determination that the Secretary plans to address some or all of these substances prior to proceeding with a thorough scientific review of data concerning other substances on the Candidate List. The inclusion or exclusion of any substance on these lists shall not be subject to judicial review or be the basis for any legal action. The Secretary may regulate a potential occupational carcinogen which has not been placed on these lists. The inclusion of a substance on either of these lists does not reflect a final scientific determination that the substance is, in fact, a Category I Potential Carcinogen or a Category II Potential Carcinogen.

EFFECTIVE DATE NOTE: At 48 FR 243, Jan. 4, 1983, § 1990.131 was stayed in order to evaluate the impact of publishing the Candidate List and Priority Lists and to reconsider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).

### § 1990.132 Factors to be considered.

(a) The setting of priorities is a complex matter which requires subjective and policy judgments. It is not appropriate to establish a rigid formula or to assign predetermined weight to each factor. The identification of some of the elements is to guide the OSHA staff and inform the public on the development of priorities. It is not intended to create any legal rights with respect to the setting of priorities.

(b) Some factors which may be taken into account in setting priorities for regulating potential occupational carcinogens, when such data are available, are:

(1) The estimated number of workers exposed;

(2) The estimated levels of human exposure;

(3) The levels of exposure to the substance which have been reported to cause an increased incidence of neoplasms in exposed humans, animals or both;

(4) The extent to which regulatory action could reduce not only risks of contracting cancer but also other occupational and environmental health hazards;

(5) Whether the molecular structure of the substance is similar to the molecular structure of another substance which meets the definition of a potential occupational carcinogen;

(6) Whether there are substitutes that pose a lower risk of cancer or other serious human health problems, or available evidence otherwise suggests that the social and economic costs of regulation would be small; and

(7) OSHA will also consider its responsibilities for dealing with other health and safety hazards and will consider the actions being taken or planned by other governmental agencies in dealing with the same or similar health and safety hazards.

### § 1990.133 Publication.

(a) The Secretary shall publish the Candidate List in the FEDERAL REGISTER at least annually.

(b) The Secretary shall publish the Priority Lists in the FEDERAL REGISTER at least every six months and may seek public comment thereon.

(c) The Secretary may periodically publish in the FEDERAL REGISTER a notice requesting information concerning the classification and establishment of priorities for substances on the Candidate List together with a brief statement describing the type of information being sought.

EFFECTIVE DATE NOTE: At 48 FR 243, Jan. 4, 1983, § 1990.133 was stayed in order to evaluate the impact of publishing the Candidate List and Priority Lists and to reconsider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).

## REGULATION OF POTENTIAL OCCUPATIONAL CARCINOGENS

### § 1990.141 Advance notice of proposed rulemaking.

(a) Within thirty (30) days after OSHA initiates a study concerning the economic and/or technological feasibility of specific standards that might be applied in the regulation of a potential occupational carcinogen, the Secretary will normally publish, in the FEDERAL REGISTER, a notice which includes at least the following:

(1) The name of the substance(s),

(2) The scope of the study, including where possible,

(i) Affected industries,

(ii) Levels of exposure being studied,

(iii) The anticipated completion date of the study;

(3) A brief summary of the available data on health effects;

(4) An estimate of when the Secretary anticipates the issuance of a proposal;

(5) An invitation to interested parties to provide relevant information;

(6) A statement that persons wishing to provide OSHA with their own study should complete it within 30 days after the anticipated proposal date; and

(7) A statement of the procedural requirements that must be met before substantial new issues or substantial new evidence will be considered in the proceeding pursuant to §1990.145.

(b) Where the Secretary determines to discontinue a feasibility study, the Secretary should publish, within 30 days, a notice in the FEDERAL REGISTER so indicating.

### §1990.142 Initiation of a rulemaking.

Where the Secretary decides to regulate a potential occupational carcinogen, the Secretary shall initiate a rulemaking proceeding in accordance with one of the following procedures, as appropriate.

(a) *Notice of proposed rulemakings (section 6(b) of the Act)*—(1) *General.* The Secretary may issue a notice of proposed rulemaking in the FEDERAL REGISTER, pursuant to section 6(b) of the Act and part 1911 of this chapter. The notice shall provide for no more than a sixty (60) day comment period, and may provide for a hearing, which shall be scheduled for no later than one hundred (100) days after publication of the Notice of Proposed Rulemaking. The commencement of the hearing may be postponed once, for no more than thirty (30) days, for good cause shown.

