Sunshine Act Meetings

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This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL RESERVE SYSTEM

Committee on Employee Benefits

TIME AND DATE: 4:00 p.m., Tuesday, September 20, 1988.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. The Committee's agenda will consist of matters relating to: (a) The general administrative policies and procedures of the Retirement Plan, Thrift Plan, Long-Term Disabililty Income Plan, and Insurance Plan for Employees of the Federal Reserve System; (b) general supervision of the operations of the Plans; (c) the maintenance of proper accounts and accounting procedures in respect to the Plans; (d) the preparation and submission of an annual report on the operations of each of such Plans; (e) the maintenance and staffing of the Office of the Federal Reserve Employee Benefits System; and (f) the arrangement for such legal, actuarial, accounting, administrative, and other services as the Committee deems necessary to carry out the provisions of the Plans.

Specific items include: (1) Early retirement program for a Federal Reserve Bank; and (2) Amendment to the System's pension plan.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Date: September 12, 1988.

William W. Wiles,

Secretary of the Board.

[FR Doc. 88-21051 Filed 9-12-88; 2:57 pm]

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federal register

Wednesday
September 14, 1988

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 886

Ophthalmic Devices; Exemptions From Premarket Notification; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. 86N-0013]

Ophthalmic Devices; Exemptions From Premarket Notification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting from the requirement of premarket notification, with limitations, 55 generic types of class I ophthalmic devices. For the exempted devices, FDA has determined that manufacturers submissions of premarket notifications are unnecessary for the protection of the public health and that review of such notifications by the agency will not advance FDA's public health mission. Granting the exemptions will allow the agency to make better use of its resources and thus better serve the public.

EFFECTIVE DATE: Otober 14, 1988.

FOR FURTHER INFORMATION CONTACT: Richard E. Lippman, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7320.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (the amendments) Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance and safety and effectiveness: class I, general controls; class II, performance standards; and class III, premarket approval.

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A)) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR Part 807, Subpart E. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for preamendment devices, the agency did not routinely evaluate whether it should grant to manufacturers of devices placed in class I an exemption from the requirement of premarket notification. Generally, FDA considered such exemptions only when the advisory panels specifically included them in recommendations made to the agency. Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification, to reduce the number of unnecessary premarket notifications, thereby freeing agency resources for the review of more complex notifications.

FDA believes that exempting certain devices from premarket notification will allow the agency to make better use of its resources and thus better serve the public. In other words, the process of exempting devices from the premarket notification program of section 510(k) of the act (21 U.S.C. 360(k)), where premarket notification will not advance FDA's public health mission, will free additional resources to address pressing regulatory concerns and will make the agency more efficient. The development of exemption criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification will help implement a goal in FDA's May 1987 "A Plan for Action Phase II" (Ref. 1).

On September 2, 1987 (52 FR 33346), FDA published a final regulation classifying 109 ophthalmic devices. Also on September 2, 1987 (52 FR 33366), FDA proposed to exempt from the requirement of premarket notification, with limitations, 55 of those class I ophthalmic devices. Interested persons were given until November 2, 1987, to comment. No comments were received. Therefore, FDA is adopting the regulation as proposed.

Criteria for 510(k) Exemptions

FDA is exempting a generic type of class I device from the requirement of premarket notification, with the limitations described below, if the agency determines that premarket notification is unnecessary for the protection of the public health. FDA is granting an exemption if both of the following criteria are met:

1. FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials. When making these determinations, FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors.

2. FDA has determined that: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that are of the type that could affect safety and effectiveness will (i) be readily detectable by users by visual examination or other means, such as routine testing, e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm; or (ii) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) that any changes in the device will not be likely to result in a change in the device's classification.

FDA will make the determination above based on its knowledge of the device, including past experience and relevant reports or studies on device performance. FDA may, if it has concerns only about certain types of changes in a class I device, grant a limited exemption from premarket notification for the generic type of device. A limited exemption will specify what types of changes manufacturers must continue to report to FDA in the context of premarket notification. For example, FDA may exempt a device except when a manufacturer intends to use a different material.

FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic of a device that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(1) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(2) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical

instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Reference

The following information has been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Food and Drug Administration—A Plan for Action Phase II," Public Health Service, Department of Health and Human Services, May 1987, p. 19.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Economic Impact

FDA has carefully analyzed the economic effects of this final rule and has determined that the final rule would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this final rule has been carefully analyzed, and it has been determined that the final rule does not constitute a major rule as defined in section 1(b) of the Executive Order.

The devices subject to this final rule are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j), with certain exemptions.

List of Subjects in 21 CFR Part 886

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

1. The authority citation for 21 CFR Part 886 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. Section 886.9 is added to Subpart A to read as follows:

§ 886.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

3. Section 886.1040 is amended by revising paragraph (b) to read as follows:

§ 886.1040 Ocular esthesiometer.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

4. Section 886.1140 is amended by revising paragraph (b) to read as follows:

§ 886.1140 Ophthalmic chair.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

5. Section 886.1150 is amended by revising paragraph (b) to read as follows:

§ 886.1150 Visual acuity chart.

* * * * *

(b) *Classification.* The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

6. Section 886.1170 is amended by revising paragraph (b) to read as follows:

§ 886.1170 Color vision tester.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

7. Section 886.1190 is amended by revising paragraph (b) to read as follows:

§ 886.1190 Distometer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

8. Section 886.1200 is amended by revising paragraph (b) to read as follows:

§ 886.1200 Optokinetic drum.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

9. Section 886.1270 is amended by revising paragraph (b) to read as follows:

§ 886.1270 Exophthalmometer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter.

10. Section 886.1320 is amended by revising paragraph (b) to read as follows:

§ 886.1320 Fornixscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

11. Section 886.1330 is amended by revising paragraph (b) to read as follows:

§ 886.1330 Amsler grid.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

12. Section 886.1350 is amended by revising paragraph (b) to read as follows:

§ 886.1350 Keratoscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

13. Section 886.1375 is amended by revising paragraph (b) to read as follows:

§ 886.1375 Bagolini lens.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

14. Section 886.1380 is amended by revising paragraph (b) to read as follows:

§ 886.1380 Diagnostic condensing lens.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

15. Section 886.1390 is amended by revising paragraph (b) to read as follows:

§ 886.1390 Flexible diagnostic Fresnel lens.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

16. Section 886.1395 is amended by revising paragraph (b) to read as follows:

§ 886.1395 Diagnostic Hruby fundus lens.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

17. Section 886.1400 is amended by revising paragraph (b) to read as follows:

§ 886.1400 Maddox lens.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

18. Section 886.1410 is amended by revising paragraph (b) to read as follows:

§ 886.1410 Ophthalmic trial lens clip.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

19. Section 886.1415 is amended by revising paragraph (b) to read as follows:

§ 886.1415 Ophthalmic trial lens frame.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

20. Section 886.1420 is amended by revising paragraph (b) to read as follows:

§ 886.1420 Ophthalmic lens gauge.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter.

21. Section 886.1460 is amended by revising paragraph (b) to read as follows:

§ 886.1460 Stereopsis measuring instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

22. Section 886.1500 is amended by revising paragraph (b) to read as follows:

§ 886.1500 Headband mirror.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

23. Section 886.1605 is amended by revising paragraph (b) to read as follows:

§ 886.1605 Perimeter.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

24. Section 886.1650 is amended by revising paragraph (b) to read as follows:

§ 886.1650 Ophthalmic bar prism.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

25. Section 886.1655 is amended by revising paragraph (b) to read as follows:

§ 886.1655 Ophthalmic Fresnel prism.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

26. Section 886.1660 is amended by revising paragraph (b) to read as follows:

§ 886.1660 Gonioscopic prism.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter.

27. Section 886.1665 is amended by revising paragraph (b) to read as follows:

§ 886.1665 Ophthalmic rotary prism.

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(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

28. Section 886.1700 is amended by revising paragraph (b) to read as follows:

§ 886.1700 Pupillometer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

29. Section 886.1770 is amended by revising paragraph (b) to read as follows:

§ 886.1770 Manual refractor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

30. Section 886.1790 is amended by revising paragraph (b) to read as follows:

§ 886.1790 Nearpoint ruler.

* * * * *

(b) *Classification.* Class I. The device also is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

31. Section 886.1800 is amended by revising paragraph (b) to read as follows:

§ 886.1800 Schirmer strip.

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(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter.

32. Section 886.1810 is amended by revising paragraph (b) to read as follows:

§ 886.1810 Tangent screen (campimeter).

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

33. Section 886.1840 is amended by revising paragraph (b) to read as follows:

§ 886.1840 Simulation (including crossed cylinder).

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good

manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

34. Section 886.1860 is amended by revising paragraph (b) to read as follows:

§ 886.1860 Ophthalmic instrument stand.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

35. Section 886.1870 is amended by revising paragraph (b) to read as follows:

§ 886.1870 Stereoscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

36. Section 886.1880 is amended by revising paragraph (b) to read as follows:

§ 886.1880 Fusion and stereoscopic target.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

37. Section 886.1905 is amended by revising paragraph (b) to read as follows:

§ 886.1905 Nystagmus tape.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

38. Section 886.1910 is amended by revising paragraph (b) to read as follows:

§ 886.1910 Spectacle dissociation test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

39. Section 886.4230 is amended by revising paragraph (b) to read as follows:

§ 886.4230 Ophthalmic knife test drum.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

40. Section 886.4335 is amended by revising paragraph (b) to read as follows:

§ 886.4335 Operating headlamp.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter.

41. Section 886.4350 is amended by revising paragraph (b) to read as follows:

§ 886.4350 Manual ophthalmic surgical instrument.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter.

42. Section 886.4360 is amended by revising paragraph (b) to read as follows:

§ 886.4360 Ocular surgery irrigation device.

* * * * *

(b) *Classification.* Class I. If the device does not directly contact the patient's body, the device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter.

43. Section 886.4445 is amended by revising paragraph (b) to read as follows:

§ 886.4445 Permanent magnet.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

44. Section 886.4570 is amended by revising paragraph (b) to read as follows:

§ 886.4570 Ophthalmic surgical marker.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

45. Section 886.4770 is amended by revising paragraph (b) to read as follows:

§ 886.4770 Ophthalmic operating spectacles (loupes).

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

46. Section 886.4855 is amended by revising paragraph (b) to read as follows:

§ 886.4855 Ophthalmic instrument table.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807,

Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

47. Section 886.5120 is amended by revising paragraph (b) to read as follows:

§ 886.5120 Low-power binocular loupe.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

48. Section 886.5420 is amended by revising paragraph (b) to read as follows:

§ 886.5420 Contact lens inserter/remover.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter.

49. Section 886.5540 is amended by revising paragraph (b) to read as follows:

§ 886.5540 Low-vision magnifier.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

50. Section 886.5600 is amended by revising paragraph (b) to read as follows:

§ 886.5600 Ptosis crutch.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

51. Section 886.5800 is amended by revising paragraph (b) to read as follows:

§ 886.5800 Ophthalmic bar reader.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

52. Section 886.5810 is amended by revising paragraph (b) to read as follows:

§ 886.5810 Ophthalmic prism reader.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

53. Section 886.5840 is amended by revising paragraph (b) to read as follows:

§ 886.5840 Magnifying spectacles.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements.

54. Section 886.5844 is amended by revising paragraph (b) to read as follows:

§ 886.5844 Prescription spectacle lens.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter.

55. Section 886.5870 is amended by revising paragraph (b) to read as follows:

§ 886.5870 Low-vision telescope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

56. Section 886.5910 is amended by revising paragraph (b) to read as follows:

§ 886.5910 Image intensification vision aid.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

57. Section 886.5915 is amended by revising paragraph (b) to read as follows:

§ 886.5915 Optical vision aid.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Part 807, Subpart E of this chapter. The device also is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Dated: August 22, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-20692 Filed 9-13-88; 8:45 am]

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Part III

Department of Labor

Occupation Safety and Health Administration

29 CFR Parts 1910 and 1926

Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite; Final Rules; Amendment

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910 and 1926

[Docket No. H-033]

Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rules; amendment.

SUMMARY: On June 20, 1986 OSHA published revised standards governing occupational exposure to asbestos, tremolite, anthophyllite and actinolite in general industry and construction. In these standards, OSHA reduced the 8-hour time weighted average (TWA) permissible exposure limit (PEL) to 0.2 f/cc. but did not issue a short term exposure limit (STEL) or excursion limit for exposure to these materials. OSHA is now amending these rules by adding an excursion limit of 1 f/cc average over a sampling period of 30 minutes.

The Agency has based this determination on its review of the asbestos rulemaking record using criteria set forth by the Court of Appeals for the District of Columbia Circuit (*Public Citizen Health Research Group* v. *Tyson*, 796 F. 2d 1479 (D.C. Cir., 1986) and *Building and Construction Trades Department, AFL–CIO* v. *Brock*, 838 F. 2d 1258, 1273 (D.C. Cir., 1988)). Based on this review, OSHA has determined that the record supports the issuance of a 1 f/cc excursion limit measured over 30 minutes for all workplaces affected by the revised asbestos standards and is amending the standards to that effect. In addition employers are required to take other protective actions when employee exposures exceed the EL. The evidence and considerations supporting this determination are set out in the supplementary information section of this document.

EFFECTIVE DATE: This final standard will become effective October 14, 1988 except the information collection requirements of 29 CFR 1910.1001 (d)(2), (d)(3), (d)(5), (d)(7), (f)(2), (f)(3)(i), (j)(5), (l), and (m), and 29 CFR 1926.58 (f)(2), (f)(3), (f)(6), (h)(3)(i), (k)(3), (k)(4), (m) and (n) as they apply to the excursion limit which will be submitted to OMB for approval. OSHA will publish a document in the future establishing an effective date for the information collection requirements.

FOR FURTHER INFORMATION CONTACT: Mr. James Foster, OSHA, U.S. Department of Labor, Office of Public Affairs, Room N3647, 200 Constitution Avenue NW., Washington, DC 20210. Telephone (202) 523–8151.

SUPPLEMENTARY INFORMATION:

I. Clearance of Information Collection Requirements

On March 31, 1983, the Office of Management and Budget (OMB) published 5 CFR Part 1320, implementing the information collection provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. (48 FR 13666). Part 1320, which became effective on April 30, 1983 and was revised May 10, 1988 **Federal Register**, Vol. 53, No. 90), sets forth procedures for agencies to follow in obtaining OMB clearance for information collection requirements. The sections of this final standard which may create recordkeeping requirements are the following: 29 CFR 1910.1001 (d)(2), (d)(3), (d)(5), (d)(7), (f)(2), (f)(3)(i), (j)(5), (l), and (m), and 29 CFR 1926.58 (f)(2), (f)(3), (f)(6), (h)(3)(i), (k)(3), (k)(4), (m) and (n).

