

§ 1952.362 [Redesignated from § 1952.364]

§ 1952.364 [Reserved]

4. Section 1952.364 ("Completion of developmental steps and certification") is redesignated as § 1952.362, and a new § 1952.364 is added and reserved.

§ 1952.361 [Redesignated as § 1952.366]

5. Section 1952.361 is redesignated as § 1952.366 and revised to read as follows:

§ 1952.366 Where the plan may be inspected.

A copy of the principal documents comprising the plan may be inspected and copied during normal business hours at the following locations: Office of State Programs, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Room N3700, Washington, D.C. 20210; Office of the Regional Administrator, Occupational Safety and Health Administration, U.S. Department of Labor, Room 602, 525 Griffin Street, Dallas, Texas 75202; and New Mexico Environment Department, Occupational Safety and Health Bureau, 1190 St. Francis Drive, Santa Fe, New Mexico 87502.

§ 1952.361 [Redesignated from § 1952.363]

6. Section 1952.363 is redesignated as § 1952.361 and a new § 1952.363 is added to read as follows:

§ 1952.363 Compliance staffing benchmarks.

Under the terms of the 1978 Court Order in *AFL-CIO v. Marshall*, compliance staffing levels ("benchmarks") necessary for a "fully effective" enforcement program were required for each State operating an approved State plan. In May 1992, New Mexico completed, in conjunction with OSHA, a reassessment of the staffing levels initially established in 1980 and proposed revised benchmarks of 7 safety and 3 health compliance officers. After opportunity for public comment and service on the AFL-CIO, the Assistant Secretary approved these revised staffing requirements on August 11, 1994.

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## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 3

RIN 2900-AG29

#### Claims Based on Chronic Effects of Exposure to Mustard Gas or Lewisite

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

**SUMMARY:** The Department of Veterans Affairs (VA) has amended its adjudication regulations concerning compensation for disabilities or deaths resulting from the chronic effects of in-service exposure to mustard gas and Lewisite. This regulation is based on a National Academy of Sciences (NAS) study of the long-term health effects of exposure to these vesicant (blistering) agents, commissioned by VA, which found a relationship between such exposure and the subsequent development of certain conditions. The intended effect of this amendment is to expand the list of conditions covered and apply the presumption to a broader group of veterans.

**EFFECTIVE DATE:** This amendment is effective January 6, 1993.

**FOR FURTHER INFORMATION CONTACT:** Donald England, Chief, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 273-7210.

**SUPPLEMENTARY INFORMATION:** On July 31, 1992, VA published a final regulation (38 CFR 3.316) authorizing service connection in claims from veterans who underwent full-body exposure to mustard gas during field or chamber experiments to test protective clothing or equipment during World War II, and who subsequently develop chronic forms of laryngitis, bronchitis, emphysema, asthma, conjunctivitis, keratitis, or corneal opacities (See 57 FR 1699-1700 and 57 FR 33875-77). VA also contracted with NAS to conduct a review of the world medical and scientific literature, including that published in languages other than English, to determine the long-term health effects of exposure to mustard agents and Lewisite. After reviewing almost 2,000 medical and scientific papers, consulting with outside experts, and conducting public hearings, NAS issued its report, entitled "Veterans at Risk: The Health Effects of Mustard Gas and Lewisite", on January 6, 1993.

After reviewing the NAS report, VA published a proposal to amend 38 CFR 3.316 to expand compensation

eligibility based on the long-term health effects of exposure to vesicant agents in the Federal Register of January 24, 1994 (59 FR 3532-34). Interested persons were invited to submit written comments, suggestions or objections concerning the proposal on or before March 25, 1994. We received nine comments: One from the American Legion, one from the Disabled American Veterans, and seven from concerned individuals.

One commenter stated that the proposed rule seems very confusing and is filled with terms that the normal citizen would not understand.

Based on this comment we have revised the heading of the regulation, substituting the phrase "mustard gas or Lewisite" for the term "vesicant agents," to make it easier for the average individual to identify the topic of the regulation from the table of contents. However, because the NAS study was based on a comprehensive review of scientific and medical literature that uses highly technical medical terms both for specific disabilities and for vesicant agents with different but similar chemical composition, we found it necessary to use the same terms in the regulation in order to accurately and precisely express the Secretary's decision. In simple terms, this amendment provides presumptive service connection for certain respiratory conditions, eye conditions and cancers based on full-body exposure to mustard gas and Lewisite.

Two commenter stated that the proposed regulation does not adequately provide for veterans who have one of the requisite conditions but cannot verify exposure to mustard gas or Lewisite because they lack access to government records. One of them suggested that service connection not be denied if their is no clear and convincing evidence of intercurrent cause.

VA does not concur. Generally, a presumption eases the burden of proof on a veteran by attaching certain consequences to the establishment of certain basic evidentiary facts. In the case of this regulation, establishment of certain basic evidentiary facts—full-body exposure to a vesicant agent during military service and the subsequent development of a specified disease—triggers the presumption that the disease is due to that exposure even where there is no medical evidence of an association between the veteran's disease and his or her military service.

