



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

MAR 25 2008

REPLY TO THE ATTENTION OF:

AE-17J

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kenny McCleary, Site Services Manager
Eli Lilly and Company
Tippecanoe Laboratories
1650 Lilly Road
Lafayette, Indiana 47909

Brian Brown, Project Engineer
Eli Lilly and Company
Lilly Corporate Center
893 South Delaware
Indianapolis, Indiana 46285

Re: Finding of Violation
Eli Lilly and Company – Tippecanoe Laboratories, Lafayette, Indiana;
Eli Lilly and Company – Lilly Technology Center, Indianapolis, Indiana

Dear Messrs. McCleary and Brown:

The U.S. Environmental Protection Agency is issuing the enclosed Finding of Violation (FOV) to Eli Lilly and Company's Lafayette, Indiana and Indianapolis, Indiana facilities (collectively, you). We find that you are violating Section 112 of the Clean Air Act (the Act), 42 U.S.C. § 7412, at both facilities.

Section 113 of the Act gives us several enforcement options to resolve these violations, including: issuing an administrative compliance order, issuing an administrative penalty order, bringing a judicial civil action, and bringing a judicial criminal action. Section 113 of the Act provides you with the opportunity to request a conference with us to discuss the violations cited in the FOV. This conference will provide you a chance to present information on the identified violations, any efforts you have taken to comply, and the steps you will take to prevent future violations. Please plan for your facility's technical and management personnel to take part in these discussions. You may have an attorney represent and accompany you at this conference.

The EPA contact in this matter is Ray Cullen. You may call him at (312) 886-0538 if you wish to request a conference. You should make the request within 10 calendar days following receipt of this letter. We should hold any conference within 30 days following receipt of this letter.

Sincerely,

Cheryl L. Newton, Acting Director
Air and Radiation Division

Enclosure

cc: David McIver, Chief
Office of Enforcement Air Section
Indiana Department of Environmental Management
100 North Senate Avenue, Room 1001
Indianapolis, Indiana 46206-6015

Protecting the environment is everyone's responsibility. Help EPA fight pollution by reporting possible harmful environmental activity. To do so, visit EPA's website at <http://www.epa.gov/compliance/complaints/index.html>.

4. The Pharma-MACT, at 40 C.F.R. § 1250(a)(1), defines an affected source as a pharmaceutical manufacturing operation that a) manufactures a pharmaceutical product; b) is located at a plant site that is a major source as defined in Section 112(a) of the Act; and c) processes, produces, or uses HAPs.
5. The leak detection and repair (LDAR) provisions of Subpart H and the Pharma-MACT apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems that are intended to operate in organic HAP service 300 hours or more during the calendar year, as stated under 40 C.F.R. §§ 63.1255(a)(1) and 63.160(a), respectively.
6. Subpart H and the Pharma-MACT, at 40 C.F.R. §§ 63.161 and 63.1251, respectively, define equipment in organic HAP service as equipment that either contains or contacts a fluid that is at least 5 percent by weight of total organic HAPs.

Tippecanoe Laboratories

7. Subpart H, at 40 C.F.R. § 63.174(d), requires the owner or operator of an affected source to make a first attempt at repair of a connector in gas/vapor or light liquid service subject to Subpart H no later than 5 calendar days after a leak is detected.
8. Subpart H, at 40 C.F.R. § 63.161, defines first attempt at repair as taking action for the purpose of stopping or reducing leakage of organic material to the atmosphere, followed by monitoring as specified in Sections 63.180(b) and (c), as appropriate, to verify whether the leak is repaired, unless the owner or operator determines by other means that the leak is not repaired.
9. During a September 2007 inspection, EPA discovered a work order (10612) showing that Lilly failed to attempt to repair a leaking connector within 5 days of detecting the leak, in violation of 40 C.F.R. § 63.174(d).
10. Subpart H, at 40 C.F.R. § 63.178(b)(2), requires the owner or operator of an affected source electing to use pressure testing of process equipment as an alternative to complying with the requirements of Sections 63.163 through 63.171 and 63.173 through 63.176, to test the process equipment using the procedures specified in Section 63.180(f) for pressure or vacuum loss.
11. Subpart H, at 40 C.F.R. § 63.180(f)(4), states that the pressure shall be measured using a pressure measurement device which has a precision of ± 2.5 mm Hg in the range of test pressure and is capable of measuring pressures up to the relief set pressure of the pressure relief device. If such a pressure measurement device is not reasonably available, the owner or operator shall use a pressure measurement device with a precision of at least ± 10 percent of the test pressure of the equipment and shall extend the duration of the test for the time necessary to detect a pressure loss or rise that equals a rate of one pound (lb) per square inch gauge (psig) per hour.

