

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5**

**IN THE MATTER OF:** )  
 )  
 IBA/Griffith Micro Science ) **Administrative Order**  
 Willowbrook, Illinois )  
 ) **EPA-5-03-113(a) IL-01**  
 Proceeding Under Sections )  
 113(a)(3) and 114(a)(1) of )  
 the Clean Air Act, 42 U.S.C. )  
 §§ 7413(a)(3) and 7414(a)(1) )

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**Administrative Order**

1. The Director of the Air and Radiation Division, United States Environmental Protection Agency (U.S. EPA), Region 5, is issuing this Order to IBA/Griffith Micro Science under Sections 113(a)(3) and 114(a)(1) of the Clean Air Act (Act), 42 U.S.C. §§ 7413(a)(3) and 7414(a)(1).

**Statutory and Regulatory Background**

2. The Administrator of U.S. EPA may promulgate regulations establishing National Emission Standards for Hazardous Air Pollutants (NESHAP) under Section 112 of the Act, 42 U.S.C. § 7412.

3. Under Section 112 of the Act, the Administrator promulgated the NESHAP General Provisions at 40 C.F.R. §§ 63.1 through 63.15 (Subpart A). Subpart A applies to owners or operators who are subject to subsequent Subparts of Part 63.

4. Subpart A, at 40 C.F.R. § 63.4(a)(2), prohibits owners and operators subject to Part 63 from failing to keep records required, notify, report, or revise reports as required under Part 63.

5. Subpart A, at 40 C.F.R. § 63.7(a)(2)(i) requires owners or operators of an affected source required to do performance testing under a relevant standard to perform such tests within 180 days after the effective date of a relevant standard for a new source that has an initial startup date before the effective date.

6. Subpart A, at 40 C.F.R. § 63.7(a)(2)(iii) requires owners or operators of an affected source required to do performance testing under a relevant standard to perform such tests within 180 days after the compliance date specified in an applicable subpart of Part 63 for an existing source subject to an emission standard established pursuant to section 112(d) of the Act.

7. Subpart A, at 40 C.F.R. § 63.8(b)(1), requires owners and operators to conduct monitoring as set forth in § 63.8 and the relevant standard(s).

8. Subpart A, at 40 C.F.R. § 63.8(c)(1), requires owners and operators of affected sources to maintain and operate continuous monitoring systems (CMS) as specified in § 63.8, or in a relevant standard, and in a manner consistent with good air pollution control practices.

9. Subpart A, at 40 C.F.R. § 63.8(c)(2), requires all CMS to be installed such that representative measurements of emissions or process parameters from the affected source are obtained.

10. Subpart A, at 40 C.F.R. § 63.8(c)(3), requires all CMS to be installed, operational, and the data verified as specified in the relevant standard either prior to or in conjunction with conducting performance tests under § 63.7. Verification of operational status shall, at a minimum, include completion of the manufacturer's written specifications or recommendations for installation, operation, and calibration of the system.

11. Subpart A, at 40 C.F.R. § 63.10(b)(1) requires the owner or operator of an affected source subject to the provisions of Part 63 to maintain files of all information (including all reports and notifications) required by Part 63 recorded in a form suitable and readily available for expeditious inspection and review. The files shall be retained for at least 5 years following the date of each occurrence, measurement, maintenance, corrective action, report, or record. At a minimum, the most recent 2 years of data shall be retained on site. The remaining 3 years of data may be retained off site. Such files may be maintained on microfilm, on a computer, on computer floppy disks, on magnetic tape disks, or on microfiche.

12. Subpart A, at 40 C.F.R. § 63.10(b)(2)(vii), requires the owner or operator of an affected source subject to Part 63 to maintain relevant records for such source of all required measurements needed to demonstrate compliance with a relevant

standard.

13. Under Section 112 of the Act, the Administrator of U.S. EPA promulgated the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Sterilization Facilities at 40 C.F.R. §§ 63.360 through 63.367 (Subpart O).

14. Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities (Subpart O), at 40 C.F.R. § 63.360(a), subjects all sterilization sources using 1 ton [of ethylene oxide] in sterilization or fumigation operations to the emissions standards in § 63.362, except as specified in paragraphs (b) through (e) of § 63.360.

