



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

JUN 23 2014

REPLY TO THE ATTENTION OF:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

T.J. Stewart
Industrial Hygienist
United States Department of Veteran Affairs
Northern Indiana Healthcare System
2121 Lake Avenue
Fort Wayne, Indiana 46805

Re: Administrative Consent Order

Dear Mr. Stewart:

Enclosed is an Administrative Consent Order which resolves Case Docket No. EPA-5-14-113(a)-
IN-02.

Please direct any questions regarding this case to Louise Gross, Associate Regional Counsel,
(312) 886-6844.

Sincerely,

A handwritten signature in cursive script that reads "Brian Dickens".

Brian Dickens, Chief
Minnesota/Ohio Air Enforcement and Compliance Assurance Section

Enclosures

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

In the Matter of:) EPA-5-14-113(a)-IN-02
)
United States Department of Veteran Affairs) Proceeding Under Sections 113(a)(3) and
Northern Indiana Healthcare System) 114(a)(1) of the Clean Air Act, 42 U.S.C.
Marion, Indiana) §§ 7413(a)(3) and 7414(a)(1)

Administrative Consent Order

1. The Director of the Air and Radiation Division, U.S. Environmental Protection Agency (EPA), Region 5, is issuing this Order to the United States Department of Veteran Affairs – Northern Indiana Healthcare System (VA -NIHS) under Sections 113(a)(3) and 114(a)(1) of the Clean Air Act (CAA), 42 U.S.C. §§ 7413(a)(3) and 7414(a)(1).

Statutory and Regulatory Background

2. Section 112 (a)(1) of the CAA, 42 U.S.C. § 7412(a)(1), defines “major source” as “any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants.” *See also* 40 C.F.R. § 63.2.

3. Section 112(a)(2) of the CAA, 42 U.S.C. § 7412(a)(2), defines “area source” as “any stationary source of hazardous air pollutants that is not a major source.” *See also* 40 C.F.R. § 63.2.

4. Section 112(b) of the CAA, 42 U.S.C. § 7412(b), as revised in 61 Fed. Reg. 30816 (June 18, 1996), lists 188 Hazardous Air Pollutants (HAPs) that cause adverse health or environmental effects.

5. Section 112(d)(1) of the CAA, 42 U.S.C. § 7412(d)(1), requires the Administrator to promulgate regulations establishing emissions standards for each category or subcategory of major and area sources of HAPs listed for regulation pursuant to subsections (c) and (e) of Section 112. These standards are known as National Emissions Standards for the Regulation of Hazardous Air Pollutants (NESHAPs).

6. Section 112(d)(5) of the CAA, 42 U.S.C. § 7412(d)(5), allows the Administrator to elect to promulgate standards or requirements for area sources which provide for the use of generally available control technologies or management practices by such sources to reduce emissions of hazardous air pollutants.

7. Section 112(i)(1) of the CAA, 42 U.S.C. § 7412(i)(1), prohibits the operation of an existing source in violation of the standards, limitations or regulations promulgated under Section 112.

8. Section 114(a)(1) of the CAA, 42 U.S.C. § 7414(a)(1), authorizes the Administrator of EPA to require any person who owns or operates an emission source to make reports and provide information required by the Administrator. The Administrator has delegated this authority to the Director of the Air and Radiation Division Region 5.

9. On March 16, 1994, EPA promulgated the General Provisions for the Part 63 NESHAP standards at 40 C.F.R. Part 63, Subpart A, §§ 63.1 - 63.15. 59 Fed. Reg. 12408.

10. 40 C.F.R § 63.1(a)(4)(i) states that “[e]ach relevant standard in this part 63 must identify explicitly whether each provision in this subpart A is or is not included in such relevant standard.”

11. 40 C.F.R § 63.2 defines “major source” as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has

the potential to emit considering controls, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants, unless the Administrator establishes a lesser quantity, or in the case of radionuclides, different criteria from those specified in this sentence.”

12. 40 C.F.R § 63.2 defines “area source” as “any stationary source of hazardous air pollutants that is not a major source as defined in this part.”

13. 40 C.F.R § 63.4(a)(1) prohibits the owner or operator subject to Part 63 from operating any affected source in violation of the requirements of Part 63.

14. 40 C.F.R § 63.4(a)(2) prohibits the owner or operator subject to Part 63 from failing to keep records, notify, report, or revise reports as required under Part 63.

15. 40 C.F.R § 63.6(c)(1) requires the owner or operator of an existing source to comply with the applicable standard by the compliance date established in the applicable subpart(s) of Part 63.

16. 40 C.F.R § 63.9(j) requires the owner or operator of a source subject to a subpart under Part 63 to notify the Administrator within 15 calendar days of any change in the information already provided under 40 C.F.R. § 63.9.

17. On December 28, 2007, EPA promulgated the National Emission Standards for Hospital Ethylene Oxide Sterilizers at 40 C.F.R. Part 63, Subpart WWWW, §§ 63.10382 - 63.10448 (Subpart WWWW). 72 Fed. Reg. 73611.

