

those in the 1985 edition with the following exceptions:

(1) In the second paragraph under "Apparatus," the 1985 edition states "A membrane generally suitable for sterility testing has a normal porosity of .45 +/- 0.02um, * * *," while the 1995 edition does not include the "+/-0.02um"; and

(2) the 1985 edition did not have a section on "Filterable Solids," because information of filterable solids was not available in 1985. The 1995 edition now has this information.

Because these differences in the two editions of the USP are insignificant, and the 1995 edition is more readily available to the public, the agency believes that the regulation should be amended, as indicated herein, to reflect the more recent version of the test standards. Accordingly § 610.12(f) is being amended to reflect the 1995 edition of the USP (23d Revision, 1995).

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)). Notice and public procedure are unnecessary because FDA is merely updating a reference in its regulations.

List of Subjects in 21 CFR Part 610

Biologics, Incorporation by reference, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

2. Section 610.12 is amended by revising paragraph (f) to read as follows:

§ 610.12 Sterility.

* * * * *

(f) *Membrane filtration.* Bulk and final container material or products containing oil products in water-insoluble ointments may be tested for sterility using the membrane filtration procedure set forth in the United States Pharmacopeia (23d Revision, 1995), section entitled "Test Procedures Using Membrane Filtration," pp. 1689 to 1690, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from

the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or available for inspection at the Center for Drug Evaluation and Research's Division of Medical Library, 5600 Fishers Lane, rm. 11B-40, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC, except that:

(1) The test samples shall conform with paragraph (d) of this section; and

(2) In addition, for products containing a mercurial preservative, the product shall be tested in a second test using Fluid Thioglycollate Medium incubated at 20 to 25 °C in lieu of the test in Soybean-Casein Digest Medium.

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Dated: September 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

RIN 1218-AA95

Methylene Chloride; Amendment; Extension of Start-Up Date

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

ACTION: Final Rule; amendment; extension of start-up date for compliance.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is extending the start-up date for most provisions of the methylene chloride by 30 days to November 6, 1997 for larger employers. Employers with fewer than 20 employees and foam manufacturers with 20 to 99 employees have substantially later start-up dates which are not changed.

DATES: The effective date of this amendment is September 15, 1997.

Compliance: The start-up date for all provisions of the methylene chloride standard except initial monitoring and engineering controls for employers specified in § 1910.1052(n)(2)(iii)(c) is extended to November 6, 1997 (210 days after the effective date of the standard).

FOR FURTHER INFORMATION CONTACT: Bonnie Freeman, Director, OSHA Office of Public Affairs, U.S. Department of Labor, Room N3647, 200 Constitution

Avenue, NW., Washington, DC 20210, telephone (202) 219-8151.

SUPPLEMENTARY INFORMATION: OSHA published a new methylene chloride standard January 10, 1997 (62 FR 1494). That standard included extended start-up dates for its various provisions depending on the size of the employer. The three categories of employers were employees with fewer than 20 employees, foam manufacturers with 20-99 employees and "all other employers."

OSHA published notification of OMB approval of information collection requirements on August 8, 1997 (62 FR 42666). As the start-up date for initial monitoring for "all other employers" was August 8, 1997, OSHA extended that date to September 7, 1997 to provide added notice to implement compliance.

The next start-up date specified for "all other employers" is October 7, 1997 for all provisions except engineering controls and initial monitoring. That is only 30 days after the extended date for completion of initial monitoring.

OSHA has concluded that more time is needed between completion of initial monitoring and implementation of the other provisions except engineering controls. This allows for a more efficient and effective implementation of those provisions such as for training, medical surveillance and other specified provisions. This is also consistent with OSHA's initial determination that 60 days is needed between completion of initial monitoring and implementation of the other provisions. OSHA is amending § 1910.1052(n)(2)(iii)(c) to implement this decision.

The date for completion of initial monitoring for employers with fewer than 20 employees is February 4, 1998 and for foam manufacturers with 20-99 employees is November 6, 1997. The date for all other provisions except engineering controls is 60 days later for each group. See 62 FR 1606 (January 10, 1997) for a listing of effective and start-up dates.

OSHA finds that there is good cause to issue this extension without notice and public comment because following such procedures would be impractical, unnecessary or contrary to the public interest in this case. OSHA believes that it is in the public interest to give certain employers additional time between completion of initial monitoring and implementation of other provisions.

Authority And Signature

This document was prepared under the direction of Gregory R. Watchman, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S.

Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 9th day of September 1997.

Gregory R. Watchman,

Acting Assistant Secretary of Labor.

PART 1910—[AMENDED]

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

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), or 6-96 (62 FR 111), as applicable; and 29 CFR Part 1911.

* * * * *

2. Paragraph (n)(2)(iii)(C) of § 1910.1052 is revised to read as follows:

§ 1910.1052 Methylene chloride.

* * * * *

- (n) * * *
- (2) * * *
- (iii) * * *

(C) For all other employers, within 210 days after the effective date of this section.

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[FR Doc. 97-24350 Filed 9-12-97; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans prescribes interest assumptions for

valuing benefits under terminating single-employer plans. This final rule amends the regulation to adopt interest assumptions for plans with valuation dates in October 1997.

EFFECTIVE DATE: October 1, 1997.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024 (202-326-4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION: The PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions for valuing plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

Among the actuarial assumptions prescribed in part 4044 are interest assumptions. These interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Two sets of interest assumptions are prescribed, one set for the valuation of benefits to be paid as annuities and one set for the valuation of benefits to be paid as lump sums. This amendment adds to appendix B to part 4044 the annuity and lump sum interest assumptions for valuing benefits in plans with valuation dates during October 1997.

For annuity benefits, the interest assumptions will be 5.90 percent for the first 25 years following the valuation date and 5.00 percent thereafter. The annuity interest assumptions represent an increase (from those in effect for September 1997) of 0.20 percent for the first 25 years following the valuation date and are otherwise unchanged. For benefits to be paid as lump sums, the interest assumptions to be used by the PBGC will be 4.75 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay

status. The lump sum interest assumptions represent an increase (from those in effect for September 1997) of 0.25 percent for the period during which a benefit is in pay status; they are otherwise unchanged.

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation of benefits in plans with valuation dates during October 1997, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4044

Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

2. In appendix B, a new entry is added to Table I, and Rate Set 48 is added to Table II, as set forth below. The introductory text of each table is republished for the convenience of the reader and remains unchanged.

Appendix B to Part 4044—Interest Rates Used To Value Annuities and Lump Sums

TABLE I.—ANNUITY VALUATIONS

[This table sets forth, for each indicated calendar month, the interest rates (denoted by i_1, i_2, \dots , and referred to generally as i_t) assumed to be in effect between specified anniversaries of a valuation date that occurs within that calendar month; those anniversaries are specified in the columns adjacent to the rates. The last listed rate is assumed to be in effect after the last listed anniversary date.]

For valuation dates occurring in the month—	The values of i_t are:			
	i_t	for $t=$	i_t	for $t=$
	*	*	*	*
October 19970590	1-25	.0500	>25 N/A N/A