(2) *Charging for an approved drug obtained from another entity for use as an active control or in combination with another drug.* A sponsor who wishes to charge for an approved drug that it must obtain from another entity for use as an active control or in combination with its investigational drug in a clinical trial of the sponsor's investigational drug must:

(i) Demonstrate that the clinical trial is adequately designed to evaluate the safety or effectiveness of the sponsor's drug; and

(ii) Demonstrate that the holder of the approved application is not providing the drug to the sponsor free of charge.

(3) *Charging for an approved drug obtained from another entity in a clinical trial of that drug.* A sponsor who wishes to charge for an approved drug that it must obtain from another source for use in a clinical trial intended to evaluate the acquired drug must:

(i) Demonstrate that the clinical trial is adequately designed to evaluate the safety or effectiveness of a new indication or to provide important safety information related to an approved indication; and

(ii) Demonstrate that the holder of the approved application is not providing the drug to the sponsor free of charge.

(4) *Duration of charging in a clinical trial.* Unless FDA specifies a shorter period, charging may continue for the length of the clinical trial.

(c) *Charging for expanded access to investigational drug for treatment use.* (1) A sponsor who wishes to charge for expanded access to an investigational drug for treatment use under subpart I of this part must provide reasonable assurance that charging will not interfere with developing the drug for marketing approval.

(2) For expanded access under § 312.320, such assurance must include:

(i) Evidence of sufficient enrollment in any ongoing clinical trial(s) needed for marketing approval to reasonably assure FDA that the trial(s) will be successfully completed as planned;

(ii) Evidence of adequate progress in the development of the drug for marketing approval; and

(iii) Information submitted under the general investigational plan (§ 312.23(a)(3)(iv)) specifying the drug development milestones the sponsor plans to meet in the next year.

(3) The authorization to charge is limited to the number of patients authorized to receive the drug under the treatment use, if there is a limitation.

(4) Unless FDA specifies a shorter period, charging for expanded access to an investigational drug for treatment use under subpart I of this part may continue for one year from the time of FDA authorization. A sponsor may request that FDA reauthorize charging for additional periods.

(d) *Costs recoverable when charging for an investigational drug.* (1) A sponsor may recover only the direct costs of making the investigational drug available.

(i) Direct costs are costs incurred by a sponsor that can be specifically and exclusively attributed to providing the drug for the investigational use for which FDA has authorized cost recovery. Direct costs include costs per unit to manufacture the drug (e.g., raw materials, labor, and nonreusable supplies and equipment used to manufacture the quantity of drug needed for the use for which charging is authorized) or costs to acquire the drug from another manufacturing source, and direct costs to ship and handle (e.g., store) the drug.

(ii) Indirect costs include costs incurred primarily to produce the drug for commercial sale (e.g., costs for facilities and equipment used to manufacture the supply of investigational drug, but that are primarily intended to produce large quantities of drug for eventual commercial sale) and research and development, administrative, labor, or other costs that would be incurred even if the clinical trial or treatment use for which charging is authorized did not occur.

(2) For expanded access to an investigational drug for treatment use under §§ 312.315 and 312.320, in addition to the direct costs described in paragraph (d)(1)(i) of this section, a sponsor may recover the costs of monitoring the expanded access IND or protocol, complying with IND reporting requirements, and other administrative costs directly associated with the expanded access.

(3) To support its calculation for cost recovery, a sponsor must provide supporting documentation to show that the calculation is consistent with the requirements of paragraphs (d)(1) and, if applicable, (d)(2) of this section.

Dated: December 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–9685 Filed 12–11–06; 10:01 am]

BILLING CODE 4160–01–S

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4050 and 4281

RIN 1212–AB08

Mortality Assumptions

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Proposed rule.

SUMMARY: This proposed rule is a companion to PBGC's direct final rule (published today in the ''Rules and Regulations'' section of the **Federal Register**) making changes to the mortality assumptions under parts 4050 (Missing Participants) and 4281 (Duties of Plan Sponsor Following Mass Withdrawal) of its regulations. PBGC is making these changes as a direct final rule without prior proposal because we view them as non-controversial revisions and anticipate no significant adverse comment. We have explained our reasons in the preamble to the direct final rule. If we receive no significant adverse comment, no further action on this proposed rule will be taken. However, if we receive significant adverse comment, we will withdraw the direct final rule and it will not take effect. In that case, we will address all public comments in a subsequent final rule based on this proposed rule. We will not institute a second comment period on this rule. Any parties interested in commenting must do so at this time.

DATES: Comments must be received on or before January 16, 2007.