(2) *Provisions of the proposed standard for Category I Potential Carcinogens.* Whenever the Secretary issues a notice of proposed rulemaking to regulate a substance as a Category I Potential Carcinogen:

(i) The proposed standard shall contain at least provisions for scope and application, definitions, notification of use, a permissible exposure limit, monitoring, regulated areas, methods of compliance including the development of a compliance plan, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, hygiene facilities, medical surveillance, employee information and training, signs and labels, recordkeeping, and employee observation of monitoring as set forth in §1990.151, unless the Secretary explains why any or all such provisions are not appropriate;

(ii) The model standard set forth in §1990.151 shall be used as a guideline, and

(iii) The permissible exposure limit shall be achieved primarily through engineering and work practice controls except that if a suitable substitute is available for one or more uses no occupational exposure shall be permitted for those uses.

(3) *Provisions of the proposed standard for Category II Potential Carcinogens.* Whenever the Secretary issues a Notice of Proposed Rulemaking to regulate a substance as a Category II Potential Carcinogen:

(i) The proposed standard shall contain at least provisions for scope and application, definitions, notification of use, monitoring, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, recordkeeping and employee observation of monitoring as set forth in §1990.151, unless the Secretary explains why any or all such provisions are not appropriate; and

(ii) The model standard set forth in §1990.151 shall be used as a guideline; and

(iii) Worker exposure to Category II Potential Carcinogens will be reduced as appropriate and consistent with the statutory requirements on a case-by-case basis in the individual rulemaking proceedings. Any permissible exposure level so established shall be met primarily through engineering and work practice controls.

(b) *Emergency temporary standards (section 6(c) of the Act)*—(1) *General.* The Secretary may issue an Emergency Temporary Standard (ETS) for a Category I Potential Carcinogen in accordance with section 6(c) of the Act.

(2) *Provisions of the ETS.* (i) The ETS shall contain at least provisions for scope and application, definitions, notification of use, a permissible exposure limit, monitoring, methods of

compliance including the development of a compliance plan, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, signs and labels, recordkeeping and employee observation of monitoring, unless the Secretary explains why any or all such provisions are not appropriate.

(ii) The model standard set forth in §1990.152 shall be used as a guideline.

(iii) The permissible exposure limit shall be achieved through any practicable combination of engineering controls, work practice controls and respiratory protection.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

### §1990.143 General provisions for the use of human and animal data.

Human and animal data which are scientifically evaluated to be positive evidence for carcinogenicity including the following policies shall be uniformly relied upon for the identification of potential occupational carcinogens. Arguments challenging the following provisions or their application to specific substances will be considered in individual rulemaking proceedings only if the evidence presented in support of the arguments meets the criteria for consideration specified in §1990.144 or §1990.145.

(a) *Positive human studies.* Positive results obtained in one or more human epidemiologic studies will be used to establish the qualitative inference of carcinogenic hazards to workers.

(b) *Positive animal studies.* Positive results obtained in one or more experimental studies conducted in one or more mammalian species will be used to establish the qualitative inference of carcinogenic hazard to workers. Arguments that positive results obtained in mammalian species should not be relied upon will be considered only if evidence is presented which meets the criteria for consideration specified in §1990.144(c) or 1990.144(f).

(c) *Non-positive human studies.* Positive results in human or mammalian studies generally will be used for the qualitative identification of potential occupational carcinogens, even where non-positive results from human studies exist. Such non-positive results will be considered by the Secretary only if the studies or results meet the criteria set forth in §1990.144(a).

(d) *Non-positive animal studies.* Positive results in one or more mammalian studies will be used for the qualitative identification of potential occupational carcinogens, even where non-positive studies exist in other mammalian species. Where non-positive and positive results exist in studies in the same species, the non-positive results will be evaluated.

(e) *Spontaneous tumors.* Positive results in human or mammalian studies for the induction or acceleration of induction of tumors of a type which occurs ''spontaneously'' in unexposed individuals will be used for the qualitative identification of potential occupational carcinogens.

(f) *Routes of exposure.* (1) Positive results in studies in which mammals are exposed via the oral, respiratory or dermal routes will be used for the qualitative identification of potential occupational carcinogens, whether tumors are induced at the site of application or distant sites.

