

**§ 640.100 Immune Globulin (Human).**

(a) \* \* \* The product is defined as a sterile solution containing antibodies derived from human plasma.

(b) *Source material.* The source material of Immune Globulin (Human) shall be plasma recovered from Whole Blood prepared as prescribed in §§ 640.1 through 640.5, or Source Plasma prepared as prescribed in §§ 640.60 through 640.76.

(c) *Additives in source material.* The source material shall contain no additives other than citrate or acid citrate dextrose anticoagulant solution, unless it is shown that the processing method yields a product free of the additive to such an extent that the safety, purity, and potency of the product will not be affected adversely.

**§ 640.101 [Amended]**

11. Section 640.101 *General requirements* is amended by removing the heading of paragraph (b) "*Hydrogen ion concentration*" and by adding in its place "*pH*" and by removing paragraphs (e)(3), (e)(4), and (f).

12. Section 640.102 is amended by revising the last sentence of paragraph (e) to read as follows:

**640.102 Manufacture of Immune Globulin (Human).**

\* \* \* \* \*

(e) \* \* \* At no time during processing shall the product be exposed to temperatures above 45 °C and after sterilization the product shall not be exposed to temperatures above 32 °C for more than 72 hours.

13. Section 640.103 is amended by revising paragraph (b) to read as follows:

**§ 640.103 The final product.**

\* \* \* \* \*

(b) *Protein composition.* At least 96 percent of the total protein shall be immunoglobulin G (IgG), as determined by a method that has been approved for each manufacturer by the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

14. Section 640.104 is amended by revising paragraphs (b)(2), (b)(3), (c)(1), and (c)(2) to read as follows:

**§ 640.104 Potency.**

\* \* \* \* \*

(b) \* \* \*  
(2) A measles neutralizing antibody level that, when compared with that of a reference material designated by the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, as indicated in paragraph (c) of this section, demonstrates adequate potency. The

Director, CBER, shall notify manufacturers when a new reference material will be used and will advise manufacturers of an appropriate antibody level taking into account a comparison of the new reference material to the previous reference material.

(3) A poliomyelitis Type 1, Type 2, or Type 3 neutralizing antibody level that, when compared with that of a reference material designated by the Center for Biologics Evaluation and Research, Food and Drug Administration, as indicated in paragraph (c) of this section, demonstrates adequate potency. The Director, CBER, shall notify manufacturers when a new reference material will be used and will advise manufacturers of an appropriate antibody level taking into account a comparison of the new reference material to the previous reference material.

(c) \* \* \*

(1) Reference Immune Globulin for correlation of measles antibody titers.

(2) Reference Immune Globulin for correlation of poliomyelitis antibody titers, Types 1, 2, and 3.

Dated: April 20, 1999.

**Jane E. Henney,**

*Commissioner of Food and Drugs.*

**Donna E. Shalala,**

*Secretary of Health and Human Services.*

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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 June 1999. Interest assumptions are also published on the PBGC's web site (<http://www.pbgc.gov>).

**EFFECTIVE DATE:** June 1, 1999.

**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. (For TTY/TDD users, call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

**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 June 1999.

For annuity benefits, the interest assumptions will be 5.70 percent for the first 20 years following the valuation date and 5.25 percent thereafter. For benefits to be paid as lump sums, the interest assumptions to be used by the PBGC will be 4.25 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. These annuity and lump sum interest assumptions are unchanged from those in effect for May 1999.

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 June 1999, 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 68 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 $t =$	$i_t$	for $t =$
June 1999 .....	.0570	1–20	.0525	>20	N/A	N/A

TABLE II.—LUMP SUM VALUATIONS

[In using this table: (1) For benefits for which the participant or beneficiary is entitled to be in pay status on the valuation date, the immediate annuity rate shall apply; (2) For benefits for which the deferral period is  $y$  years (where  $y$  is an integer and  $0 < y \leq n_1$ ), interest rate  $i_1$  shall apply from the valuation date for a period of  $y$  years, and thereafter the immediate annuity rate shall apply; (3) For benefits for which the deferral period is  $y$  years (where  $y$  is an integer and  $n_1 < y \leq n_1 + n_2$ ), interest rate  $i_2$  shall apply from the valuation date for a period of  $y - n_1$  years, interest rate  $i_1$  shall apply for the following  $n_1$  years, and thereafter the immediate annuity rate shall apply; (4) For benefits for which the deferral period is  $y$  years (where  $y$  is an integer and  $y > n_1 + n_2$ ), interest rate  $i_3$  shall apply from the valuation date for a period of  $y - n_1 - n_2$  years, interest rate  $i_2$  shall apply for the following  $n_2$  years, interest rate  $i_1$  shall apply for the following  $n_1$  years, and thereafter the immediate annuity rate shall apply.]

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)					
	On or after	Before		$i_1$	$i_2$	$i_3$	$n_1$	$n_2$	
68	06–1–99	07–1–99	4.25	4.00	4.00	4.00	7	8	

Issued in Washington, DC, on this 10th day of May 1999.

**David M. Strauss,**

*Executive Director, Pension Benefit Guaranty Corporation.*

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**DEPARTMENT OF THE INTERIOR**

**Office of Surface Mining Reclamation and Enforcement**

**30 CFR Part 948**

[WV–077–FOR]

**West Virginia Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Final rule; decision on amendment.

**SUMMARY:** OSM is announcing that it is not approving an amendment to the West Virginia permanent regulatory program under the Surface Mining

Control and Reclamation Act of 1977 (SMCRA). The amendment would have revised the West Virginia Surface Coal Mining and Reclamation Act, and concerns fish and wildlife habitat and recreation lands as a postmining land use for mountaintop removal operations with variances from approximate original contour.

**EFFECTIVE DATE:** May 14, 1999.

**FOR FURTHER INFORMATION CONTACT:** Mr. Roger W. Calhoun, Director, Charleston Field Office, Telephone: (304) 347–7158.

**SUPPLEMENTARY INFORMATION:**

- I. Background on the West Virginia Program
- II. Submission of the Amendment
- III. Director's Finding
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

**I. Background on the West Virginia Program**

On January 21, 1981, the Secretary of the Interior conditionally approved the West Virginia program. You can find background information on the West Virginia program, including the

Secretary's findings, the disposition of comments, and the conditions of the approval in the January 21, 1981, **Federal Register** (46 FR 5915–5956). You can find later actions concerning the West Virginia program and previous amendments at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

**II. Submission of the Amendment**

By letter dated April 28, 1997 (Administrative Record Number WV–1056), the West Virginia Division of Environmental Protection (WVDEP) submitted an amendment to its approved permanent regulatory program pursuant to 30 CFR 732.17. By letter dated May 14, 1997 (Administrative Record Number WV–1057), WVDEP submitted some revisions to the original submittal. The amendment contained revisions to section 38–2–1 *et seq.* of the West Virginia Surface Mining Reclamation Regulations [Code of State Regulations (CSR)] and to section 22–3–1 *et seq.* of the West Virginia Surface Coal Mining and Reclamation Act (WVSCMRA). The amendment mainly consisted of changes to implement the