18. Subpart WWWW at 40 C.F.R § 63.10382(a) provides that owners or operators of ethylene oxide sterilization facilities at hospitals that are area sources of HAPs are subject to Subpart WWWW.

19. Subpart WWWW at 40 C.F.R. § 63.10448 defines “sterilization facility” to mean the group of ethylene oxide sterilization units at a hospital using ethylene oxide gas or an ethylene oxide/inert mixture for the purpose of sterilizing.

20. Subpart WWWW at 40 C.F.R. § 63.10448 defines “sterilization unit” to mean any enclosed vessel that is filled with ethylene oxide gas or an ethylene oxide/inert gas mixture for the purpose of sterilizing. As used in this subpart, the term includes combination sterilization units. A sterilization unit is existing if its construction or reconstruction commenced prior to November 6, 2006, and new if construction or reconstruction commenced on or after November 6, 2006.

21. Subpart WWWW at 40 C.F.R § 63.10384(a) requires existing sources to comply with the applicable requirements by December 29, 2008.

22. Subpart WWWW at 40 C.F.R § 63.10390 requires owners or operators of affected sterilization units to sterilize items having a common aeration time at full load, except under medically necessary circumstances. Alternatively, owners or operator may equip their sterilization units with an add-on air pollution control device in accord with 40 C.F.R. § 63.10400.

23. Subpart WWWW at 40 C.F.R. § 63.10448 defines “full load” to mean the maximum number of items that does not impede proper air removal, humidification of the load, or sterilant penetration and evacuation in the sterilization unit.

24. Subpart WWWW at 40 C.F.R. § 63.10448 defines “medically necessary” to mean circumstances that a hospital central services staff, a hospital administrator, or a physician concludes, based on generally accepted medical practices, necessitate sterilizing without a full load in order to protect human health.

25. Subpart WWWW at 40 C.F.R § 63.10420 requires that for each sterilization unit not equipped with an air pollution control device, continuous compliance with 40 C.F.R. § 63.10390 be demonstrated by “recording the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and, if not, a statement from a hospital central services staff, a hospital administrator, or a physician that it was medically necessary.”

26. Subpart WWWW at 40 C.F.R § 63.10430 requires the submission of an Initial Notification of Compliance Status no later than 180 calendar days after the applicable compliance date.

27. Subpart WWWW at 40 C.F.R §§ 63.10432 – 63.10434 requires that the records of the Initial Notification of Compliance Status and the records required under 40 C.F.R § 63.104020 be kept for 5 years.

28. Table 1 to Subpart WWWW shows that 40 C.F.R. §§ 63.4(a)(1), 63.4(a)(2) and 63.6(c)(1) all apply to facilities that are subject to Subpart WWWW.

Findings

29. VA – NIHS owns and operates a hospital at 1700 E. 38th Street, Marion, Indiana (the Facility).

30. The Facility has two enclosed vessels that use ethylene oxide gas or an ethylene oxide/inert mixture for the purpose of sterilizing, thus constituting a “sterilization unit,” as that term is defined at 40 C.F.R. § 63.10448.

31. The Facility has two ethylene oxide sterilization units, thus constituting a “sterilization facility,” as that term is defined at 40 C.F.R. § 63.10449.

32. VA –NIHS commenced construction on the sterilizers prior to November 6, 2006, making them “existing sources,” as that term is defined at 40 C.F.R. § 63.10382(b)(1)

33. The Facility is an “area source of HAP emissions,” as that term is defined at 40 C.F.R. § 63.2.

34. VA – NIHS owns and operates an “emission source” within the meaning of Section 114(a)(1) of the CAA, 42 U.S.C. § 7414(a)(1). VA – NIHS is therefore subject to the requirements of Section 114(a)(1).

35. On June 23, 2008, VA – NIHS submitted an Initial Notification of Compliance Status pursuant to 40 C.F.R § 63.10430. The Initial Notification of Compliance Status, identified the facility’s two ethylene oxide sterilizers, stated that they did not vent to an add-on air pollution control device, and certified that they were sterilizing full loads of medical items having a common aeration time, except under medically necessary circumstances.

36. On October 25, 2013, EPA sent a Section 114 Information Request to the Facility.

37. On November 21, 2013, VA – NIHS submitted a response to EPA’s Section 114 Information Request.

38. Based on the November 21, 2013, response, VA – NIHS has not kept the records required by 40 C.F.R § 63.104020 for a period of 5 years. Additionally, the records that were kept did not include all of the information required pursuant to 40 C.F.R § 63.104020.

39. VA – NIHS has informed EPA that it has plans to begin use of an add-on air pollution control device to control the emissions from its ethylene oxide sterilizers.

Compliance Program

40. By the effective date of this Order, VA – NIHS must keep records of each sterilization cycle, as required by 40 C.F.R § 63.10420, or it must use an add-on air pollution control device to control emissions from each sterilization cycle.