In accordance with the provisions of the Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA certifies that it will be submitting the information collection requirements for the standards under control numbers 1218–0133 and 1218–0134 to OMB for review under section 3504(h) of that Act.

Public reporting burden for this collection of information for General Industry is estimated to average 0.73 hours per response and 0.03 hours per response for the Construction Industry, which includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or and other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Information Management, Department of Labor, Room N–1301, 200 Constitution Avenue., NW., Washington, DC 20210; and to the Office of Information and regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

II. Regulatory and Legal Authority Background

On June 17, 1986, OSHA issued revised standards governing occupational exposure to asbestos, tremolite, anthophyllite and actinolite for general industry and construction (51 FR 22612 *et seq.*, Pub. June 20, 1986). Effective July 21, 1986, the revised standards amended OSHA's previous asbestos standard issued in 1972. The 1972 standard included a 10 f/cc "ceiling" limit as well as a 2 f/cc time weighted average (TWA) permissible exposure limit.

Chief among the revised standards provisions was a tenfold reduction in the TWA PEL to 0.2 f/cc from 2 f/cc. However, although the April 1984 notice of proposed rulemaking stated that OSHA would consider a revised ceiling limit, in the final revised standards OSHA determined not to issue an explicit short term limit (51 FR 22682–3, 22709).

OSHA based this determination on its finding that the rulemaking record consisting of "toxicological and dose-response data failed to show that short-term exposure to asbestos is associated with an independent or greater adverse health effect than is exposure to a corresponding dose spread over an 8-hour day; that is, there is no evidence that exposure to asbestos results in a "dose-rate" effect * * *" OSHA further stated that its decision was "consistent with OSHA's recent policy decision described in the Supplemental Statement of Reasons for the Final Rule for Ethylene Oxide (50 FR 64) in which OSHA established that short term exposure limits for toxic substances are not warranted in the absence of health evidence demonstrating a dose-rate effect (51 FR at 22709)." OSHA's decision to not issue a STEL was challenged in petitions filed in the Court of Appeals for the District of Columbia.

Subsequently, on July 25, 1986, the United States Court of Appeals for the District of Columbia reviewed the ethylene oxide (EtO) standard which OSHA had relied on in its decision to not issue an asbestos EL. It held that OSHA contravened the OSH Act when it failed to issue a short term limit for ethylene oxide based on the Agency's finding that the EtO record did not support a "dose-rate effect." The Court held that the OSH Act compels the Agency to adopt a short term limit if the rulemaking record shows that it would further reduce a significant health risk and is feasible to implement regardless of whether the record supports a "dose-rate" effect (796 F. 2nd at 1505). This decision states that "(B)arring alternative avenues to the same result, OSHA shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence that no employees will suffer material impairment of health. 29 U.S.C. 655 (b)(5) (1982). "(S)ince OSHA has found that a significant health hazard remains even with the (TWA) PEL, the agency must find either that a STEL will have no effect on that risk, or that a STEL is not

feasible, if the Agency declines to impose a short term limit" (796. F. 2nd at 1505).

Because OSHA had relied on the EtO rationale in making its asbestos decision, OSHA decided to reconsider its decision not to issue an excursion limit for asbestos and informed the Court of its intention to reconsider the STEL issue based on the existing record.

The Court issued its decision reviewing the asbestos standards in February 1988 (*B.C.T.D., AFL-CIO* v. *Brock* 838 F. 2d 1258). Therein, the Court noted OSHA's commitment to complete reconsideration of the STEL issue and ordered "that reconsideration be completed within 60 days of the issuance of the mandate in this case, which issued on July 6, 1988.

The Court also reiterated the criteria requiring an agency to adopt a STEL: *viz*, that the measure will result in a further reduction in significant health risk and that it is feasible to implement.

OSHA has reviewed the asbestos rulemaking record in order to apply these criteria. The agency finds that compliance with a short term excursion limit would further reduce a significant health risk remaining after the TWA limit of 0.2 f/cc was imposed. Secondly, the Agency finds that the lowest excursion level which is feasible both to measure and to institute primarily through engineering and work practice controls is 1 fiber per cc measured over 30 minutes. OSHA therefore is imposing this level as an excursion limit to be met by all employers covered by the revised standards. The Agency also is withdrawing its previous determination to not issue an excursion limit or STEL.

OSHA notes that it is adopting the term "excursion limit" to refer to the short term permissible exposure limit established here, so that the terminology used by the American Conference of Governmental Industrial Hygienists (ACGIH) and by OSHA will not conflict. The term "excursion limit" is used by the ACGIH to refer to a limitation on short term exposures which are called for by industrial hygiene considerations, where toxicological data are unavailable. The term "STEL" is used by the American Conference of Governmental Industrial Hygienists (ACGIH) to refer to a short term limit dictated by specific toxicologic or hazard data (ACGIH Threshold Limit Values and Biological Exposure Indices for 1986–1987, 3–5). Because OSHA is not basing the short term permissible limit for asbestos on toxicological data, OSHA instead is using the term "excursion limit" to designate that limit.

The term "ceiling limit" historically was used by OSHA to refer to both a "peak" limit, *ie*, with no duration specified, and to a limit measured over a given time period, such as 30 minutes. Because of this dual usage, the term was imprecise and OSHA believes it should be replaced with "excursion limit."

This preamble, in some places, uses "STEL" and "excursion limit" interchangeably, mostly in quoting from previous discussions to conform to previous usage. The following discussion further explains the reasons for OSHA's decision to adopt an excursion limit of 1 f/cc measured over 30 minutes.

A. The Excursion Limit Chosen Will Further Reduce a Significant Health Risk

OSHA finds that compliance with a reduced excursion limit would further reduce a significant health risk from asbestos exposure which exits after imposing a 0.2 f/cc time-weighted PEL.

OSHA's risk assessment showed that lowering the TWA PEL from 2 f/cc to 0.2 f/cc reduces the asbestos related cancer mortality risk from lifetime exposure from 64 deaths per 1,000 worker to 6.7 deaths per 1,000 workers. OSHA estimated that the incidence of asbestosis would be 5 cases per 1,000 workers exposed for a working lifetime under the TWA PEL of 0.2 f/cc. Counterpart risk figures for 20 years of exposure are excess cancer risks of 4.5 per 1,000 workers and an estimated asbestosis incidence of 2 cases per 1,000 workers.

OSHA's risk assessment also showed the persistence of a significant risk at the 0.1 f/cc action level. The excess cancer risk remaining at that level is a lifetime risk of 3.4 per 1,000 workers and a 20 year exposure risk of 2.3 per 1,000 workers. OSHA concludes therefore that continued exposure to asbestos at the TWA permitted level and action level presents residual risks to employees which are still significant.

Imposing the excursion limit will reduce risk to employees whose asbestos exposure is limited to one or two short term bursts, lasting 30 minutes each. If the periods of exposure are less than 30 minutes then employees with more "bursts" will also have their risk reduced by the excursion limit. The maximum reduction will be felt by employees with non-detectable background asbestos exposures, whose only detectable exposure is a single burst (or bursts) lasting no longer than 30 minutes and which measure no more than 3.2 f/cc (the short term equivalent of the 0.2 f/cc TWA PEL).

To calculate the degree of risk reduction for such employees we note that the 8-hour time-weighted average exposure equivalent of the excursion limit established here is 0.063 f/cc. That is, if a worker is exposed to asbestos at the excursion limit of 1 f/cc for 30 minutes and exposed to no other asbestos for the remainder of the day, the 8 hour TWA exposure would be 0.063 f/cc. This figure is calculated by dividing the excursion limit of 1 f/cc by the number of 30 minute periods in an eight hour work day (16).

The risk assessment methods previously employed in the final asbestos standards (the linear cumulative dose model) can be used to calculate cancer risks for workers exposed only to one burst of asbestos for 30 minutes at the 1 f/cc excursion limit (equivalent to 0.063 f/cc as an 8-hour TWA). Using linear proportionality to previously calculated risks, these predictions are a lifetime (45 year) excess risk of 2.3 per 1,000 workers, and an excess cancer risk for 20 years exposure of 1.5 per 1,000 workers. OSHA believes that these risks are clearly not insignificant. In this case where workers are exposed only to one burst of asbestos per day, asbestos exposure and thus also cancer risk are substantially reduced by 67%. Where additional exposures occur beyond the 30-minute exposure, the reduction in risk is lower than calculated, and conversely, the cancer risk is greater than calculated.

The impact of this reduction will be felt by approximately 35,800 employees estimated by OSHA as having 8-hour TWA exposures below the current 0.2 f/cc PEL but short term exposures which exceed the excursion limit. (See Table 2, infra).

Thus, in accordance with the *Public Citizen* decision, the imposition of an excursion limit will further reduce significant risk remaining under the current standard. OSHA estimates, based on the total estimated affected population, and the risk factors cited, that about 118 lives will be saved based on lifetime exposures and 79 lives based on 20 year exposure because of the imposition of this excursion limit.

OSHA also finds that unregulated short-term exposures to asbestos unnecessarily elevate cumulative exposures even if the time weighted average is below the PEL. Because OSHA has found that significant risks of asbestos-related disease exist at cumulative exposures below the 1986 PEL of 0.2 f/cc, compliance with an excursion limit would further reduce such risks as well (See 51 FR at 26647–8), although these reductions have not been quantified.

The ways the institution of an excursion limit of 1 f/cc over 30 minutes will reduce risks to employees are illustrated by the following examples from the rulemaking record.

In some important operations exposure patterns consist of frequent short term rather that continuous levels of exposure. In the construction industry, asbestos removal and repair of asbestos-containing products are often short-term and generate peak exposures (Ex. 84–474, 84–462). Installation of new construction materials also involves intermittent peak exposures, for example, drilling and sawing pipe and sheet.

When asbestos-cement pipe is installed, cutting and machining of pipe can result in potentially high exposures. A representative of the Association of A/C Pipe Producers (AACPP) recommended work practices involving shrouded tools, which if followed were said to limit peak exposures for 15 minutes to 0.75 f/cc and 8-hour TWA exposures to under 0.1 f/cc (Ex. 91–16).

OSHA believes that the use of shrouded tools on-site will increase because of the adoption of an excursion limit. Where only a small amount of cutting on the construction site is needed, it is possible that a 0.2 f/cc TWA can be attained with unshrouded tools. With a short term excursion limit, the employer is more likely to require and the employee is more likely to use the shrouded tools to ensure compliance. In so doing, the employee's cumulative exposure will be significantly reduced and the risk of developing asbestos related disease will be correspondingly reduced.

In general industry, the largest group of exposed workers, brake repair workers, are subject to peak exposures. Their work can be intermittent and the evidence shows that for workers performing occasional brake repair jobs, their exposures occur in short spurts which can be above 1.0 f/cc, but when averaged over an 8 hour day fall within the permissible TWA limit.

OSHA believes the imposition of an excursion limit will increase the probability that employers will utilize the more effective but not required, work practices to assure compliance with the new excursion limit. OSHA had prohibited one method of cleaning brake linings using compressed air because the evidence showed that using that method likely would exceed the new TWA PEL in almost all cases. Other practices, although discouraged, are not prohibited. The evidence indicated that brushing the asbestos residue from affected parts sometimes exceeded a 1 f/cc excursion limit, although the new time-weighted PEL of 0.2 f/cc might still be met (Exh. 84–263, 90–148). Additional information about practices which will result in lower short-term as well as TWA exposures levels is set out in Appendix F to § 1910.1001. Consequently, safer working conditions will result for the large number of employees performing automotive brake repair operations.

Other general industry employees will benefit from an excursion limit. In secondary manufacturing, especially gasket manufacturing, asbestos operations often are conducted on an intermittent basis (Exh. 235 A). The time-weighted average would mostly be met even with the use of inferior control equipment. Issuance of an excursion limit would require the use of the best available control equipment and would thus reduce the risk of asbestos related disease for secondary manufacturing workers whose TWA exposures were at or below the PEL.

In addition, control of short term exposures will help employers identify and control the sources that result in variable exposures. OSHA notes that an employee's exposure to toxic substances in the workplace varies from day-to-day and varies within the day's work shift. The meaning of day-to-day variability was considered in the promulgation of the 0.2 f/cc, 8-hour TWA PEL (see 51 FR 22652 to 22654).

OSHA recognizes that various factors cause day-to-day variability, including sampling error in the measurement of the airborne asbestos concentrations, changes in work practices, and changes in ventilation due to misapplication or malfunction. OSHA has concluded that the major sources of day-to-day variability can be moderated by diligent employer control (51 FR 22653). In addition, OSHA has specified a sampling and analytical method which would standardize measurement procedures and greatly reduce sampling error. OSHA determined that the 0.2. f/cc PEL is technologically feasible and will not result in an unfair citation to the conscientious employer. The reviewing Court upheld OSHA's findings in these respects.

Based on its analysis, OSHA believes, for industries that manufacture asbestos products, where asbestos is used as part of a continuing process, that the causes of excursions within a day are similar to the causes of day-to-day variability. Changes in work practice and malfunctioning equipment could cause exposure excursions. Break-downs were identified as a major reason for excursions in manufacturing (AIA/NA, P.H. brief III–44). Within-day-variability may also occur in industries where work with asbestos occurs intermittently during the day; the work cycle will result in temporary and high dust concentrations. Poor maintenance and deterioration of ventilation equipment, such as fan belt slippage, clogged filters and system damage can also influence within day variability as the ventilation system copes increasingly less successfully with the high end of the day's distribution of airborne fibers.

OSHA believes that industries that use asbestos on a continuous basis in well controlled processes such as the manufacture of asbestos products, should keep air concentrations from fluctuating greatly; that the 0.2 f/cc TWA PEL will force the use of the best technology and will require that diligent work practices, maintenance procedure and housekeeping be applied. Thus the 1.0 f/cc excursion limit should have minimal impact on these industry sectors and will not require the installation of new equipment and controls. However, OSHA believes that here too, the 1.0 f/cc excursion limit will provide a quantitative measure of the diligence of the applied work practices, maintenance procedures and housekeeping, and thus will have an overall beneficial effect to limit both interday and within-day-variability.

For the foregoing reasons, OSHA believes that imposing an excursion limit will further reduce the significant risk of asbestos related disease remaining after compliance with the TWA PEL of 0.2 f/cc.

B. Feasibility and Costs of Meeting the New Excursion Limit

The second prong of the legal test requiring OSHA to adopt an excursion limit, is that such a limit is feasible to implement, (*Public Citizen*, 796 F.2d at 1505). Because section 6(b)(5) of the Act provides that OSHA may promulgate standards to the extent that they are both economically and technologically feasible, the following discussion explores both aspects of feasibility. This discussion is organized into a summary discussion of technological and economic feasibility for all sectors; a sector by sector operational discussion of technological feasibility, and a discussion of the capability of the OSHA reference method (ORM) to measure the excursion limit.

