reported, or information corrected on these forms after your verification;

(ii) For each event code provided by the user facility under § 803.32(e)(10) or the importer under § 803.42(e)(10), you must include a statement of whether the type of the event represented by the code is addressed in the device labeling; and

(iii) If your report omits any required information, you must explain why this information was not provided and the steps taken to obtain this information.

§ 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?

You must submit a 5-day report to us with the information required by § 803.52 in accordance with the requirements of § 803.12(a) no later than 5 work days after the day that you become aware that:

(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis or

(b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?

If you are a manufacturer, when you obtain information required under this part that you did not provide because it was not known or was not available when you submitted the initial report, you must submit the supplemental information to us within 30 calendar days of the day that you receive this information. You must submit the supplemental or followup report in accordance with the requirements of § 803.12(a). On a supplemental or followup report, you must:

(a) Indicate that the report being submitted is a supplemental or followup report;

(b) Submit the appropriate identification numbers of the report that you are updating with the supplemental information (e.g., your original manufacturer report number and the user facility or importer report number of any report on which your report was based), if applicable; and

(c) Include only the new, changed, or corrected information.

§ 803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and § 807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of § 803.50;

(3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(4) Maintain complaint files in accordance with § 803.18; and

(5) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

§ 803.58 [Amended]

3. Section 803.58 is stayed indefinitely.

Dated: February 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03279 Filed 2–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

[Docket No. OSHA 2012–0029]

RIN 1218–AC89

Hawaii State Plan for Occupational Safety and Health; Operational Status Agreement Revisions

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: This document announces revisions to the Operational Status Agreement between the Occupational Safety and Health Administration (OSHA) and the Hawaii State Plan, which specifies the respective areas of federal and state authority, and under which Hawaii will reassume additional coverage.

DATES: Effective February 14, 2014.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Francis Meilinger, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email: *meilinger.francis2@dol.gov.*

For general and technical information: Douglas J. Kalinowski, Director, OSHA Directorate of Cooperative and State Programs, Room N–3700, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210; telephone: (202) 693–2200; email: *kalinowski.doug@dol.gov.*

SUPPLEMENTARY INFORMATION:

Background

Hawaii administers an OSHA-approved state plan to develop and enforce occupational safety and health standards for public and private sector employers, pursuant to the provisions of Section 18 of the Occupational Safety and Health Act (the Act). Pursuant to Section 18(e) of the Act, OSHA granted Hawaii ''final approval'' effective April 30, 1984 (49 FR 19182). A final approval determination results in the relinquishment of federal concurrent enforcement authority in the state with respect to occupational safety and health issues covered by the plan. 29 U.S.C. 667(e).

From 2009–2012, the Hawaii State Plan faced major budgetary and staffing restraints that significantly affected its program. Therefore, the Hawaii Director of Labor and Industrial Relations requested a temporary modification of the state plan's approval status from final approval to initial approval, to permit exercise of supplemental federal enforcement activity and to allow Hawaii sufficient time and assistance to strengthen its state plan. On June 22, 2012, a Notice of Proposed Rulemaking was published and on September 21, 2012, OSHA published a Final Rule in the **Federal Register** (77 FR 58488) that modified the Hawaii State Plan's ''final approval'' determination under Section 18(e) of the Act, transitioned the Plan to ''initial approval'' status under Section 18(b) of the Act, and reinstated concurrent federal enforcement authority over occupational safety and health issues in the private sector. That

Federal Register notice also provided notice of the Operational Status Agreement (OSA) between OSHA and the Hawaii Occupational Safety and Health Division (HIOSH), which specified the respective areas of federal and state authority.

After the first year of the planned three-year developmental period, Hawaii's Department of Labor and Industrial Relations has taken the initial steps in rebuilding the capacity of HIOSH. Hawaii is committed to redeveloping its State Plan, and has increased its staff recruitment to reach its staffing benchmark, and has increased its inspection activity by 148% over the prior fiscal year. HIOSH and OSHA have worked together to strengthen the State Plan. A meeting between federal and state representatives on September 11–13, 2013 discussed the successes and challenges of the first year under the OSA and worked to clarify the next steps needed to be taken as the state agency further develops. OSHA and HIOSH agreed to amend the OSA to return greater responsibility to HIOSH for Fiscal Year 2014. Accordingly, this final rule amends OSHA regulations to reflect this change in the OSA between the parties by removing the reference to the specific 2012 OSA.