(2) Positive results in studies in which mammals are exposed via any route of exposure and in which tumors are induced at sites distant from the site of administration will be used for the qualitative identification of potential occupational carcinogens.

(3)(i) Positive results in mammalian studies in which tumors are induced only at the site of administration, in which a substance or mixture of substances is administered by routes other than oral, respiratory or dermal, will be used as ''concordant'' evidence that a substance is a potential occupational carcinogen.

(ii) Arguments that such studies should not be relied upon will be considered only if evidence which meets the criteria set forth in §1990.144(b) is provided.

(g) *Use of high doses in animal testing.* Positive results for carcinogenicity obtained in mammals exposed to high doses of a substance will be used to establish the qualitative inference of carcinogenic hazard to workers. Arguments that such studies should not be relied upon will be considered only if

evidence which meets the criteria set forth in §1990.144(d) is provided.

(h) *''Threshold'' or ''No-effect'' Levels.* No determination will be made that a ''threshold'' or ''no-effect'' level of exposure can be established for a human population exposed to carcinogens in general, or to any specific substance.

(i) *Benign tumors.* Results based on the induction of benign or malignant tumors, or both, will be used to establish a qualitative inference of carcinogenic hazard to workers. Arguments that substances that induce benign tumors do not present a carcinogenic risk to workers will be considered only if evidence that meets the criteria set forth in §1990.144(e) is provided.

(j) *Statistical evaluation.* Statistical evaluation will be used in the determination of whether results in human, animal or short-term studies provide positive evidence for carcinogenicity, but will not be the exclusive means for such evaluation.

(k) *Carcinogenicity of metabolites.* A substance which is metabolized by mammals to yield one or more potential occupational carcinogens will itself be identified and classified as a potential occupational carcinogen, whether or not there is direct evidence that it induces tumors in humans or experimental animals. Evidence for such metabolism will normally be derived from *in vivo* studies in mammals. In appropriate circumstances, evidence may be derived from *in vitro* studies of mammalian tissues or fractions thereof. Arguments that evidence from *in vivo* metabolic studies in mammals is not relevant to the inference of carcinogenic hazard to humans will be considered only if such evidence meets the criteria set forth in §1990.144(c).

[45 FR 5282, Jan. 22, 1980; 45 FR 43405, June 27, 1980]

### § 1990.144 Criteria for consideration of arguments on certain issues.

Arguments on the following issues will be considered by the Secretary in identifying or classifying any substance pursuant to this part, if evidence for the specific substance subject to the rulemaking conforms to the following criteria. Such arguments and evidence will be evaluated based upon scientific and policy judgments.

(a) *Non-positive results obtained in human epidemiologic studies.* Non-positive results obtained in human epidemiologic studies regarding the substance subject to the rulemaking or to a similar or closely related substance will be considered by the Secretary only if they meet the following criteria:

*Criteria.* (i) The epidemiologic study involved at least 20 years' exposure of a group of subjects to the substance and at least 30 years' observation of the subjects after initial exposure;

(ii) Documented reasons are provided for predicting the site(s) at which the substance would induce cancer if it were carcinogenic in humans; and

(iii) The group of exposed subjects was large enough for an increase in cancer incidence of 50% above that in unexposed controls to have been detected at any of the predicted sites.

Arguments that non-positive results obtained in human epidemiologic studies should be used to establish numerical upper limits on potential risks to humans exposed to specific levels of a substance will be considered only if criteria (i) and (ii) are met and, in addition:

(iv) Specific data on the level of exposure of the group of workers are provided, based either on direct measurements made periodically throughout the period of exposure, or upon other data which provide reliable evidence of the magnitude of exposure.

(b) *Tumors induced at site of administration.* Arguments that tumors at the site of administration should not be considered will be considered only if:

(i) The route of administration is not oral, respiratory or dermal; and

(ii) Evidence is provided which establishes that induction of local tumors is related to the physical configuration or formulation of the material administered (e.g., crystalline form or dimensions of a solid material, or matrix of an impregnated implant) and that tumors are not induced when the same material is administered in a different configuration or formula.

