

**PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS**

■ 5. The authority citation for part 812 continues to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360bbb–8b, 371, 372, 374, 379e, 379k–1, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 6. In § 812.38, revise paragraph (b)(4) to read as follows:

**§ 812.38 Confidentiality of data and information.**

\* \* \* \* \*

(b) \* \* \*

(4) Notwithstanding paragraph (b)(2) of this section, FDA will make available to the public, upon request, the information in the IDE that was required to be filed in Docket Number FDA–1995–S–0036 in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, for investigations involving an exception from informed consent under § 50.24 of this chapter. Persons wishing to request this information shall submit a request under the Freedom of Information Act.

\* \* \* \* \*

■ 7. In § 812.47, revise paragraph (a) to read as follows:

**§ 812.47 Emergency research under § 50.24 of this chapter.**

(a) The sponsor shall monitor the progress of all investigations involving an exception from informed consent under § 50.24 of this chapter. When the sponsor receives from the IRB information concerning the public disclosures under § 50.24(a)(7)(ii) and (iii) of this chapter, the sponsor shall promptly submit to the IDE file and to Docket Number FDA–1995–S–0036 in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, copies of the information that was disclosed, identified by the IDE number.

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**PART 822—POSTMARKET SURVEILLANCE**

■ 8. The authority citation for part 822 continues to read as follows:

**Authority:** 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

■ 9. In § 822.1, revise the introductory text and paragraphs (b) and (c) and add paragraph (d) to read as follows:

**§ 822.1 What does this part cover?**

This part implements section 522 of the Federal Food, Drug, and Cosmetic

Act by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:

\* \* \* \* \*

(b) The device is intended to be implanted in the human body for more than 1 year;

(c) The device is intended to be used outside a user facility to support or sustain life. If you fail to comply with requirements that we order under section 522 of the Federal Food, Drug, and Cosmetic Act and this part, your device is considered misbranded under section 502(t)(3) of the Federal Food, Drug, and Cosmetic Act and you are in violation of section 301(q)(1)(C) of the Federal Food, Drug, and Cosmetic Act; or

(d) The device is expected to have significant use in pediatric populations.

■ 10. In § 822.4, revise the introductory text and paragraphs (b) and (c) and add paragraph (d) to read as follows:

**§ 822.4 Does this part apply to me?**

If we have ordered you to conduct postmarket surveillance of a medical device under section 522 of the Federal Food, Drug, and Cosmetic Act, this part applies to you. We have the authority to order postmarket surveillance of any class II or class III medical device, including a device reviewed under the licensing provisions of section 351 of the Public Health Service Act, that meets any of the following criteria:

\* \* \* \* \*

(b) The device is intended to be implanted in the human body for more than 1 year;

(c) The device is intended to be used to support or sustain life and to be used outside a user facility; or

(d) The device is expected to have significant use in pediatric populations.

■ 11. In § 822.7, revise paragraph (a)(1) to read as follows:

**§ 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?**

(a) \* \* \*

(1) Requesting a meeting with the Director of the Office that issued the order for postmarket surveillance;

\* \* \* \* \*

■ 12. Revise § 822.24 to read as follows:

**§ 822.24 What are my responsibilities once I am notified that I am required to conduct postmarket surveillance?**

You must submit your plan to conduct postmarket surveillance to us within 30 days from receipt of the order (letter) notifying you that you are

required to conduct postmarket surveillance of a device. The manufacturer shall commence surveillance not later than 15 months after the day the order was issued.

Dated: March 15, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF LABOR**

**Occupational Safety and Health Administration**

**29 CFR Part 1952**

**Maine State Plan for State and Local Government Employees; Approval of Plan Supplements and Certification of Completion of Developmental Steps**

**AGENCY:** Occupational Safety and Health Administration (OSHA), Labor.

**ACTION:** Notification of certification of the State Plan.

**SUMMARY:** The Maine Department of Labor, Bureau of Labor Standards submitted documentation attesting to the completion of all structural and developmental aspects of its State Plan for State and Local Government Employees as approved by OSHA. After extensive review of the submissions and opportunity for correction, the Maine State Plan (MEOSH) submitted updated and revised documents. OSHA is approving the revised State Plan, which documents the satisfactory completion of all structural and developmental aspects of Maine’s approved State Plan, and is certifying this completion. This certification attests to the fact that the Maine State Plan now has in place those structural components necessary for an effective State Plan for State and Local Government Employees. (Enforcement of occupational safety and health standards with regard to private sector employers and employees in the State of Maine remains the responsibility of the U.S. Department of Labor, OSHA.)

