



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

REPLY TO THE ATTENTION OF

DEC 22 2004

(AE-17J)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Daniel Wozniak, Air Compliance Manager
Abbott Laboratories
1401 Sheridan Road
North Chicago, Illinois 60064

Re: Finding of Violation
Abbott Laboratories
North Chicago, Illinois

Dear Mr. Wozniak:

The United States Environmental Protection Agency (U.S. EPA) is issuing the enclosed Finding of Violation (FOV) to Abbott Laboratories (you). We find that you are violating Section 112 of the Clean Air Act, 42 U.S.C. § 7412, at your North Chicago, Illinois facility.

We have several enforcement options under Section 113(a)(3) of the Clean Air Act, 42 U.S.C. § 7413(a)(3). These options include issuing an administrative compliance order, issuing an administrative penalty order, and bringing a judicial civil or criminal action. The options we select may depend on, among other things, the length of time you take to achieve and demonstrate continuous compliance with the rules cited in the FOV.

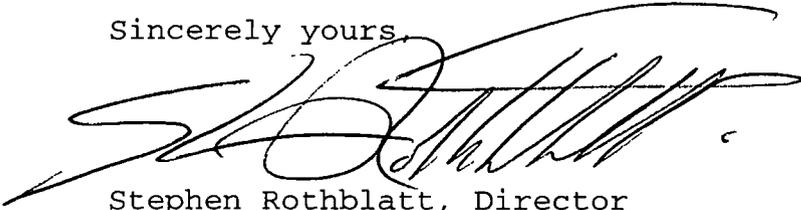
We are offering you an opportunity to confer with us about the violations alleged in the FOV. The conference will give you the opportunity to present information on the specific findings of violation, the efforts you have taken to comply, and the steps you will take to prevent future violations.

Please plan for your facility's technical and management personnel to attend the conference to discuss compliance measures and commitments. You may have an attorney represent you at this conference.

The U.S. EPA contact in this matter is Ray Cullen. You may call him at (312) 886-0538 to request a conference. You should make

the request as soon as possible, but no later than 10 calendar days after you receive this letter. We should hold any conference within 30 calendar days of your receipt of this letter.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Rothblatt', written over a horizontal line.

Stephen Rothblatt, Director
Air and Radiation Division

Enclosure

cc: Julie Armitage, Section Manager
Compliance and Systems Management Section
Illinois Environmental Protection Agency
P.O. Box 19506
Springfield, Illinois 62794-9506

Emilio Salis, Regional Manager
Region 1
Illinois Environmental Protection Agency
9511 West Harrison Street
Des Plaines, Illinois 60016

**United States Environmental Protection Agency
Region 5**

IN THE MATTER OF:)
)
Abbott Laboratories) **FINDING OF VIOLATION**
1401 Sheridan Road)
North Chicago, Illinois 60064) **EPA-5-05-IL-05**
)
Proceedings Pursuant to)
the Clean Air Act,)
42 U.S.C. §§ 7401 et seq.)

FINDING OF VIOLATION

The United States Environmental Protection Agency (U.S. EPA) finds that Abbott Laboratories (Abbott) has violated Section 112 of the Clean Air Act (the Act), 42 U.S.C. § 7412. Specifically, Abbott has violated the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Equipment Leaks at 40 C.F.R. Part 63, Subpart H (the HON), the NESHAP for Pharmaceuticals Production at 40 C.F.R. Part 63, Subpart GGG (the Pharma-MACT), and EPA Reference Method 21 at 40 C.F.R. Part 60, Appendix A as follows:

Regulatory Authority

1. The HON was proposed on December 31, 1992 and became final on April 22, 1994. It states that the owner or operator of an affected source under another subpart in 40 C.F.R. Part 63 that references Subpart H must be in compliance by the date specified in that subpart, as required under 40 C.F.R. § 63.161.
2. The NESHAP for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks, 40 C.F.R. Part 63, Subpart I, at 40 C.F.R. § 63.190(b), states that Subpart H applies to emissions of the designated HAP from the group of processes specified in paragraphs (b)(1) through (b)(6) of 40 C.F.R. § 63.190 that are located at a plant site that is a major source as defined in Section 112(a) of the Act.
3. The NESHAP for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks, at 40 C.F.R. § 63.190(b)(5), states that pharmaceutical production processes using carbon tetrachloride or methylene chloride are affected sources.