OSHA finds that the new excursion limit of 1 f/cc measured over ½ hour is technologically feasible for most significant operations in most affected industries using the same engineering and work practice controls that were determined necessary to meet the PEL. OSHA believes also that the additional

cost of the engineering and work practice controls will be minimal. Thus, compliance with the new excursion limit is technologically feasible at minimal additional costs, which are well below the threshold of economic infeasibility. For some operations, OSHA has determined that compliance with the new limit will require respirators. Since these operations in large part are the same which OSHA previously determined will require respiratory protection to meet the time weighted average PEL of 0.2 f/cc in the revised standards, OSHA believes that the cost of the additional respirators will also be minimal. OSHA also believes that the costs of the ancillary provisions triggered by the excursion limit are similarly minimal and feasible for affected industries.

The evidence supporting these determinations consists of data and comments previously discussed and analyzed by OSHA in its Final Economic Impact and Regulatory Flexibility Analysis set out in 51 FR 22650 *et seq.*, and of data in the rulemaking record illustrating historic industry capability to meet the excursion limit. OSHA projects that this capability will improve because the new limit requires optimum use of existing technology.

1. General Industry

As stated above, OSHA finds that the excursion limit is feasible to achieve in most sectors using the same engineering and work practice controls necessary to achieve the time weighted average limit. In some cases, increased attention to maintenance of controls, diligence in their application, and housekeeping will achieve compliance with the excursion limit, when a more relaxed application of the same controls would meet the TWA PEL. The data submitted to the record specifically showing short term exposures indicate that troublesome areas in meeting the new excursion limit in general industry are essentially the same areas as OSHA determined would have difficulty in meeting the TWA limits. Thus data from 1979 showing 60 minute exposures in asbestos cement sheet plants indicated that as with TWA exposures the operations likely to experience compliance difficulty were finishing or sanding operations (Exh. 235A, Table VI) which are unique to A/C sheet. Although these data also imply difficulty for the mixing stage of the sheet process, OSHA notes that it has determined the wet and dry mixing stages for A/C sheet are "virtually the same as the mixing stages of A/C pipe", which was judged capable for reducing exposures to required levels (51 FR 22656).

The relatively poor reported levels in mixing reflect the fact that the A/C sheet industry has lagged behind the pipe industry in using the best available control technology. (See 51 FR 22657.) Pipe-coupling cutoff operations were also judged to have difficulty in meeting the permissible limits (51 FR 22657).

For both the sheet and pipe manufacturing operations, therefore, OSHA believes that only in sheet finishing and pipe coupling should there be problems in feasibility of compliance without respirator use. Because respirator use is likely to be needed to comply with the TWA as well as excursion limit in finishing, OSHA finds the new excursion limit feasible for these industries.

For friction products, since no data was introduced specially relating to short term limits, OSHA analysis essentially turns on its knowledge of the operations constituting the manufacturing of these products. As explained in the preamble to the revised standards, the asbestos friction products include drum brake linings, disc brake linings, disc brake pads, and clutch facings as well as other materials for motion control in industrial applications. As in the A/C sheet industry, troublesome operations needing respirators for compliance may occur in finishing operations, similar to the projections for compliance with the time-weighted average limit (51 FR 22657).

Other primary manufacturing industries, such as gasket and packings, asbestos paper coatings and sealants and asbestos reinforced plastics are expected to have similar capabilities to respond to the new excursion limit. OSHA believes the feasibility analysis for the TWA permissible limits indicates the feasibility of the 1 fiber excursion limit. OSHA notes that its detailed feasibility analysis based on measurements in such sectors for the time weighted average PEL identified sectors where OSHA believed that even in dry mechanical processing, the newly reduced TWA PEL could be met. Thus the agency concluded that the gasket and packings industry could meet the 0.2 f/cc TWA PEL in dry mechanical operations based on data showing levels below 0.2 f/cc; the asbestos paper industry also, on the basis of measurement showing a mean TWA exposure in dry mechanical operations of 0.14 f/cc, was found to be able to meet the TWA PEL of 0.2 f/cc (51 FR 22657–59).

With respect to secondary manufacturing, the Agency noted in the feasibility analysis for the revised standards that in general, receiving and handling primary asbestos products do not pose exposure problems. Compared with the primary processing steps of fiber introduction, mixing, and covering loose fibers, secondary fabrication takes place in a more controllable environment. OSHA had determined that it is feasible for these industries to comply with the 0.2 f/cc TWA PEL in all operations with the exception of some maintenance activities (e.g. repairing or servicing the controls that protect the other workers and a limited number of dry mechanical operations, 51 FR 22660). OSHA believes this judgment applies equally to the new 1 fiber excursion limit.

With respect to ship repair, OSHA has already determined that respirators will be required to comply with the PEL in many jobs because of the problems associated with ship safety rules, confined spaces and nuclear power plants. This imposition of an excursion limit should not result in additional compliance problems for this sector.

12. New Construction

OSHA believes that the new excursion limit of 1 f/cc measured over one-half an hour is feasible for most operations without relying on respirators. OSHA bases this determination on measurement data in the rulemaking record and the feasibility analysis set out in the June, 1986 preamble to the final revised standards.

First, the data on short term exposures in the record, even measurements taken 10 years ago, show that in most new construction activities, the 1 fiber excursion limit is easily compiled with. For example in a 1977 study of operations involving A/C pipe installation, virtually all hour long measurements were well below the new limit. After adjustment to the new 1 fiber limit measured over ½ hour, the only operations which would not be in compliance are cutting of pipe with an abrasive disc saw, and cutting and machining pipe with a doty tool without a shroud and wet methods (Consad final report, table 3.2, (p. 39).

Joe Jackson of the Association of A/C Pipe Producers (AACPP) stated that workers following AACPP's recommended work practices could almost always ensure that they would avoid peak exposures in excess of 0.75 f/cc over 15 minutes, while eight-hour time weighted average exposures would remain at 0.1 f/cc or below (Exhibit 91–16, Section p. 12). OSHA stated that "the

current trend is for more of these activities to be performed by the manufacturer rather than in the field" (51 FR at 22662, citing to Exhibit 333, Sections G, O, Q), and that the potential for these exposures has decreased substantially since the 1977 study upon which he based his conclusions. For those operations which will be continued to be performed in the field the study referenced above and Jackson's testimony support OSHA's conclusion that the use of shrouded and doty tools will result in exposure below the new excursion limit.

For A/C sheet installation, measurement results of more recent studies also indicate that with the use of shrouded tools most operations can comply with the new excursion limit. Thus personal exposure monitoring results from use of a shrouded circular saw and drill on flat A/C sheet resulted in 40 minute exposure levels of 0.1 f/cc, well below the 1.0 fiber excursion limit measured over 30 minutes (cite) and use of a shrouded circulator saw, sabre and drill in a 1979 study for period of under one half hour resulted in measurements no higher than 0.15 f/cc. (Consad Tables 3.3 and 3.4).

Installation of asbestos floor products is an operation which generally results in very low exposures (see e.g. Ex. 84–474). Although certain activities involved in removing old flooring may produce exposures which would exceed the TWA and excursion limits, there appears to be virtually no possibility that the excursion limit would be exceeded if the recommendations of the Resilient Floor Covering Institute were followed. (See, for example Table 3.5 in Consad's report, which indicates that TWA exposures of 2.0 f/cc were measured when dry removal or dry sweeping was performed. However, the Institute would prohibit powersanding and blowing asbestos dust and would require wet sweeping and handling.)

Other operations involving the installation of construction products similarly are expected to have few problems complying with the new excursion limit. The installation of new roofing felts and removal of old asbestos-containing felts, have reported measurements which range from significantly below, to above the TWA permissible limit of 0.2 f/cc. Because the geometric mean concentration, however, is below 0.1 for all activities involved in roofing installation and removal, OSHA believes that the excursion limit will be achievable in most cases. Where based upon circumstances such as the age and condition of the materials removed, the wind, and location of the job, if appears that exposures may exceed this mean, and respiratory protection may be called for to meet both the new excursion limit as well as the PEL.

Installation of asbestos sheet gaskets, on the other hand, should easily meet the new limit without reliance on respirators. Measurement data reporting mostly one-half hour measurements; (the sample ranged from 15 to 95 minutes measurements, with most activities measured up to 37 minutes (Consad, Table 3–8), shows exposures not exceeding 0.39 f/cc measured over 28 minutes. Based on this data, OSHA finds that the new excursion limit is feasible for this sector.

3. Construction, Abatement and Demolition

In the feasibility analysis performed relative to the TWA permissible limit of 0.2 f/cc, OSHA determined that engineering controls cannot routinely reduce exposure below the 0.2 f/cc PEL during major asbestos removal projects and that the supplemental use of respirators may be required. (51 FR 22663). Smaller abatement projects, on the other hand, were judged capable of meeting the TWA limit, because the levels measured over a day's work ranged from less than 0.1 f/cc to 0.57 f/cc with a geometric mean value of 0.09 f/cc (51 FR 22664 citing to 84–74, Table 3.10). Compliance expectations for the new excursion limit are that for major removal projects, respirator usage is expected and employees will be protected against both permissible levels by such equipment. For small projects, such as removal of insulation covering pipes in small areas, glove boxes may be available and can, at least some of the time, result in exposures low enough to meet both the TWA and excursion permissible limits (see 51 FR 22664).

Renovation activities involve asbestos exposure when asbestos materials used for pipe and boiler insulation, fireproofing, drywall tape and spackling, and acoustical plasters are disturbed during renovation projects. OSHA concluded in the feasibility analysis in the revised asbestos standards that "engineering controls are generally effective in limiting exposures after asbestos-containing materials have been disturbed, but that workers who actively disturb these materials will probably require respiratory protection to comply with the 0.2 f/cc PEL." 51 FR 22664.

OSHA's contractor noted that "as in asbestos abatement, exposures in renovation vary tremendously depending on the condition and friability of the asbestos materials, and the nature of the work being performed." (Clayton report, Exh. 3 at 32). Data submitted on the work exposures of renovation workers reflect TWA measurements, not short term levels. However, based on the time weighted average levels reported, OSHA concludes that most renovation workers who are indirectly exposed to asbestos will be protected against the limit by engineering and work practice controls but workers who directly disturb asbestos will need respiratory protection to comply with the new excursion limit, as OSHA similarly concluded with the respect to the TWA PEL.

Maintenance workers will not need respiratory protection for compliance with the new excursion limit in most situations. OSHA bases this determination on limited record data which shows concentrations during routine maintenance activities in a building in which serious deterioration of the asbestos materials had occurred and which appear to be short-term peak measurements. (Clayton report, Exh. 3 at 33).

These measurements ranged from 0.02 to 1.4 f/cc. Because these measurements appear to be a worst case situation, OSHA believes that engineering and work practice controls will adequately control exposures during routine maintenance activities within the new excursion limit of 1 f/cc measured over one-half hour.

III. Regulatory Analysis

Executive Order 12291 (46 FR 13197, Feb. 19, 1981) requires that a regulatory analysis be conducted for any rule having major economic consequences. OSHA has analyzed the economic consequences of the asbestos standards as promulgated in 1986 at that time. The further analysis required for these revisions follows.

A. Population-At-Risk and Benefits

As part of this analysis, OSHA estimates that, under the current asbestos rule, at least 36,000 workers in general industry and construction remain unprotected from asbestos fiber levels above the 1 f/cc excursion limit. For general industry, about one-tenth of the workers within plant operations with 8-hour TWA exposures of between 0.1 and 0.2 f/cc may exceed the excursion limit for thirty minutes a day. This fraction was applied to the sectoral exposure data reported in the Asbestos Regulatory Impact Analysis (RIA) [App. G] to yield OSHA's estimate of 2,703 workers affected by the excursion limit in general industry.

In automotive repair, approximately five percent of the population at risk to asbestos fibers are estimated to exceed the excursion limit. Hence, of the 527,000 workers exposed to asbestos in this sector, approximately 26,000 face thirty-minute exposures above 1 f/cc. In its RIA, OSHA estimated the costs and benefits of using solvent spray on brake-repair work in all affected establishments under the assumption that all firms would find it cost-effective to keep exposures below the action level by using the solvents on all repair jobs. OSHA now believes that some establishments are able to comply with the current standard without excursion-level controls and that the costs and benefits estimated for this industry sector in the RIA were too high.

To comply with the proposed excursion limit provisions, these brake-repair establishments would now be required to use the solvent spray, thereby ensuring protection of the total population-at-risk in the sector. Assuming workers affected by the excursion limit perform one two-hour brake job per day—during which peak exposures—OSHA estimates that use of the spray will reduce 8-hour TWA exposures from around 0.13 f/cc to 0.06 f/cc (Ex. 84–263). Based on the mortality rates for asbestos exposure given in the RIA, OSHA estimates that, in brake repair, approximately 3 of the 39 avoided fatalities that were estimated in the RIA should be assigned to the benefits of the proposed excursion limit standard.

In ship repair, OSHA assumed that all workers were provided vacuum cleaners and air-purifying respirators for the purpose of reducing TWA exposures. This equipment carries protection factors ranging from 10 to 1,000 and therefore would also protect employees from high excursion levels (see Asbestos RIA, Tables G–16 and G–18). For this reason, OSHA projects that few ship repair workers are exposed above the excursion limit.

In new construction, only asbestos/cement pipe installers are expected to be currently exposed to high excursion levels at frequent intervals. The estimated 16,000 workers involved in a/c pipe installation can be divided into 3,200 crews (five per crew). In the absence of controls, high fiber exposures can occur during the machining and cutting of pipe prior to installation. Employers experiencing excursion-level exposures can use shrouded tools during these activities to comply with paragraph (g)(2)(i) in the asbestos construction standard. Given the trend to have most of the machining done by the fabricator, and given the expense of purchasing shrouded tools, it is anticipated that only one-third of the crews will cut pipe at the worksite. Therefore, assuming one person on each crew is involved in cutting pipe, the population at risk in a/c pipe installation is expected to be around 1,100.

During most asbestos abatement, demolition and renovation jobs, the use of engineering controls and respirators to meet the TWA PEL will also reduce exposures to below the excursion limit (see Asbestos RIA, Table G–20). OSHA anticipates that the excursion level will be exceeded only during occasional small-scale jobs, where these controls are not needed to meet the TWA PEL. Similarly, in two activities within new construction, a/c sheet installation and asbestos roofing installation, the use of shrouded tools, vacuums, clothing and respirators needed to meet the TWA PEL are expected to prevent exposure levels from exceeding the excursion limit in all but a few short-duration activities. Thus, some minor, non-quantifiable benefits are expected in these sectors once the existing engineering controls and respirators are applied in the small jobs.