**DATES:** Effective March 21, 2023.

**FOR FURTHER INFORMATION CONTACT:**

*For press inquiries:* Contact Frank Meilinger, OSHA Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email [meilinger.francis2@dol.gov](mailto:meilinger.francis2@dol.gov).

*For general and technical information:* Contact Douglas J. Kalinowski, Director, OSHA Directorate of Cooperative and State Programs, U.S. Department of Labor; telephone (202) 693–2200; email: [kalinowski.doug@dol.gov](mailto:kalinowski.doug@dol.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

Section 18 of the Occupational Safety and Health Act of 1970 (the “OSH Act”), 29 U.S.C. 667, provides that a state which desires to assume responsibility for the development and enforcement of occupational safety and health standards may submit for OSHA review and approval a State Plan for such development and enforcement. Regulations at 29 CFR part 1956 provide that a state may voluntarily submit a State Plan for the development and enforcement of occupational safety and health standards applicable only to employers and employees of the state and its political subdivisions. State and local government employers are excluded from Federal OSHA coverage under section 3(5) of the OSH Act.

Under these regulations, the Assistant Secretary of Labor for Occupational Safety and Health (“Assistant Secretary”) may approve a State Plan for State and Local Government Employees if the Plan provides for the development and enforcement of standards relating to hazards in employment covered by the Plan which are or will be at least as effective in providing safe and healthful employment and places of employment for public employees as standards promulgated and enforced by Federal OSHA under section 6 of the OSH Act, giving due consideration to differences between public and private sector employment. See 29 CFR 1956.2(a). Following initial approval, the state may begin enforcement of its safety and health standards in the public sector and receive up to 50 percent federal funding for the cost of Plan operations.

A State Plan for State and Local Government Employees may receive initial approval even though, at the time of submission, not all essential components of the Plan are in place. Pursuant to 29 CFR 1956.2(b), the Assistant Secretary may initially approve the submission as a “developmental plan,” and a schedule within which the state must complete all “developmental steps” within a three-year period is issued as part of the initial approval decision. 29 CFR part 1953 provides procedures for the review and approval of changes and progress in the development and implementation of the State Plan.

When the Assistant Secretary has reviewed and approved all developmental submissions and finds that the state has satisfactorily completed all developmental steps specified in the initial approval decision, a notice certifying such completion is published in the **Federal**

**Register** (see 29 CFR 1956.23 and 1902.34). Certification attests to the structural completeness of the Plan but does not render judgment as to the adequacy or effectiveness of state performance.

**II. State Plan History**

The Bureau of Labor and Industry, now known as the Bureau of Labor Standards (Bureau), was established in 1873 as an activity of the Secretary of State. In 1971, Title 26 of the Maine Revised Statutes (M.R.S.; or alternatively referred to as M.R.S.A., in reference to the Maine Revised Statutes Annotated) was enacted, defining the power and duties of the Director of the Bureau under Chapter 3, Section 42. Chapter 6, Section 565 defines the powers and duties of the Board of Occupational Safety and Health (Board or BOSH), which approves the adoption of standards, and is an independent review authority for the review of contested cases. Since 1971, the Maine Department of Labor, Bureau of Labor Standards, Workplace Safety and Health Division (Division), has proposed standards for the Board’s approval and performed inspections in state and local government workplaces (which includes state, county, and municipal employers) as outlined under the provisions of the state’s existing enabling legislation.

In 2012, Maine began working on a State and Local Government State Plan and submitted a draft Plan to OSHA in February 2013. OSHA determined that the Maine statutes, as structured, and the proposed State Plan needed minor changes in order to meet the State and Local Government State Plan approval criteria in 29 CFR 1956. Amendments to M.R.S., Title 26 were proposed and enacted by the Maine Legislature and signed into law by the Governor in 2014. The amended legislation provides the basis for establishing a comprehensive occupational safety and health program applicable to the state and local government employees in the state. With this amended legislation in place, in August 2015, OSHA approved Maine as a developmental State Plan for State and Local Government Employees only.

