

Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff." That guidance can be obtained through the Internet on the CDRH home page at <http://www.fda.gov/cdrh> or by facsimile through CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111. Specify "159" when prompted for the document shelf number.

### III. Petition

On March 25, 2001, FDA received a petition requesting an exemption from premarket notification for the F-Spoon, a manual compression device that allows a radiologist to press on the abdomen during a fluoroscopic procedure without exposing his or her hand to the x-ray beam. In the **Federal Register** of June 18, 2001 (66 FR 32828), FDA published a notice announcing that this petition had been received and provided an opportunity for interested persons to submit comments on the petition by July 18, 2001. FDA also announced that it intended to expand the exemption to include all fluoroscopic compression devices of this generic type, subject to limitations in 21 CFR 892.9. FDA received no comments. FDA has reviewed the petition and has determined that this device meets the criteria for exemption described previously and is, therefore, issuing this order exempting the device from the requirements of premarket notification. The fluoroscopic compression device is an accessory to the image-intensified fluoroscopic x-ray system classified under 21 CFR 892.1650.

### IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

### V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104-121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health

and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule will relieve a burden and simplify the marketing of these devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

### VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

### List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

### PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR part 892 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 892.1650 is amended by revising paragraph (b) to read as follows:

### § 892.1650 Image-intensified fluoroscopic x-ray system.

\* \* \* \* \*

(b) *Classification.* Class II. When intended as an accessory to the device described in paragraph (a) of this section, the fluoroscopic compression device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 892.9.

Dated: October 25, 2001.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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### PENSION BENEFIT GUARANTY CORPORATION

#### 29 CFR Parts 4022 and 4044

#### Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Final rule.

**SUMMARY:** The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in December 2001. Interest assumptions are also published on the PBGC's Web site (<http://www.pbgc.gov>).

**EFFECTIVE DATE:** December 1, 2001.

**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. (TTY/TDD users may 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 regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) a set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to Part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to Part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to Part 4022).

Accordingly, this amendment (1) adds to Appendix B to Part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during December 2001, (2) adds to Appendix B to Part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during December 2001, and (3) adds to Appendix C to Part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during December 2001.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 6.10 percent for the first 20 years following the valuation date and 6.25 percent thereafter. These interest assumptions represent a decrease (from those in

effect for November 2001) of 0.40 percent for the first 20 years following the valuation date and are otherwise unchanged.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 4.50 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 interest assumptions represent a decrease (from those in effect for November 2001) of 0.25 percent for the period during which a benefit is in pay status and are otherwise unchanged.

For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

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 and payment of benefits in plans with valuation dates during December 2001, 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**

*29 CFR Part 4022*

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

*29 CFR Part 4044*

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

**PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS**

1. The authority citation for part 4022 continues to read as follows:

**Authority:** 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

2. In appendix B to part 4022, Rate Set 98, as set forth below, is added to the table. (The introductory text of the table is omitted.)

**Appendix B to Part 4022—Lump Sum Interest Rates For PBGC Payments**

\* \* \* \* \*

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		$i_1$	$i_2$	$i_3$	$n_1$	$n_2$
* 98	* 12-1-01	* 1-1-02	* 4.50	* 4.00	* 4.00	* 4.00	* 7	* 8

3. In appendix C to part 4022, Rate Set 98, as set forth below, is added to the table. (The introductory text of the table is omitted.)

**Appendix C to Part 4022—Lump Sum Interest Rates For Private-Sector Payments**

\* \* \* \* \*

Rate set	For plans with a valuation date		Immediate annuities rate (percent)	Deferred annuity (percent)				
	On or after	Before		$i_1$	$i_2$	$i_3$	$n_1$	$n_2$
* 98	* 12-1-01	* 1-1-02	* 4.50	* 4.00	* 4.00	* 4.00	* 7	* 8

**PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS**

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

**Authority:** 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.  
5. In appendix B to part 4044, a new entry, as set forth below, is added to the

table. (The introductory text of the table is omitted.)  
**Appendix B to Part 4044—Interest Rates Used to Value Benefits**  
\* \* \* \* \*

For valuation dates occurring in the month—	The values of $i_t$ are:					
	$i_t$	for $t =$	$i_t$	for $t =$	$i_t$	for $t =$
December 2001 .....	.0610	1–20	.0625	>20	N/A	N/A

Issued in Washington, DC, on this 7th day of November 2001.

