

**§ 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.

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