15. Subpart O, at 40 C.F.R. §§ 63.360(a) and (g)(4), requires the owner or operator of any sterilization facility with an initial startup date before December 6, 2000, using 1 or more tons of ethylene oxide, to comply with the emission standards in § 63.362 for aeration room vents by December 6, 2000.

16. Subpart O, at 40 C.F.R. § 63.363(a)(1), requires the owner or operator of a source subject to emission standards in § 63.362 to conduct an initial performance test using the procedures listed in § 63.7 according to the applicability in Table 1 of § 63.360, the procedures listed in § 63.363, and the test methods listed in § 63.365.

17. Subpart O, at 40 C.F.R. § 63.363(a)(2) requires the owner or operator of all sources subject to the emission standards in § 63.362 to complete performance testing within 180 days after the compliance date for the specific source as determined in § 63.360(g).

18. Subpart O, at 40 C.F.R. § 63.363(e), requires the owner or operator of facilities complying with the emissions limits under § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers to provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating parameter(s) to be measured during the performance test. During the performance test required in paragraph (a) of this section, using the methods approved in § 63.365(g), the owner or operator shall determine the site-specific operating limits for the operating parameters approved by the Administrator.

19. Subpart O, at 40 C.F.R. § 63.364(a)(1), requires the owner or operator of a source subject to the emissions standards in § 63.362 to comply with the monitoring requirements in § 63.8 and § 63.364.

20. Subpart O, at 40 C.F.R. § 63.364(a)(2), requires the owner or operator of an ethylene oxide sterilization facility subject to the emissions standards of Subpart O to monitor the parameters specified in § 63.364.

21. Subpart O, at 40 C.F.R. § 63.364(d), requires the owner or operator of sterilization facilities complying with 40 C.F.R. § 63.363(b) or (c) through the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers to monitor parameters as approved by the Administrator using the methods and procedures in § 63.365(g).

22. Subpart O, at 40 C.F.R. § 63.365(g), requires an owner or operator of a sterilization facility seeking to demonstrate compliance with the standards found at § 63.362(c), (d), or (e) with a control device other than an acid-water scrubber or catalytic or thermal oxidation unit to provide to the Administrator the information requested under § 63.363(f). **[Reference to § 63.363(f) in § 63.365(g), as specified in this paragraph and Order, shall mean § 63.363(e).]** The owner or operator shall submit: a description of the device; test results collected in accordance with § 63.363(f) verifying the performance of the device for controlling ethylene oxide emissions to the atmosphere to the levels required by the applicable standards; the appropriate operating parameters that will be monitored; and the frequency of measuring and recording to establish continuous compliance with the standards. The monitoring plan submitted identifying the compliance monitoring is subject to the Administrator's approval. The owner or operator of the sterilization facility shall install, calibrate, operate, and maintain the monitor(s) approved by the Administrator based on the information submitted by the owner or operator. The owner or operator shall include in the information submitted to the Administrator proposed performance specifications and quality assurance procedures for their monitors. The Administrator may request further information and shall approve appropriate test methods and procedures.

23. Subpart O, at 40 C.F.R. § 63.367(a) requires the owner or operator of a source subject to § 63.362 to comply with the recordkeeping requirements in § 63.10(b) and (c), according to the applicability in Table 1 of § 63.360, and in § 63.367.

24. Under Section 113(a)(3) of the Act, 42 U.S.C. § 7413(a)(3), the Administrator of U.S. EPA may issue an order requiring compliance to any person who has violated or is violating the NESHAP regulations. The Administrator has delegated this authority to the Director of the Air and Radiation Division.

25. Under Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1), the Administrator of U.S. EPA may require any person who owns or operates an emission source to "make reports; install, use and maintain monitoring equipment; and sample emissions." The Administrator has delegated this authority to the Director of the Air and Radiation Division.

### Findings

26. IBA/Griffith Micro Science (IBA) owns and operates a commercial ethylene oxide sterilization facility with process operations located at 7775 Quincy Street, Willowbrook, Illinois, and 830 Midway Drive, Willowbrook, Illinois.

27. The Quincy Street and Midway Drive locations are collectively known as the Willowbrook facility.

28. IBA notified the Illinois Environmental Protection Agency (IEPA) on September 29, 1997, that the Quincy Street operations are an existing source subject to Subpart O with ethylene oxide usage greater than 10 tons per year.

