

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

IN THE MATTER OF:)
)
Cook Incorporated) **Administrative Consent Order**
Ellettsville, Indiana)
) **EPA-5-03-113(a)-IN-02**
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))

Administrative Consent 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 Cook Incorporated 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, 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 40 C.F.R. § 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 defined in 40 C.F.R. § 63.2 and as specified in 40 C.F.R. § 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 § 63.364 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 Acting 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 Acting Director of the Air and Radiation Division.

Findings

26. Cook Incorporated (Cook) owns and operates a commercial ethylene oxide sterilization facility with process operations located at 6330 North Matthews Drive, Ellettsville, Indiana.

27. Cook operates six (6) ethylene oxide sterilization chambers constructed between 1985 and 1998.

28. Cook operates fourteen aeration rooms constructed in 1989 and 1998.

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

30. Cook'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, Cook is subject to the requirements of Section 114(a)(1) of the Act.

31. Cook installed a scrubber/dry bed reactor system to control ethylene oxide emissions from the aeration room vents.

32. Cook did not submit to the Administrator for review and approval information describing the design and operation of its air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance, in violation of 40 C.F.R. § 63.363(e).

33. Cook did not install a CMS approved by U.S. EPA at its Ellettsville facility to measure emissions or process parameters from the aeration room vents, in violation of 40 C.F.R.

§ 63.8(c)(2) and 40 C.F.R. § 63.364(a)(1).

34. Cook does not monitor emissions from the aeration room vents in a manner approved by U.S. EPA, as required by 40 C.F.R. § 63.364(a)(2).

35. Cook does not maintain records of all required measurements needed to demonstrate compliance with the aforementioned emission limits in a manner approved by U.S. EPA, as required by 40 C.F.R. §§ 63.4(a)(2), 63.10(b)(2) and 63.367(a).

Compliance Program

36. Cook must achieve, demonstrate, and maintain compliance with the NESHAP Subparts A and O at its Ellettsville, Indiana, facility within 120 days of the effective date of this Order.

37. Cook must submit to the U.S. EPA for approval a plan for continuous monitoring of emissions from the all of the aeration room vents' emissions control equipment at the Ellettsville facility within 30 days of the effective date of this Order. The plan shall be consistent with the requirements specified at 40 C.F.R. §§ 63.363(e) and 63.365(g) and shall be reviewed in accordance with the procedures of 40 C.F.R. 63.8(f). The plan must include a summary of results from the June 3-4, 1999 performance testing.

38. Cook must install, calibrate, operate, and maintain a CMS for all aeration room vents' emissions control equipment at the Ellettsville facility within 30 days of U.S. EPA approval of the monitoring plan submitted pursuant to paragraph 37.

39. Cook must conduct performance testing of all of the aeration room vents' emissions control equipment at the Ellettsville facility to determine the site-specific operating limit(s) for the operating parameter(s) specified in the monitoring plan approved by the U.S. EPA, within 30 days of U.S. EPA approval of the monitoring plan submitted pursuant to paragraph 37. Cook shall conduct the performance testing and submit reports, as specified in Appendix A, under Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1).

40. Cook shall commence recording of the compliance parameter(s) monitored pursuant to this Order immediately upon completion of the performance testing and shall maintain and retain such records on site for at least 2 years.

41. Cook shall submit copies of the compliance monitoring records to the U.S. EPA and IDEM on a quarterly basis, for one year after the effective date of this Order.

42. Cook must 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:

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

General Provisions

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

44. Cook Incorporated neither admits nor denies the violations alleged in this Order.

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

46. 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 Cook's violations of the NESHAP Subparts A and O.

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

48. The terms of this Order are binding on Cook, its assignees and successors. Cook 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 Cook has given the notice.

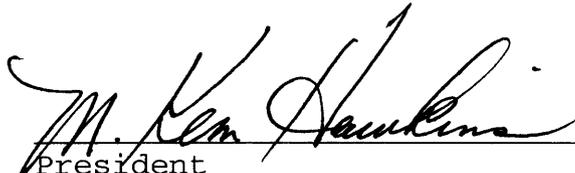
49. This Order is not subject to the Paperwork Reduction Act, 44 U.S.C. §§ 3501 et seq., because it seeks collection of information by an agency from specific individuals or entities as part of an administrative action or investigation.

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

51. Cook agrees to the terms of this Order.

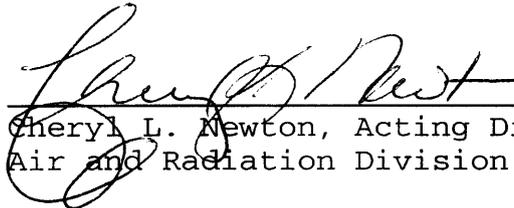
52. This Order is effective on the date of signature by the Acting Director of the Air and Radiation Division. This Order will expire one year from the effective date, if Cook has complied with all of its terms.

3/17/03
Date



President
Cook Incorporated

4/7/03
Date



Cheryl L. Newton, Acting Director
Air and Radiation Division

Enclosure

Appendix A

1. Cook shall conduct performance testing of the aeration room vents' emissions control system at the Ellettsville facility in accordance with the test methods and procedures at 40 C.F.R. § 63.365 and applicable test methods at 40 C.F.R. part 60, Appendix A.
2. Cook shall conduct the performance testing under normal operating conditions representative of the maximum ethylene oxide emissions potential.
3. Cook shall notify U.S. EPA and the Indiana Department of Environmental Management (IDEM) of the scheduled test date at least 15 days prior to the test, to allow a representative of U.S. EPA and/or IDEM to observe the test.
4. If Cook is unable to conduct the test on the date specified in the notification due to unforeseeable circumstances beyond Cook's control, Cook shall notify U.S. EPA and IDEM 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 Order will be adjusted by U.S. EPA in writing, if necessary, upon aforementioned demonstration and notice by Cook.
5. Cook shall submit complete data and results of all testing to U.S. EPA and IDEM within 30 days of completion of testing.
6. Cook shall submit the results of any other emission test runs it has conducted or attempted within three months before the performance testing required by this Order to U.S. EPA and IDEM along with the results of the performance testing required by this Order.

CERTIFICATE OF MAILING

I, Betty Williams, certify that I sent the Administrative Consent Order, EPA Order No. EPA-5-03-113(a)-IN-02, by Certified Mail, Return Receipt Requested, to:

Larry Price, Safety Director
Cook Incorporated
750 Daniels Way
Bloomington, Indiana 47402-0489

I also certify that I sent a copy of the Administrative Consent Order, EPA Order No. EPA-5-03-113(a)-IN-02, by First Class Mail to:

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

Lawrence A. Vanore, Attorney at Law
Sommer & Barnard
4000 Bank One Tower
111 Monument Circle
Indianapolis, Indiana 46204-5140

Art Harris, Sterilization Manager
Cook Incorporated
6300 N. Matthews Drive
Ellettsville, Indiana 47429-9495

on the 7th day of April 2003.


Betty Williams, Secretary
AECAS (IL/IN)

CERTIFIED MAIL RECEIPT NUMBER: 7001032600060183035