4. The NESHAP for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks, at 40 C.F.R. § 63.190(e)(2), states that existing sources shall be in compliance with Subpart H no later than October 24, 1994 for process units subject to Subpart I.
5. The Pharma-MACT was proposed on April 2, 1997 and became final on September 21, 1998. The owner or operator of an existing affected source must comply with the provisions of Subpart GGG no later than October 21, 2002, as required under 40 C.F.R. § 63.1250(f)(1).
6. The NESHAP for Pharmaceuticals Production, at 40 C.F.R. § 63.1250(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, uses, or produces HAPs.
7. The Leak Detection and Repair (LDAR) Provisions of the HON 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. §§ 63.160(a) and 63.1255(a)(1), respectively.
8. The NESHAP, at 40 C.F.R. §§ 63.161 and 63.1251, defines equipment in organic HAP service as equipment that either contains or contacts a fluid that is at least 5% by weight of total organic HAPs.
9. The NESHAP, at 40 C.F.R. § 63.162(c), requires the owner or operator of a process unit to identify equipment subject to the LDAR Provisions such that it can be distinguished readily from equipment that is not subject.
10. The NESHAP, at 40 C.F.R. § 63.161, defines a process unit as a chemical manufacturing process unit as defined in Subpart F of Part 63, a process subject to the provisions of Subpart I of Part 63, or a process subject to another subpart in 40 C.F.R. Part 63 that references Subpart H.
11. The NESHAP, 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.

12. The NESHAP, at 40 C.F.R. § 63.168(b), requires the owner or operator of a source subject to Subpart H to monitor all valves in gas/vapor and light liquid service subject to the LDAR Provisions at the intervals specified in 40 C.F.R. §§ 63.168(c) and (d).
13. The NESHAP, at 40 C.F.R. § 63.168(c), states that in Phases I and II, each valve shall be monitored quarterly.
14. The NESHAP, at 40 C.F.R. §§ 63.168(a)(1)(i)(A), (B), and (C), defines Phase I, Phase II, and Phase III as beginning on the compliance date, beginning no later than one year after the compliance date, and beginning no later than 2½ years after compliance date, respectively, for each group of existing process units at existing sources subject to the provisions of Subpart F or I of Part 63.
15. The NESHAP, at 40 C.F.R. § 63.1255(e)(2), requires the owner or operator of an existing affected source to monitor all valves in gas/vapor and light liquid service subject to the LDAR Provisions by no later than one year after the compliance date.
16. The NESHAP, at 40 C.F.R. § 63.174(a), requires the owner or operator of a process unit subject to Subpart H to monitor all connectors in gas/vapor and light liquid service subject to the LDAR Provisions at the intervals specified in 40 C.F.R. § 63.174(b).
17. The NESHAP, at 40 C.F.R. § 63.174(b)(1), requires the owner or operator of an existing process unit within an existing source to monitor all connectors in gas/vapor and light liquid service subject to the LDAR Provisions by no later than one year after the compliance date.
18. The NESHAP, at 40 C.F.R. § 63.168(d)(2), requires the owner or operator of a process unit with less than 2% leaking valves to monitor each valve in gas/vapor and light liquid service subject to the LDAR Provisions once each quarter in Phase III.
19. The NESHAP, at 40 C.F.R. § 63.163(b)(1), requires the owner or operator of a process unit subject to Subpart H to monitor each pump in light liquid service subject to the LDAR Provisions monthly to detect leaks by the method specified in Section 63.180(b) of Subpart H.

