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

SEP 2 8 2016

REPLY TO THE ATTENTION OF:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dow Carter
Leica Biosystems Richmond, Inc.
5205 US Route 12
Richmond, Illinois 60071

Re: Notice of Violation and Finding of Violation
Leica Biosystems Richmond, Inc.
Richmond, Illinois

Dear Mr. Carter:

The U.S. Environmental Protection Agency is issuing the enclosed Notice of Violation and Finding of Violation (NOV/FOV) to Leica Biosystems Richmond, Inc. (you) under Sections 113(a)(1) and (3) of the Clean Air Act (CAA), 42 U.S.C. §§ 7413(a)(1) and (3). We find that you have violated the CAA and the Illinois State Implementation Plan at your Richmond, Illinois facility.

Section 113 of the CAA gives us several enforcement options. These options include issuing an administrative compliance order, issuing an administrative penalty order, and bringing a judicial civil or criminal action.

We are offering you an opportunity to confer with us about the violations alleged in the NOV/FOV. The conference will give you an opportunity to present information on the specific findings of violation, any efforts you have taken to comply, and the steps you will take to prevent future violations. In addition, in order to make the conference more productive, we encourage you to submit to us information responsive to the NOV/FOV before the conference date.

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.

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The EPA contact in this matter is Scott Connolly. You may call him at (312) 886-1493 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 calendar days following receipt of this letter.

Sincerely,

Edward Nam
Acting Director
Air and Radiation Division

Enclosure

cc: Yasmine Keppener-Bauman,
Acting Manager
Compliance Section
Illinois EPA Bureau of Air

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

IN THE MATTER OF:	)	
	)	
Leica Biosystems Richmond, Inc. Richmond, Illinois	))	**NOTICE OF VIOLATION and FINDING OF VIOLATION**
	)	
Proceedings Pursuant to Sections 113(a)(1) and 113(a)(3) of the Clean Air Act, 42 U.S.C. §§ 7413(a)(1) and (3)	))))	**EPA-5-16-IL-13**

NOTICE AND FINDING OF VIOLATION

The U.S. Environmental Protection Agency (EPA) is issuing this Notice of Violation and Finding of Violation (NOV/FOV) under Sections 113(a)(1) and (3) of the Clean Air Act (CAA), 42 U.S.C. §§ 7413(a)(1) and (3). The authority to issue this NOV/FOV has been delegated to the Regional Administrator of EPA Region 5 and redelegated to the Director of the Air and Radiation Division. EPA finds that Leica Biosystems Richmond, Inc. (Leica) is violating the CAA and Illinois State Implementation Plan (Illinois SIP), as follows:

Statutory and Regulatory Background

1. The CAA is designed to protect and enhance the quality of the nation's air so as to promote the public health and welfare and the productive capacity of its population. Section 101(b)(1) of the CAA, 42 U.S.C. § 7401(b)(l).

2. As defined under 35 Ill. Admin. Code §§ 201.102, 211.0121, 218.104, a "person" is any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of Illinois, any other State or political subdivision or agency thereof or any legal successor, representative, agent or agency of the foregoing.

3. As defined under 42 U.S.C. § 7602(e), a "person" includes an individual, corporation, partnership, association, State, municipality, political subdivision of a State, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

Title V Permit Program and Federal Regulations

4. Title V of the CAA, 42 U.S.C. §§ 7661a-7661f, establishes an operating permit program for certain sources, including "major sources."

5. Section 502(a) of the CAA, 42 U.S.C. § 7661a(a), and 40 C.F.R. § 70.7(b) provide that, after the effective date of any permit program approved or promulgated under Title V of the CAA, no source subject to Title V may operate except in compliance with a Title V

permit.

6. 40 C.F.R. § 70.1(b) provides that all sources subject to the Part 70 regulations shall have a permit to operate that assures compliance by the source with all applicable requirements, as defined in 40 C.F.R. § 70.2.

7. Section 503(c) of the CAA, 42 U.S.C. § 7661b(c) and 40 C.F.R. § 70.5(a), provide that any person required to have a permit under Title V must timely submit an application for a permit.

8. EPA granted full approval to the Illinois Title V operating permit program (CAAPP) on December 4, 2001, set forth at 415 Illinois Complied Statues (ILCS) Section 5/39.5. The program became effective on November 30, 2001. 66 Fed. Reg. 62946.

9. Section 39.5(6)(b) of the Illinois Environmental Protection Act states that no person shall operate a CAAPP source without a CAAPP permit unless a CAAPP permit or renewal application has been timely submitted. 415 ILCS § 5/39.5(6)(b).

10. Section 502 of the CAA, 42 U.S.C. § 7661a, applies to all major sources, defined at Section 501 of the CAA, 42 U.S.C. § 7661(2).

11. Section 39.5 of the Illinois Environmental Protection Act applies to any source defined as a major source. 415 ILCS § 5/39.5(2)(a)(i).

