

■ 2. Section 870.1 is amended by adding paragraph (e) to read as follows:

§ 870.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

■ 3. Section 870.1025 is revised to read as follows:

§ 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).

(a) *Identification.* The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs.

(b) *Classification.* Class II (special controls). The guidance document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" will serve as the special control. See § 870.1 for the availability of this guidance document.

■ 4. Section 870.5310 is added to subpart F to read as follows:

§ 870.5310 Automated external defibrillator.

(a) *Identification.* An automated external defibrillator (AED) is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal hearth rhythm) the atria or ventricles of the heart. An AED analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

(b) *Classification.* Class III (premarket approval)

(c) *Date PMA or notice of PDP is required.* No effective date has been established of the requirement for premarket approval. See § 870.3.

Dated: October 2, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4000, 4003, 4007, 4010, 4011, 4022, 4041, 4041A, 4043, 4050, 4062, 4203, 4204, 4207, 4208, 4211, 4219, 4220, 4221, 4231, 4245, 4281, 4901, 4902, 4903 and 4907

RIN 1212-AA89

Rules on Filings, Issuances, Computation of Time, and Electronic Means of Record Retention

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: Consistent with the Government Paperwork Elimination Act, we are removing requirements from our regulations that might limit electronic filing with us or electronic issuances to others. These rules give us flexibility to keep pace with ever-changing technology. In addition, they simplify and consolidate our rules on what methods you may use to send us a filing or provide an issuance to someone other than us, on how to determine the date we treat you as having made your filing or provided your issuance, and on how to compute various periods of time (including those for filings with us and for issuances to third parties). Finally, they provide rules for maintaining records by electronic means.

DATES: This final rule is effective November 28, 2003.

Applicability date: See "Applicability of New Rules in Determining Your Filing or Issuance Date" under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, or Thomas H. Gabriel, Attorney, Office of the General Counsel, PBGC, 1200 K Street, NW., Washington, DC 20005-4026; 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: On February 14, 2003, we published a proposed rule on filings, issuances, computation of time, and electronic means of record retention (65 FR 7454). We received no comments on the proposal and are now issuing it in final form with only minor editorial modifications.

These final rules are part of our ongoing implementation of the Government Paperwork Elimination Act (GPEA) and are consistent with the Office of Management and Budget directive to remove regulatory

impediments to electronic transactions. They address electronic means for filings with us, issuances to third parties, and recordkeeping. They build in the flexibility needed to allow us to continue to expand the availability of electronic options as technology advances. Under these rules, much of the detailed information on permitted electronic means will be on our Web site, <http://www.pb.gc.gov>, which will be updated from time to time.

The final rules make it easier for you to make a filing or provide an issuance on time by treating most types of submissions as filed or issued on the date sent (provided you meet certain requirements) rather than on the date received. In addition, the rules are easier to use—they are simpler, more uniform, and appear together in a single part of the regulations. The final rules make similar simplifying changes to the rules for computing periods of time.

Under this final rule, our filing, issuance, computation-of-time, and electronic record-retention rules are consolidated in new subparts A through E of part 4000.

- New subpart A tells you what methods you may use for sending a filing to us. These new rules apply to any filing with us under our regulations where the particular regulation calls for their application. For these purposes, we treat any payment to us under our regulations as a filing.

- New subpart B tells you what methods you may use to issue a notice or otherwise provide information to any person other than us. These new rules apply to any issuance (except a payment) under our regulations where the particular regulation calls for their application.

- New subpart C tells you how we determine the date you send us a filing and the date you provide an issuance to someone other than us (such as a participant). These new rules apply to any filing or issuance under our regulations where the particular regulation calls for their application.

- New subpart D tells you how to compute time periods. These new rules apply to any time period under our regulations (e.g., for filings with us and issuances to third parties) where the particular regulation calls for their application.

- New subpart E tells you how to comply with any recordkeeping requirement under our regulations using electronic means.

Existing Part 4000's distribution and derivation tables, which show the changes that occurred as a result of the PBGC's July 1, 1996, reorganization and renumbering of its regulations (61 FR