The overall population at risk from exceeding the excursion limit in construction maintenance is estimated at 32,000. In commercial/residential building maintenance, approximately 90,000 workers in small-scale jobs are potentially exposed to asbestos (RIA, p. F–20). However, OSHA believes that only about ten percent of these workers will be routinely exposed to asbestos. Thus, OSHA estimates that approximately 10,000 employees, working in two-person crews, will specialize in small-scale repair and renovation work involving contact with asbestos. In routine maintenance for general industry, of the approximately 220,000 workers exposed to asbestos and not equipped with respirators, an estimated ten percent, or 22,000, are assumed to be exposed to levels above the excursion limit.

Thus, the overall population at risk to exposures above the excursion limit is expected to be approximately 36,000 workers (not counting the population at risk in automotive repair). In the construction maintenance sectors affected by the standard, exposures are not expected to occur on a daily basis. For the purpose of estimating the incremental benefits of an excursion limit, the population at risk must be expressed as the number of full-time equivalent workers. Accordingly, OSHA estimates that the 36,000 workers with some exposures above the excursion limit translate to the equivalent of 10,000 full-time employees.

To develop a quantitative estimate of the expected incremental benefits of an excursion limit, OSHA conservatively assumes that the use of engineering controls, respirators and other measures will reduce 8-hour exposure levels by a factor of ten. Table 1 shows the number of expected cancer deaths for each sector at 0.13 f/cc TWA—estimated as the current mean exposure level for all industry establishments impacted by the excursion limit—and .013 f/cc TWA, the level after the tenfold exposure reduction. For each exposure level the number of expected deaths in manufacturing and construction is summed. Taking the difference of these two sums yields the figure for avoided cancer deaths. As indicated in the table, OSHA's risk assessment model predicts that an excursion limit of 1 f/cc for thirty minutes will prevent approximately two cancer fatalities per year in the indicated sectors (not counting the benefits in automotive repair discussed above).

TABLE 1.—ESTIMATED EXCESS CANCER DEATHS AVOIDED DUE TO PROMULGATION OF A THIRTY-MINUTE EXCURSION LIMIT OF 1/FCC FOR ONE YEAR [a]

Sector	No. of full-time equivalent workers	Expected cancer death at .13f/cc TWA [b]	Expected cancer deaths at .013 f/cc TWA [c]	No. of cancer deaths avoided
Primary manufacturing	784	0.152	0.016	0.136
Secondary manufacturing	1,919	0.368	0.037	0.331
Construction	6,980	1,340	0.133	1.207

TABLE 1.—ESTIMATED EXCESS CANCER DEATHS AVOIDED DUE TO PROMULGATION OF A THIRTY-MINUTE EXCURSION LIMIT OF 1/FCC FOR ONE YEAR [a]—Continued

Sector	No. of full-time equivalent workers	Expected cancer death at .13f/cc TWA [b]	Expected cancer deaths at .013 f/cc TWA [c]	No. of cancer deaths avoided
Total	9,683	1.86	0.186	1.674

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.
[a] Automotive repair workers exposed to excursion levels are excluded from the analysis in the table.
[b] Based on exposure data in the Asbestos RIA [App. G], OSHA estimates that the population at risk from short-term levels experiences a mean of 0.13 f/cc TWA.
[c] Use of engineering controls and respirators are assumed to result in a tenfold reduction in TWA exposures.

Moreover, as explained in Chapter V in the Asbestos RIA, the estimated number of lives saved understates the total benefits derived from lowering worker exposure. Additional expected benefits (but not quantified) should appear in the form of reduced worker disability from asbestosis and a reduced incidence of asbestos-related diseases in groups outside the directly exposed work force.

B. Compliance Costs

OSHA estimates that the total annual compliance costs for achieving a thirty-minute excursion limit of 1 f/cc in the sectors shown in Table 1 will be approximately $29 million. (Some additional compliance costs in automotive repair were already estimated in OSHA's original RIA and are discussed below.) Table 2 shows the number of exposed workers in each industry sector and the breakdown of compliance costs by regulatory provision. In general, the exposure distributions and the compliance cost formulae presented in the RIA were reemployed here. The majority of the costs will occur in the construction industry, where the annual costs are estimated to be $23 million. Primary and secondary manufacturing are expected to incur annual costs of $2.0 million and $4.4 million, respectively. In ship repair, additional compliance costs are expected to be insignificant because it is assumed that most firms already use adequate controls in order to comply with the existing provisions of the asbestos standard.

TABLE 2.—ASBESTOS EXCURSION LIMIT[aa] Annual Compliance Costs [By sector and provision, in dollars]

Sector	Number of exposed workers	Engineering controls	Shower/change rm total	Respirators	Clothing	Monitoring	Medical surveillance	Training	Grand total
Primary manufacturing:									
A/C pipe	29	0	34,557	4,923	21,750	2,712	373	208	64,523
A/C sheet	20	0	23,833	3,395	15,000	3,255	514	144	46,139
Textiles	3	0	3,575	509	2,250	1,505	39	22	7,898
Floor tile	24	0	28,599	4,074	18,000	1,505	308	172	52,658
Coatings	102	0	121,547	17,314	76,500	35,941	1,310	732	253,344
Friction	510	0	607,733	86,569	382,500	27,664	6,551	3,662	1,114,679
Paper	39	0	46,474	6,620	29,250	11,933	501	280	95,058
Gaskets	32	0	38,132	5,432	24,000	9,764	411	230	77,968
Plastics	25	0	29,791	4,244	18,750	2,006	321	180	55,291
Subtotal	784	[b] 0	934,241	133,079	588,000	96,284	10,070	5,629	1,767,303
Secondary manufacturing:									
A/C sheet	35	0	41,707	5,941	26,250	10,598	450	251	85,197
Textiles	17	0	20,258	2,886	12,750	23,500	218	122	59,734
Friction	150	0	178,745	25,462	112,500	16,798	1,927	1,077	336,509
Gaskets	997	0	1,188,058	169,234	747,750	121,368	12,806	7,158	2,246,378
Plastics	245	0	291,950	41,587	183,750	102,890	3,147	1,759	625,084
Auto remanufacturing	475	0	566,026	80,628	356,250	83,401	6,101	3,411	1,095,817
Subtotal	1,919	[b] 0	2,286,744	325,738	1,439,250	358,556	24,650	13,778	4,448,717
Contruction:									
A/C pipe installation	1,100	1,650,000	0	N/R	N/R	0	113,916	15,796	1,779,712
Routine maint. in C/R	10,000	7,417,947	0	2,238,004	3,450,000	0	1,035,600	143,600	14,285,151
Routine maint. in GI	22,000	147,400	0	5,330,609	660,000	0	0	315,920	6,453,929
Subtotal	33,100	9,215,347	[c] 0	7,568,612	4,110,000	[d] 0	1,149,516	475,316	22,518,791
Total	35,803	9,215,347	3,220,985	8,027,430	6,137,250	454,840	1,184,236	494,724	28,734,811

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.
[a] Compliance costs in automotive repair are not reported in the table (see discussion in text).
[b] No additional controls are expected beyond those required to meet the TWA PEL.
[c] Additional decontamination facilites are assumed not to be necessary because either they would have been required to meet the existing standard or because the operations are excluded due to their small-scale, short-duration nature.
[d] Employers are expected to minimize the need for additional monitoring through the use of objective data or by equipping their workers with air-supplied respirators.

1. Construction

Annual compliance costs in construction are estimated at $23 million to protect approximately 33,000 workers in asbestos/cement pipe installation, routine maintenance in commercial/residential buildings, and routine maintenance in general industry. The Two maintenance sectors in construction account for over 92 percent of the costs in construction, with a/c pipe installation accounting for the remaining cost. Asbestos abatement, demolition and renovation are not expected to incur additional compliance costs. With the exception of a minor number of small-scale jobs, exposures in those sectors, and in a/c sheet installation and asbestos roofing installation, are projected to remain below the excursion limit through the use of engineering controls and respirators put in place to meet the TWA PEL. During these jobs, additional use of existing controls and respirators will be required without any incremental costs beyond those previously estimated.

As shown in Table 2, compliance costs for additional engineering controls, respirators and disposable clothing in construction are expected to total $9.2 million, $7.6 million and $4.1 million, respectively. No decontamination costs are anticiapted because the activities in these sectors are of short duration and are exempted from this provision.

In a/c pipe installation, it is anticipated that short-term exposures will be reduced through the use of shrouded tools during machining and cutting of pipe. In the maintenance sectors, supplied-air respirators, glove bags, HEPA vacuums and filters, and disposable clothing and gloves will protect workers during activities when fiber concentrations may exceed the excursion limit. Office workers and the general public in commercial and residential buildings (c/r) will also benefit from signs alerting them to the hazards at the worksite. Applying a unit cost of 50 cents for each sign put in place, the costs of warning signs are expected to total $1.8 million annually in c/r maintenance.

In routine maintenance in general industry, OSHA estimates that approximately 85,000 gasket projects will face asbestos level excursion. Most of these jobs will be small and therefore will require only one sign in most cases. At a unit cost of 50 cents per sign, the total compliance cost for the regulated-area provisions will be approximately $43,000 in gasket maintenance.

To avoid the costs of monitoring exposure levels at each project, it is assumed that construction maintenance crews will purchase supplied-air respirators and compressors at unit costs of $278.25 and $1,000, respectively, and capitalize them over five years. In addition, firms in commercial/residential maintenance and a/c pipe installation will incur costs associated with the medical and training provisions when the excursion limit is exceeded. (Workers in routine maintenance in general industry are exempted from the medical surveillance provisions because they will be exposed for fewer than 30 days.) Assuming a medical exam/lost-work-time cost of $100 and recordkeeping costs of around $3.50 per employee, annual medical costs for these workers are estimated to be approximately $1.1 million.

Training costs in construction are based on the assumption that a supervisor (at a wage rate of $13.10 per hour in construction and $17.11 per hour in general industry (routine maintenance)) will conduct one-half hour training sessions for groups of five employees (at an hourly wage rate of $11.91 in construction and $16.37 in general industry). Added to these costs of instruction are recordkeeping costs (estimated in the RIA, p. VI–41, to be $0.85 per record in construction and $1.50 per record in general industry), bringing the total cost of training in construction to around $475,000.

2. General Industry

OSHA estimates annual compliance costs of $6.2 million in primary and secondary manufacturing. As noted above, the ship repair sector should not experience costs to comply with the excursion limit since controls currently in use to meet the TWA PEL prevent thirty-minute levels from exceeding 1 f/cc. OSHA expects automotive repair, however, to incur some compliance costs from the use of solvent spray to meet the excursion limit. Assuming one-third of the affected employees are currently in compliance, and assuming (as in the RIA) that approximately thirty seconds of worker time is spent spraying an entire can of solvent spray (at $1.75 per can) on the brake surface to minimize the number of airborne fibers, compliance cost is estimated to be $4.0 million in this sector. As noted above, these compliance costs were already included in the RIA for the TWA permissible exposure level. Hence, the costs are not incremental as are the excursion limit costs in the other sectors and therefore are not reported in Table 2.

Half of the total cost in general industry, $3.1 million, or $1,192 per worker, will be spent on decontamination of workers after high fiber exposures. To comply with the decontamination provisions, employers are expected to expand shower rooms and change rooms (see pp. VI 15–16 in the RIA for details of the calculation) in order to accommodate the estimated 2,700 workers who are exposed below the 0.2 f/cc TWA but above the 1 f/cc excursion limit. In addition, OSHA assumed that each of those workers would be given one change of disposable clothing and gloves each day, at a cost of $3 per set.

Initial monitoring is necessary to help firms determine the need for respiratory protection and to provide the objective data required by the standard where such data does not currently exist. Because exposure levels in primary and secondary manufacturing will occasionally exceed 1 f/cc for thirty minutes despite the presence of engineering controls, OSHA assumed that all employers will perform initial monitoring at each workstation in all establishments. This assumption tends to overstate actual costs because in some instances other objective data will be available. Based on the expected variation in these exposures, OSHA estimates that approximately 50 percent of the workstations will have exposures above the excursion limit. These workstations are expected to continue monitoring twice a year and to equip their workers with cartridge respirators during peak exposure periods.

For the workstations where exposures exceed the excursion limit but not the TWA action level, medical surveillance and training would be required. OSHA estimated that half of the workers expected to exceed the excursion limit will be affected by these provisions for the first time (the balance of these workers are in establishments where these costs are currently required under the existing rule). Annual medical and training costs for these workers is calculated to be about $55,000.

IV. Economic and Environmental Impacts

OSHA anticipates no major economic or environmental impacts from the promulgation of the excursion limit. In most manufacturing sectors, estimated annual compliance costs fall below $100,000. The highest compliance costs in manufacturing will be felt in secondary gasket production and primary friction products. In these two sectors the additional annual compliance costs are not expected to exceed one-half of one percent of annual revenue. Thus, OSHA does not anticipate a significant economic impact

in manufacturing due to compliance with the excursion limit.

Although automotive repair is expected to face compliance costs to meet the excursion limit, these costs were estimated previously and were applied to the economic impact computed in the RIA. The overall economic impact on this sector as described in the original RIA was not significant.

Compliance costs in the construction industry are expected to be higher than in general industry. OSHA estimates that annual compliance costs in a/c pipe installation will be approximately $1,500 per exposed worker, while the per-worker costs in routine maintenance in commercial/residential buildings and in routine maintenance in general industry will be $1,400 and $300, respectively. However, OSHA expects that firms within the affected sectors will be able to pass along compliance costs to the building owners and project developers. As noted in OSHA's Asbestos RIA, higher construction and maintenance costs are routinely passed forward to owners and developers. Further, annual compliance costs in these sectors represent a minor percentage of the total value of the structure being built or repaired. Therefore, it is anticipated that the impact of the excursion limit on final rents and prices will be negligible.

In accordance ith the Regulatory Flexibility Act, OSHA has assessed the economic impact of a 1 f/cc excursion limit on small establishments and certifies that those establishments will not be adversely affected. In addition, OSHA does not foresee a significant environmental impact from the excursion limit provision.

V. Feasibility of Measuring Excursion Limit

OSHA also has determined, based on the rulemaking record of the revised standard, that the lowest feasible short term limit which can be reliably measured for purposes of the OSHA compliance programs, is 1 f/cc measured over 30 minutes. OSHA reaffirms that the OSHA Reference Method (ORM) provides the optimal technology for assessing worker exposure to airborne asbestos.