29. IBA notified IEPA on March 8, 2000, that sterilization operations at Midway Drive started up on February 27, 2000.

30. IBA's Willowbrook facility uses at least 10 tons of ethylene oxide per year and is therefore subject to the emission standards of Subpart O.

31. IBA's Willowbrook facility includes 4 aeration rooms and 11 aeration cells vented to ethylene oxide emissions control equipment consisting of acid water scrubbers in line with dry bed reactors.

32. IBA's aeration room vents constitute an "emission source" within the meaning of Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1). Therefore, IBA is subject to the requirements of Section 114(a)(1) of the Act.

33. IBA failed to install a CMS at its Willowbrook facility

to measure emissions or process parameters from the aeration room vents prior to or in conjunction with conducting performance tests of the aeration room vents' emission control systems in violation of 40 C.F.R. § 63.8(c)(2) and 40 C.F.R. § 63.364(a)(1).

34. IBA failed to monitor emissions from the aeration room vents in violation of 40 C.F.R. § 63.364(a)(2).

35. IBA failed to maintain records of all required measurements needed to demonstrate compliance with the aforementioned emission limits in violation of 40 C.F.R. §§ 63.4(a)(2), 63.10(b)(2) and 63.367(a).

### **Compliance Program**

36. IBA shall achieve, demonstrate, and maintain compliance with the NESHAP Subparts A and O at its Willowbrook, Illinois, facility within 90 days of the effective date of this Order, as specified in Attachment A.

37. IBA shall install, calibrate, operate, and maintain a CMS consistent with the alternative monitoring plan, approved by U.S. EPA on December 19, 2002, for all aeration room vents' emissions control equipment at the Willowbrook facility within 30 days of the effective date of this Order.

38. IBA shall conduct performance testing of all of the aeration room vents' emissions control equipment at the Willowbrook facility to determine compliance status with respect to the site-specific limit(s) for the parameter(s) in the alternative monitoring plan approved by U.S. EPA within 30 days of the effective date of this Order.

39. IBA shall conduct performance testing and submit reports, as specified in Attachment A and under Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1).

40. IBA shall commence weekly recording of the ethylene oxide concentration at the aeration room vents' control equipment exhaust stacks at the Willowbrook facility immediately upon completion of the performance testing and shall maintain and retain such records on site for at least 2 years.

41. IBA shall send all reports required by this Order to:

Attention: Compliance Tracker (AE-17J)  
Air Enforcement and Compliance Assurance Branch

U.S. EPA, Region 5  
77 West Jackson Boulevard  
Chicago, Illinois 60604.

and, as specified, to:

Julie Armitage, Section Manager  
Compliance and Systems Management Section  
Bureau of Air  
Illinois Environmental Protection Agency  
1021 North Grand Avenue  
Springfield, Illinois 62702

### **General Provisions**

42. This Order does not affect IBA's responsibility to comply with other local, State, and Federal laws and regulations.

43. This Order does not restrict U.S. EPA's authority to enforce Section 112 of the Act, or any other section of the Act.

44. Nothing in this Order limits U.S. EPA's authority to seek appropriate relief, including penalties under Section 113 of the Act, 42 U.S.C. § 7413, for IBA's violations of the NESHAP Subparts A and O.

45. Failure to comply with this Order may subject IBA to penalties of up to \$27,500 per day for each violation under Section 113 of the Act, 42 U.S.C. § 7413.

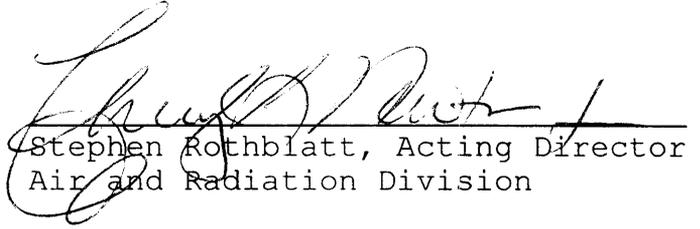
46. The terms of this Order are binding on IBA, its assignees and successors. IBA must give notice of this Order to any successors in interest, prior to transferring ownership, and must simultaneously verify to U.S. EPA, at the above address, that IBA has given the notice.

47. 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.

48. U.S. EPA may use any information submitted under this Order in an administrative, civil or criminal action.

49. This Order is effective on the date of signature by the Acting Director of the Air and Radiation Division. This Order will expire one year from the effective date, if IBA has complied with all of its terms.