**John Seal,**  
Acting Executive Director, Pension Benefit Guaranty Corporation.  
[FR Doc. 01–28623 Filed 11–14–01; 8:45 am]  
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**DEPARTMENT OF THE TREASURY**

**Office of Foreign Assets Control**

**31 CFR Chapter V and Part 539**

**Additional Designations and Removal of Persons Listed in Appendix A to 31 CFR Chapter V and Appendix I to 31 CFR Part 539, Weapons of Mass Destruction Trade Control Regulations**

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Amendment of final rule.

**SUMMARY:** The Treasury Department is amending appendix A to 31 CFR chapter V to add or remove, as appropriate, the names of individuals and entities designated as specially designated narcotics traffickers, a foreign terrorist organization, or blocked persons or specially designated nationals designated pursuant to Executive Orders 13088, 13192, or 13219; amending the notes to the appendices to 31 CFR chapter V to reflect the revisions to appendix A and the publication of the Taliban (Afghanistan) Sanctions Regulations, 31 CFR part 545; and amending appendix I to 31 CFR part 539 to remove two entities previously designated as designated foreign persons.

**EFFECTIVE DATE:** November 9, 2001.

**FOR FURTHER INFORMATION CONTACT:** Office of Foreign Assets Control, Department of the Treasury, Washington, D.C. 20220, tel.: 202/622–2520.

**SUPPLEMENTARY INFORMATION:**

**Electronic and Facsimile Availability**

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**Background**

*A. Amendments to Appendix A and the Notes to the Appendices to 31 CFR Chapter V*

Appendix A to 31 CFR chapter V lists the names of blocked persons, specially designated nationals, specially designated terrorists, foreign terrorist organizations, and specially designated narcotics traffickers with respect to whom transactions are subject to the various economic sanctions programs administered by the Treasury Department’s Office of Foreign Assets Control (“OFAC”). OFAC, acting under authority delegated by the Secretary of the Treasury, is amending appendix A to add or remove, as appropriate, the names of individuals and entities designated as specially designated narcotics traffickers, a foreign terrorist organization, or blocked persons or specially designated nationals designated pursuant to Executive Orders 13088, 13192, or 13219. OFAC is also amending notes 4 and 6 to the notes to the appendices to 31 CFR chapter V to

reflect the revisions to appendix A and the publication of the Taliban (Afghanistan) Sanctions Regulations, 31 CFR part 545.

*Specially Designated Narcotics Traffickers.* On June 1, 2001, President Bush identified twelve individuals as significant foreign narcotics traffickers pursuant to section 804(b) of the Foreign Narcotics Kingpin Designation Act, 21 U.S.C. 1903(b). In accordance with § 598.314 of the Foreign Narcotics Kingpin Sanctions Regulations, 31 CFR part 598, those twelve individuals and their known aliases are added to appendix A as specially designated narcotics traffickers identified by the term “[SDNTK].”

As of June 1, 2001, all property and interests in property, including but not limited to all accounts, that are or come within the United States or that are or come within the possession or control of U.S. persons, including their overseas branches, that are owned or controlled by any of those twelve persons are with limited exceptions blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in. All transactions or dealings by U.S. persons or within the United States in property or interests in property of any of those twelve persons are prohibited unless licensed by OFAC or otherwise authorized.

*Foreign Terrorist Organization.* On May 16, 2001, the Secretary of State in a notice published in the **Federal Register** (66 FR 27442) designated the “Real IRA” a foreign terrorist organization pursuant to section 302 of the Antiterrorism and Effective Death Penalty Act of 1996, 8 U.S.C. 1189 (“AEDPA”). In furtherance of section 303 of AEDPA, 18 U.S.C. 2339B, implemented in part by the Foreign Terrorist Organizations Sanctions Regulations, 31 CFR part 597 (the “FTO Regulations”), the “Real IRA” and its known aliases are added to appendix A as a foreign terrorist organization identified by the term “[FTO].”