A brief review of the ORM is necessary to an understanding of this determination. The ORM is based largely on NIOSH Method 7400, a method widely acknowledged in the record as superior to the earlier NIOSH P&CAM 239 method previously prescribed by OSHA [Exs. 117–A; 123–A; 328; 330; Tr. 6/20, p. 10; Tr. 6/21, p. 186; Tr. 7/81, p. 69].

In the preamble to the revised standards OSHA explained the relationship of the ORM to NIOSH P&CAM 239 and to the revised NIOSH 7400 method (51 FR 22688).

Because the NIOSH 7400 method takes advantage of technological improvements that have been adopted worldwide for asbestos sample analysis, but retains the same counting rules as the NIOSH P&CAM 239, OSHA has used the major features of the NIOSH 7400 method as the basis for developing a required standardized sampling and analytical method measuring airborne asbestos concentrations. The method required by the revised asbestos standards for both general industry and construction, referred to as the OSHA Reference Method (ORM), is detailed in the mandatory Appendix A of each standard. (§ 1910.1001 and 1926.58).

These appendices require that the employer collect airborne asbestos samples using 25 mm diameter mixed cellulose filters and a 50 mm electrically conductive extension cowl. Samples must be analyzed using a phase contrast microscope calibrated using a phase shift test slide and equipped with a Walton-Beckett graticule. The ORM also requires that filter samples be prepared using acetone-triacetin clearing solution and be counted in accordance with the rules specified.

The ORM differs from the NIOSH 7400 method in two important respects. The ORM mandates a flow rate for asbestos sampling of between 0.5 and 2.5 lpm, which is similar to the flow rate range permitted by the NIOSH P&CAM 239 method (1.0 to 2.5 lpm). In contrast, the NIOSH 7400 method permits the use of any flow rate between 0.5 lpm and 16 lpm. Secondly, the ORM permits the use of the large 37 mm diameter filter when the employer has written justification explaining the need to use a larger filter to obtain readable samples. Both of these departures from the NIOSH 7400 method were made in response to commenters who pointed out that the use of high flow rates (e.g., 4 lpm) combined with the use of the smaller 25 mm filter may result in samples that are too overloaded with dust to permit the counting of asbestos fibers. This is particularly true in construction where nonasbestos dust particles released to the air as a result of demolition or renovation activities may interfere with analyzing samples that were collected using high flow rates and the smaller filter. OSHA believes that, by limiting the flow rate and permitting the use of the 37 mm filter in certain circumstances, employers will be more likely to obtain readable samples in dusty environments. As explained below however, the 37 mm filter will be allowed to measure short term exposures only when they are above the EL. Since short term exposures in impacted construction activities are likely to exceed the EL, OSHA believes that many employers will continue to have the flexibility to pick the filter and flow rate to best assure reliable measurement results. In addition, record evidence suggests that the use of high flow rates may increase electrostatic charges in the filter apparatus, preventing some fibers from reaching the filter and resulting in lower fiber counts [Ex. 84–478: Tr 7/6., p. 99]. OSHA adopted these specific provisions to establish uniformity to the asbestos exposure determination.

To determine whether the ORM could be used to analyze short-term samples, and what the lowest feasible excursion limit is, the limit of reliable detection for 15-and 30-minute samples was evaluated. OSHA calculated the lowest reliable limit of quantitation using the following formulas:

$$E = \frac{(f)}{(n)(Af)}$$

where:

E is the fiber density in fibers per square millimeter;
f is the total fiber count;
n is the number of microscope fields examined;
Af is the field area (0.00785 mm^2 for a properly calibrated Walton-Beckett graticule); and

$$C = \frac{(E)(Ac)}{(V)(1000)}$$

where:

E is as above;
Ac is the effective area of the filter (nominally 385 mm^2 for a 25-mm-diameter filter and 855 mm^2 for a 37-mm diameter filter; and
V is the sample volume.

Prior to the ORM, analysts could use different procedures which resulted in different asbestos counts from one laboratory to the next. In addition the ORM method contains procedures that reduce variability in asbetos counts within a laboratory. In the final rule OSHA acknowledged that the use of the phase contrast light microscope method was approaching its limits of use with the new PEL, but OSHA determined the method, with the procedures required by the ORM, could reliably measure 8 hour TWA exposures at 0.1 f/cc for purposes of the OSHA compliance program.

Using the minimum filter loading that is suggested for the ORM (i.e., 80 fibers/100 fields, or 100 fibers/mm²), OSHA examined the relationships among these two sampling periods (15 and 30 minutes), the two filter sizes (25- and 37-mm in diameter), and various possible flow rates ranging between 2.5 lpm and 0.5 lpm.

The results set out in the Table show that 1 f/cc measured over 30 minutes is the lowet level which can be reliably measured for most operations likely to be affected by an excursion limit.

The ORM has been designed to provide needed flexibility to reliably measure exposures in the wide variety of operations where asbestos, tremolite, anthophyllite and actinolite are used. As explained in the preamble to OSHA's revised standards, filter overload or interference by other particles in dusty environments is accommodated by the ORM by permitting the use of the 37 mm filter when justified, and by reducing the flow rate. OSHA believed that in most cases reducing the flow rate will minimize filter overload for TWA exposure measurements, but allowed the 37 mm filter for stubborn situations, with written justification (51 FR 22690–1).

The major industries and operations affected by the imposition of an excursion limit; construction, and maintenance and brake repair in general industry, expose employees to the kinds of dusty environments which may result in filter overload. In addition, short term bursts of dust containing asbestos may contribute to overloading the filter.

The flexibility needed to reliably measure excursions in these operations, requires the ability to sample at low flow rates. Table *X* shows that only at the relatively high flow rates of 1.6 lpm and above are levels less than 1 f/cc over 30 minutes quantifiable. We note, based on the results in the Table that the use of the 37 mm filter is precluded for measuring short term limits down to 1 f/cc over 30 minutes. OSHA therefore finds 1 f/cc measured over 30 minutes is the lowest level feasibly measured for the operations impacted by this amendment.

OSHA notes that these considerations apply to measurements at or below the excursion limit, the level which must be capable of being measured for most enforcement and compliance purposes. The employer is not precluded from using the 37 mm filter to reliably measure short term exposures *above* the excursion limit so long as the level measured falls within the limits or reliability set out in the table. OSHA therefore will allow the use of the 37 mm filter for measuring short term exposures for the same reasons and requiring the same justification as time-weighted average measurements. If an employer uses measurement results to show exposures below the excursion limit, he must use the 25 mm filter.

Also, OSHA has determined that employers can comply with the 1 f/cc excursion limit within the accuracy requirements of the revised asbestos standards. As discussed at length in the preamble to the final rules (see 51 FR 22686–22691), the key factor in sampling precision is fiber loading. Using the minimum loading suggested by the ORM (80 fibers/100 fields, or 100 fibers/mm²), employers can be confident that they are measuring the actual airborne concentrations of asbestos in their workplaces within a standard sampling and analytical error (SAE) of +/−25%.[1]

OSHA points out, as stated earlier, that a superficial contradiction exists between OSHA's finding that 1 f/cc measured over 30 minutes is the lowet reliable level of detection, and data cited regarding lower levels in brake repair (51 FR 22662). Those measurements, mainly derived from studies, were made by NIOSH with expert analytical capabilities under controlled conditions. In addition these measurements do not reflect the differences in results that occur due to common statistical sampling factors. As stated above, OSHA does not believe, based on a full rulemaking record, that such low levels can reliably be measured by employers for regulatory requirements. OSHA considers the recorded levels indicative of a range of exposures for the brake repair industry, and has not used these results for any other regulatory purposes.

Thus, OSHA's finding that the excursion limit of 1 f/cc for 30 minutes is the lowest that can be reliably measured is based upon the enforceability of the limit, recognizing that in some situations, lower exposures could theoretically be measured and are reported in the rulemaking record. In reaching this decision, OSHA has relied upon the asbestos rulemaking record, the equations described above being part of the record.

[1] OSHA evaluates the precision of the ORM (implemented as NIOSH 7400) as follows: NIOSH has estimated that the overall precision, expressed as the coefficient of variation (CV_t), of the 7400 method ranges from 0.13 to 0.115 for samples in which 80 to 100 fibers per 100 fields have been counted [Ex. 84–444]. For filters at the minimum loading suggested by the ORM, (80 fibers/100 fields) the CV_t is 0.13. This yields a 95% One Sided Upper Confidence Interval of 21.4%. This is lower than the SAE of 25% currently listed for this method in OSHA's Industrial Hygiene Technical Manual.

VI. The Process for Promulgating the Excursion Limit

As the foregoing discussion indicates, the *Public Citizen* Court explicitly rejected OSHA's reliance in the EtO standard on the need for a "dose-rate effect" to justify an excursion limit. OSHA based its determination in the revised asbetos standards on the same rationale. The Agency hereby withdraws the determination. Instead, OSHA has made a new determination based on appropriate criteria and a review of the rulemaking record concerning whether and what excursion limit should be required in the revised asbestos standards.

Table *X* shows the results of OSHA's analysis.

TABLE *X*—RELIABLE QUANTITATION LIMITS FOR SHORT-TERM ASBESTOS SAMPLING USING THE OSHA REFERENCE METHOD

[fiber density of 100 f/mm²]

Flow rate (liters/min)	Sampling time	Lower limit of quantification (fibers/cc)
For 25 mm filters:		
2.5	15	1.05
2.0	15	1.31
1.6	15	1.63
1.0	15	2.61
0.5	15	5.23
2.5	30	.51
2.0	30	.65
1.6	30	.82
1.0	30	1.31
0.5	30	2.61
For 37 mm filters:		
2.5	15	2.32
2.0	15	2.91
1.6	15	3.63
1.0	15	5.81
2.5	30	1.16
2.0	30	1.45
1.6	30	1.82
1.0	30	2.91

OSHA's previous STEL determination did not apply the criteria which the Court held must compel the issuance of a short term limit. However, these

criteria; feasibility of the limit and further reduction of significant risk were raised by OSHA in its proposal (see 49 FR 14116, 14122), and were the subjects of data and comment submitted to the record as well as testimony at the hearing. Therefore all aspects of OSHA's statutory rulemaking requirements, consisting of notice, comment and hearing, have been compiled with concerning whether OSHA must issue an excursion limit (See section 6(b) of the Act).

Ample notice on all relevant issues was provided by OSHA. In its proposal the Agency stated it was considering reducing the prior "ceiling limit" of 10 f/cc to a limit based, in large part on the TWA-PEL which would be required. OSHA specifically mentioned the possibility of imposing a 5 f/cc limit measured over 15 minutes if a 0.5 f/cc TWA-PEL were chosen and a 2 f/cc "ceiling limit" if a 0.2 f/cc limit were chosen, and requested comments on these as well as "other suggested limits". OSHA noted that ceiling limits "may be necessary to ensure further that employees are not exposed to dangerous concentration(s) of asbestos fibers" and also asked for "(i)nformation concerning the feasibility of achieving (the limits mentioned or others) particularly in industries with variable exposures" (49 FR at 14123).

Comment and evidence submitted to the record responded to all relevant issues and provided an ample evidentiary base for OSHA to make determinations regarding a revised excursion limit for asbestos exposure. Participants representing both industry and employee groups recommended that OSHA adopt a "short term limit ranging from 0.5 f/cc measured over 30 minutes" (BCTD, Exh. 330 at 155), to 5.0 f/cc measured over 15 minutes (AIA/NA, P.H. brief, III-45).

Data introduced during the rulemaking, as discussed previously, shows the feasibility of the limit adopted. Most data relates to service industries and construction. The relative scarcity of data for general industry was explained by AIA/NA as resulting from the fact that "at least in manufacturing plants, there are few routine operations where exposures are episodic. Consequently, the occurrence of peak exposures is generally an unexpected event such as an equipment breakdown." (AIA/NA, P.H. brief III-44).

Data used in OSHA's risk assessment and regulatory analysis similarly show that the imposition of an excursion limit of 1 f/cc measured over 30 minutes will further reduce the significant risk remaining after a TWA exposure limit of 0.2 f/cc is achieved.

OSHA finds pursuant to 5 U.S.C. 553(b), that additional notice and comment are unnecessary. OSHA believes that additional notice of the intent to consider an excursion limit would merely duplicate the prior notice. As discussed above, public participation has already taken place during the extensive rulemaking held to develop the 1986 standards.

VII. Summary and Explanation

The requirements set forth in this notice are those which, based on currently available data, OSHA believes are necessary and appropriate to provide additional protection to employees who are now exposed to airborne concentrations of asbestos at levels that pose a significant risk of material impairment to their health. OSHA has considered all data and recommendations on the short-term limit issue contained in the asbestos docket (H-033).

The following sections discuss new individual requirements of the asbestos standard. The final standard adopts an additional permissible exposure limit of 1 f/cc excursion limit averaged over a sampling period of 30 minutes. As with the TWA-PEL, engineering controls and work practices when feasible are the preferred methods to reach the excursion limit.

Other provisions of the revised standards are being amended to also require certain ancillary protective actions when the excursion limit is exceeded. For example, regulated areas must be established, and decontamination facilities be provided for employees whose exposure exceeds the EL. Employers must measure the exposure of employees to ascertain whether the EL is being exceeded. For purposes of this preamble, OSHA is combining the discussion of general industry and construction standard provisions which relate to the same subject matter. Of course, the respective regulatory texts remain separately designated and codified. For example, the discussion on both the general industry and construction revised requirements on monitoring is combined. Any differences in application or text between these industries will be noted in the discussion, as well as, where required, in the respective regulatory texts. OSHA believes that this combined discussion will aid interpretation of the requirements since a unified rationale, where appropriate, is presented, and differences are highlighted where they exist.

Permissible Exposure Limit, Paragraph (c)(2), (General Industry and Construction)

In the final amendment, OSHA establishes a 1 f/cc excursion limit for asbestos and revises existing paragraph (c) to incorporate an excursion limit and to clarify that the excursion limit is to be determined as a time-weighted average over a sampling time of 30 minutes.

In the proposed rule of 1984, OSHA stated that it was considering a ceiling limit of 2.0 f/cc for a 15-minute period if a TWA of 0.2 f/cc was established. The 1984 proposal specifically asked participants for recommendations for specific ceiling levels. In response, some participants recommended a 5 f/cc ceiling limit (Exs. 92-045, 90-180); a ceiling limit equivalent to 10 times the PEL (Ex. 127) and the AFL-CIO recommended that OSHA should lower the ceiling level for the asbestos standard proportionally to the reduction in the permissible exposure limit which would be 0.5 f/cc, based on the AFL-CIO recommended 0.1 f/cc time-weighted average PEL (Ex. 335, p. 46).

