



Billing Code: 4163-18

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 85a

[Docket No. CDC-2014-0001; NIOSH-271]

RIN 0920-AA51

**Occupational Safety and Health Investigations of Places of
Employment; Technical Amendments**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Direct final rule.

SUMMARY: The Department of Health and Human Services (HHS) intends to amend its regulations pertaining to occupational safety and health investigations of places of employment conducted by the National Institute for Occupational Safety and Health (NIOSH) in the Centers for Disease Control and Prevention (CDC), to update outdated terminology and strike references to obsolete government offices or divisions. These changes will not

affect current practices.

DATES: This rule is effective [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] without further action, unless significant adverse comment is received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. If significant adverse comment is received, HHS will publish a withdrawal of the rule in the **Federal Register** within 30 days after the close of the comment period. If no significant adverse comment is received, HHS will publish a notice in the **Federal Register** confirming the effective date of the Direct Final Rule.

ADDRESSES: Written comments: You may submit comments by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>.
Follow the instructions for submitting comments.
- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MSC-34, 4676 Columbia Parkway, Cincinnati, OH 45226.

Instructions: All submissions received must include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC-2014-0001; NIOSH-271) or Regulation Identifier Number (0920-AA51) for this rulemaking. All relevant comments, including any personal information provided, will be posted without change to

<http://www.regulations.gov>. For detailed instructions on submitting public comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

DOCKET: For access to the docket go to

<http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Teresa Schnorr PhD, Director NIOSH Division of Surveillance, Hazard Evaluations and Field Studies (DSHEFS); 4676 Columbia Parkway, Cincinnati, OH 45226; 513-841-4428 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

This notice is organized as follows:

- I. Executive Summary
 - A. Purpose of Regulatory Action
 - B. Summary of Major Provisions
 - C. Costs and Benefits
- II. Public Participation
- III. Statutory Authority
- IV. Summary of Final Rule
- V. Regulatory Assessment Requirements

I. Executive Summary

A. Purpose of Regulatory Action

The purpose of this direct final rule (DFR) is to make minor technical changes to HHS regulations in 42 CFR part 85a,

pertaining to occupational safety and health investigations of places of employment. Amendments to the existing rule include striking references to obsolete government offices or agencies, updating the proper NIOSH office from which to request specific reports of investigations, and correcting outdated terms such as "motion pictures." Obsolete terms and outdated language in Part 85a were identified during the agency's retrospective analysis of existing regulations, in accordance with Executive Order 13563.

B. Summary of Major Provisions

Amendments are made to 42 CFR 85a.2 (alphabetize definitions and strike definitions of "NIOSH Regional Office," and "BOM (Bureau of Mines)" and remove reference to "Public Health Service" within the definition of "NIOSH"), 85a.4 (clarify that the union at the place of employment must be notified of the investigation, and strike reference to BOM), 85a.5 (replace "motion pictures or videotapes" with "video recordings" and "Humans Subjects Review Board" with "Institutional Review Board"), and 85a.8 (replace "NIOSH Regional Consultant for Occupational Safety and Health" with "NIOSH Education and Information Division."

C. Costs and Benefits

Because there are no substantive changes to 42 CFR part 85a, there are no changes made to current practices. Therefore, there are no costs or benefits associated with this rulemaking.

II. Public Participation

This DFR is being published because HHS finds that the updates to Part 85a add clarity to the regulation and are non-controversial; HHS does not expect to receive any significant adverse comments on this rulemaking. However, HHS is publishing a companion notice of proposed rulemaking in this issue of the **Federal Register**, in which the same amendments to Part 85a are proposed. If HHS does not receive any significant adverse comments on this DFR within the specified comment period, we will publish a notice in the **Federal Register** confirming the effective date of the final rule within 30 days after the close of the public comment period and withdraw the notice of proposed rulemaking. Interested parties may participate in this rulemaking by submitting written views, opinions, recommendations, and data. If significant adverse comments are received, HHS will publish a notice in the **Federal Register** to withdraw this DFR. A final rule will subsequently be published, which will include the Agency's response to comments.

Comments received, including attachments and other

supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you do not wish to be disclosed. You may submit comments on any topic related to this DFR.