In October 2020, MEOSH submitted a revised State Plan narrative (*i.e.*, an overall description of the State Plan and all its aspects) to OSHA indicating that it had completed all 10 steps in its developmental program. Upon review, OSHA determined that the Maine State Plan needed to adopt OSHA’s recordkeeping and reporting rule (29 CFR part 1904) and amend its rulemaking procedures so that it could adopt OSHA’s emergency temporary

standards within 30 days of the **Federal Register Notice**, with an immediate effective date upon adoption. BOSH adopted 29 CFR part 1904 in November 2021, and the state legislature amended Title 26, Chapter 6, Section 565 to remove the requirement that “rules shall not become effective sooner than 90 days after the date of adoption and promulgation” in December 2021. This amendment enables MEOSH to adopt OSHA’s emergency temporary standards within 30 days from the **Federal Register Notice**, to take effect immediately upon publication. BOSH also adopted Maine’s statutory requirements for state and local government dive team operations (26 M.R.S.A. § 565), public sector firefighting operations (26 M.R.S.A. §§ 2101–2107), and driver training requirements for fire apparatuses (26 M.R.S.A. § 2107), and provided OSHA with the required comparison of the diving standard to the Federal standard.

**III. Description of the Revised State Plan**

The revised State Plan updates and documents all structural components of the Maine program. Each of the key component parts of the revised State Plan are described below. The documents described below are being approved in this notice.

**A. The Plan Narrative and Appendices**

The Maine Department of Labor is designated by Title 26 of M.R.S. as the sole agency responsible for administering and enforcing the state and local government employee protection program in Maine. The Maine Department of Labor, Bureau of Labor Standards is designated as the agency responsible for the State and Local Government Only State Plan.

The Plan narrative provides a general overview of MEOSH’s legal authority, standards and variances, regulations, enforcement policies and procedures (the MEOSH Field Operations Manual (FOM)), voluntary compliance activities (including consultative services and training and outreach programs), occupational safety and health laboratory support services, personnel policies and procedures, recordkeeping and reporting requirements, budget, staffing, and funding, all of which, together with the supporting documents contained in various appendices, have been determined to provide authority which is “at least as effective as” that of the OSH Act and to meet the criteria and indices for plan approval contained in 29 CFR part 1956.

The State Plan appendices submitted to OSHA contain a variety of state

statutes and other documents related to the Maine State Plan. These include letters from the Maine Governor and Attorney General, the MEOSH FOM, inspection scheduling system, personnel policies, the MEOSH organizational chart, budget, and state job descriptions for all positions in the State Plan.

The appendices also contain the following state statutes and regulations: The Maine Administrative Procedure Act (Title 5, Chapter 375); regulations that incorporate 29 CFR parts 1903, 1904, 1905, 1908, 1910, 1926, and 1977; and regulations pertaining to minimum driver training requirements for fire apparatuses, occupational safety and health standards for public safety diving, and occupational safety and health requirements for firefighting in the public sector.

### *B. Legislation*

The legislative authority establishing the Maine State Plan, and the respective occupational safety and health obligations of employers and employees, is found in Title 26, Chapters 1, 3, and 6 of the M.R.S.A. These provisions define the powers and duties of MEOSH, including authority to adopt occupational safety and health rules, right of entry, inspections, citations, proposed penalties, employee rights, variances, non-discrimination, recordkeeping and reporting, etc. The provisions further establish the duty of public employers to provide employment and a place of employment free from recognized hazards, to comply with the Maine Department of Labor's occupational safety and health rules, to report injuries and deaths, to inform employees of their protections and obligations, and to provide information on hazards in the workplace. Chapter 6 additionally establishes the duty for public employees to comply with all occupational safety and health rules applicable to their own actions and conduct.

MEOSH covers all state and local government employees of the state, which is defined by Title 26, Chapter 6, Section 563 to include employees of the state, a state agency, county, municipal corporation, school district, or other public corporation or political subdivision. Volunteers under the direction of a public employer or other public corporation or political subdivision are also covered. No employees of any political subdivision are excluded from the Plan. However, the definition of public employee does not extend to students, incarcerated individuals, or individuals committed in public institutions.