Based on the rulemaking record of the revised standard, OSHA determined that the lowest feasible short term level which can be reliably measured using the OSHA Reference Method (ORM) is 1 f/cc measured over 30 minutes. OSHA has also determined that a 1 f/cc EL is effective at lowering total asbestos dose below that achievable through the 0.2 f/cc 8-hour TWA alone. OSHA has determined that, based on the evidence in the record, a 1 f/cc 30 minute EL is feasible and can be reliably and consistently monitored, using available monitoring methodology. There is insufficient evidence on the feasibility of monitoring and attaining lower short-term exposure levels.

With respect to the length of the permitted sampling period, OSHA believes that collection of asbestos over 30 minutes is necessary to ensure that a sufficient amount of asbestos is collected for accurate analysis. It should also be noted that the newly established ceiling limit of 1 f/cc over 30 minutes, in terms of dose exposure to asbestos, is similar to the limits that OSHA considered in the proposal, that is, a 2 f/cc ceiling for 15 minutes.

OSHA has determined that exposure to asbestos under the present standard still presents a significant risk of material impairment to employees. Based on the current record, OSHA believes that compliance with the excursion limit as set-forth in this paragraph will further reduce such significant risk.

Exposure Monitoring: Paragraphs (d)(1)(i), (d)(1)(ii), (d)(2)(i), (d)(2)(ii), (d)(2)(iii), (d)(3), (d)(4), (d)(5), and (d)(7)(ii) (General Industry); Paragraphs (f)(1)(ii), (f)(1)(iii), (f)(2)(ii), (f)(4) (Construction)

Section 6(b)(7) of the Act (29 U.S.C., 655) mandates that any standard promulgated under section 6(b) shall, where appropriate, "provide for monitoring or measuring of employee exposures at such locations and intervals, and in such a manner as may be necessary for the protection of employees." The primary purpose of monitoring is to determine the extent of employee exposures to asbestos.

Exposure monitoring informs the employer whether the employer is meeting the obligation to keep employee exposures below the established permissible exposure limits. Exposure monitoring also permits the employer to evaluate the effectiveness of engineering and work practice controls and informs the employer whether additional controls need to be installed. In addition, section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)) requires employers to notify promptly any employee who has been or is being exposed to toxic materials or harmful physical agents at levels that exceed those prescribed by an applicable occupational safety or health standard. Finally, the results of exposure monitoring are part of the information that must be supplied to the physician, and these results may contribute information on the causes and prevention of occupational illness.

Short-term monitoring is required whenever asbestos concentration will not be uniform throughout the workday and where high concentrations of asbestos reasonably may be expected to be released or created in excess of the EL. For example, in the manufacture of asbestos products, peak exposures could be expected during the dry handling of asbestos in manual debagging and charging operations, and during mechanical operations such as cutting, lathing, machining, sawing, drilling, and sanding. Peak exposures could also be expected during maintenance and repair activities where asbestos insulation is disturbed and in automotive repair during brake and clutch servicing.

Amended paragraphs (d)(1)(i) (general industry), and (f)(1)(ii) (construction), set out general requirements for monitoring required under the standards. They now require that the employer perform breathing zone sampling that is representative of the 30-minute short-term exposure of each employee as well as TWA exposures. Paragraphs (d)(1)(ii) (general industry), and (f)(1)(iii) (construction), require that representative 30-minute short-term employee exposures be determined on the basis of one or more samples representing 30-minute exposures associated with operations that are most likely to produce exposures above the excursion limit for each shift for each job classification in each work area.

These exposure monitoring provisions require that the monitoring yield information enabling the employer to determine the short-term exposure for each employee. However, it does not necessarily require separate measurements for each employee. If a number of employees perform essentially the same job under the same conditions, it may be sufficient to monitor a fraction of such employees.

Representative personal sampling for employees engaged in similar work and exposed to similar short-term asbestos levels can be achieved by measuring the exposure of that member of the exposed group who can reasonably be expected to have the highest exposure. This result would then be attributed to the remaining employees of the group.

In many specific work situations, the representative monitoring approach can be more cost-effective in identifying the exposures of affected employees. However, employers may use any monitoring strategy that correctly identifies the extent to which their employees are exposed.

Paragraphs (d)(2)(i) (general industry), and (f)(2)(i) (construction), cover the duty to conduct "initial monitoring" so that employers have baseline data on which to determine whether they must conduct further periodic monitoring. Now employers must perform initial monitoring to determine accurately the short-term airborne concentrations of asbestos to which employees are exposed as well as TWA exposures. However, paragraph (d)(2)(ii) (general industry), contains a provision designed to eliminate unnecessary monitoring in general industry where employers have monitored short-term employee exposures to asbestos within a six-month period immediately preceding publication of this final rule in the **Federal Register.** In such cases initial monitoring may be excused, pursuant to paragraph (d)(2)(i) (general industry), if the results of the earlier monitoring show that their employees are not exposed to asbestos levels above the excursion limit.

The results of prior monitoring should be acceptable if such sampling was conducted in accordance with the monitoring provisions prescribed for excursion limit monitoring in this standard: i.e., prior exposure determinations were made from breathing zone air samples that are representative of 30 minute short-term exposures (paragraph (d)(1)(ii) (general industry)), such determinations were associated with operations that are most likely to produce exposures above the excursion limit and if the monitoring method was accurate, to a confidence level of 95 percent, within plus or minus 25 percent for airborne concentrations of asbestos at the excursion limit of 1 f/cc.

Based on the discussion above, paragraph (d)(2)(ii) (general industry), permits the use of prior monitoring results to fullfill the initial monitoring requirements prescribed under paragrah (d), as long as such monitoring satisfies all other requirements of the new monitoring provisions.

In addition, paragraph (f)(2)(iii) (construction) provides an exemption from new initial monitoring for construction employers who have historical monitoring data (prior monitoring results). This exemption prevents these employers from having to repeat monitoring activity for construction jobs that are substantially similar to previous jobs for which monitoring was conducted. The data the employer uses, upon which judgments are based, must be obtained under workplace conditions closely resembling the process, type of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations. Additionally, paragraph (d)(2)(iii) (general industry), and (f)(2)(ii) (construction), excuse initial monitoring, when the employer can demonstrate, on the basis of "objective data", that the asbestos-containing product or material being handled cannot cause exposures above the action level and/or excursion limit under those work conditions having the greatest potential for releasing asbestos.

"Objective data" is limited to information demonstrating that a particular product or material containing asbestos or a specific process, operation, or activity involving asbestos, cannot release fibers in concentrations above either the action level or Eleven under worst-case release conditions. Objective data can be obtained from an industry-wide study, from manufacturers of asbestos-containing products or materials, or from laboratory test results of an asbestos containing product. For the employer who relies upon an industry-wide study, the data he uses must be obtained under workplace conditions closely resembling the processes, type of material, control

methods, work practices, and environmental conditions used and prevailing in the employer's current operations. Sampling and analytical procedures must conform to NIOSH and/or OSHA approved methods. The following three examples illustrate how an employer may use "objective data" to avoid the burden of initial monitoring.

In the automotive brake and clutch repair industry (the largest group of exposed workers) OSHA has determined that employers can successfully reduce their employees' exposures to asbestos to below the EL by employing the enclosed cylinder/HEPA vacuum system method as described in Appendix F to § 1910.1001. This determination is based on evidence in the rulemaking record (NIOSH Report 32.4, Ex. 84–263). The effectiveness of the vacuum/enclosure is dependent upon the mechanic being adequately trained so that he/she can perform the manufacturer's recommended sequence of steps with care and skill. OSHA therefore believes that employers in the brake and clutch repair industry will be able to avail themselves of exemption from initial monitoring in this amended standard if they conscientiously employ the enclosed cylinder/HEPA vacuum system.

In construction, where certain operations are short-term, intermittent in nature and generate peak exposures, data show that the use of shrouded tools may limit peak exposures to below the EL. An example of a detailed study, which can be used as objective data in lieu of exposure monitoring is Ex. 84–279. This study by the A/C Pipe Producers Association shows that under certain conditions (e.g. experienced workmen, properly maintained equipment, strict adherence to recommended work practices), cutting and machining A/C pressure and sewer pipe, using wet methods and a shrouded Doty tool will limit exposures to below 0.5 f/cc.

Small-scale, short-duration maintenance or renovation activities where the use of glove bags and wet methods are capable of keeping employee exposures to asbestos below the 0.1 f/cc action level and 1 f/cc EL is another situation where objective data could be used to obviate the need for exposure monitoring. The success of glove bag asbestos removal operations relies heavily on the use of workers specially trained in asbestos abatement working under well controlled conditions. Generally, two persons are required to perform removal especially with the use of heavy bags or in elevated locations. Diligence on the part of management and employees is essential for minimizing contamination. Appendix G to § 1926.58 (51 FR 22785)—"Work Practices and Engineering Controls for Small-Scale, Short Duration Asbestos Renovation and Maintenance Activities", provides requirements for glove-bag procedures which when followed by employers, will satisfy the requirements for relying on "objective data" to be relieved from monitoring duties.

In general industry the amended provisions regarding initial monitoring, periodic monitoring, and termination of monitoring requirements relative to the excursion limit are found in paragraphs (d)(2)(i), (d)(3), and (d)(4). These provisions do not change the frequency and termination of monitoring provisions as they apply to the action level.

Where the employer has kept exposures below the applicable action level and excursion limit, the regulatory scheme normally excuses periodic monitoring. Existing paragraph (d)(5) (general industry) of OSHA's asbestos standard requires a new exposure determination for TWA exposures whenever there has been a change in production, process, control equipment, personnel or work practices that may result in new or additional asbestos exposures. With the adoption of an excursion limit, revised paragraph (d)(5) will also require additional excursion limit monitoring or determination where the employer suspects that workplace changes may increase short-term exposures. Short-term monitoring or an allowable determination should be repeated whenever situations arise or workplace changes occur which could increase employee short-term exposure.

In construction, initial monitoring and termination of monitoring requirements are found in paragraph (f)(2)(i) and (f)(4). As in general industry, the excursion limit does not change the current frequency of initial monitoring and termination of monitoring provisions.

The construction employer can lessen the burden of daily monitoring in a regulated area during removal, demolition and renovation operations, by providing all employees, within the regulated area, supplied-air respirators operated in the positive-pressure mode (§ 1926.58(f)(3)).

Paragraphs (d)(6) (general industry) and (f)(5) (construction) of the current asbestos standards require that monitoring methods be accurate to within plus or minus 25% of the OSHA Reference Method (ORM) results with a 95% confidence level as demonstrated by a statistically valid protocol. It is clear to OSHA, based on data in record, that adoption of excursion limit accuracy requirements are necessary to ensure that employees exposures are adequately determined. OSHA also finds that the record supports adoption of accuracy parameters of plus or minus 25 percent at the 95 percent confidence level (See discussion *supra*).

OSHA, therefore, adopts in final paragraph (d)(6)(ii), the requirement that monitoring to a confidence level of 95 percent, shall be accurate, to within plus or minus 25 percent for airborne concentrations of asbestos at the 30 minute excursion limit of 1 f/cc.

Paragraph (d)(7)(i) (general industry) and (f)(6)(i) (construction) require that employers notify employees of the results of excursion limit monitoring performed pursuant to the standard. Such notification has been determined to be appropriate where TWA monitoring is performed, and is believed to be appropriate where excursion limit monitoring is performed.

Regulated Areas: Paragraph (e)(1), (General Industry and Construction)

The amended provision of paragraph (e) in the general industry standard now will require employers to designate as regulated areas any locations in their workplaces where occupational exposures to airborne concentrations of asbestos exceed the excursion limit as well as the TWA–PEL. This regulated area concept is consistent with other OSHA toxic substance standards.

The intent of OSHA's regulated area requirement is to protect employees from unknowingly entering areas where their exposures exceed either PEL. They will be warned of the need to wear respirators and to keep out if they have no need to be present.

Only authorized persons may enter regulated areas, which are required to be clearly marked to ensure that employees are aware of these locations. Warning signs are to be posted at each regulated area and at all approaches to regulated areas so that an employee can take the necessary protective steps before entering the area. The final standard gives employers an option of whether to use, for example, ropes, markings, temporary barricades, gates or more permanent enclosures to demarcate and limit access to these areas.

Paragraph (e) of the construction standard now requires employers to establish regulated areas whenever the PELs are exceeded. Regulated areas required by the standard can take two forms. For most employers who perform asbestos removal, demolition, or

renovation operations (other than small-scale short-duration), the regulated area must consist of a negative-pressure enclosure that will confine the asbestos fibers being generated to the area within the enclosure and will thus protect other employees and bystanders on the site from exposure to excessive levels of asbestos. For small-scale, short-duration removal, demolition and renovation operations and for asbestos work operations that do not involve asbestos removal, demolition, or renovation, the employer may simply demarcate the regulated area by posted signs that limit the number of employees entering the area.

Regulated areas do not have to be established when engineering and work practice controls reduce employee exposures to asbestos to levels below the standard's TWA and excursion permissible limits.

Methods of Compliance: Paragraphs (f)(1)(i), (f)(1)(ii), (f)(2)(i) and (f)(2)(iv) (General Industry); Paragraphs (g)(1)(i), (g)(2)(ii), and (g)(3) (Construction)

As discussed previously (see section on Summary of Regulatory Flexibility and Impact Analysis) OSHA believes that compliance with both the excursion limit and 8-hour TWA PELs can be accomplished by the majority of the asbestos industry through implementation of feasible engineering and work practice controls. OSHA, therefore, requires in paragraph (f)(1)(i) (general industry), and (g)(1)(i) (construction), of the amended asbestos standards, that the employer institute engineering and work practice controls to reduce and maintain employee exposure to or below the PELs except to the extent that such controls are not feasible. The amended rule further requires, in paragraph (f)(1)(ii) (general industry) and (g)(1)(ii) (construction), that wherever feasible engineering controls and work practices that can be instituted are not sufficient to reduce employee exposure to or below the PELs, the employer shall use them to reduce exposure to the lowest levels achievable by those controls, and shall supplement them by the use of respirators. Based on available evidence, OSHA believes that the use of engineering and work practices controls will reduce employer exposure to or below the PELs for many work situations.

The methods used to control the EL will of course vary with the operation. In the revised general industry standard employers in the automotive brake and clutch repair industry can successfully reduce their employees' exposures to asbestos to below the EL by employing the enclosed cylinder/HEPA vacuum system method as detailed in Appendix F to § 1910.1001.

In the revised construction standard, OSHA listed general categories of work practices and engineering controls acceptable for meeting the PEL (§ 1926.58(g)(1)). One activity likely to be impacted by this EL is maintenance and repair operations. These employers can use either singly or in combination: local exhaust ventilation equipped with HEPA filter dust collection systems, general ventilation systems, wet methods, vacuum cleaners equipped with HEPA filters, enclosure or process isolation, and prompt disposal of asbestos waste, all of which are listed in the previous cited provision.