III. Statutory Authority

Subsection 20(b) of the Occupational Safety and Health (OSH) Act of 1970 authorizes the Secretary of Health and Human Services to make inspections and question employers and employees as provided in section 8 of the OSH Act in order to carry out the Secretary's functions and responsibilities under section 20 [29 U.S.C. 669; 29 U.S.C. 657]. Section 8(g)(2) instructs the Secretary to prescribe such regulations as are deemed necessary to carry out the responsibilities of the agency to conduct inspections of an employer's establishment. Sections 103 and 501 of the Federal Mine Safety and Health (FMSH) Act of 1977 authorize the Secretary to make inspections and investigations at coal mines in order to conduct research as may be appropriate to improve working conditions [30 U.S.C. 813(a) and 951, respectively].

IV. Summary of Final Rule

The provisions in Part 85a govern procedures NIOSH follows in conducting safety and health investigations at places of employment. The amendments described below are all non-substantive and will have no practical effect on NIOSH procedures or practices, but are being made in accordance with Executive Order 13563, section 6, which requires that Federal agencies conduct retrospective analyses of existing rules. In conducting the analysis, NIOSH discovered that certain terms and references in part 85a were outdated.

Section 85a.1 Applicability.

Section 85a.1 states that the provisions in Part 85a pertain to investigations of places of employment conducted by NIOSH pursuant to the statutory authorities noted above. The section also affirms that the provisions in this part do not apply to activities covered by HHS regulations in 42 CFR part 85. HHS is making no changes to this section.

Section 85a.2 Definitions.

Section 85a.2 offers definitions for terms used in this part. HHS is making a number of changes to this section. First, the paragraph designations are removed and the terms are listed alphabetically. Next, the definitions of BOM (Bureau of Mines)

and NIOSH Regional Office are stricken from § 85a.2, because BOM is obsolete and because the addresses of the regional offices referenced here are no longer relevant to this rule. The phrase "Public Health Service" is stricken from the definition of "NIOSH," and the definition of "FMSH Act," is teased apart from the existing definition of "OSH Act" and is made a stand-alone definition. None of the changes to this section are substantive.

Section 85a.3 Authority for investigations of places of employment.

Section 85a.3 establishes procedures by which NIOSH authorized representatives may enter a place of employment for the purpose of conducting investigations under the OSH Act and the FMSH Act. This section also establishes that investigations will be conducted in a reasonable manner. HHS is making a minor change to this section to correct punctuation.

85a.4 Procedures for initiating investigations of places of employment.

Section 85a.4 states that the NIOSH authorized representative will contact an official representative of the place of employment prior to a site visit. The NIOSH official will also notify a representative of the appropriate State agency, the local union at the place of employment, the

appropriate OSHA Assistant Regional Director, and the appropriate MSHA District Office. HHS is making minor changes to § 85a.4(a)(2) to strike unnecessary language specifying which union official must be notified, thereby clarifying that the union must be notified; a change is also made to § 85a.4(a)(4) to remove reference to the obsolete Bureau of Mines. Section 85a.4(b) is edited to correspond with the change in paragraph (a)(2). One final change is made to §85a.4(c) to add the term "or organizations" to specify that the investigating NIOSH official will notify the individuals or organizations referenced above. HHS is making no further changes to this section.

Section 85a.5 Conduct of investigations of places of employment.

Section 85a.5 establishes the procedures NIOSH representatives will follow to conduct a workplace investigation. HHS is amending this section to replace the outdated terms "motion pictures or videotapes" with "video recordings" and "Human Subjects Review Board" with "Institutional Review Board," and correcting "contact agreement," which should properly be "contract agreement" in paragraph (b)(2). HHS is making no further changes to this section.

Section 85a.6 Provision of suitable space for employee

interviews and examinations.

Section 85a.6 requires that the employer, owner, operator, or agent in charge at the investigated place of employment must provide a suitable space for the NIOSH representative to conduct private interviews. HHS is making no changes to this section.

Section 85a.7 Imminent dangers.