### *C. Standards*

Under the Plan's enabling legislation, Title 26 of the M.R.S.A., the Maine Department of Labor has full authority to adopt standards and regulations through BOSH and enforce and administer all laws and rules protecting the safety and health of employees of the state and its political subdivisions. Title 26, Chapter 6, Section 565 provides that all rules adopted by BOSH must at a minimum conform to Federal standards of occupational safety and health so that the State Plan can continue as a Federally approved State and Local Government State Plan. The procedures for state adoption of Federal occupational safety and health standards include giving public notice, opportunity for public comment, and opportunity for a public hearing, in accordance with the Maine Administrative Procedure Act (M.R.S.A. Title 5, Chapter 375). MEOSH has adopted state standards identical to federal occupational safety and health standards as promulgated through August 31, 2022. The State Plan also provides that future OSHA standards and revisions will be adopted by the state within six months of Federal promulgation in accordance with the requirements at 29 CFR 1953.5. The Plan also provides for the adoption of Federal emergency temporary standards within 30 days of Federal promulgation, that can be made effective in the state immediately upon publication.

Under the Plan, the Maine Department of Labor (through BOSH) has the authority to adopt alternative or different occupational health and safety standards where no Federal standards are applicable to the conditions or circumstances or where standards that are more stringent than the Federal standards are deemed advisable. Such standards will be adopted in accordance with M.R.S.A. Title 26 and the Maine Administrative Procedure Act, which includes provisions allowing submissions from interested persons and the opportunity for interested persons to participate in any hearing for the development, modification, or establishment of standards. MEOSH has generally adopted identical standards to the Federal standards but does have a unique respirator protection standard and video display terminal standard. In addition, in November 2021, the Maine State Plan (through BOSH) adopted Maine's statutory requirements for state and local government dive team operations (26 M.R.S.A. § 565), public sector firefighting operations (26 M.R.S.A. §§ 2101–2107), and driver

training requirements for fire apparatuses (26 M.R.S.A. § 2107).

### *D. Variances*

Title 26, Chapter 6, Section 571 of the M.R.S.A. includes provisions for the granting of permanent and temporary variances from state standards to public employers in terms substantially similar to the variance provisions contained in the Federal OSH Act. The state provisions require employee notification of variance applications, as well as employee rights to participate in hearings held on variance applications. A variance may not be granted unless it is established that adequate protection is afforded employees under the terms of the variance.

On June 1, 2018, MEOSH (through BOSH) adopted, where applicable to public employees, the regulations at 29 CFR part 1905, establishing the policies and procedures for variances.

### *E. Employee Discrimination Protection*

Title 26, Chapter 6, Section 570 of the M.R.S.A. provides that a person cannot discharge or in any manner discriminate against an employee because that employee has filed a complaint alleging an occupational safety or health hazard, has testified or is about to testify in any proceeding relating to employee safety and health, or has exercised any right under chapter 6 of Title 26.

Section 570 further provides that an employee who believes that they have been discharged or otherwise discriminated against in violation of this section may, within 30 days after the alleged violation occurs, file a complaint with the Director of the Bureau, alleging discrimination. If, upon investigation, the Director determines that the provisions of this chapter have been violated, the Director shall bring an action in Superior Court for all appropriate relief, including rehiring or reinstatement of the employee to their former position with back pay. Within 90 days of the receipt of a complaint filed under this section, the Director shall notify the complainant of the Director's determination.

On June 1, 2018, MEOSH (through BOSH) adopted, where applicable to public employees, the regulations at 29 CFR part 1977, establishing the policies and procedures for addressing discrimination against employees.

### *F. Inspections and Enforcement*

Title 26, Chapter 3, Sections 44 and 50 of the M.R.S.A provide for inspections of covered workplaces, including inspections in response to employee complaints, by the Director of the Bureau. If a determination is made

that an employee complaint does not warrant an inspection, the complainant will be notified in writing of such determination. The complainant will be notified of the results of any inspection in writing and provided a copy of any citation that is issued. Employee complainants may request that their names not be revealed.