Notice of Revisions to the Operational Status Agreement

Federal OSHA and HIOSH will exercise their respective enforcement authority according to the terms of the 2012 OSA between OSHA and HIOSH, which specifies the respective areas of federal and state authority, with revisions agreed to in September 2013. Under the 2012 OSA, Federal OSHA retained coverage over all Federal employees and sites, private sector maritime activities, private sector employees within the secured borders of all military installations where access is controlled, and United States Postal Service including contract workers and contractor operated facilities, and assumed coverage over agriculture and most of general industry including facilities that include processes covered by the Process Safety Management standard (29 CFR 1910.119) as well as provisions of general industry and construction standards (29 CFR 1910 and 1926) appropriate to hazards found in that employment. Hawaii retained coverage over the construction industry, transportation and warehousing, and state and local government as an employer. All terms of the 2012 OSA remain in effect, except that Hawaii will resume responsibility over Manufacturing (NAICS 31 through 33) except Refineries (NAICS 324) and any other private sector facilities that include processes covered by the Process Safety Management standard (29 CFR 1910.119). Federal OSHA will also enforce provisions of the Act and of the general industry and construction standards appropriate to hazards found in facilities with processes that are covered by the Process Safety Management standard. Further, the revised OSA provides a mechanism for the most-available agency to respond to life-threatening situations on neighbor islands.

Regulatory Flexibility Analysis and Unfunded Mandates

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. (as amended), OSHA examined the regulatory requirements of the final rule to determine whether it would have a significant economic impact on a substantial number of small entities. Since no employer of any size will have any new compliance obligations, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. OSHA also reviewed this final rule in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 et seq.) and Executive Order 12875 (56 FR 58093). Because this rule imposes no new compliance obligations, it requires no additional expenditures by either private employers or State, local, and tribal governments.

Federalism

Executive Order 13132, ''Federalism,'' (64 FR 43255, August 10, 1999) emphasizes consultation between Federal agencies and the States and establishes specific review procedures the Federal government must follow as it carries out policies which affect State or local governments. OSHA has consulted extensively with Hawaii about this modification of the Operational Status Agreement. Although OSHA has determined that the requirements and consultation procedures provided in Executive Order 13132 are not applicable to approval decisions under the Act, which have no effect outside the particular State, OSHA has reviewed this final rule, and believes it is consistent with the principles and criteria set forth in the Executive Order.

Administrative Procedures

This **Federal Register** document is designated a ''final rule.'' That designation is necessary because OSHA publishes a general description of every state plan in 29 CFR part 1952. Because they are set forth in the Code of Federal Regulation, these descriptions can be updated only by publishing a ''final rule'' document in the final rules section of the **Federal Register.** Such rules do not contain any new federal regulatory requirements, but merely provide public information about the state plan.

OSHA finds that good cause exists for making this rule effective immediately upon publication in the **Federal Register.** Today's action is solely a change in Federal OSHA's procedures. It does not impose any new compliance obligations on affected employers, since Hawaii's safety and health standards and regulations are virtually all identical to OSHA's regulations. There are a very few instances in which Hawaii has more stringent requirements; however these state standards remain in effect and OSHA will make referrals to the state when needed. Therefore, employers' compliance obligations are not legally affected by the amendment to the OSA announced in this notice. For these reasons, public notice and comment are unnecessary, and good cause exists for making this final rule effective upon publication in the **Federal Register.** Accordingly, OSHA finds that public participation is unnecessary, and this rule is effective upon publication in the **Federal Register.**

List of Subjects in 29 CFR Part 1952

Intergovernmental relations, Law enforcement, Occupational safety and health.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC, authorized the preparation of this notice. OSHA is issuing this notice under the authority specified by Section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667), Secretary of Labor's Order No. 1–2012 (77 FR 3912), and 29 CFR part 1902.

Signed in Washington, DC, on February 10, 2014.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Accordingly, for the reasons set forth in the Preamble, 29 CFR Part 1952 is amended as set forth below.

PART 1952—[AMENDED]

■ 1. The authority citation for part 1952 continues to read as follows:

Authority: Sec. 18, 84 Stat. 1608 (29 U.S.C. 667); 29 CFR part 1902; Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Subpart Y—Hawaii

■ 2. Amend § 1952.314 by revising paragraph (b) to read as follows:

§ 1952.314 Level of Federal enforcement.

* * * * *

(b) To provide a workable division of enforcement responsibilities, Hawaii and Federal OSHA have entered into an operational status agreement. Electronic copies of the agreement are available at: *http://www.osha.gov/dcsp/osp/stateprogs/hawaii.html.*

[FR Doc. 2014–03286 Filed 2–13–14; 8:45 am]

BILLING CODE 4510–26–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in March 2014. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective March 1, 2014.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, 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: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR Part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for March 2014.[1]

The March 2014 interest assumptions under the benefit payments regulation will be 1.50 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. In comparison with the interest assumptions in effect for February 2014, these interest assumptions represent a decrease of 0.25 percent in the immediate annuity rate and are otherwise unchanged.

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 current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during March 2014, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

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 4022

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

In consideration of the foregoing, 29 CFR part 4022 is 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 245, as set forth below, is added to the table.

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
*	*		*	*	*	*	*	
245	3–1–14	4–1–14	1.50	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 245, as set forth below, is added to the table.

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

* * * * *

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR Part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.