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§ 85.11 Notification of determination to employers, affected employees and Department of Labor.

(a) Upon conclusion of an investigation, NIOSH will make a determination concerning the potentially toxic or hazardous effects of each substance or physical agent investigated as a result of the request for health hazard evaluation. At a minimum, the determination will: (1) Identify each substance or physical agent involved and describe, where appropriate, the concentrations or levels of the substance or physical agent found in the place of employment and the conditions of use, and (2) state whether each substance or physical agent has potentially toxic or hazardous effects in the concentrations or levels found, as well as the basis for the judgments.

(b) Copies of the determination will be mailed to the employer and to the authorized representatives of employees.

(c) Except as hereinafter provided, the employer shall post a copy of the determination for a period of 30 calendar days at or near the workplace(s) of affected employees. The employer shall take steps to insure that the posted determinations are not altered, defaced, or covered by other material during such period. The employer will not be required to post the determination if the employer requests that copies of the determination be mailed to affected employees and furnishes NIOSH with a list of the names and mailing addresses of the employees employed in the workplace(s) designated by the NIOSH Officer. In the latter event, NIOSH will mail such copies to affected employees at the mailing addresses provided by the employer.

(d) For purposes of this section, the term ''affected employees'' means those employees determined by NIOSH to be exposed to the substance(s) or physical agent(s) which is the subject of the health hazard evaluation.

(e) Copies of determinations made under the OSH Act will be forwarded to the Department of Labor and the appropriate State agency designated under section 18(b) of the OSH Act. Copies of determinations made under the FMSH Act will be forwarded to the Mine Safety and Health Administration of the Department of Labor; the Bureau of Mines, Department of the Interior; and the State agency which, in the judgment of NIOSH, would benefit the most from the information. If NIOSH determines that any substance or physical agent has potentially toxic or hazardous effects at the concentrations or levels at which it is used or found in a place of employment, and the substance or physical agent is not covered by a safety or health standard established under section 6 of the OSH Act or section 101 of the FMSH Act, NIOSH will immediately submit the determination to the Secretary of Labor, together with all pertinent criteria.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980]

§ 85.12 Subsequent requests for health hazard evaluations.

If a request is received for a health hazard evaluation in a place of employment in which an evaluation under this part was made previously, NIOSH may make another investigation if, as a result of the passage of time or additional information, another investigation would be consistent with the purposes of the Acts.

[45 FR 2654, Jan. 14, 1980]

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

Sec.

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

§ 85a.1 Applicability.

(a) Except as otherwise provided in paragraph (b) of this section, the provisions of this part apply to investigations of places of employment which are conducted by NIOSH under sections 20 and 8 of the Occupational Safety and Health Act of 1970 and sections 501 and 103 of the Federal Mine Safety and Health Act of 1977.

(b) The provisions of this part do not apply to those activities covered by part 85 of this chapter.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 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:

(a) *OSH Act* means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*) and *FMSH Act* means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 *et seq.*).

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

(c) *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.

(d) *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.

(e) *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.

(f) *NIOSH* means the National Institute for Occupational Safety and Health of the Center for Disease Control, Public Health Service, Department of Health and Human Services.

(g) *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.

(h) *NIOSH Regional Office* means any one of the ten Department of Health and Human Services Regional Offices, the addresses of which are specified in § 5.31 of title 45, Code of Federal Regulations.

(i) *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.

(j) *MSHA District Office* means any one of the Mine Safety and Health Administration's District Offices.

(k) *BOM* means the Bureau of Mines, Department of the Interior.

(l) *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.

(m) *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.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

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

(a) NIOSH authorized representatives who have been issued official NIOSH credentials are authorized by the Director, NIOSH, under sections 20 and 8 of the OSH Act, sections 501 and 103 of the FMSH Act, and this part. To enter without delay any place of employment for the purpose of conducting investigations of all pertinent processes, conditions, structures, machines, apparatus, devices, equipment, and materials within the place of employment; and to conduct medical examinations, anthropometric measurements and functional tests of employees within the place of employment as may be directly related to the specific investigation being conducted. Such investigations will be conducted in a reasonable manner, during regular working hours or at other reasonable times and within reasonable limits. In connection with any investigations, such NIOSH authorized representatives may question privately any employer, owner, operator, agent, or employee from the place of employment; and review, abstract, or duplicate employment records, medical records, records required by the Act and regulations, and other related records. In those instances where systems of records subject to review, abstraction or duplication are of a confidential nature, such as medical records, and are abstracted or duplicated, NIOSH will maintain such systems in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the implementing regulation of the Department of Health and Human Services (45 CFR part 5b).

