

§ 1990.103

29 CFR Ch. XVII (7-1-04 Edition)

feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired (section 6(b)(5)).

It is the purpose of the regulations of this part to carry out the intent of the Act with respect to the identification, classification, and regulation of potential occupational carcinogens.

§ 1990.103 Definitions.

Terms used in this part shall have the meanings set forth in the Act. In addition, as used in this part, the following terms shall have the meanings set forth below:

Act means the Occupational Safety and Health Act of 1970 (Pub. L. 91-596, 84 Stat. 1590 *et seq.*, 29 U.S.C. 551 *et seq.*).

Administrator of EPA means the Administrator of the United States Environmental Protection Agency, or designee.

Chairperson of CPSC means the Chairman of the United States Consumer Product Safety Commission, or designee.

Commissioner of FDA means the Commissioner of the Food and Drug Administration, United States Department of Health and Human Services, or designee.

Director of NCI means the Director of the National Cancer Institute, United States Department of Health and Human Services, or designee.

Director of NIEHS means the Director of the National Institute of Environmental Health Sciences, United States Department of Health and Human Services, or designee.

Director of NIOSH means the Director of the National Institute for Occupational Safety and Health, United States Department of Health and Human Services, or designee.

Mutagenesis means the induction of heritable changes in the genetic material of either somatic or germinal cells.

Positive results in short-term tests means positive results in assays for two or more of the following types of effect:

- (1) The induction of DNA damage and/or repair;
- (2) Mutagenesis in bacteria, yeast, *Neurospora* or *Drosophila melanogaster*;

(3) Mutagenesis in mammalian somatic cells;

(4) Mutagenesis in mammalian germinal cells; or

(5) Neoplastic transformation of mammalian cells in culture.

Potential occupational carcinogen means any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals.

Secretary of HHS means the Secretary of the United States Department of Health and Human Services, or designee.

§ 1990.104 Scientific review panel.

(a) *General.* At any time, the Secretary may request the Director of NCI, the Director of NIEHS and/or the Director of NIOSH to convene a scientific review panel ("the panel") to provide recommendations to the Secretary in the identification, classification, or regulation of any potential occupational carcinogen.

(b) *Membership.* The panel will consist of individuals chosen by the respective Director(s). The panel will consist of individuals who are appropriately qualified in the disciplines relevant to the issues to be considered, and who are employed by the United States. The panel does not constitute an advisory committee within the meaning of section 6(b) or 7(b) of the Act, or the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770).

(c) *Report.* The Secretary shall request that the panel submit a report of its evaluation within ninety (90) days after the appointment of the members of the panel. The Secretary shall place a copy of the report in the record of any relevant rulemaking undertaken pursuant to this part and allow an appropriate time for public review and

comment. If a panel is not established or fails to file a timely report, or if the Secretary determines that it is necessary to proceed without waiting for the panel's report, the Secretary may proceed in making any determination without such report.

(d) *Other aid and assistance.* Nothing herein precludes the Secretary from obtaining advice or other aid from any person or organization including NCI, NIEHS, and NIOSH.

§ 1990.105 Advisory committees.

The Secretary may appoint an Advisory Committee, pursuant to sections 6(b) and 7 of the Act, and 29 CFR part 1912, concerning any potential occupational carcinogen. The Secretary shall require the Advisory Committee to submit its recommendations to assist the Secretary in standard setting no later than ninety (90) days from the date of the Advisory Committee's appointment, unless extended by the Secretary for exceptional circumstances. If an Advisory Committee fails to file a timely report, the Secretary may proceed in standard setting activities without such a report.

§ 1990.106 Amendments to this policy.

(a) *Initiation of review of this policy—*
(1) *Secretary's request.* No later than every three (3) years from the effective date of this part, or from the last general review, the Secretary shall request the Director of NCI, the Director of NIEHS and/or the Director of NIOSH, to review this part and render their opinions on whether significant scientific or technical advances made since the effective date of this part warrant any amendment to this part. The request shall ask that the answer be provided to the Secretary within one hundred twenty (120) days.

(2) *Recommendations by the institutes.* At any time, the Director of NCI, the Director of NIEHS and/or the Director of NIOSH may submit recommendations to the Secretary for amendments to this part whenever any of them believes that scientific or technical advances justify such amendments.

(3) *Petitions from the public.* (i) Any interested person may petition the Secretary concerning amendments to this

part based upon substantial new issues or substantial new evidence.

(ii) For the purposes of this part, substantial new evidence is evidence which differs significantly from that presented in establishing this part, including amendments.

(iii) For the purposes of this part, substantial new issues are issues which differ significantly from those upon which the Secretary has reached a conclusion in the rulemaking establishing this part (including the conclusions reached in the preamble).

(iv) Each petition to amend this part shall contain at least the following information:

- (A) Name and address of petitioner;
- (B) The provisions which the petitioner believes are inappropriate;
- (C) All data, views and arguments relied upon by the petitioner; and
- (D) A detailed statement and analysis as to why the petitioner believes that the data, views and arguments presented by petitioner:
 - (1) Constitute substantial new issues or substantial new evidence; and
 - (2) Are so significant as to warrant amendment of this part.

(b) *Response to recommendations and petitions—*(1) *By the institutes.* Whenever any Director recommends an amendment to this part, the Secretary shall, within one hundred twenty (120) days after receipt of the recommendation, publish in the FEDERAL REGISTER, a notice which:

- (i) States the reasons why the Secretary has determined not to commence a rulemaking proceeding to amend this part, in whole or in part, at that time; or
- (ii) Commences a rulemaking proceeding to consider amending this part accordingly; or

(iii) Appoints an Advisory Committee as provided for by § 1990.105 of this part and sections 6(b) and 7 of the Act.

(2) *By the public.* Within ninety (90) days, or as soon thereafter as possible, after receipt of a petition pursuant to § 1990.106(a)(3), the Secretary shall:

- (i) Refer the petition to the Director of NCI, the Director of NIEHS and/or the Director of NIOSH, in which case the provisions of § 1990.106 (a)(1) and (b)(1) are applicable; or
- (ii) Appoint an advisory committee;