Title 26, Chapter 3, Section 44a of the M.R.S.A. provides the opportunity for employer and employee representatives to accompany a Bureau of Labor Standards inspector for the purpose of aiding the inspection. Where there is no authorized employee representative, the inspectors are required to consult with a reasonable number of employees concerning matters of safety and health in the workplace.

Through Title 26, Chapter 3, Sections 44 and 45 of the M.R.S.A., the Plan provides for notification to employees of their protections and obligations under the Plan by such means as a state poster, required posting of notices of a violation, etc.

Section 44 also authorizes the Director of the Bureau to issue rules requiring employers to maintain accurate records relating to occupational safety and health. Information on employee exposure to regulated agents, access to medical and exposure records, and provision and use of suitable protective equipment is provided through state standards.

Title 26, Chapter 3, Section 49 of the M.R.S.A. provides that the Director may petition the Superior Court to restrain any conditions or practices in any workplace subject to Section 45 in which such a danger exists which will reasonably be expected to cause death or serious physical harm immediately or before the danger could be eliminated through the enforcement process.

Title 26, Chapter 6, Section 566 of the M.R.S.A. authorizes the Director of the Bureau or their representatives to perform any necessary inspections or investigations. The Bureau designates the Division of Workplace Safety and Health to carry out these provisions. Title 26, Chapter 3, Section 44 provides that the Director of the Bureau has the right to inspect and investigate during regular working hours. The inspectors are provided the right of entry without delay and at reasonable times. If the public employer refuses entry or hinders the inspection process in any way, the inspector has the right to terminate the inspection and initiate the compulsory legal process and/or obtain a warrant for entry. The inspector has the right to interview all parties and review records as they relate directly to the inspection.

Title 26, Chapter 3, Section 46 prohibits advance notice of inspections. Advance notice of any inspection, without permission of the Bureau Director, is subject to a penalty of not less than \$500 or more than \$1,000 or by imprisonment for not more than 6 months, or both. Criminal penalties may also be imposed under the Maine criminal code on any person who knowingly makes a false statement under oath or affirmation; who knowingly makes a written false statement on a form bearing notification by statute or regulation to the effect that false statements made therein are punishable; or who knowingly makes a written false statement with the intent to deceive a public servant in the performance of their official duties. Thus, any employer who makes any false statement in any application, record, report, plan, or other document filed or required to be maintained by the State Plan may be in violation of the Maine criminal code and punished thereunder.

Title 26, Chapter 3, Section 45 establishes the authority and general procedures for the Director of the Bureau to promptly notify public employers and employees of violations, abatement requirements, and to compel compliance. If a Bureau inspector finds that a violation of a safety and health standard exists, they will issue a written citation to the employer with reasonable promptness. Section 45 provides that when an inspection of an establishment has been made, and the Director of the Bureau has issued a citation, the employer shall post such citation or a copy thereof at or near the location where the violation occurred. Each citation shall be in writing; describe with particularity the nature of the violation and include a reference to the provision of the statute, standard, rule, regulation, or order alleged to have been violated; and fix a reasonable time for the abatement of the violation.

Title 26, Chapter 3, Section 46 contains authority for a system of monetary penalties. Monetary penalties are required to be issued for serious citations and for violations of the posting requirements, up to \$1,000 for each such violation. The Director of the Bureau has discretionary authority for civil penalties of up to \$1,000 per day the violation continues for repeat and willful violations. Other-than-serious violations may be assessed a penalty of up to \$1,000 per violation, and failure-to-correct violations may be assessed a penalty of up to \$1,000 per day. In addition, criminal penalties can be issued to public employers who willfully violate any standard, rule, or

order. An alternative enforcement mechanism that includes administrative orders may be used in limited circumstances.