(b) Areas under investigation which contain information classified by any agency of the United States Government in the interest of national security will be investigated only by NIOSH authorized representatives who have obtained the appropriate security clearance and authorization.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

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

(a) Except as otherwise provided in paragraph (b) of this section, NIOSH authorized representatives will contact an official representative of the place of employment prior to any site visits and will provide the details of why an investigation of the place of employment is being conducted. Prior to the initiation of a site visit of a place of employment, representatives of the following organizations will be advised of the site visit and the reason for its conduct:

(1) The appropriate State agency designated under section 18(b) of the OSH Act, or if no State agency has been designated under the OSH Act and in the case of the FMSH Act, the State agency which, in the judgment of NIOSH, would benefit the most from the investigation's findings;

(2) If there is a local union at the place of employment, the local president, business manager or other appropriate individual;

(3) The appropriate Assistant Regional Director, when investigations are conducted under the OSH Act;

(4) The appropriate MSHA District Office; the Director, BOM, and the Assistant Director for Mining, BOM, 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 those individuals 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 stipulated in paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) of this section about the nature and details of the investigation.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

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

(a)(1) Prior to beginning a site visit, NIOSH authorized representatives will present their credentials to the employer, owner, operator or agent in charge at the place of employment, explain the nature, purpose and scope of the investigation and the records specified in § 85a.3 which they wish to review, abstract or duplicate.

(2) In those instances where site visits are not necessary to the conduct of an investigation and the initial contact is made verbally, NIOSH authorized representatives will, at the request of the employer, owner, operator or agent in charge at the place of employment, provide a written explanation of the nature, purpose and scope of the investigation and the records specified in § 85a.3 which they wish to review, abstract or duplicate.

(b)(1) At the commencement of an investigation, the employer, owner, operator or agent in charge at the place of employment shall precisely identify that information which is trade secret and might be seen or obtained by the NIOSH authorized representatives during the investigation. If the NIOSH authorized representatives have no clear reason to question such identification, such information will not be disclosed by NIOSH in accordance with the provisions of section 15 of the OSH Act. Generally, NIOSH will not question trade secret designations; however, if NIOSH at any time does question such identification, not less than 15 days' notice to the employer, owner, operator or agent will be given of the intention to remove the trade secret designation from such information. The employer, owner, operator or agent may within that period submit a request to the Director, NIOSH, to reconsider this intention and may provide additional information in support of the trade secret designation. The Director, NIOSH, will notify the employer, owner, operator or agent in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

(2) In those instances where the NIOSH authorized representative is a person fulfilling a contact 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.

(c)(1) NIOSH authorized representatives will be in charge of site visits conducted pursuant to this part.

(2) Where there is a request by the representative of the State agency and/or employees, who were notified pursuant to § 85a.4(a)(1) or § 85a.4(a)(2) to accompany the NIOSH authorized representatives during the site visit of the place of employment, the NIOSH authorized representatives will allow this request if they determine that this will aid the investigation; or where, in the judgment of the NIOSH authorized representatives, good cause has been shown why accompaniment by a third party who is not an employee of the employer is reasonably necessary to the conduct of an effective and thorough site visit, they may permit such third party to accompany them during the site visit: *Provided however*, That access by such person(s) to areas described in § 85a.5(c)(4) shall be in accordance with the requirements of such provision and access to areas containing trade secrets shall be with the consent of the employer, owner, operator or agent in charge at the place of employment.

(3) NIOSH authorized representatives are authorized to deny the right of accompaniment under this paragraph to

any person whose conduct in their judgment interferes with a fair and orderly site visit. In all instances, a representative of the employer shall be permitted to accompany the NIOSH authorized representatives during the site visit of the place of employment.

