CFR, 60.4230(c), Ferndale Labs is not required to obtain Title V / RO Permit.

During the inspection, I asked Ferndale Labs to obtain an emission certificate (US EPA) from the vendor. Ms. Cecile Cruz of Ferndale Labs submitted a US EPA certificate (Certificate No. CGNXB.9992ST-036) via August 30, 2017 e-mail (Wed 8/30/2017 10:39 AM; Cruz, Cecile CCruz@ferndalelabs.com)

Certified stationary internal combustion engine means an engine that belongs to an engine family that has a certificate of conformity that complies with the emission standards and requirements in this Part 60, or of 40 CFR Part 90, 40 CFR Part 1048, or 40 CFR part 1054, as appropriate.

GENRAC Guardian SI RICE is subject to existing Area source NESHAP / MACT ZZZZ / MACT 4Z / RICE MACT, Standards of Performance for Stationary Spark Ignition Internal Combustion Engines and National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines / Final rule (Page 3568, Federal Register / Vol. 73, No. 13 / Friday, January 18, 2008 / Rules and Regulations / Final rule; Page 51570 Federal Register / Vol. 75, No. 161 / Friday, August 20, 2010 / Rules and Regulations / Final Rule; Page 12863 Federal Register / Vol. 76, No. 46 / Wednesday, March 9, 2011 / Rules and Regulations / Direct final rule; amendments for August 20, 2010, final rule; Page 6674 Federal Register / Vol. 78, No. 20 / Wednesday, January 30, 2013 / Rules and Regulations / Final rule. Page 48072 Federal Register / Vol. 79, No. 158 / Friday, August 15, 2014 / Rules and Regulations / Notice of final decision on reconsideration, etc.). AQD has decided not to take delegation of these standards and therefore no attempt has been made evaluate Ferndale's compliance with NESHAP / MACT 4Z. Besides, SI RICE produces only 20 kW of power during electric power supply interruptions.

There are three regulations that apply to Reciprocating Internal Combustion Engines (RICE), depending on the type of engine and the date of construction: the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Stationary RICE, New Source Performance Standards (NSPS) for Stationary Compression Ignition (CI) Engines and NSPS for Stationary Spark Ignition (SI) Engines. Some engines will be subject to both the NESHAP and one of the NSPS rules. If an engine is a dual fuel engine, i.e. one that burns both natural gas and diesel, then, for the purposes of these rules, the engine is considered CI if 2% or more of the energy is obtained from burning diesel in the engine on an annual average.

NSPS 4J applies to new, modified and reconstructed SI engines. For the NSPS for SI engines, RICE is a new source if:

1. it was ordered after June 12, 2006 and manufactured on or after:
 - July 1, 2007 if ≥ 500 hp (except lean burn $500 \leq \text{hp} < 1,350$);
 - January 1, 2008 if < 500 hp; or
 - January 1, 2009 (if emergency) > 25 hp; OR
2. if it was modified/reconstructed after June 12, 2006.

Focus is on criteria pollutants (VOC, NOx, PM, CO, SO2). 25 July 1, 2008):

Boilers

One Cleaver Brooks CB Package Boiler (Model C-8700-100, 150 psi steam, 4.1 MMBTU per hour, NG only, installed on March 14, 2003) process boiler and one Cleaver Brooks CBH Package Boiler (2 MMBTU per hour, NG only) hot water boiler are present. The boilers are exempt from Rule 336.1201 pursuant to Rule 336.1282(b) and NSPS Dc ($<< 10$ MM BTU / hour).

Conclusion

The manufacturing processes are exempt from Rule 336.1201 (Permit-to-Install) pursuant to either Rule 336.1285 or Rule 336.1290. All HEPA filters must work properly in order to qualify for FDA clean room.

NAME

J. Mennerhall

DATE

09/01/2017

SUPERVISOR

John B.

Konanahalli, Iranna (DEQ)

From: Cruz, Cecile <CCruz@ferndalelabs.com>
Sent: Wednesday, August 30, 2017 10:39 AM
To: Konanahalli, Iranna (DEQ)
Cc: Sloane (Wash), Lori; Allen, Bill
Subject: generator engine emissions certificate
Attachments: GeneracEPACertificate.pdf

Good Morning Mr. Konanahalli,

Attached as per your request is the emissions certificate for the generator engine as supplied by the manufacturer, please let me know if there is anything else needed.

Thank you,
Cecile

Cecile Cruz

Regulatory Affairs
Ferndale Laboratories, Inc.
780 W Eight Mile Rd.
Ferndale, MI 48220
248.548.0900 ext 522
248.548.4790 fax
ccruz@ferndalelabs.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
2012 MODEL YEAR
CERTIFICATE OF CONFORMITY
WITH THE CLEAN AIR ACT OF 1990

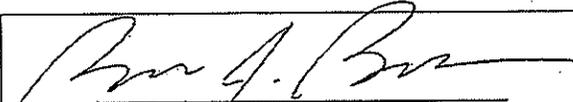
OFFICE OF TRANSPORTATION
AND AIR QUALITY
ANN ARBOR, MICHIGAN 48105

Certificate Issued To: Generac Power Systems, Inc.
(U.S. Manufacturer or Importer)

Certificate Number: CGNXB.9992ST-036

Effective Date:
11/18/2011

Expiration Date:
12/31/2012


Byron J. Bunker, Acting Division Director
Compliance Division

Issue Date:
11/18/2011

Revision Date:
N/A

Manufacturer: Generac Power Systems, Inc.
Engine Family: CGNXB.9992ST
Certificate Number: CGNXB.9992ST-036
Certification Type: Stationary (Part 60)
Fuel : Natural Gas (CNG/LNG)
Emission Standards : HC + NOx (g/kW-hr) : 13.4
NMHC + NOx (g/kW-hr) : 13.4
CO (g/kW-hr) : 519
Emergency Use Only : Y

Pursuant to Section 213 of the Clean Air Act (42 U.S.C. section 7547) and 40 CFR Part 60, 1065, 1068, and 60 (stationary only and combined stationary and mobile) and subject to the terms and conditions prescribed in those provisions, this certificate of conformity is hereby issued with respect to the test engines which have been found to conform to applicable requirements and which represent the following nonroad engines, by engine family, more fully described in the documentation required by 40 CFR Part 60 and produced in the stated model year.

This certificate of conformity covers only those new nonroad spark-ignition engines which conform in all material respects to the design specifications that applied to those engines described in the documentation required by 40 CFR Part 60 and which are produced during the model year stated on this certificate of the said manufacturer, as defined in 40 CFR Part 60. This certificate of conformity does not cover nonroad engines imported prior to the effective date of the certificate.

It is a term of this certificate that the manufacturer shall consent to all inspections described in 40 CFR 1068.20 and authorized in a warrant or court order. Failure to comply with the requirements of such a warrant or court order may lead to revocation or suspension of this certificate for reasons specified in 40 CFR Part 60. It is also a term of this certificate that this certificate may be revoked or suspended or rendered void *ab initio* for other reasons specified in 40 CFR Part 60.

This certificate does not cover large nonroad engines sold, offered for sale, or introduced, or delivered for introduction, into commerce in the U.S. prior to the effective date of the certificate.