#### *G. Compliance Manual*

MEOSH has adopted Federal OSHA's revised FOM, CPL 02-00-164, with some exceptions, which provides guidance to MEOSH compliance staff concerning general staff responsibilities, pre-inspection procedures (including inspection scheduling and priorities, complaints and other unprogrammed inspections, and inspection preparation), inspection procedures (including conduct of the inspection, opening conference, closing conference, physical examination of the workplace, follow-up inspections, fatality/catastrophe investigations, imminent danger investigations, and construction inspections), inspection documentation (including types of violations, violations of the general duty clause, writing citations, and grouping/combining violations), and post-inspection procedures (including abatement, citations, penalties, and post-citation processes). MEOSH has adopted different FOM provisions for Chapter 6, penalty amounts, and for the provisions in Chapter 7 related to informal conference procedures. And MEOSH does not follow Federal OSHA's revised FOM Chapters 1, 8, 9, 10, and 13-17, or specific subsections of Chapters 2, 3, 4, and 5, which are inapplicable to MEOSH's program. MEOSH also uses the OSHA Technical Manual (TED 01-00-015), which replaced the former Industrial Hygiene Manual, as guidance for its staff. The Maine Department of Labor, Workplace Safety and Health Division has adopted the OSHA Whistleblower Investigations Manual (WIM) (CPL 02-03-011 04/29/2022), except for the sections on appeals and settlement agreements. MEOSH has an internal policy for appeals and settlement agreements, which is contained in Appendix D of the State Plan documents submitted to OSHA.

#### *H. Review Procedures*

Title 26, Chapter 6, Section 568 of the M.R.S.A. and Code of Maine Rules (CMR) 12-179, Chapter 1 establish the authority and general procedures for employer contests of violations alleged by the state, penalties and sanctions, and abatement requirements. State and local government employers or their representatives who receive a citation, a proposed assessment of penalty, or a notification of failure to correct a violation may, within 15 working days from receipt of the notice, request in writing a hearing before BOSH on the

citation, notice of penalty, or abatement period. Any public employee or representative thereof may, within 15 working days of the issuance of a citation, file a request in writing for a hearing before BOSH on whether the period of time fixed in the citation for abatement is unreasonable.

All interested parties are allowed to participate in the hearing and introduce evidence. BOSH shall affirm, modify, or vacate the citation or proposed penalty or direct other appropriate relief. Any party adversely affected by a final order or determination by the BOSH has the right to appeal and obtain judicial review by the Superior Court.

The Director of the Bureau will remain responsible for the enforcement process, including the issuance of citations and penalties, and their defense, if contested. Informal reviews can be held at the division management level prior to a formal contest.

#### *I. Budget and Personnel*

The Plan includes the FY 2023 grant application under section 23(g) of the OSH Act, which includes a current organizational chart and detailed information on staffing and funding. The state has given satisfactory assurances of adequate funding to support the Plan. In FY 2023, the State Plan was funded at \$538,100 in Federal section 23(g) funds, \$538,100 in matching state funds, and \$102,315 in 100% state funds, for a total Federal and state contribution of \$1,178,515. The state has given satisfactory assurance that it will meet the staffing requirements of 29 CFR 1956.10. OSHA considers MEOSH's current staffing and funding levels to be adequate and appropriate.

#### *J. Records and Reports*

The Plan provides that state and local government employers in Maine will maintain appropriate records and make timely reports on occupational injuries and illnesses in a manner substantially identical to and "at least as effective as" that required for private sector employers under Federal OSHA. MEOSH has assured that it will continue its participation in the Bureau of Labor Statistics Annual Survey of Injuries and Illnesses in the public sector. The Plan also contains assurances that it will provide reports to OSHA in such form as the Assistant Secretary may require and that MEOSH will continue to use the OSHA Information System (OIS).

MEOSH's agency work rule on Recording Occupational Injuries and Illnesses in the Public Sector (ME CMR 12-179, Chapter 6) has incorporated by

reference OSHA's recordkeeping and reporting regulations in 29 CFR part 1904. Title 26, Chapter 1, Section 2 and Chapter 3 of the M.R.S.A. impose parallel requirements on state and local government employers to maintain accurate records of and to make reports on work-related deaths, injuries, and illnesses. Such records are available to any state agency requiring them and are held confidential. Where there is overlap between the Maine statute provisions and the Chapter 6 agency work rule, employers must comply with whichever requirement is more protective.

#### *K. Voluntary Compliance Programs*

MEOSH has adopted, where applicable, 29 CFR part 1908, establishing requirements for a state and local government consultation program. The MEOSH consultation program generally follows OSHA's Consultation Policies and Procedures Manual, CSP 02-00-004.