(4) With regard to information classified by an agency of the United States Government in the interest of national security, only persons authorized to have access to such information may accompany NIOSH authorized representatives in areas containing such information.

(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, motion pictures or videotapes 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, motion pictures, and videotapes 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 Human Subjects Review Board and no employee examination, measurement or test will be undertaken without the informed consent of such employee.

(e) NIOSH authorized representatives will comply with all safety and health rules and practices at the place of employment and all NIOSH, Occupational Safety and Health Administration, and Mine Safety and Health Administration regulations and policies during a site visit and will provide and use appropriate protective clothing and equipment. In situations requiring specialized or unique types of protective equipment, such equipment shall be furnished by the employer, owner, operator or agent in charge at the place of employment.

(f) The conduct of site visits will be such as to preclude unreasonable disruption of the operations of the place of employment.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980; 49 FR 4739, Feb. 8, 1984]

§ 85a.6 Provision of suitable space for employee interviews and examinations.

An employer, owner, operator or agent in charge at the place of employment shall, on request of the NIOSH authorized representatives, provide suitable space at the place of employment, if such space is reasonably available, to NIOSH to conduct private interviews with, and medical examinations, anthropometric measurements and functional tests of employees. NIOSH authorized representatives will consult with the employer, owner, operator or agent as to the time and place of the private interviews, medical examination, anthropometric measurements and functional tests and will schedule same so as to avoid undue disruption of work at the place of employment. NIOSH will conduct the medical interviews, measurements, examinations and tests specified under this part at its own expense.

[41 FR 45002, Oct. 14, 1976]

§ 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)(1), (a)(3), and (a)(4).

[41 FR 45002, Oct. 16, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

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

(a)(1) Specific reports of investigations of each place of employment under this part, with identification of the place of employment, will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, with copies to the appropriate officials and Agencies notified pursuant to § 85a.4(a). Prior to release of such reports, a preliminary report will be sent by NIOSH to the employer, owner, operator or agent for review for trade secret information and technical inaccuracies that may inadvertently be presented in the report. If requested in writing, the data used to compile the reports will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, except that data will not be released in a form that is individually identifiable.

(2) All specific reports of investigations of each place of employment under this part will be available to the public from the NIOSH Regional Consultant for Occupational Safety and Health in the appropriate NIOSH Regional Office.

(3) In certain instances, specific reports of investigations of each place of employment will not be prepared. In such instances, a closing conference at the place of employment will be conducted by the NIOSH authorized representatives and those individuals participating in the site visit to discuss the findings of the site visit and appropriate recommendations.

(b)(1) Any specific findings of individual employee medical examinations, anthropometric measurements and functional tests will be released by NIOSH authorized representatives to the company physician, private physician, or other person only pursuant to the written authorization of the employee; otherwise, the specific findings and other personal records concerning individuals will be maintained in accordance with 45 CFR part 5b and section 3 of the Privacy Act of 1974 (5 U.S.C. 552a). Notice of all NIOSH systems of records as defined in 45 CFR 5b.1(n) as a result of the investigations of places of employment pursuant to this part will be published in the FEDERAL REGISTER under Notices of Systems of Records for the Department of Health and Human Services.

(2) In cases where an employee shows positive significant medical findings, the employee and the physician(s) designated by the employee under § 85a.8(b)(1) will be immediately notified by NIOSH.

(3) A summary of the findings of the examinations for each employee will be sent by NIOSH to the individual.

(c) The findings of a total investigation generally will be disseminated as part of NIOSH criteria documents, NIOSH technical reports, NIOSH information packets, scientific journals, presentations at technical meetings, or in other similar manners. These findings of a total investigation will be presented in a manner which does not identify any specific place of employment; however, it should be noted that the specific reports of investigations of each place of employment under this part are subject to mandatory disclosure, upon request, under the provisions of the Freedom of Information Act (5 U.S.C. 552).

[41 FR 45002, Oct. 14, 1976]

PART 86—GRANTS FOR EDUCATION PROGRAMS IN OCCUPATIONAL SAFETY AND HEALTH

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