(c) *Metabolic differences.* Arguments that differences in metabolic profiles can be used to demonstrate that a chemical found positive in an experimental study in a mammalian species would pose no potential carcinogenic

risk to exposed workers will be considered by the Secretary only if the evidence presented for the specific substance subject to the rulemaking meets the following criteria:

*Criteria.* (i) A complete metabolic profile, including identities of trace metabolites, is presented for the experimental animal species;

(ii) A complete metabolic profile, including identities of trace metabolites, is available for a human population group representative of those who are occupationally exposed;

(iii) Documented evidence is provided for ascribing the carcinogenic activity of the substance in the test animal species to metabolite(s) produced only in that species and not in humans; and

(iv) Documented evidence is provided to show that other metabolites produced also in humans have been adequately tested and have not been shown to be carcinogenic.

(d) *Use of high doses in animal testing.* Arguments that positive results obtained in carcinogenesis bioassays with experimental animals subjected to high doses of a substance are not relevant to potential carcinogenic risks to exposed workers will be considered by the Secretary only if the evidence for the specific substance subject to the rulemaking meets the following criteria:

*Criteria.* (i) Documented evidence is presented to show that the substance in question is metabolized by the experimental animal species exposed at the dose levels used in the bioassay(s) to metabolic products which include one or more that are not produced in the same species at lower doses.

(ii) Documented evidence is presented to show that the metabolite(s) produced only at high doses in the experimental animal species are the ultimate carcinogen(s) and that the metabolites produced at low doses are not also carcinogenic; and

(iii) Documented evidence is presented to show that the metabolite(s) produced only at high doses in the experimental animal species are not produced in humans exposed to low doses.

(e) *Benign tumors.* The Secretary will consider evidence that the substance subject to the rulemaking proceeding is capable only of inducing benign tumors in humans or experimental animals provided that the evidence for the specific substance meets the following criteria:

*Criteria.* (i) Data are available from at least two well-conducted bioassays in each of two species of mammals (or from equivalent evidence in more than two species);

(ii) Each of the bioassays to be considered has been conducted for the full lifetime of the experimental animals;

(iii) The relevant tissue slides are made available to OSHA or its designee and the diagnoses of the tumors as benign are made by at least one qualified pathologist who has personally examined each of the slides and who provides specific diagnostic criteria and descriptions; and

(iv) All of the induced tumors must be shown to belong to a type which is known not to progress to malignancy or to be at a benign stage when observed. In the latter case, data must be presented to show that multiple sections of the affected organ(s) were adequately examined to search for invasion of the tumor cells into adjacent tissue, and that multiple sections of other organs were adequately examined to search for tumor metastases.

(f) *Indirect mechanisms.* The Secretary will consider evidence that positive results obtained in a carcinogenesis bioassay with experimental animals are not relevant to a determination of a carcinogenic risk to exposed workers, if the evidence demonstrates that the mechanism by which the observed tumor incidence is effected is indirect and would not occur if humans were exposed. As examples, evidence will be considered that a substance causes a carcinogenic effect by augmenting caloric intake or that the carcinogenic effect from exposure to a substance is demonstrated to be the result of the presence of a carcinogenic virus and it is demonstrated that, in either case, the effect would not take place in the absence of the particular carcinogenic virus or the augmented caloric intake.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

### § 1990.145 Consideration of substantial new issues or substantial new evidence.

(a) *Substantial new issues.* Notwithstanding any other provision of this part, the Secretary will consider in a rulemaking proceeding on a specific substance any substantial new issues upon which the Secretary did not reach a conclusion in the rulemaking proceeding(s) underlying this part including conclusions presented in the preamble.

(b) *Substantial new evidence.* Notwithstanding any other provision of this part, the Secretary will consider in a rulemaking proceeding on a specific substance any arguments, data or views which he determines are based upon substantial new evidence which may warrant the amendment of one or more provisions of this part. For the purposes of this part, ''substantial new evidence'' is evidence directly relevant to any provision of this part and is based upon data, views or arguments which differ significantly from those presented in establishing this part, including amendments thereto.

(c) *Petitions for consideration of substantial new evidence*—(1) *Petition.* Any interested person may file a written petition with the Secretary to consider ''substantial new evidence'' or one or more ''substantial new issues'' which contains the information specified in paragraph (c)(2) of this section. The Secretary shall treat such a petition as a request to amend this part, as well as a petition to consider ''substantial new evidence''.