20. The NESHAP, at 40 C.F.R. § 63.173(a)(1), requires the owner or operator of a source subject to Subpart H to monitor each agitator in gas/vapor and light liquid service subject to the LDAR Provisions monthly to detect leaks by the method specified in Section 63.180(b) of Subpart H.
21. The NESHAP, at 40 C.F.R. § 63.1255(c)(2)(i), requires the owner or operator of a source subject to 40 C.F.R. § 63.1255 to monitor each pump in light liquid service and agitator in gas/vapor and light liquid service subject to the LDAR Provisions quarterly to detect leaks by the method specified in Section 63.180(b) of Subpart H.
22. The NESHAP, at 40 C.F.R. § 63.163(b)(3), requires the owner or operator of a process unit subject to Subpart H to check by visual inspection each calendar week each pump in light liquid service subject to the LDAR Provisions for indications of liquids dripping from the pump seal.
23. The NESHAP, at 40 C.F.R. § 63.173(b)(1), requires the owner or operator of a source subject to Subpart H to check by visual inspection each calendar week each agitator in gas/vapor and light liquid service subject to the LDAR Provisions for indications of liquids dripping from the agitator.
24. The NESHAP, at 40 C.F.R. § 63.1255(c)(2)(iii), requires the owner or operator of a source subject to 40 C.F.R. § 63.1255 to check by visual inspection each calendar week each pump in light liquid service and agitator in gas/vapor and light liquid service subject to the LDAR Provisions for indications of liquids dripping from the pump or agitator seal.
25. The NESHAP, at 40 C.F.R. § 63.168(b)(1), requires the owner or operator of a source subject to Subpart H to monitor valves in gas/vapor and light liquid service subject to the LDAR Provisions by the method specified in Section 63.180(b) of Subpart H.
26. The NESHAP, at 40 C.F.R. § 63.1255(e)(3)(i), requires the owner or operator of a source subject to 40 C.F.R. § 63.1255 to monitor valves in gas/vapor and light liquid service subject to the LDAR Provisions by the method specified in Section 63.180(b) of Subpart H.
27. The NESHAP, at 40 C.F.R. § 63.174(a)(1), requires the owner or operator of a process unit subject to Subpart H to

monitor connectors in gas/vapor and light liquid service subject to the LDAR Provisions by the method specified in Section 63.180(b) of Subpart H.

28. The NESHAP, at 40 C.F.R. § 63.180(b)(1), requires the owner or operator of an affected source subject to Subpart H to comply with the monitoring procedures and requirements of Method 21 of 40 C.F.R. Part 60, Appendix A.
29. Method 21, at 40 C.F.R. Part 60, Appendix A, Section 8.3.1, requires the owner or operator of an affected source to slowly sample the interface of a component where leakage is indicated until the maximum meter reading is obtained.
30. The NESHAP, at 40 C.F.R. § 63.1258(b)(1)(iv)(A)(4), requires the owner or operator of an affected source to establish the minimum regeneration steam flow rate under worst-case conditions for each regenerative carbon adsorber.
31. The NESHAP, at 40 C.F.R. § 63.1258(b)(8), states that exceedances of parameters monitored according to the provisions of paragraph (b)(1)(iv), and excursions as defined by paragraphs (b)(7)(i) through (iii), constitute violations of the operating limit.
32. The NESHAP, at 40 C.F.R. § 63.1258(h)(2)(iii)(A), requires the owner or operator of fixed roof vapor suppression equipment with a capacity greater than 0.42m³ to conduct an initial inspection according to the procedures in paragraph (h)(3) of 40 C.F.R. § 63.1258.
33. The NESHAP, at 40 C.F.R. § 63.1258(h)(3)(i), states that inspections shall be conducted in accordance with Method 21 of 40 C.F.R. Part 60, Appendix A.

Factual Background

34. Abbott owns and operates a health care products manufacturing plant site at 1401 Sheridan Road, North Chicago, Illinois.
35. At the North Chicago plant site, Buildings R-5, R-6, R-6C, and R-10, along with Tank Farm Areas S-7, S-30, and S-32, contain pharmaceutical production process units that used carbon tetrachloride and/or methylene chloride between October 24, 1994 and October 21, 2002. The North Chicago plant site also has been a major source, as defined in Section 112(a) of the Act, since before October 24, 1994.

Therefore, prior to October 21, 2002, Abbott was an affected source subject to the LDAR Provisions of the HON.

36. At the North Chicago plant site, Buildings C-10, R-5, R-6, R-6C, and R-10, along with Tank Farm Areas S-7, S-30, and S-32, contain manufacturing operations that have produced a pharmaceutical product and have been processing, producing, or using organic HAP since October 21, 2002. As noted in paragraph 35 above, the North Chicago plant site also has been a major source, as defined in Section 112(a) of the Act, since before October 24, 1994. Therefore, as of October 21, 2002, Abbott has been an affected source subject to the LDAR Provisions of the Pharma-MACT.
37. U.S. EPA inspected the North Chicago plant site on June 22-24, 2004. U.S. EPA also issued an Information Request to Abbott on July 22, 2004. Abbott responded to the Information Request on August 31, 2004.
38. Abbott did not identify 1176 components (summarized in Table A) as subject to the LDAR Provisions until August 18, 2004, when it allegedly discovered that it had incorrectly identified these components as being exempt from the LDAR Provisions of the HON and the Pharma-MACT.