ADDRESSES: Comments, identified by RIN number 1212–AB08, may be submitted by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the Web site instructions for submitting comments.
- E-mail: *reg.comments@pbgc.gov.*
- Fax: 202–326–4224.
- Mail or Hand Delivery: Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026.

All submissions must include the Regulatory Information Number for this rulemaking (RIN number 1212–AB08). Comments received, including personal information provided, will be posted to *http://www.pbgc.gov.* Copies of comments may also be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corp., 1200 K Street, NW, Washington, DC 20005–4026 or calling

202–326–4040 during normal business hours. (TTY and TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.)

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, or James L. Beller, Jr., Attorney, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corp., 1200 K Street, NW., Suite 1200, Washington, DC 20005–4026; 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: In the ''Rules and Regulations'' section of today's **Federal Register**, PBGC is publishing a direct final rule making changes to the mortality assumptions under parts 4050 (Missing Participants) and 4281 (Duties of Plan Sponsor Following Mass Withdrawal) of its regulations. The provisions proposed here are those contained in the direct final rule. Please refer to the preamble and regulatory text of the direct final rule for further information and the actual text of the revisions. Additionally, all information regarding Statutory and Executive Orders for this proposed rule can be found in the Supplementary Information section of the direct final rule.

Issued in Washington, DC, this 8th day of December, 2006.

Vincent K. Snowbarger,

Interim Director, Pension Benefit Guaranty Corporation.

[FR Doc. E6–21279 Filed 12–13–06; 8:45 am]

BILLING CODE 7709–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0009; FRL–8256–2]

RIN 2060–AK22

National Air Emission Standards for Hazardous Air Pollutants, Halogenated Solvent Cleaning: Notice of Data Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability.

SUMMARY: EPA is issuing this Notice of Data Availability (NODA) in support of the proposed rule issued August 17, 2006, entitled ''National Emission Standards for Hazardous Air Pollutants—Halogenated Solvent Cleaning''. EPA received a number of comments on the proposed rule and is in the process of evaluating those comments. This NODA addresses certain new data and information that EPA received concerning the unique nature and size of the degreasing machines used by the following facilities: narrow tubing manufacturing facilities, facilities that manufacture specialized products requiring continuous web cleaning, aerospace manufacturing and maintenance facilities, large military vehicle maintenance operations, and facilities that use multiple degreasing machines. Specifically, the new data and information that form the basis of this NODA relates to the following three issues; the ability of the above-noted facilities meeting the proposed facility-wide emission limits; the cost impacts associated with the above-noted facilities implementing the proposed facility-wide emission limits; and, the time frame needed for the above-noted facilities to comply with the proposed facility-wide emission limits.

Although we recognize that the public has access to comments submitted during the comment period, we are nonetheless issuing this NODA because the new data and information at issue in this NODA are directly relevant to the alternative proposed standards described in the proposed rule. We are seeking comment only on the three issues identified above that relate to the unique nature and size of the degreasing machines used by the facilities specified above. We do not intend to respond to comments addressing any other aspect of the proposed rule.

DATES: Comments on the NODA must be received on or before January 29, 2007.

ADDRESSES: Comments on the NODA should be submitted to Docket ID No. EPA–HQ–OAR–2002–0009. Comments may be submitted by one of the following methods: Federal eRulemaking Portal: *http://http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

Agency Web site: *http://www.epa.gov/edocket*. EDOCKET, EPA's electronic public docket and comment system is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

E-mail: *A-and-R-Docket@epa.gov*.

Mail: Air Docket, National Emission Standards for Hazardous Air Pollutants—Halogenated Solvent Cleaning, Environmental Protection Agency, Mail Code: 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies.

Hand Delivery: EPA Docket Center, 1301 Constitution Avenue, NW., Room B108, Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Note: The EPA Docket Center suffered damage due to the flooding during the last week of June 2006. The Docket Center is continuing to operate. During the cleanup, however, there will be temporary changes to Docket Center telephone numbers, addresses, and hours of operation for people who wish to make hand deliveries or visit the Public Reading Room to view documents. Consult the EPA Web site at *http://www.epa.gov/eaphome/dockets.htm* for current information on docket operations, locations and telephone numbers. The Docket Center's mailing address for U.S. mail and the procedure for submitting comments to *www.regulations.gov* are not affected by the flooding and will remain the same.

Instructions: Direct your comments on the NODA to Docket ID No. EPA–HQ–OAR–2002–0009. The EPA's policy is that all comments received will be included in the public docket(s) without change and may be made available online at *http://www.epa.gov/edocket*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the Federal regulations.gov Web sites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your E-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is