Section 85a.7 authorizes the NIOSH representative to advise the employer, owner, operator, or agent in charge, any employees who appear to be in danger, and any of the individuals or agencies identified in § 85a.4 that an imminent danger exists. HHS is making no changes to this section.

Section 85a.8 Reporting of results of investigations of places of employment.

Section 85a.8 states that NIOSH will make specific reports of investigations available to the employer, owner, operator, or agent in charge, as well as to those individuals or agencies identified in § 85a.4. HHS is amending § 85a.8(a)(2) to strike reference to "NIOSH Regional Consultant for Occupational Safety and Health" and replace it with the name of the office that will make specific reports available, the "NIOSH Education and Information Division." HHS is making no further changes to this section.

V. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This direct final rule has been determined not to be a "significant regulatory action" under section 3(f) of E.O. 12866. The amendments in this notice alphabetize the definitions section, strike reference to the former Bureau of Mines and NIOSH Regional Office, update where specific reports of investigations may be obtained, and update language used to describe "motion pictures." Because this DFR is entirely administrative and does not affect the economic impact, cost, or policies of the activities authorized by part 85a, HHS has not prepared an economic analysis and the Office of Management and Budget (OMB) has not reviewed this rulemaking.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. Because no substantive changes are being made to 42 CFR part 85a as a result of this action, HHS certifies that this rule has “no significant economic impact upon a substantial number of small entities” within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

C. Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. Data collection and recordkeeping requirements for the health investigations of places of employment program receive OMB approval on an as-needed basis. The amendments in this rulemaking do not impact the collection of data.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), HHS

will report the promulgation of this rule to Congress prior to its effective date.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 et seq.) directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this direct final rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million by State, local or Tribal governments in the aggregate, or by the private sector. For 2013, the inflation adjusted threshold is \$150 million.

F. Executive Order 12988 (Civil Justice)

This direct final rule has been drafted and reviewed in accordance with Executive Order 12988, "Civil Justice Reform," and will not unduly burden the Federal court system. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

HHS has reviewed this direct final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does not "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."

H. Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this direct final rule on children. HHS has determined that the rule would have no environmental health and safety effect on children.

I. Executive Order 13211 (Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this direct final rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law 111-274 (October 13, 2010), executive

Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating the direct final rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 85a

Archives and records, Employee management relations, Hazardous substances, Health hazards, Health records, Industry, Investigations, Labor, Mine safety and health, Occupational injury, Occupational safety and health, Reporting and recordkeeping requirements, Research, Respiratory diseases, Right of entry, Toxic substances, Unions.

Final Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR part 85a as follows:

PART 85a—OCCUPATIONAL SAFETY AND HEALTH INVESTIGATIONS OF PLACES OF EMPLOYMENT

1. The authority citation for part 85a continues to read as

follows:

Authority: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g) and sec. 508, 83 Stat. 803; 30 U.S.C. 957.

2. Revise § 85a.2 to read as follows:

§ 85a.2 Definitions.

Any term defined in the Occupational Safety and Health Act of 1970 or the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the Acts. As used in this part:

Assistant Regional Director means any one of the ten Occupational Safety and Health Administration Assistant Regional Directors for Occupational Safety and Health.

Employee has the same meaning as stated in the OSH Act and for the purposes of this part includes miner as defined in the FMSH Act.

Employer has the same meaning as stated in the OSH Act and for the purposes of this part includes operator as defined in the FMSH Act.

FMSH Act means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.).

Informed consent means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of

constraint or coercion. The basic elements of information necessary to such consent include:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) A description of any attendant discomforts and risks reasonably to be expected;

(3) A description of any benefits reasonably to be expected;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) An offer to answer any inquiries concerning the procedures; and

(6) An instruction that the person is free to withdraw his consent and to discontinue participation in the investigation any time without prejudice to the subject.

Investigation means research projects, experiments, demonstrations, studies, and similar activities of NIOSH which are conducted under section 20 of the OSH Act and section 501 of the FMSH Act.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedure.

MSHA District Office means any one of the Mine Safety and

Health Administration's District Offices.

NIOSH means the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention, Department of Health and Human Services.

NIOSH authorized representative means a person authorized by NIOSH to conduct investigations of places of employment, including any person that is fulfilling a contract agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act.

