

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5

IN THE MATTER OF: )  
 )  
Cosmed of Illinois ) Administrative Order  
Waukegan, Illinois )  
 ) EPA-5-02-113(a) -IL-03  
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 Cosmed of Illinois 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. § 63.8(b)(1), requires owners

and operators to conduct monitoring as set forth in § 63.8 and the relevant standard(s).

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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).

13. 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 in sterilization or fumigation operations to the emissions standards in § 63.362, except as specified in paragraphs (b) through (e) of § 63.360.

14. 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.

15. 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.

16. 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).

17. 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.

18. 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.

19. 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.

20. 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" under Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1). The Administrator has delegated this authority to the Director of the Air and Radiation Division.

### Findings

21. Cosmed of Illinois (Cosmed) owns and operates a commercial ethylene oxide sterilization facility with process operations at 1160 Northpoint Boulevard, Waukegan, Illinois.

22. Cosmed notified the Illinois Environmental Protection Agency (IEPA) on April 4, 1995, that sterilization operations at the Waukegan facility started up on May 29, 1994.

23. Cosmed's May 29, 1994 notification states that upon startup, Cosmed was using more than ten (10) tons per year of ethylene oxide at the Waukegan facility. Therefore, Cosmed is subject to the emission standards of Subpart O.

24. Cosmed's Waukegan facility includes aeration rooms vented to ethylene oxide emissions control equipment consisting of two acid water scrubbers. Cosmed'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, Cosmed is subject to the requirements of Section 114(a)(1) of the Act.

25. Cosmed failed to conduct a performance test of the aeration room vents' emissions control system at its Waukegan facility, in violation of 40 C.F.R. §§ 63.7(a)(2)(i) and 63.363(a)(2).

26. Cosmed failed to install a continuous monitoring system (CMS) at its Waukegan facility to measure emissions or process parameters from the aeration room vents, in violation of 40 C.F.R. § 63.8(c)(2).

27. Cosmed 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

28. Cosmed must achieve, demonstrate, and maintain compliance with NESHAP Subparts A and O at its Waukegan, Illinois, facility within 45 days of the effective date of this Order, as specified in Appendix A.

29. Cosmed must conduct performance testing and submit reports, as specified in Appendix A, and required under Section 114(a)(1) of the Act, 42 U.S.C. § 7414(a)(1).

30. Cosmed 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.

### General Provisions

31. This Order does not affect Cosmed's responsibility to comply with any local, State, and Federal laws and regulations.

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

33. 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 Cosmed's violations of the NESHAP Subparts A and O.

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

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

36. 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.

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

38. This Order is effective on the date of signature by the Acting Director of the Air and Radiation Division.

7/3/02  
Date

AS A ACTING  
Stephen Rothblatt, Acting Director  
Air and Radiation Division

Enclosure

## Appendix A

1. Cosmed shall conduct performance testing of the aeration room vents' emissions control system in accordance with the test methods and procedures at 40 C.F.R. § 63.365 and with the Test Protocol for Ethylene Oxide Packed Tower Scrubber Emission Testing submitted by Cosmed to U.S. EPA on May 31, 2002.
2. Cosmed shall establish either scrubber liquor tank level or scrubber liquor ethylene glycol concentration as a compliance parameter in conjunction with the performance testing, in accordance with 40 C.F.R. § 63.365(e)(1) or (2).
3. Cosmed shall conduct the performance testing under normal operating conditions representative of the maximum ethylene oxide emissions potential.
4. Cosmed has notified U.S. EPA that performance testing will tentatively be conducted on July 10, 2002. Cosmed shall allow a representative of U.S. EPA and/or IEPA to observe the test.
5. If Cosmed is unable to conduct the test on the July 10, 2002, due to unforeseeable circumstances beyond Cosmed's control, Cosmed shall notify U.S. EPA and the IEPA within 5 days prior to the scheduled performance test date and specify the date when the performance test is rescheduled, to allow a representative of U.S. EPA and/or IEPA to observe the test.
6. Cosmed shall submit results of all testing, as specified in the Test Protocol for Ethylene Oxide Packed Tower Scrubber Emission Testing, to U.S. EPA and IEPA within 30 days of completion of testing.
7. Cosmed shall submit the results of any other emission test runs conducted or attempted within three months before the performance testing required by this Order to U.S. EPA and IEPA along with the results of the performance testing required by this Order.
8. Cosmed shall begin monitoring either scrubber liquor tank level or ethylene glycol concentration as specified at 40 C.F.R. § 63.364(b)(1) or (2) immediately upon completion of the performance testing.
9. Cosmed shall commence weekly recording of the compliance parameter monitored pursuant to paragraph 8 of the Appendix immediately upon completion of the performance testing and shall retain such records on site for at least 2 years.

CERTIFICATE OF MAILING

I, Betty Williams, certify that I sent the Administrative Order, EPA -5-02-113(a)-IL-03, by Certified Mail, Return Receipt Requested, to:

Ms. Monica Figueroa  
General Manager  
Cosmed of Illinois  
1160 Northpoint Boulevard  
Waukegan, IL 60085

I also certify that I sent a copy of the Administrative Order, EPA -5-02-113(a)-IL-03, 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

Ms. Colleen E. Baime, Esq.  
McDermott, Will & Emery  
227 West Monroe Street  
Chicago, Illinois 60606-5096

Mark D. Kloster, Process Engineer  
Cosmed of Illinois  
1160 Northpoint Boulevard  
Waukegan, IL 60085

on the 8<sup>th</sup> day of July 2002.

  
Betty Williams, Secretary  
AECAS (IL/IN)

CERTIFIED MAIL RECEIPT NUMBER: 7099 346 0000 9586-6215