12. Despite using pressure measurement devices with a precision exceeding ± 2.5 mm Hg, Lilly has never extended the duration of a pressure test for the time necessary to detect a pressure loss or rise that equals a rate of one lb per psig per hour, in violation of 40 C.F.R. § 63.180(f)(4).
13. Subpart H, at 40 C.F.R. § 63.160(a), states that the provisions of Subpart H apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, surge control vessels, bottoms receivers, instrumentation systems, and control devices or closed vent systems required by this subpart that are intended to operate in organic HAP service 300 hours or more during the calendar year within a source subject to the provisions of a specific subpart in 40 C.F.R. Part 63 that references this subpart.
14. Subpart H, at 40 C.F.R. § 63.174(i)(2), requires the owner or operator to calculate the percent of leaking connectors by the following equation:

$$\%C_L = [(C_L - C_{AN}) / (C_1 + C_C)] \times 100$$

Where:

- $\%C_L$ = percent leaking connectors as determined through periodic monitoring;
- C_L = number of connectors, including nonrepairables, measured at 500 parts per million (ppm) or greater by the method specified in Section 63.180;
- C_{AN} = number of allowable nonrepairable connectors, as determined by monitoring required in paragraphs (b)(3) and (c) of this section, not to exceed 2-percent of C_1 ;
- C_1 = total number of monitored connectors, including nonrepairables, in the process unit;
- C_C = optional credit for removed connectors.

15. The Pharma-MACT, at 40 C.F.R. § 63.1255(c)(1), states that the provisions of this section apply to each pump that is in light organic HAP liquid service.
16. The Pharma-MACT, at 40 C.F.R. § 63.1255(c)(4)(iv), requires the owner or operator to calculate the percent of leaking pumps by the following equation:

$$\%P_L = [(P_L - P_S) / (P_T - P_S)] \times 100$$

Where:

- $\%P_L$ = percent of leaking pumps;
- P_L = number of pumps found leaking as determined through periodic monitoring;
- P_T = total number of pumps in organic HAP service;
- P_S = number of pumps in a continuous process leaking within 1 quarter of startup during the current monitoring period.

17. The Pharma-MACT, at 40 C.F.R. § 63.1255(e)(1), states that the provisions of this section apply to valves that are either in gas organic HAP service or in light liquid organic HAP service.
18. The Pharma-MACT, at 40 C.F.R. § 63.1255(e)(6)(ii), requires the owner or operator to calculate the percent of leaking valves by the following equation:

$$\%V_L = [V_L/V_T] \times 100$$

Where:

$\%V_L$ = percent of leaking valves;

V_L = number of valves found leaking as determined through periodic monitoring;

V_T = total number of valves monitored.

19. During the September 2007 inspection, Lilly admitted that it does not separate connectors, pumps, and valves in HAP service from those in non-HAP service when calculating leak rate percentages, in violation of 40 C.F.R. §§ 63.174(i)(2), 63.1255(c)(4)(iv), and 63.1255(e)(6)(ii), respectively.
20. The Pharma-MACT, at 40 C.F.R. § 63.1255(a)(7), requires the owner or operator of an affected source to identify equipment subject to the LDAR provisions such that it can be distinguished readily from equipment that is not subject.
21. In an October 5, 2007 email to EPA, Lilly states that there were 48 untagged components in HAP service during EPA's September 2007 inspection of the facility, in violation of 40 C.F.R. § 63.1255(a)(7).
22. The Pharma-MACT, at 40 C.F.R. § 63.1255(d)(1)(i), requires the owner or operator of an affected source to equip each open-ended valve or line with a cap, blind flange, plug, or second valve, which must, according to Section 63.1255(d)(1)(ii), seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance and repair.
23. During its September 2007 inspection, EPA monitored a capped open-ended line and obtained a reading of 910 parts per million. Since, at the time of discovery, operations did not require process fluid flow through the line and Lilly was not conducting maintenance on the line, Lilly failed to seal properly the open-end of this line, in violation of 40 C.F.R. § 63.1255(d)(1)(ii).
24. The Pharma-MACT, at 40 C.F.R. § 63.1260(g)(1), requires the owner or operator of an affected source to submit periodic reports semiannually, starting no later than 240 days after the Notification of Compliance Status report is due.
25. During the September 2007 inspection, Lilly stated that it has never submitted a periodic report specifically for the Pharma-MACT, in violation of 40 C.F.R. § 63.1260(g)(1).