Table A.

	C-10	R-5	R-6	R-6C	R-10	S-7	S-30	S-32
Valves	2	8	3	14	20	0	9	0
Connectors	915	1	15	43	64	47	22	5
Pressure-relief devices	0	0	1	0	4	0	0	0
Pumps	0	0	0	2	0	0	0	0
Agitators	0	0	0	0	1	0	0	0

39. Prior to August 2004, Abbott never monitored the valves and connectors referenced in Table A.
40. Abbott never found more than 2% of valves in a process group to be leaking from July 1999 through October 2002, although there were some quarters during this time when the equipment was not in organic HAP service, as shown in Table B.

Table B.

	R-5	R-6	R-6C	R-10	S-30
3rd quarter 1999	Yes	Yes	Yes	Down	Yes
4th quarter 1999	Yes	Yes	Yes	Down	Yes
1st quarter 2000	Down	Down	Down	Down	Down
2nd quarter 2000	Yes	Yes	Yes	Yes	Yes
3rd quarter 2000	Yes	Yes	Yes	Yes	Yes
4th quarter 2000	Yes	Yes	Down	Yes	Down
1st quarter 2001	Yes	Yes	Yes	Yes	Yes
2nd quarter 2001	Down	Yes	Yes	Down	Yes
3rd quarter 2001	Down	Yes	Down	Down	Yes
4th quarter 2001	Yes	Yes	Down	Down	Down
1st quarter 2002	Yes	Yes	Down	Down	Yes
2nd quarter 2002	Yes	Yes	Yes	Down	Yes
3rd quarter 2002	Yes	Yes	Yes	Down	Yes
4th quarter 2002	Yes	Yes	Yes	Down	Yes

41. Abbott found less than 0.25% of valves leaking during its initial monitoring survey for the Pharma-MACT.
42. From January 2001 to August 2004, Abbott never monitored or visually inspected the two pumps in R-6C referenced in Table A.
43. Prior to August 2004, Abbott never monitored or visually inspected the agitator in R-10 referenced in Table A.
44. Abbott failed to visually inspect six pumps in R-2B the week of January 18, 2004, a pump in S-7 the weeks of January 12, 2003 through September 19, 2004, and four agitators in R-5 the weeks of July 1, 1999 through September 13, 2004.
45. An LDAR technician monitored 1318, 1083, 2652, 1272, 2087, 1161, 1016, 1161, 1720, 1468, 1881, 1648, 1140, 1763, 1207, 1439, 1479, 1340, and 1239 components on 8/5/99, 8/11/99, 9/8/99, 11/23/99, 6/12/00, 6/20/00, 9/7/00, 3/15/01, 6/6/02, 12/6/02, 4/15/03, 4/19/03, 8/8/03, 9/3/03, 9/5/03, 9/8/03,

9/9/03, 9/10/03, and 9/11/03, respectively.

46. Abbott owns and operates a regenerative carbon adsorber subject to the Pharma-MACT in S-32.
47. On October 7, 2002, Abbott conducted a performance test on the S-32 carbon adsorber and verified that a regeneration steam flow rate of at least 5419 lbs/hr will regenerate the carbon beds to maintain a 98% efficiency for control of methylene chloride emissions.
48. Abbott tracked the regeneration steam flow rate of the S-32 carbon adsorber against an established minimum flow rate of 4877 lbs/hr from October 2002 until February 2004.
49. According to a Periodic Report submitted to the U.S. EPA on May 13, 2004, there were 30 instances from December 21, 2003 to March 20, 2004 when the bed regeneration frequency for the S-32 carbon adsorber was below the minimum limit of 51 minutes.
50. According to Periodic Reports submitted to the U.S. EPA on November 14, 2003, February 11, 2004, and May 13, 2004, there were 14 instances from March 20, 2003 to September 20, 2003, 7 instances from September 21, 2003 to December 20, 2003, and 4 instances from December 21, 2003 to March 20, 2004 when the pH for scrubber SC-5003 in Building C-10 was below the minimum limit.
51. Abbott uses 200-300 gallon totes to transport wastewater from the manufacturing area of a process to on-site holding tanks.
52. Abbott has never inspected the totes per Method 21.