In the installation of new construction materials such as A/C pipe and sheet the use of tools fitted with local exhaust shrouds connected to a HEPA vacuum have been demonstrated to reduce airborne asbestos concentrations significantly. Such shrouded tools are capable of reducing exposures below the excursion limit (Ex. 84–279).

OSHA in general believes that the imposition of the EL will not require the purchase of new controls or the development of new or different processes. Since many firms already use adequate controls in order to comply with the existing provisions of the asbestos standards, OSHA believes that meeting the EL will often require increased diligence in the application of existing controls and work practices implemented for the 8-hour TWA–PEL. These measures include such items as, but not limited to: (1) Frequently checking the effectiveness of exhaust systems, (2) increased attention to good housekeeping, employing a regular cleanup schedule using HEPA filtered vacuum cleaners, (3) periodic inspection and maintenance of process and control equipment to prevent system failure, (4) better trained workers to carry out their job functions with greater care and skill, and (5) improved supervision ensuring that work practices are carried out properly. In addition to the above measures the employer should consider shutting-off or temporarily modifying the air-hauling system to prevent the distribution of asbestos fibers to areas outside the work site and to other areas in the building.

Amended paragraph (f)(2)(i) (general industry) requires, where either PEL is exceeded, that the employer establish and implement a written program to reduce employer exposure to or below the excursion limit, by means of engineering and work practice controls, and by the use of respirators when permitted.

It is OSHA's belief that the written plan for achieving the excursion limit is as essential as the written plan requirement adopted for achieving the TWA, in ensuring that the employer implement the necessary controls to reduce exposure. The plan also provides the information that would allow OSHA, the employer, and employees to examine the excursion limit control methods chosen and to evaluate the extent to which these planned controls are being implemented. As with the TWA written plan, the excursion limit compliance plan will be accessible to individuals designated in paragraph (f)(2)(iii) (general industry) for inspection and copying.

Final paragraph (f)(2)(iv) (general industry) and (g)(3) (construction), prohibits employee rotation as a means of compliance with the excursion limit for the same reasons that employee rotation is not permitted for compliance with the TWA. This prohibition is consistent with OSHA's view that this control strategy is not appropriate in occupational environments involving exposure to potential carcinogens. It results in exposure of a larger number of employees to levels of asbestos which still present a significant risk.

Respiratory Protection: Paragraph (g)(1) (General Industry); Paragraph (h)(1)

The amended standards provide that respirators be used to limit short-term employee exposure to asbestos in the following circumstances:

(i) During the interval necessary to install or implement feasible engineering and work practice controls;

(ii) In work operations such as maintenance and repair activities or vessel cleaning or other activities for which the employer establishes that engineering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the excursion limit.

These same requirements apply under the current standard with respect to respirator use in complying with the TWA, and are based on OSHA's established policy on compliance methodology (see preamble discussion in the current asbestos standard, 51 FR 22692).

OSHA has estimated that respirator use will be required to meet the excursion limit in a number of general industry operations as well as routine maintenance and repair in general industry and construction. So that respirator use will be effective OSHA

has incorporated the requirements of § 1910.134 into the revised standards supplemented by requirements such as fit testing protocols for respirator use. OSHA is concerned about relying on respirator use to meet the EL in the maintenance and repair sector of the construction industry. Although maintenance crews employed by larger building maintenance firms may often be specialized for asbestos work and trained accordingly, smaller building firms where work with asbestos is spotty and perhaps not always recognized may not institute adequate respirator programs.

The imposition of an EL hopefully will fill lapses in respirator programs in such firms, if ony because a specific short-term limit corresponds with the asbestos exposure of most maintenance employees and thus highlights the need for protection, i.e., respiratory control.

Of course, engineering and work practice controls are still preferred, but as discussed earlier, for these operations respiratory protection often will be the feasible control strategy.

Other requirements under these paragraphs dealing with "Respirator selection" and "Respirator program," remain unchanged and apply where respirators are used to achieve the excursion limit.

Protective Work Clothing: Paragraphs (h)(1), (h)(3)(iii), (h)(3)(iv) (General Industry); Paragraphs (i)(1), (i)(2)(i), (i)(2)(ii) (Construction).

Existing paragraphs (h)(1) (general industry), and (i)(1) (construction), require that the employer provide to employees and ensure that the employees use appropriate protective clothing and equipment whenever the employees are exposed above the 8-hour TWA-PEL.

OSHA adopts in this rule, a similar requirement relative to the excursion limit, that protective clothing such as coveralls or similar full-body work clothing, gloves, head coverings, foot coverings, and face shields or other appropriate eye protection (when necessary to prevent eye irritation) be provided to employees exposed above the excursion limit.

It is OSHA's belief that protective clothing and foot coverings be required above the EL to prevent contamination of the employee's street clothing and shoes, so that exposure is not extended both beyond the time period and work area when the excusion limit was exceeded and beyond the workday and workplace.

The amended standards (h)(3)(iii), (h)(3)(iv) (general industry), and (i)(2)(i), (i)(2)(ii) (construction) require that the employer ensure that laundering of contaminated clothing be done in a manner that prevents the release of airborne asbestos fibers in excess of the PELs, and to inform those who launder or clean the contminated protective clothing to exercise caution to prevent the release of fibers in excess of the PELs. These provisions are designed to make clear the need to use proper care in handling of the contaminated clothing.

Hygiene Facilities and Practices: Paragraphs (i)(1)(i), (i)(2)(i), (i)(3)(i), (i)(3)(iii), (General Industry); Paragraph (j)(1)(iii), (Construction).

The amended provisions in general industry, require that the employer provide hygiene facilities and ensure that employees engage in good personal hygiene when asbestos exposures exceed both the 8-hour TWA-PEL and excursion limit. Specifically, employers are required to provide clean changerooms, showers, and lunchroom facilities and ensure that employees that work in areas where their exposures exceed either PEL, wash their hands and faces prior to eating, drinking and smoking and shower at the end of the work shift.

Similar provisions for hygiene facilities and good personal hygiene practices are found in the construction standard and are required whenever the 8-hour TWA-PEL or excursion limit is exceeded. However, unlike the general industry standard that requires the lunchroom be provided with a positive-pressure filtered air supply, the construction standard requires that airborne asbestos concentrations within lunchrooms be kept below the action level and excursion limit.

Communication of Asbestos Hazards to Employees: Paragraph (j)(5)(i) (General Industry); Paragraph (k)(3)(i) (Construction).

Existing paragraphs (j)(3)(i) (general industry) and (k)(3)(i) (construction) require that information and training concerning asbestos be provided to employees exposed at or above the action level. OSHA adopts in this rule, a requirement that information and training on asbestos be also provided to employees exposed at or above the excursion limit.

OSHA is adopting this provision based on the determination that informing employees through training, that high levels of asbestos might be released into the workplace, will better enable affected employees to take precautionary measures to protect themselves.

Medical Surveillance: Paragraphs (l)(1)i), (l)(4)(i) (General Industry); Paragraph (m)(1)(i) (Construction)

The amended standard for general industry requires each employer to institute a medical surveillance program for all employees who are or will be exposed to asbestos at or above the action level and/or excursion limit.

The amended standard for construction requires employers to implement the medical surveillance program only for employees required by the standard to wear negative-pressure respirators and for employees exposed to levels of asbestos at or above the action level and/or above the excursion limit for 30 or more days per year.

Since significant health risks are likely to be present at the excursion limit OSHA believes that it is essential that workers are provided medical surveillance whenever worker exposure exceeds the EL as well as at or above the action level. The initial and annual medical examination and evaluation is an important tool in protecting the worker exposed to asbestos by: detecting changes in a worker's physical condition, detecting biological effects of inhalation of asbestos as early as possible, providing a way to re-evaluate the workplace conditions, and evaluating the worker's suitability to continue doing the same job. For these reasons OSHA feels that the amended standards should require medical surveillance triggered above the excursion limit as well as by the action level.

Dates, Paragraph (o), (General Industry and Construction)

Effective Date

The amendments to the asbestos standards will become effective thirty (30) days following publication in the **Federal Register**. OSHA believes that a 30 day period between issuance of these standards and their effective date provides sufficient time for employers and employees to become informed of the existence of the standards and their requirements.

Start-up Dates

Since there was little record evidence on this issue, OSHA is using its experience in making a determination on the startup dates for these standards. The start-up dates discussed below provide the time required for employers to implement training programs and medical surveillance; to order and receive protective equipment and respirators; to construct changerooms, showers, lavoratories, and lunchrooms;

to plan, order, receive and install engineering controls; and to implement work practice controls. OSHA believes that the dates set in this standard should be adequate in all but unusual circumstances.

OSHA believes that expeditious action by employers to achieve compliance with the provisions of these amended standards is warranted. Employees under the current standard are being exposed to asbestos at concentrations that present a significant risk of adverse health effects. Compliance with the excursion limit will further reduce total asbestos dose, and therefore the risk, to which employees are presently being exposed under the existing rule.

The information available to OSHA clearly indicates that, with few exceptions, affected employers can be reasonably expected to be able to implement feasible engineering and/or work practice controls that would bring their workplaces into compliance with the amended standards' excursion limit within 6-months from the effective date of this standard.

As stated earlier in this discussion OSHA believes that the imposition of the EL will not necessarily require the purchase of new controls or the development of new or different processes. Many firms already use adequate controls in order to comply with the existing provisions of the asbestos standards. Therefore, OSHA believes that meeting the EL will often require increased diligence in the application of existing controls and work practices implemented for the 8-hour TWA-PEL. Consequently, employers should be able to comply with this provision in the time-frame specified.

OSHA believes that employers should be able to achieve compliance with changerooms, showers, lavatories and lunchroom facilities within one year after the effective date. This time-frame appears to be reasonable, since it allows employers an additional six months after engineering controls are completed to install hygiene and lunchroom facilities, should engineering and work practice controls fail to reduce exposures below the EL. The amended standards like the current standards do not require the immediate installation of changerooms, showers, lavatories, and lunchrooms if installation of engineering controls would only make their use necessary for a few months.

Additionally, compliance with all the other requirements of the standard within ninety (90) days of the effective date also is believed by OSHA to be appropriate. In response to the requirements set forth in OSHA's 1986 asbestos standard, asbestos employers have aready instituted programs regarding training, compliance plans, respirators, exposure monitoring and work practices, recordkeeping, signs and labels, and regulated areas. Thus, compliance with new burdens imposed by adoption of the excursion limit within the periods specified is believed to be reasonable and appropriate.

If the time period for meeting any of these startup dates cannot be met because of technical difficulties, employers are entitled to petition the Assistant Secretary for a temporary variance under section 6(b)(6)(A) of the Act.

VIII. State Plan Applicability

Twenty-four states and U.S. territories have their own OSHA-approved occupational safety and health plans. These states and territories are: Alaska, Arizona, California, Connecticut (for state and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. These states and territories are to adopt a standard comparable to that of OSHA's within 6 months of the effective date of the Federal rule.

List of Subjects

29 CFR Part 1910

Asbestos, Cancer, Health, Labeling, Occupational safety and health, Protective equipment, Respiratory protection, Signs and symbols.

29 CFR Part 1926

Asbestos, Cancer, Construction industry, Hazardous materials, Health, Labeling, Occupational safety and health, Protective equipment, Respiratory protection, Signs and symbols.

IX. Authority

This document was prepared under the direction of John A. Pendergrass, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Accordingly, pursuant to sections 4, 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), section 107 of the Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333), the Longshoremen's and Harbor Workers' Compensation Act (33 U.S.C. 941), 29 CFR Part 1911 and Secretary of Labor's Order No. 9-83 (48 FR 35736), 29 CFR Parts 1910 and 1926 are hereby amended as set forth below.

Signed at Washington, DC, this 6 day of September, 1988.

John A. Pendergrass,

Assistant Secretary of Labor.

Parts 1910 and 1926 of Title 29 of the Code of Federal Regulations are amended as set forth below:

X. Amended Standards

Part 1910 of Title 29 of the Code of Federal Regulations is amended as set forth below:

PART 1910—[AMENDED]

1. The authority citation for Subpart Z of 29 CFR Part 1910 continues, in pertinent part, to read as follows:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, (29 U.S.C. 655, 657); Secretary of Labor's Orders No. 12-71 (36 FR 8754); 8-76 (41 FR 25050), or 9-86 (48 FR 35736), as applicable; and 29 CFR Part 1911.

* * * * *

2. In § 1910.1001, paragraphs (c), (d)(1), (d)(2), (d)(3), (d)(4), (d)(5), (d)(7)(ii), (e)(1), (f)(1)(i), (f)(1)(ii), (f)(1)(iii), (f)(1)(v), (f)(1)(vi), (f)(1)(viii), (f)(2)(i), (f)(2)(iv), (g)(1)(iii), (h)(1) introductory text, (h)(3)(iii), (h)(3)(iv), (i)(1)(i), (i)(2)(i), (i)(3)(i), (i)(3)(iii), (j)(4)(i), (j)(5)(i), (l)(1((i), (l)(4)(i), and the last sentence of (o)(1) are revised and (o)(3) is added to read as follows:

§ 1910.1001 Asbestos, tremolite, anthophyllite, and actinolite.

* * * * *

(c) *Permissible exposure limits (PELS)*—(1) *Time-weighted average limit (TWA).* The employer shall ensure that no employee is exposed to an airborne concentration of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals in excess of 0.2 fiber per cubic centimeter of air as an eight (8)-hour time-weighted average (TWA) as determined by the method prescribed in Appendix A of this section, or by an equivalent method.

(2) *Excursion limit.* The employer shall ensure that no employee is exposed to an airborne concentration of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals, in excess of 1.0 fiber per cubic centimeter of air (1 f/cc) as averaged over a sampling period of thirty (30) minutes.

(d) * * *

(1) General.

(i) Determinations of employee exposure shall be made from breathing zone air samples that are representative

of the 8-hour TWA and 30-minute short-term exposures of each employee.

(ii) Representative 8-hour TWA employee exposures shall be determined on the basis of one or more samples representing full-shift exposures for each shift for each employee in each job classification in each work area. Representative 30-minute short-term employee exposures shall be determined on the basis of one or more samples representing 30 minute exposures associated with operations that are most likely to produce exposures above the excursion limit for each shift for each job classification in each work area.

(2) Initial monitoring.

(i) Each employer who has a workplace or work operation covered by this standard, except as provided for in paragraphs (d)(2)(ii) and (d)(2)(iii) of this section, shall perform initial monitoring of employees who are, or may reasonably be expected to be exposed to airborne concentrations at or above the action level and/or excursion limit.