12/24/12  
Date

  
Stephen Rothblatt, Acting Director  
Air and Radiation Division

Enclosure

## Attachment A

1. IBA shall conduct performance testing of all aeration room vents' emissions control systems at the Willowbrook facility (site I and site II) in accordance with the test methods and procedures at 40 C.F.R. § 63.365.
2. IBA shall conduct the performance testing under normal operating conditions representative of the maximum ethylene oxide emissions potential.
3. IBA shall conduct the performance testing after a period of at least 3 weeks of operating during which no cleaning or rehabilitation (other than normal maintenance) of any tested control equipment has occurred.
4. During each performance test run, IBA shall measure and record the ethylene oxide concentration at the aeration room vents' control equipment outlets, using each of the two portable Flame Ionization Detectors (FID) for at least 15 minutes. All procedures shall conform with the alternative monitoring plan approved by U.S. EPA on December 19, 2002.
5. During each performance test run, IBA shall measure and record the ethylene oxide concentration at the aeration room vents' control equipment outlets by collecting a 15 minute bag sample to be analyzed by each gas chromatograph (GC) on site. All procedures shall conform with the alternative monitoring plan approved by U.S. EPA on December 19, 2002.
6. IBA shall notify U.S. EPA and IEPA of the scheduled test date at least 15 days prior to the test, to allow a representative of U.S. EPA and/or IEPA to observe the test.
7. If IBA is unable to conduct the test on the date specified in the notification due to unforeseeable circumstances beyond IBA's control, IBA shall notify U.S. EPA and IEPA within 5 days prior to the scheduled performance test date and specify the date when the performance test is rescheduled. Compliance dates specified in the Administrative Order will be adjusted by U.S. EPA, if necessary, upon aforementioned demonstration and notice by IBA.
8. IBA shall submit to U.S. EPA and IEPA complete results, including all field data and records of outlet concentrations measured with the FIDs and GCs, of all testing conducted pursuant to this Order within 30 days of completion of testing.

9. IBA shall include the results of any other emission test runs, conducted or attempted within three months before the performance testing required by this Order, along with the results of the performance testing required by this Order.
10. IBA shall submit reports to U.S. EPA and IEPA, consisting of copies of the weekly monitoring records specified in paragraph 40 of the Order. The reports shall be submitted on a calendar-quarterly basis for one year after the effective date of this Order, starting with the first complete calendar quarter after the effective date of this Order. The reports shall be submitted within 30 days of the end of the reporting quarter.
11. IBA shall include in the quarterly reports specified in paragraph 10 of Attachment A copies of any and all Method 18 analysis results conducted in accordance with Section 5.1 and 5.2 of IBA's Willowbrook I and Willowbrook II Facilities Monitoring Plans, approved by U.S. EPA on December 19, 2002.
12. IBA shall include in the quarterly reports specified in paragraph 10 of Attachment A the dates of any change-out of the dry bed packing material at the Willowbrook facility.

CERTIFICATE OF MAILING

I, Betty Williams, certify that I sent the Administrative Order, EPA Order No. EPA-5-03-113(a) IL-01, by Certified Mail, Return Receipt Requested, to:

Stephen Dana Morris, Director  
Environmental Health and Safety  
IBA/Griffith Micro Science  
2015 Spring Road, Suite 650  
Oak Brook, Illinois 60523

I also certify that I sent a copy of the Administrative Order, EPA Order No. EPA-5-03-113(a) IL-01, by First Class Mail to:

Julie Armitage, Section Manager  
Compliance and Systems Management Section  
Bureau of Air  
Illinois Environmental Protection Agency  
1021 North Grand Avenue  
Springfield, Illinois 62702

Byron F. Taylor, Esq.  
Sidley Austin Brown & Wood  
Bank One Plaza  
10 South Dearborn  
Chicago, Illinois 60603

Mark R. Bogs, Plant Manager  
IBA/Griffith Micro Science  
7775 Quincy Street  
Willowbrook, Illinois 60521

on the 24<sup>th</sup> day of December 2002.

  
Betty Williams, Secretary  
AECAS (IL/IN)

CERTIFIED MAIL RECEIPT NUMBER: 7001 0320 0006 0178 3752