§ 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 anti-coagulant 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.

(c) * * * *(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.

(d) * * *
(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.


Jane E. Henney,
Commissioner of Food and Drugs.

Donna E. Shalala,
Secretary of Health and Human Services.

[FR Doc. 99-9987 Filed 5-13-99; 8:45 am]

BILLING CODE 4160-01-F

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 single-employer 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 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.

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.

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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.—ANNUALITY VALUATIONS

[This table sets forth, for each indicated calendar month, the interest rates (denoted by \( i_t \), \( i_2 \), \( i_3 \), and referred to generally as \( i \)) 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.]

<table>
<thead>
<tr>
<th>For valuation dates occurring in the month—</th>
<th>The values of ( i ) are:</th>
<th>( i )</th>
<th>( i )</th>
<th>( i )</th>
<th>( i )</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 1999</td>
<td></td>
<td>0.0570</td>
<td>1–20</td>
<td>0.0525</td>
<td>&gt;20 N/A</td>
</tr>
</tbody>
</table>

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 \( y < n_1 + n_2 \)), interest rate \( i_2 \) shall apply from the valuation date for a period of \( y \) 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 \( y \) years, and thereafter the immediate annuity rate shall apply.]

<table>
<thead>
<tr>
<th>Rate set</th>
<th>For plans with a valuation date</th>
<th>Immediate annuity rate (percent)</th>
<th>Deferred annuities (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>On or after</td>
<td>Before</td>
<td>( i_1 )</td>
</tr>
<tr>
<td>68</td>
<td>06–1–99</td>
<td>07–1–99</td>
<td>4.25</td>
</tr>
</tbody>
</table>

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

David M. Strauss,
Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 99–12175 Filed 5–13–99; 8:45 am]
BILLING CODE 7708–01–P

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. Caihoun, 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 permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment mainly consisted of changes to implement the...