12. The definition of "major source" includes any stationary source that emits or has the potential to emit 10 tons per year (tpy) or more of any single hazardous air pollutant listed in Section 112(b) of the CAA. 42 U.S.C. § 7661(2); 415 ILCS § 5/39.5(2)(c)(i).

13. Potential to emit is defined as the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation is enforceable by EPA. 40 C.F.R. § 70.2; 415 ILCS § 5/39.5(1).

14. Xylene is classified as a hazardous air pollutant under Section 112(b) of the CAA, 42 U.S.C. § 7412(b).

15. Section 113(a)(3) of the CAA, 42 U.S.C. § 7413(a)(3), authorizes the Administrator to initiate an enforcement action whenever, among other things, the Administrator finds that any person has violated or is in violation of a requirement or prohibition of Title V of the CAA, or any rule promulgated, issued, or approved under Title V of the CAA.

Illinois SIP

16. Section 110(a) of the CAA, 42 U.S.C. § 7410(a), establishes a program by which states prepare and submit to EPA plans to provide for the attainment and maintenance of the

National Ambient Air Quality Standards. Once EPA approves a state's submission, it becomes part of the federally enforceable State Implementation Plan.

17. On September 9, 1994, and October 21, 1996, EPA approved major revisions to the federally enforceable Illinois SIP, including the Chicago Area VOC Rules, at 35 Illinois Administrative Code (Ill. Admin. Code) Part 218. 59 Fed. Reg. 46562; 61 Fed. Reg. 54556.

18. The "Chicago area," as defined in Part 218 of the Illinois SIP, consists "of Cook, DuPage, Kane, Lake, McHenry and Will Counties and Aux Sable Township and Goose Lake Township in Grundy County and Oswego Township in Kendall County." 35 Ill. Admin. Code §§ 218.100(a), 218.103.

19. Section 218.122 of the Illinois SIP states that "[n]o person shall cause or allow the loading of any organic material into any stationary tank having a storage capacity of greater than 946 L (250 gal), unless such tank is equipped with a permanent submerged loading pipe or an equivalent device approved by the Agency according to the provisions of 35 Ill. Admin. Code 201, and further processed consistent with Section 218.108 of this Part, or unless such tank is a pressure tank as described in Section 218.121(a) of this Part or is fitted with a recovery system as described in Section 218.121(b)(2) of this Part." 35 Ill. Admin. Code § 218.122.

20. Section 218.301 of the Illinois SIP states that "[n]o person shall cause or allow the discharge of more than 3.6 kg/hr (8 lbs/hr) of organic material into the atmosphere from any emission source, except as provided in Sections 218.302, 218.303, 218.304 of this Part and the following exception: If no odor nuisance exists the limitation of this Subpart shall apply only to photochemically reactive material." 35 Ill. Admin. Code § 218.301.

21. As defined under 35 Ill. Admin. Code §§ 218.104, 211.4250, "organic material" means, for the purpose of 35 Ill. Adm. Code 215, 218 and 219, any chemical compound of carbon including diluents and thinners which are liquids at standard conditions and which are used as dissolvers, viscosity reducers, or cleaning agents, but excluding methane, acetone, carbon monoxide, carbon dioxide, carbonic acid, metallic carbonic acid, metallic carbide, metallic carbonates, and ammonium carbonate.

22. "Photochemically reactive material" includes, among other things, a material that contains more than 8 percent by volume of aromatic compound combinations that contain eight or more carbon atoms per molecule, except ethylbenzene. *See* 35 Ill. Admin. Code §§ 218.104, 211.4690.

23. As defined under 35 Ill. Admin. Code §§ 218.104, 211.6390, "stationary storage tank" means any container of liquid or gas which is designed and constructed to remain at one site.

24. As defined under 35 Ill. Admin. Code §§ 218.104, 211.6470, "submerged loading pipe" means, for purposes of 35 Ill. Adm. Code 218 and 219, any discharge pipe or nozzle which meets either of the following conditions: (1) Where the tank is filled from the top,

the end of the discharge pipe or nozzle must be totally submerged when the liquid level is 15 cm (6 in.) above the bottom of the tank; (2) Where the tank is filled from the side, the discharge pipe or nozzle must be totally submerged when the liquid level is 46 cm (18 in.) above the bottom of the tank.

25. Section 113(a)(1) of the CAA, 42 U.S.C. § 7413(a)(1), authorizes the Administrator to initiate an enforcement action whenever, among other things, the Administrator finds that any person has violated or is in violation of a requirement or prohibition of the applicable SIP.

Findings of Fact

26. Leica is a corporation authorized to do business in the state of Illinois.

27. Leica is a "person" within the meaning of the Title 35 of the Illinois Administrative Code, 35 Ill. Admin. Code §§ 201.102, 211.0121, 218.104, and as the term is defined in Section 302(e) of the CAA, 42 U.S.C. § 7602(e).

28. During the time period relevant to this NOV/FOV, Leica has owned and operated a medical materials manufacturing facility at 5205 US Route 12, Richmond, Illinois.

29. On March 10, 2016, EPA issued an information request to Leica pursuant to Section 114 of the CAA (114 Request), 42 U.S.C. § 7414.