Violations

53. Abbott failed to identify equipment subject to the LDAR Provisions such that it can be distinguished from equipment that is not subject. This is a violation of 40 C.F.R. § 63.162(c) and 40 C.F.R. § 63.1255(a)(7).
54. Abbott failed to monitor all valves and connectors in gas/vapor and light liquid service subject to the LDAR Provisions by October 24, 1994 and October 24, 1995, respectively, under the HON, and by October 21, 2003 under the Pharma-MACT. This is a violation of 40 C.F.R. § 63.168(b), 40 C.F.R. § 63.168(c), 40 C.F.R.

§ 63.1255(e)(2), 40 C.F.R. § 63.174(a), and 40 C.F.R. § 63.174(b)(1).

55. Abbott failed to monitor all valves in gas/vapor and light liquid service subject to the LDAR Provisions quarterly under the HON. This is a violation of 40 C.F.R. § 63.168(b) and 40 C.F.R. § 63.168(d)(2).
56. Abbott failed to monitor all pumps in light liquid service and all agitators in gas/vapor and light liquid service subject to the LDAR Provisions monthly under the HON and quarterly under the Pharma-MACT. This is a violation of 40 C.F.R. § 63.163(b)(1), 40 C.F.R. § 63.173(a)(1), and 40 C.F.R. § 63.1255(c)(2)(i).
57. Abbott failed to check by visual inspection each calendar week all pumps in light liquid service and agitators in gas/vapor and light liquid service subject to the LDAR Provisions. This is a violation of 40 C.F.R. § 63.163(b)(3), 40 C.F.R. § 63.173(b)(1), and 40 C.F.R. § 63.1255(c)(2)(iii).
58. Abbott failed to monitor equipment subject to the LDAR Provisions per Method 21. This is a violation of 40 C.F.R. § 63.168(b)(1), 40 C.F.R. § 63.1255(e)(3)(i), 40 C.F.R. § 63.174(a)(1), 40 C.F.R. § 63.163(b)(1), 40 C.F.R. § 63.173(a)(1), 40 C.F.R. § 63.1255(c)(2)(i), 40 C.F.R. § 63.180(b)(1), and Method 21 at 40 C.F.R. Part 60, Appendix A, Section 4.3.1.
59. Abbott failed to establish the correct minimum regeneration steam flow rate for the S-32 carbon adsorber. This is a violation of 40 C.F.R. § 63.1258(b)(1)(iv)(A)(4).
60. Abbott failed to keep the regeneration frequency of the S-32 carbon adsorber above the established minimum value. This is a violation of 40 C.F.R. § 63.1258(b)(8).
61. Abbott failed to keep the pH of scrubber SC-5003 above the established minimum value. This is a violation of 40 C.F.R. § 63.1258(b)(8).

62. Abbott failed to inspect vapor suppression equipment in accordance with Method 21. This is a violation of 40 C.F.R. § 63.1258(h)(2)(iii)(A) and 40 C.F.R. § 63.1258(h)(3)(i).

12/22/2004

Date

A handwritten signature in black ink, appearing to read "Stephen Rothblatt", written over a horizontal line.

Stephen Rothblatt, Director
Air and Radiation Division

CERTIFICATE OF MAILING

I, Shanee Rucker, certify that I sent a Finding of Violation, No. EPA-5-05-IL-05, by Certified Mail, Return Receipt Requested, to:

Daniel Wozniak, Air Compliance Manager
Abbott Laboratories
1401 Sheridan Road
North Chicago, Illinois 60064

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

Julie Armitage, Section Manager
Compliance and Systems Management Section
Illinois Environmental Protection Agency
P.O. Box 19506
Springfield, Illinois 62794-9506

Emilio Salis, Regional Manager
Region 1
Illinois Environmental Protection Agency
9511 West Harrison Street
Des Plaines, Illinois, 60016

on the 28th day of December, 2004.

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

CERTIFIED MAIL RECEIPT NUMBER: 70010320000589097100