(2) *Contents.* Each petition for consideration of ''substantial new evidence'' or one or more ''substantial new issues'' shall contain at least the following information:

(i) Name and address of the petitioner;

(ii) All of the data, views and arguments that the petitioner would like the Secretary to consider;

(iii) The provision or provisions that petitioner believes are inappropriate or should be added to this part in light of the new data, views, and arguments;

(iv) A statement which demonstrates that the data, views, and arguments relied upon by petitioners are directly relevant to the substance or class of substances that is the subject of a rulemaking or an Advance Notice of Proposed Rulemaking;

(v) A detailed statement and analysis as to why the petitioner believes that the data, views, and arguments presented by the petitioner:

(A) Differ significantly from those presented in the proceeding(s) which establish this part;

(B) Are so substantial as to warrant amendment of this part; and

(C) Constitute a new issue or new evidence within the meaning of paragraphs (a) and (b) of this section.

(3) *Deadline for petitions.* (i) Petitions which comply with paragraph (c) of this section, shall be filed in accordance with the schedule set forth in the Advanced Notice of Proposed Rulemaking.

(ii) In extraordinary cases the Secretary may consider evidence submitted after the deadline if the petitioner establishes that the evidence relied upon was not available and could not have reasonably been available in whole or substantial part by the deadline and that it is being submitted at the earliest possible time.

(d) *Secretary's response.* (1) The Secretary shall respond to petitions under this paragraph in accordance with §1990.106.

(2) Whenever the Secretary determines that the ''substantial new issue'' or the ''substantial new evidence'' submitted under this paragraph is sufficient to initiate a proceeding to amend this part, the Secretary shall:

(i) Issue a notice to consider amendment to this part and not proceed on the rulemaking concerning the individual substance until completion of the amendment proceeding; or

(ii) Issue a notice to consider amendment to this part and consolidate it with the proceeding on the individual substance.

### §1990.146 Issues to be considered in the rulemaking.

Except as provided in §1990.145, after issuance of the advance notice of rulemaking, the proceedings for individual substances under this part shall be limited to consideration of the following issues:

(a) Whether the substance, group of substances or combination of substances subject to the proposed rulemaking is appropriately considered in a single proceeding;

(b) Whether the substance or group of substances subject to the rulemaking meets the definition of a potential occupational carcinogen set forth in §1990.103, including whether the scientific studies are reliable;

(c) Whether the available data can appropriately be applied to the substance, group of substances or combination of substances covered by the rulemaking;

(d) Whether information, data, and views that are submitted in accordance with §1990.144 are sufficient to warrant an exception to this part;

(e) Whether the data, views and arguments that are submitted in accordance with §1990.145 are sufficient to warrant amendment of this part;

(f) Whether the potential occupational carcinogen meets the criteria for a Category I Potential Carcinogen or a Category II Potential Carcinogen.

(g) The environmental impact arising from regulation of the substance;

(h) Any issues required by statute or executive order;

(i) The determination of the level to control exposures to Category I Potential Carcinogens primarily through the use of engineering and work practice controls including technological and economic considerations.

(j) The determination of the appropriate employee exposure level, consistent with the Act's requirements, for Category II Potential Carcinogens;

(k) Whether suitable substitutes are available for one or more uses of Category I Potential Carcinogens and; if so, the no occupational exposure level to be achieved solely with engineering and work practice controls and other issues relevant to substitution; and

(l) Whether the provisions of the proposal and of §§1990.151 and 1990.152 (model standards) are appropriate, except as limited by §1990.142 and whether additional regulatory provisions may be appropriate.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

### §1990.147 Final action.

(a) Within one hundred twenty (120) days from the last day of any hearing or ninety (90) days from the close of any post hearing comment period, whichever occurs first, the Secretary shall publish in the FEDERAL REGISTER:

(1) A final standard based upon the record in the proceeding; or

(2) A statement that no final standard will be issued, and the reasons therefor, or

(3) A statement that the Secretary intends to issue a final rule, but that he is unable to do so at the present time, including:

(i) The reasons therefor; and

(ii) The date by which the standard will be published, which may not exceed one hundred twenty (120) days thereafter.