The Bureau conducts educational programs for state and local government employees specifically designed to meet the regulatory requirements and needs of the state or local government employer. Consultations, including site visits, compliance assistance, and training classes, are individualized for each worksite and tailored to the employer's concerns. Training topics include, but are not limited to, bloodborne pathogens, hazard communication, confined space entry, trenching/shoring, recordkeeping, slips/trips/falls, laboratory safety, lockout/tagout, and electrical safety. The Bureau has also developed a program known as the Safety and Health Award for Public Employers (SHAPE) to recognize state and local government employers with an excellent safety and health program. This program is like OSHA's Safety and Health Achievement Recognition Program (SHARP).

#### **IV. Completion of Developmental Steps**

With the approval of the revised State Plan in today's action, all developmental steps specified in the August 5, 2015, notice of initial approval of the Maine State Plan for State and Local Government Employees (80 FR 46487) and other relevant steps, have been successfully completed and approved as follows:

In accordance with developmental step (1), MEOSH provided a comparison of ME CMR 12-179, Chapter 6 to 29 CFR part 1904. At the direction of OSHA, MEOSH subsequently adopted revisions to ME CMR 12-179, Chapter 6 to incorporate 29 CFR part 1904 and ensure that the State Plan's

recordkeeping and reporting obligations are substantially identical to the Federal requirements. This developmental step was completed in November 2021. The revised state rule is approved by the Assistant Secretary in today's notice.

In accordance with developmental step (2), MEOSH adopted regulations equivalent to 29 CFR part 1905. This developmental step was completed in July 2019 and the changes are approved by the Assistant Secretary as of today's notice.

In accordance with developmental step (3), MEOSH adopted regulations equivalent to 29 CFR part 1977. This developmental step was completed in July 2019 and the changes are approved by the Assistant Secretary as of today's notice.

In accordance with developmental step (4), the State of Maine enacted legislation revising 26 M.R.S.A. §§ 2 and 44. This developmental step was completed in June 2015 and the changes are approved by the Assistant Secretary as of today's notice.

In accordance with developmental step (5), MEOSH provided a comparison of alternative standards that Maine has adopted to Federal standards. This step was completed in November 2021 and the state standards are approved by the Assistant Secretary as of today's notice.

In accordance with developmental step (6), MEOSH provided an outline of procedures for the on-site public sector consultation program by adopting 29 CFR part 1908. This step was completed in July 2019 and the state rule is approved by the Assistant Secretary as of today's notice.

In accordance with developmental step (7), MEOSH developed a 5-year strategic plan and an annual performance plan. This step was most recently updated as of October 1, 2020, when MEOSH implemented its most current 5-year strategic plan and as of August 1, 2022, when MEOSH submitted its most recent annual performance plan for FY 2023. These plans are approved by the Assistant Secretary as of today's notice.

In accordance with developmental step (8), MEOSH reviewed and revised its FOM. The MEOSH FOM generally follows federal OSHA's revised FOM, CPL 02-00-164, with the primary exceptions of Chapters 6 and 7. The MEOSH FOM, in conjunction with the applicable Maine statutes, will ensure inspections are at least as effective as 29 CFR part 1903. The MEOSH FOM will be reviewed on an annual basis. This developmental step was completed in July 2020 and the MEOSH FOM is approved by the Assistant Secretary as of today's notice.

In accordance with developmental step (9), MEOSH transitioned to the OIS. This developmental step was completed in September 2015 and is approved by the Assistant Secretary as of today's notice.

In accordance with developmental step (10), MEOSH determined, in conjunction with Federal OSHA, that adoption of OSHA's maritime standards at 29 CFR parts 1915, 1917, and 1918 was not required based on the type of work performed in Maine's state and local government agencies. This determination is approved by the Assistant Secretary as of today's notice.

## V. Decision

### A. Approval of Plan Supplements

After careful review, opportunity for state correction, and subsequent revision, the plan supplements constituting a revised Maine State Plan for State and Local Government Employees and its components described above are found to be in substantial conformance with comparable Federal provisions and the requirements of 29 CFR part 1956 and are hereby approved under 29 CFR part 1953 as providing a revised State Plan for the development and enforcement of standards which is "at least as effective as" the Federal program, as required by section 18 of the OSH Act and 29 CFR part 1956. The right to reconsider this approval of the revised State Plan supplements is reserved should substantial objections or other information regarding any change to components of the Plan become available to the Assistant Secretary.