30. On April 21, 2016, EPA inspected the Facility (2016 inspection).

31. Leica provided responses to the 114 Request on May 16, 2016; July 11, 2016; and July 29, 2016.

Title V Permit Program and Federal Regulations

32. According to the information Leica submitted in response to the 114 Request, Leica operated at least one liquid dispensing fill line that processes liquids containing up to 100% xylene until at least February 2016.

33. Leica has the potential to emit more than 10 tpy of xylene under its physical and operational designs.

34. Leica is a "major source" as defined at 42 U.S.C. § 7661(2) and 415 ILCS § 5/39.5(2)(c)(i).

35. Leica is subject to the requirements of Title V by operating its liquid dispensing fill line(s) that has processed or does process liquids containing up to 100% xylene.

36. Leica was required to submit a complete Title V permit application to Illinois EPA no later than 12 months after the date it became the owner or operator of the liquid dispensing fill line(s) that processes or has processed liquids containing up to 100%

xylene, which, according to the information submitted by Leica, was when it acquired Surgipath Medical Industries on December 30, 2008.

37. To date, Leica has not submitted a complete Title V permit application to Illinois EPA.

Illinois SIP

38. Leica's Richmond, Illinois facility is located in McHenry County, part of the Chicago area as defined in Part 218 of the Illinois SIP, 35 Ill. Admin. Code §§ 218.100(a), 218.103.

39. Xylene is an organic material and a photochemically reactive material, as defined in the Illinois SIP at 35 Ill. Admin. Code §§ 218.104, 211.4250, 211.4690.

40. During its operations from at least January 2012 to February 2016, Leica discharged more than 8 pounds per hour of organic material, as defined in the Illinois SIP at 35 Ill. Admin. Code §§ 218.104, 211.4250, into the atmosphere from its dispensing fill line during xylene dispensing operations.

41. From at least June 2011 to the present, Leica has operated at least 5 blending tanks that process organic materials, as defined in the Illinois SIP at 35 Ill. Admin. Code §§ 218.104, 211.4250.

42. From at least June 2011 to the present, Leica operated its stationary tanks without submerged loading pipes, as defined in the Illinois SIP at 35 Ill. Admin. Code §§ 218.104, 211.6470, during its blending and loading operations involving organic material.

43. Leica's stationary tanks, as defined in the Illinois SIP at 35 Ill. Admin. Code § 211.6390, have a capacity of greater than 250 gallons.

44. From at least June 2011 to the present, Leica has not employed an oxidizer, vapor recovery system, or other air pollution recovery system that reduces by 85 percent or more the uncontrolled organic material that would otherwise be emitted to the atmosphere or that otherwise meets the requirements for an exception to the submerged loading pipe provision of the Illinois SIP, set forth at 35 Ill. Admin. Code § 218.122.

Violations

45. Based on the information from the 2016 inspection and Leica's response to the 114 Request, Leica's failure to submit a timely and complete Title V permit application to Illinois EPA constitutes a violation of Section 503 of the CAA, the regulations at 40 C.F.R. § 70.5(a), and the Illinois Environmental Protection Act at 415 ILCS § 5/39.5(5)(a).

46. Based on the information from the 2016 inspection and Leica's response to the 114 Request, Leica's operation without a Title V permit constitutes a violation of Section 502

of the CAA, the regulations at 40 C.F.R. §§ 70.1(b) and 70.7(b), and the Illinois Environmental Protection Act at 415 ILCS § 5/39.5(6)(b).

47. Based on the information from the 2016 inspection and Leica's response to the 114 Request, by discharging more than 8 pounds per hour of organic material into the atmosphere during xylene dispensing operations, Leica violated Section 218.301 of the Illinois SIP.

48. Based on the information from the 2016 inspection and Leica's response to the 114 Request, by loading organic materials into its blending tanks without a submerged loading pipe, Leica violated Section 218.122 of the Illinois SIP.

Environmental Impact of Violations

49. These violations have caused or can cause excess emissions of VOCs, including xylene and formaldehyde, which are hazardous air pollutants. Hazardous air pollutants can cause serious health problems and VOCs lead to the formation of ozone.

9/28/16
Date

Edward Nam
Acting Director
Air and Radiation Division

CERTIFICATE OF MAILING

I, Loretta Shaffer, certify that I sent a Notice of Violation and Finding of Violation, No. EPA-5-16-IL-13, by Certified Mail, Return Receipt Requested, to:

Dow Carter
Leica Biosystems Richmond, Inc.
5205 US Route 12
Richmond, IL 60071

I also certify that I sent copies of the Notice of Violation and Finding of Violation by email to:

Yasmine Keppner-Bauman,
Acting Manager, Compliance Section
Bureau of Air, Illinois EPA
Yasmine.Keppner-Bauman@Illinois.gov

On the 29 day of September 2016.

Loretta Shaffer
Program Technician
AECAB, PAS

CERTIFIED MAIL RECEIPT NUMBER: 7009 1680 0000 7667 5772