41. Within 30 days of the effective date of this Order, VA – NIHS will update its records retention policy to reflect the 5-year record retention requirement at Subpart WWWW at 40 C.F.R §§ 63.10434(b).

42. Within 30 days of the effective date of this Order, if VA – NIHS is still keeping records to demonstrate continuous compliance with 40 C.F.R § 63.10420, VA – NIHS will update its recordkeeping form to remove the option of running a partial load for testing/maintenance reasons.

43. If VA – NIHS begins use of an add-on air pollution control device for its ethylene oxide sterilizers and discontinues its recordkeeping pursuant to 40 C.F.R § 63.10420, VA – NIHS will submit a notification pursuant to 40 C.F.R § 63.9(j).

General Provisions

44. This Order does not affect VA – NIHS' responsibility to comply with other federal, state, and local laws.

45. This Order does not restrict EPA's authority to enforce Section 112 of the CAA, 42 U.S.C. § 7412, or any other section of the CAA.

46. Nothing in this Order limits EPA's authority to seek appropriate relief, including penalties, under Section 113 of the CAA, 42 U.S.C. § 7413, for VA – NIHS' violations of Subpart WWWW.

47. Failure to comply with this Order may subject VA – NIHS to penalties of up to \$37,500 per day for each violation under Section 113 of the CAA, 42 U.S.C. § 7413, and 40 C.F.R. Part 19.

48. The terms of this Order are binding on VA – NIHS, its assignees, and successors. VA – NIHS must give notice of this Order to any successors in interest prior to transferring

ownership and must simultaneously verify to EPA, at the above address, that it has given the notice.

49. VA – NIHS waives any and all remedies, claims for relief and otherwise available rights to judicial or administrative review that VA – NIHS may have with respect to any issue of fact or law set forth in this Order, including any right of judicial review of this Order under 42 U.S.C. § 7607(b(1) or 5 U.S.C. §§ 702, 704.

50. VA – NIHS may assert a claim of business confidentiality under 40 C.F.R. Part 2, Subpart B, for any portion of the information it submits to EPA. Information subject to a business confidentiality claim is available to the public only to the extent allowed by 40 C.F.R. Part 2, Subpart B. If VA – NIHS fails to assert a business confidentiality claim, EPA may make all submitted information available, without further notice, to any member of the public who requests it. Emission data provided under Section 114 of the CAA, 42 U.S.C. § 7414, is not entitled to confidential treatment under 40 C.F.R. Part 2, Subpart B. “Emission data” is defined at 40 C.F.R. § 2.301.

51. This order is not subject to the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.*, because it seeks collection of information by an agency from specific individuals or entities as part of an administrative action or investigation. To aid in EPA’s electronic recordkeeping efforts, please furnish an electronic copy on physical media such as compact disk, flash drive or other similar item. If it is not possible to submit the information electronically, submit the response to this Order without staples; paper clips and binder clips, however, are acceptable.

52. EPA may use any information submitted under this Order in an administrative, civil judicial, or criminal action.

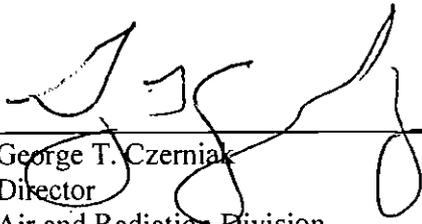
53. VA – NIHS agrees to the terms of this Order.

54. This Order is effective on the date of signature by the Director of the Air and Radiation Division. This Order will terminate two years from the effective date, provided that VA – NIHS has complied with all terms of the Order throughout its duration.

6/17/14
Date


Denise M. Deitzen
Director
VA - NIHS

6/23/14
Date


George T. Czerniak
Director
Air and Radiation Division
U.S. Environmental Protection Agency, Region 5

CERTIFICATE OF MAILING

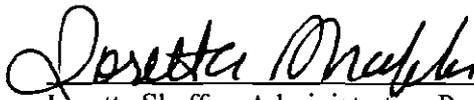
I, Loretta Shaffer, certify that I sent the Administrative Consent Order, EPA-5-14-113(a)-IN-02, by certified mail, return receipt requested, to:

T.J. Stewart
Industrial Hygienist
United States Department of Veteran Affairs
Northern Indiana Healthcare System
2121 Lake Avenue
Fort Wayne, Indiana 46805

I also certify that I sent a copy of the Administrative Consent Order, EPA-5-14-113(a)-IN-02, by first-class mail to:

Phil Perry, Chief
Compliance and Enforcement Branch
Office of Air Quality
Indiana Department of Environmental Management
100 North Senate Avenue, Room IGCN 1003
Indianapolis, Indiana 46204-2251

on the 24th day of June, 2014.



Loretta Shaffer, Administrative Program Assistant
AECAB, PAS

CERTIFIED MAIL RECEIPT NUMBER: 7001 0320 0006 0186 0002