### B. Certification

With the approval of a revised State Plan as noted above, all developmental steps have now been successfully completed, documented, and approved. In accordance with 29 CFR 1956.23, the Maine State Plan for State and Local Government Employees is certified as having successfully completed all developmental steps. This certification attests to the structural completeness of the State Plan and that it has all the necessary authorities and procedures to provide "at least as effective" standards, enforcement, and compliance assistance to the employees of the State of Maine and its political subdivisions. This action renders no judgment as to the effectiveness of the State Plan in actual operations.

## VI. Location of Basic State Plan Documentation

Copies of the revised Maine State Plan for State and Local Government

Employees are available on the State Plan's website or upon request. Contact the Regional Administrator, U.S. Department of Labor, Occupational Safety and Health Administration, 25 New Sudbury Street, Room E-340, Boston, Massachusetts 02203.

Components of the Maine State Plan, including the MEOSH FOM, recordkeeping regulations and instructions, complaint forms, and other program information are posted on the MEOSH website at: [https://www.maine.gov/labor/workplace\\_safety/publicsector.shtml](https://www.maine.gov/labor/workplace_safety/publicsector.shtml).

MEOSH is administered by the Maine Department of Labor, Bureau of Labor Standards, Workplace Safety and Health Division. To obtain more information, visit <https://www.maine.gov/labor/bls/>, call (207) 623-7900, or email [mdol@maine.gov](mailto:mdol@maine.gov).

Information on MEOSH laws and regulations can be found at: [https://www.maine.gov/labor/workplace\\_safety/publicsector.shtml](https://www.maine.gov/labor/workplace_safety/publicsector.shtml).

The state Administrative Procedure Act can be found at: <https://legislature.maine.gov/statutes/5/title5ch375sec0.html>.

Electronic copies of this **Federal Register Notice** and the related press release are available on OSHA's website at: <http://www.osha.gov>.

More information on the Maine State Plan can be found on OSHA's Office of State Programs website at: <https://www.osha.gov/stateplans/me>.

### Authority and Signature

Douglas L. Parker, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20001 authorized the preparation of this document 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. 8-2020 (85 FR 58393 (Sept. 18, 2020)), and 29 CFR part 1956.

Signed in Washington, DC, March 15, 2023.

**Douglas L. Parker,**

*Assistant Secretary of Labor for Occupational Safety and Health.*

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**BILLING CODE 4510-26-P**

## DEPARTMENT OF THE TREASURY

### Office of the Secretary of the Treasury

#### 31 CFR Parts 16, 27, and 50

#### Inflation Adjustment of Civil Monetary Penalties

**AGENCY:** Departmental Offices Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Treasury ("Department" or "Treasury") publishes this final rule to adjust its civil monetary penalties ("CMPs") for inflation as mandated by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (collectively referred to herein as "the Act"). This rule adjusts CMPs within the jurisdiction of two components of Departmental Offices for 2022 and 2023. **DATES:** *This rule is effective* March 21, 2023.

**FOR FURTHER INFORMATION CONTACT:** For information regarding the Terrorism Risk Insurance Program's CMPs, contact Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, Room 1410 MT, Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, at (202) 622-2922 (not a toll-free number), or Sherry Rowlett, Program Policy Analyst, Federal Insurance Office, at (202) 622-1890 (not a toll free number). Persons who have difficulty hearing or speaking may access these numbers via TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

For information regarding the Treasury-wide CMPs, contact Richard Dodson, Senior Counsel, General Law, Ethics, and Regulation, 202-622-9949.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In order to improve the effectiveness of CMPs and to maintain their deterrent effect, the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note ("the Inflation Adjustment Act"), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114-74) ("the 2015 Act"), requires Federal agencies to adjust each CMP provided by law within the jurisdiction of the agency. The 2015 Act requires agencies to adjust the level of CMPs with an initial "catch-up" adjustment through an interim final rulemaking and to make subsequent annual adjustments for inflation, without needing to provide notice and