OSH Act means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.).

Place of employment means any coal or other mine, factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by any employee of an employer.

3. Amend § 85a.4 by revising paragraphs (a) (2) and (4), (b), and (c) to read as follows:

§ 85a.4 Procedures for initiating investigations of places of employment.

(a) * * *

(2) The local union at the place of employment, if any;

* * * * *

(4) The appropriate MSHA District Office when investigations are conducted under the FMSH Act.

(b) Advance notice of site visits will not be given to the place of employment or local union at the place of employment when, in the judgment of the NIOSH authorized representatives, giving such notice would adversely affect the validity and effectiveness of an investigation. Those individuals and organizations specified in § 85a.4(a)(1), (a)(3), and (a)(4) will be notified prior to the initiation of such a site visit. After the site visit has been initiated, and, as soon as possible thereafter, the NIOSH authorized representatives will contact the organizations specified in § 85a.4(a)(2) concerning the nature and details of the site visit.

(c) In those instances where site visits are not necessary to the conduct of an investigation, the NIOSH authorized representatives will contact an official representative of the place of employment either verbally or through a written communication and provide the details of why an investigation of the place of employment is being conducted. If appropriate, the NIOSH authorized representatives will contact those individuals or organizations stipulated in paragraphs (a)(1) through (4) of this section about the nature and details of the investigation.

4. Amend §85a.5 by revising paragraphs (b)(2) and (d) to read as follows:

§ 85a.5 Conduct of investigations of places of employment.

* * * * *

(b) * * *

(2) In those instances where the NIOSH authorized representative is a person fulfilling a contract agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act, the employer, owner, operator or agent in charge at the place of employment may, after advising the NIOSH contractor or consultant in writing, elect to withhold information deemed to be a trade secret from such a NIOSH authorized representative or prohibit entry into the area of the place of employment where such entry will reveal trade secrets. In those instances, where the subject information is needed or access to the area of the place of employment is necessary, in the judgment of NIOSH, to fulfill the goals of the investigation, NIOSH regular employees will then obtain the information or enter the subject area of the place of employment.

* * * * *

(d) (1) NIOSH authorized representatives are authorized: To collect environmental samples and samples of substances; to measure environmental conditions and employee exposures (including measurement of employee exposure by the attachment of personal sampling devices to employees with their consent); to take or obtain photographs, video recordings related to the purpose of the investigation; to employ other reasonable investigative techniques, including medical examinations,

anthropometric measurements and standardized and experimental functional tests of employees with the informed consent of such employees; to review, abstract, and duplicate such personnel records as are pertinent to mortality, morbidity, injury, safety, and other similar studies; and to question and interview privately any employer, owner, operator, agency, or employee from the place of employment. The employer, owner, operator, or agency shall have the opportunity to review photographs, and video recordings taken or obtained for the purpose of identifying those which contain or might reveal a trade secret.

(2) Prior to the conduct of medical examinations, anthropometric measurements or functional tests of any employees, the NIOSH authorized representatives will obtain approval of the procedures to be utilized from the NIOSH Institutional Review Board and no employee examination, measurement or test will be undertaken without the informed consent of such employee.

* * * * *

5. Revise §85a.7 to read as follows:

§ 85a.7 Imminent dangers.

Whenever, during the course of, or as a result of, an investigation under this part, the NIOSH authorized representatives believe there is a reasonable basis for an allegation of an imminent danger, NIOSH will immediately advise

the employer, owner, operator or agent in charge at the place of employment and those employees who appear to be in immediate danger of such allegation and will inform the agencies identified in § 85a.4(a) through (4).

6. Amend §85a.8 by revising paragraph (a) (2) to read as follows:

§ 85a.8 Reporting of results of investigations of places of employment.

(a) * * *

(2) All specific reports of investigations of each place of employment under this part will be available to the public from the NIOSH Education and Information Division, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

* * * * *

Dated: December 18 , 2013

Kathleen Sebelius

Secretary, Department of Health and Human Services

[FR Doc. 2014-00547 Filed 01/15/2014 at 8:45 am; Publication Date: 01/16/2014]