(ii) Where the employer has monitored after December 20, 1985, for the TWA and after March 14, 1988, for the excursion limit, and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

(iii) Where the employer has relied upon objective data that demonstrates that asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals is not capable of being released in airborne concentrations at or above the action level and/or excursion limit under the expected conditions of processing, use, or handling, then no initial monitoring is required.

(3) *Monitoring frequency (periodic monitoring) and patterns.* After the initial determinations required by paragraph (d)(2)(i) of this section, samples shall be of such frequency and pattern as to represent with reasonable accuracy the levels of exposure of the employees. In no case shall sampling be at intervals greater than six months for employees whose exposures may reasonably be foreseen to exceed the action level and/or excursion limit.

(4) *Changes in monitoring frequency.* If either the initial or the periodic monitoring required by paragraphs (d)(2) and (d)(3) of this section statistically indicates that employee exposures are below the action level and/or excursion limit, the employer may discontinue the monitoring for those employees whose exposures are represented by such monitoring.

(5) *Additional monitoring.* Notwithstanding the provisions of paragraphs (d)(2)(ii) and (d)(4) of this section, the employer shall institute the exposure monitoring required under paragraphs (d)(2)(i) and (d)(3) of this section whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures above the action level and/or excursion limit or when the employer has any reason to suspect that a change may result in new or additional exposures above the action level and/or excursion limit.

* * * * *

(7) * * *

(ii) The written notification required by paragraph (d)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce employee exposure to or below the TWA and/or excursion limit, wherever monitoring results indicated that the TWA and/or excursion limit had been exceeded.

(e) * * *

(1) *Establishment.* The employer shall establish regulated areas wherever airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals are in excess of the TWA and/or excursion limit prescribed in paragraph (c) of this section.

* * * * *

(f) * * *

(1) * * *

(i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the TWA and/or excursion limit, prescribed in paragraph (c) of this section, except to the extent that such controls are not feasible.

(ii) Wherever the feasible engineering controls and work practices that can be instituted are not sufficient to reduce employee exposure to or below the TWA and/or excursion limit prescribed in paragraph (c) of this section, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(iii) For the following operations, wherever feasible engineering controls and work practices that can be instituted are not sufficient to reduce the employee exposure to or below the TWA and/or excursion limit, prescribed in paragraph (c) of this section, the employer shall use them to reduce employee exposure to or below 0.5 fiber per cubic centimeter of air (as an eight-hour time-weighted average) or 2.5 fibers/cc for 30 minutes (short-term exposure) and shall supplement them by the use of any combination of respiratory protection that complies with the requirements of paragraph (g) of this section, work practices and feasible engineering controls that will reduce employee exposure to or below the TWA and to or below the excursion limit prescribed in paragraph (c) of this section: Coupling cutoff in primary asbestos cement pipe manufacturing; sanding in primary and secondary asbestos cement sheet manufacturing; grinding in primary and secondary friction product manufacturing; carding and spinning in dry textile processes; and grinding and sanding in primary plastics manufacturing.

* * * * *

(v) *Particular tools.* All hand-operated and power-operated tools with would produce or release fibers of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals so as to expose employees to levels in excess of the TWA and/or excursion limit prescribed in paragraph (c) of this section, such as, but not limited to saws, scorers, abrasive wheels, and drills, shall be provided with local exhaust ventilation systems which comply with paragraph (f)(1)(iv) of this section.

(vi) *Wet methods.* Insofar as practicable, asbestos, tremolite, anthophyllite, or actinolite, shall be handled, mixed, applied, removed, cut, scored, or otherwise worked in a wet state sufficient to prevent the emission of airborne fibers so as to expose employees to levels in excess of the TWA and/or excursion limit, prescribed in paragraph (c) of this section, unless the usefulness of the product would be diminished thereby.

* * * * *

(viii) *Particular products and operations.* No asbestos cement, mortar, coating, grout, plaster, or similar material containing asbestos, tremolite, anthophyllite, or actinolite shall be removed from bags, cartons, or other containers in which they are shipped, without being either wetted, or enclosed, or ventilated so as to prevent effectively the release of airborne fibers of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals so as to expose employees to levels in excess of the TWA and/or excursion limit prescribed in paragraph (c) of this section.

* * * * *

(2) * * *

(i) Where the TWA and/or excursion limit is exceeded, the employer shall establish and implement a written

program to reduce employee exposure to or below the TWA and to or below the excursion limit by means of engineering and work practice controls as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section.

* * * * *

(iv) The employer shall not use employee rotation as a means of compliance with the TWA and/or excursion limit.

(g) * * *

(1) * * *

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the TWA and/or excursion limit; and

* * * * *

(h) * * *

(1) *Provision and use.* If an employee is exposed to asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals above the TWA and/or excursion limit, or where the possibility of eye irritation exists, the employer shall provide at no cost to the employee and ensure that the employee uses appropriate work clothing and equipment such as, but not limited to: * * *

* * * * *

(3) * * *

(iii) Laundering of contaminated clothing shall be done so as to prevent the release of airborne fibers of asbestos, tremolite, anthophyllite, and actinolite, or a combination of these minerals in excess of the permissible exposure limits prescribed in paragraph (c) of this section.

(iv) Any employer who gives contaminated clothing to another person for laundering shall inform such person of the requirement in paragraph (h)(3)(iii) of this section to effectively prevent the release of airborne fibers of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals in excess of the permissible exposure limits.

* * * * *

(i) * * *

(1) * * *

(i) The employer shall provide clean change rooms for employees who work in areas where their airborne exposure to asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals is above the TWA and/or excursion limit.

* * * * *

(2) * * *

(i) The employer shall ensure that employees who work in areas where their airborne exposure is above the TWA and/or excursion limit shower at the end of the work shift.

* * * * *

(3) * * *

(i) The employer shall provide lunchroom facilities for employees who work in areas where their airborne exposure is above the TWA and/or excursion limit.

* * * * *

(iii) The employer shall ensure that employees who work in areas where their airborne exposure is above the TWA and/or excursion limit wash their hands and faces prior to eating, drinking or smoking.

* * * * *

(j) * * *

(4) * * *

(i) Asbestos, tremolite, anthophyllite, or actinolite fibers have been modified by a bonding agent, coating, binder, or other material provided that the manufacturer can demonstrate that during any reasonably foreseeable use, handling, storage, disposal, processing, or transportation, no airborne concentrations of fibers of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals in excess of the action level and/or excursion limit will be released or

* * * * *

(5) * * *

(i) The employer shall institute a training program for all employees who are exposed to airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals at or above the action level and/or excursion limit and ensure their participation in the program.

* * * * *

(l) * * *

(1) * * *

(i) The employer shall institute a medical surveillance program for all employees who are or will be exposed to airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals at or above the action level and/or excursion limit.

* * * * *

(4) * * *

(i) The employer shall provide, or make available, a termination of employment medical examination for any employee who has been exposed to airborne concentrations of fibers of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals at or above the action level and/or excursion limit.

* * * * *

(o) * * *

(1) * * * The requirements in the amended paragraphs in this section which pertain only to or are triggered by the excursion limit shall become effective October 14, 1988.

* * * * *

(3) *Start-up dates for excursion limit.* Compliance with the excursion limit requirements in this section shall be as follows:

(i) Paragraphs (c), (d), (e), (g), (h), (j), (k), (l), (m) of this section, shall be complied with by December 13, 1988.

(ii) Paragraph (f) of this section, shall be complied with by March 13, 1989.

(iii) Paragraph (i) of this section, shall be complied with by September 14, 1989.

* * * * *

Part 1926 of Title 29 of the Code of Federal Regulations is amended as set forth below.

PART 1926—[AMENDED]

1. The authority citation for Subpart D of 29 CFR Part 1926 continues to read as follows:

Authority: Secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Sec. 107 Contract Work Hours and Safety Standards Act (Construction Safety Act), 40 U.S.C. 333, and Secretary of Labor's Orders 12–71 (36 FR 8754) 8–76 (41 FR 25059), or 9–83 (48 FR 35736) as applicable. Sections 1926.55(c) and 1926.58 also issued under 29 CFR Part 1911.

2. In § 1926.58 paragraphs (c), (e)(1), (e)(2), (f)(1)(ii), (f)(1)(iii), (f)(2)(ii), (f)(2)(iii), (f)(4), (g)(1)(i) introductory text, (g)(1)(ii), (g)(3), (h)(1)(iii), (i)(1), (i)(2), (j)(1)(iii), the first sentence of (k)(1)(i), (k)(2)(vi)(A), (k)(3)(i), (m)(1)(i), (n)(1)(i), the last sentence of (o)(1) and (o)(2) are revised to read as follows:

§ 1926.58 Asbestos, tremolite, anthophyllite, and actinolite.

* * * * *

(c) *Permissible exposure limits (PELS)*—(1) *Time-weighted average limit (TWA).* The employer shall ensure that no employee is exposed to an airborne concentration of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals in excess of 0.2 fiber per cubic centimeter of air as an eight (8)-hour time-weighted average (TWA) as determined by the method prescribed in Appendix A of this section, or by an equivalent method.

(2) *Excursion limit.* The employer shall ensure that no employee is exposed to an airborne concentration of asbestos in excess of 1.0 fiber per cubic centimeter of air (1 f/cc) as averaged over a sampling period of thirty (30) minutes.

* * * * *

(e) * * *

(1) *General.* The employer shall establish a regulated area in work areas where airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals exceed or can reasonably be expected to exceed the TWA and/or excursion limit prescribed in paragraph (c) of this section.

(2) *Demarcation.* The regulated area shall be demarcated in any manner that minimizes the number of persons within the area and protects persons outside the area from exposure to airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals in excess of the TWA and/or excursion limit.

* * * * *

(f) * * *

(1) * * *

(ii) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 30-minute short-term exposures of each employee.

(iii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for employees in each work area. Representative 30-minute short-term employee exposures shall be determined on the basis of one or more samples representing 30-minute exposures associated with operations that are most likely to produce exposures above the excursion limit for employees in each work area.

(2) * * *

(ii) The employer may demonstrate that employee exposures are below that action level and/or excursion limit by means of objective data demonstrating that the product or material containing asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals cannot release airborne fibers in concentrations exceeding the action level and/or excursion limit under those work conditions having the greatest potential for releasing asbestos, tremolite, anthophyllite, or actinolite.

(iii) Where the employer has monitored each asbestos, tremolite, anthophyllite, or actinolite job for the TWA, and where he has monitored after March 14, 1988, for the excursion limit, and the data were obtained during work operations conducted under workplace conditions closely resembling the processes, type of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (f)(2)(i) of this section.

* * * * *

(4) *Termination of monitoring.* If the periodic montoring required by paragraph (f)(3) of this section reveals that employee exposures, as indicated by statistically reliable measurement, are below the action level and/or excursion limit the employer may discontinue monitoring for those employees whose exposures are represented by such monitoring.

* * * * *

(g) * * *

(1) * * *

(i) The employer shall use one or any combination of the following control methods to achieve compliance with the TWA and/or excursion limit prescribed by paragraph (c) of this section: * * *

(ii) Wherever the feasible engineering and work practice controls described above are not sufficient to reduce employee exposure to or below the TWA and/or excursion limit prescribed in paragraph (c), of this section, the employer shall use them to reduce employee exposure to the lowest levels attainable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (h) of this section.

* * * * *

(3) *Employee rotation.* The employer shall not use employee rotation as a means of compliance with the TWA and/or excursion limit.

(h) * * *

(1) * * *

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the TWA and/or excursion limit; and

* * * * *

(i) * * *

(1) *General.* The employer shall provide and require the use of protective clothing, such as coveralls or similar whole body clothing, head coverings, gloves, and foot coverings for any employee exposed to airborne concentrations of asbestos, tremolite, anthophyllite, actinolite or a combination of these minerals that exceed the TWA and/or excursion limit prescribed in paragraph (c) of this section.

(2) Laundering.

(i) The employer shall ensure that laundering of contaminated clothing is done as to prevent the release of airborne asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals in excess of the TWA and/or excursion limit prescribed in paragraph (c) of this section.

(ii) Any employer who gives contaminated clothing to another person for laundering shall inform such persons of the requirement in paragraph (i)(2)(i) of this section to effectively prevent the release of airborne asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals in excess of the TWA and/or excursion limit prescribed in paragraph (c) of this section.

* * * * *

(j) * * *

(1) * * *

(iii) Whenever food or beverages are consumed at the worksite and employees are exposed to airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals in excess of the TWA and/or excursion limit, the employer shall provide lunch areas in which the airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals are below the action level and/or excursion limit.

* * * * *

(k) * * *

(1) * * *

(i) Warning signs that demarcate the regulated area shall be provided and displayed at each location where airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals may be in excess of the TWA and/or excursion limit prescribed in paragraph (c) of this section. * * *

(2) * * *

(vi) * * *

(A) Asbestos, tremolite, anthophyllite, or actinolite fibers have been modified by a bonding agent, coating, binder, or other material, provided that the manufacturer can demonstrate that, during any reasonably foreseeable use, handling, storage, disposal, processing, or transportation, no airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these mineral fibers in excess of the action level and/or excursion limit will be released, or

* * * * *

(3) * * *

(i) The employer shall institute a training program for all employees exposed to airborne concentrations of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals in excess of the action level and/or excursion limit and shall ensure their participation in the program.

* * * * *

(m) * * *

(1) * * *

(i) The employer shall institute a medical surveillance program for all employees engaged in work involving levels of asbestos, tremolite, anthophyllite, actinolite, or a combination of these minerals at or above the action level and/or excursion limit for 30 or more days per year, or who are required by this section to wear negative pressure respirators.

* * * * *

(n) * * *

(1) * * *

(i) Where the employer has relied on objective data that demonstrates that products made from or containing asbestos, tremolite, anthophyllite, or actinolite are not capable of releasing fibers or asbestos, tremolite, anthophyllite, or actinolite or a combination of these minerals, in concentrations at or above the action level and/or excursion limit under the expected conditions of processing, use, or handling to exempt such operations from the initial monitoring requirements under paragraph (f)(2) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

* * * * *

(o) * * *

(1) * * * The requirements in the amended paragraphs in this section which pertain only to or are triggered by the excursion limit shall become effective October 14, 1988.

(2) Start-up dates. The requirements of paragraphs (c) through (n) of this section, including the engineering controls specified in paragraph (g)(1) of this section, shall be complied with by January 16, 1987. Compliance with the excursion limit requirements in this section shall be as follows:

(i) Paragraphs (c), (d), (e), (f), (h), (i), (k), (l), (m), (n) of this section, shall be complied with by December 13, 1988.

(ii) Paragraph (g) of this section, shall be complied with by March 13, 1989.

(iii) Paragraph (j) of this section shall be complied with by September 14, 1989.

* * * * *

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