Lilly Technology Center (LTC)

26. The Pharma-MACT, at 40 C.F.R. § 63.1254(a), requires the owner or operator of an affected source to comply with the requirements in paragraphs (a)(1) and (3) or (a)(2) and (3) of Section 63.1254 for each affected process.
27. The Pharma-MACT, at 40 C.F.R. § 63.1254(a)(2)(i), states that actual HAP emissions from the sum of all process vents within a process must not exceed 2,000 lbs in any 365-day period.

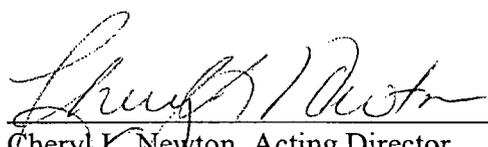
28. Lilly reported in a March 14, 2007, letter to the Indianapolis Office of Environmental Services (IOES) that HAP emissions from the KPB process had exceeded the rolling 2,000 lb process-based annual mass limit (PBAML) from March 6, 2004 through January 11, 2007, in violation of 40 C.F.R. § 63.1254(a)(2)(i).
29. The Pharma-MACT, at 40 C.F.R. § 63.1254(a)(2)(ii), states that actual HAP emissions from the sum of all process vents within processes complying with paragraph (a)(2)(i) of Section 63.1254 are limited to a maximum of 4,000 lbs in any 365-day period.
30. Lilly reported in a March 14, 2007, letter to IOES that HAP emissions from LTC exceeded the rolling 4,000 lb PBAML from October 29, 2004 through April 15, 2006, in violation of 40 C.F.R. § 63.1254(a)(2)(ii).
31. The Pharma-MACT, at 40 C.F.R. § 63.1255(d)(1)(i), requires the owner or operator of an affected source to equip each open-ended valve or line with a cap, blind flange, plug, or second valve, which must, according to Section 63.1255(d)(1)(ii), seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance and repair.
32. As reported by Lilly in its 4th quarter 2006 and 1st quarter 2007 Title V compliance reports, Lilly discovered an open-ended line in the KPB process on November 30, 2006 and five open-ended lines in the r-Glucagon process on January 26, 2007 without a cap, in violation of 40 C.F.R. § 63.1255(d)(1)(i).
33. The Pharma-MACT, at 40 C.F.R. § 63.1255(d)(2), requires the owner or operator of an affected source to operate each open-ended valve or line equipped with a second valve in a manner such that the valve on the process fluid end is closed before the second valve is closed.
34. As reported by Lilly in its 1st quarter 2007 Title V compliance report, Lilly discovered an open-ended line equipped with a second valve in BHI Control Room 5 where the second valve was not closed on January 8, 2007, in violation of 40 C.F.R. § 63.1255(d)(2).

Environmental Impact of Violations

35. Violations of the HAP standards may cause serious health effects, such as birth defects and cancer, and harmful environmental and ecological effects.

3/25/08

 Date



 Cheryl L. Newton, Acting Director
 Air and Radiation Division

CERTIFICATE OF MAILING

I, Shanee Rucker, certify that I sent a Finding of Violation, No. EPA-5-08-IN-13, by Certified Mail, Return Receipt Requested, to:

Kenny McCleary, Site Services Manager
Eli Lilly and Company
Tippecanoe Laboratories
1650 Lilly Road
Lafayette, Indiana 47909

Brian Brown, Project Engineer
Eli Lilly and Company
Lilly Corporate Center
893 South Delaware
Indianapolis, Indiana 46285

I also certify that I sent copies of the Finding of Violation by first class mail to:

David McIver, Chief
Office of Enforcement Air Section
Indiana Department of Environmental Management
100 North Senate Avenue, Room 1001
Indianapolis, Indiana 46206-6015

on the 26th day of March, 2008.

Shanee Rucker
Shanee Rucker,
Administrative Program Assistant
AECAS, (MI/WI)

CERTIFIED MAIL RECEIPT NUMBER: 7001 0320 0006 0185 95 94