(iii) The Secretary may issue no more than one such notice, unless the Secretary determines that (A) new evidence which was unavailable during the rulemaking proceeding has just become available; (B) the evidence is so important that a final rule could not reasonably be issued without this evidence, and; (C) the record is reopened for receipt of comments and/or a hearing on this evidence. This paragraph does not require the Secretary to consider any evidence which is submitted after the dates established for the submission of evidence.

(b) The failure of the Secretary to comply with the required timeframes shall not be a basis to set aside any standard or to require the issuance of a new proposal on any individual substance.

(c) The final standard shall state whether the substance or group of substances subject to the rulemaking is classified as a Category I Potential Carcinogen or as a Category II Potential Carcinogen. If the classification differs from that in the notice of proposed rulemaking, the Secretary shall explain the reasons for the change in classification in the preamble to the final standard.

(d) If the substance is classified as a Category I Potential Carcinogen, the final standard shall conform to the provisions of §1990.142(a)(2)(iii). If the final standard contains other provisions that substantially differ from the proposed provisions, the Secretary shall explain the reasons for the changes in the preamble to the final standard.

(e) If the substance is classified as a Category II potential carcinogen, the final standard shall conform to the provisions of §1990.142(a)(3)(iii). If the final standard contains other provisions that substantially differ from the proposed provisions, the Secretary shall explain the reasons for the changes in the preamble to the final standard.

(f) If the substance is classified as a Category II potential carcinogen, the Secretary shall notify the applicable federal and state agencies, including the Administrator of EPA, the Director of NCI, the Director of NIEHS, the Director of NIOSH, the Commissioner of FDA and the Chairperson of CPSC of such determination and request that the applicable agencies engage in, or stimulate, further research pursuant to their legislative authority, to develop new and additional scientific data.

(g) If, after a rulemaking, the Secretary determines that the substance under consideration should not be classified as a Category I potential carcinogen or a Category II potential carcinogen, the Secretary shall publish a notice of this determination in the FEDERAL REGISTER, together with the reasons therefor.

MODEL STANDARDS

### § 1990.151 Model standard pursuant to section 6(b) of the Act.

Occupational Exposure to _____

Permanent Standard (insert section number of standard)

(a) *Scope and application*—(1) *General.* This section applies to all occupational exposures to _____ or to (specify those uses or classes of uses of _____ [Chemical Abstracts Service Registry Number 0000] which are covered by the standard, including, where appropriate, the type of exposure to be regulated by the standard) except as provided in paragraph (a)(2).

(2) *Exemptions.* This section does not apply to (insert those uses or classes of uses of _____ which are exempted from compliance with the standard, including, where appropriate,

(i) Workplaces where exposure to _____ results from solid or liquid mixtures containing a specified percentage of _____ or less;

(ii) Workplaces where another Federal agency is exercising statutory authority to prescribe or enforce standards or regulations affecting occupational exposure to _____; or

(iii) Workplaces which are appropriately addressed in a separate standard).

(b) *Definitions.*

_____ means (definition of the substance, group of substances, *or combination of substances, to be regulated*).

*Action level* means an airborne concentration of _____ of (insert appropriate level of exposure).

NOTE: Where appropriate, consider an action level as a limitation on requirements for periodic monitoring (para. (e)(3)), medical surveillance (para. (n)), training (para. (o)), labels (para. (p)(3)), and other provisions.

*Assistant Secretary* means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

*Authorized person* means any person specifically authorized by the employer whose duties require the person to enter regulated areas or any person entering such an area as a designated representative of employees for the purpose of exercising the opportunity to observe monitoring procedures under paragraph (r) of this section.

*Director* means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, and Health Services, or designee.

*Emergency* means in any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may result in a massive release of _____ which is (insert appropriate quantitative or qualitative level of release which constitutes an emergency).

*OSHA Area Office* means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) *Permissible exposure limits provisions*—(1) *Inhalation*—(i) *Time weighted average limit (TWA).* Within (insert appropriate time period) of the effective date of this section, the employer shall assure that no employee is exposed to an airborne concentration of _____in excess of: (insert appropriate exposure limit or when it is determined by the Secretary that there are available suitable substitutes for uses or classes of uses that are less hazardous to humans, the proposal shall permit no occupational exposure) as an eight (8)-hour time-weighted average.

(Where the Secretary finds that suitable substitutes for _____may exist, the determination of the _____level