The presumption does not work in reverse, however. A presumption that the presence of a condition indicates prior exposure to a specific substance

might be possible in the case of a condition associated exclusively or almost exclusively with a single cause. The only known cause of asbestosis or mesothelioma, for example, is exposure to asbestos. There is no basis for a presumption of in-service exposure to mustard gas or Lewisite based solely on the presence of any of the conditions specified in this regulation, however, because medical science recognizes other plausible causes for all of them.

Another commenter, a medical doctor and professor of medicine, pointed out that Lewisite contains arsenic and stated that exposure to arsenic is associated with increased malignancy in humans. He suggested, based upon his own clinical experience with a patient exposed to potassium arsenite, that service connection based on exposure to vesicant agents be established for chronic leukemia, primary cancers of the liver, bronchogenic cancer and skin cancers (based on exposure to Lewisite), accelerated atherosclerosis, and neurasthenia. To support this suggestion, he cited a published case study: Regelson W., Kim U., Ospina J., Holland J.F., 1968.

Hemangioendothelial Sarcoma of Liver from Chronic Arsenic Intoxication by Fowler's Solution. *Cancer* 21: 514-522.

VA does not concur. The NAS report and recommendations which the Secretary relied upon were based upon a comprehensive literature review covering almost 2,000 medical and scientific papers including numerous epidemiological studies, industrial studies of workers in chemical factories, and studies of soldiers exposed to mustard gas in warfare. NAS found that there is so little literature of these types concerning the health risks associated with exposure to Lewisite that with few exceptions it is not possible to determine the relationship between Lewisite exposure and the onset of particular diseases. In essence, this commenter asks us to accept his medical judgment over that of a distinguished panel of experts in a wide range of specialties that had conducted an extensive literature search and review. In our judgment, the clinical experience of one person does not approach the probative weight of either the literature review conducted by NAS or the consensus opinion of the panel of specialists assembled by NAS. We also note that case studies, such as that submitted by the commenter, are anecdotal in nature and have no statistical significance. For these reasons, we find that the evidence is not sufficient to warrant presumptive service connection for the additional

conditions recommended by this commenter.

Another commenter suggested that no claim based on verified mustard gas exposure be denied solely because there is insufficient data to establish a correlation between the claimed conditions and exposure to vesicant agents. Other commenters suggested that VA recognize additional conditions stating that veterans should not be penalized because of gaps in the medical literature.

VA does not concur. NAS found that there are few data to argue either for or against a casual relationship between exposure to vesicant agents and other conditions mentioned by the commenters, and recommended that VA conduct morbidity and mortality studies in order to resolve some of the remaining questions about the health risks associated with exposure to vesicant agents. The Veterans Health Administration is preparing to conduct morbidity and mortality studies as recommended by NAS. Should those studies indicate a relationship between exposure to vesicant agents and additional conditions, we will determine whether a regulatory presumption of service connection for those disabilities is warranted at that time.

Another commenter recommended that VA recognize additional conditions by applying VA's benefit of the doubt doctrine and resolving all doubt in favor of veterans exposed to mustard gas or Lewisite.

Again, we note that NAS found that there are few data to argue either for or against a casual relationship between exposure to vesicant agents and other conditions. VA regulations at 38 CFR 3.102 (See also 38 U.S.C. 5107(b)) define reasonable doubt as a doubt which exists because of an approximate balance of positive and negative evidence which does not satisfactorily prove or disprove the claim; a substantial doubt within the range of probability as distinguished from pure speculation or remote possibility. Although the primary purpose of the regulation is to resolve doubt in favor of a claimant when there is a balance of positive and negative evidence, it was never intended for use when there is insufficient evidence to support a conclusion one way or the other.

One commenter stated that even though VA indicated that the proposal represented a liberalization of the previous criteria, verified full-body exposure is, in fact, a higher standard and would place a greater burden of proof on veterans seeking benefits under this amendment.

The requirement for full-body exposure was included in the July 31, 1992, version of this regulation, and its retention does not place a greater burden of proof on those veterans seeking benefits under this regulation. We had proposed to add the word "verified," but that change was intended as a clarification and represented no substantive change in VA's position on the type of evidence required to establish entitlement to the presumption of service connection set forth in this regulation. To avoid creating the impression that we have imposed a greater burden of proof, however, we have deleted the term "verified" from the final regulation.

The regulation published on July 31, 1992, applied only to those veterans who experienced full-body exposure to mustard gas while participating in secret tests of protective equipment during World War II. This amendment expands that regulation to cover any full-body exposure to mustard gas or Lewisite during military service, and it now applies to veterans exposed under battlefield conditions in World War I, those present at the German air raid on the harbor of Bari, Italy, in World War II, those engaged in manufacturing and handling vesicant agents during their military service, etc. By expanding the number of conditions, vesicant agents, and veterans covered, this amendment clearly represents a significant liberalization of the previous criteria.

Since July 1992 both VA and the Department of Defense (DoD) have initiated projects which will make it easier for veterans to establish entitlement to benefits under this regulation. DoD is searching its records for exposure data on mustard gas and Lewisite testing, to include the names of exposed military personnel, test protocols, etc., and will share the information it discovers with VA. VA has instituted a project, under the direction of the Environmental Epidemiology Service of Veterans Health Administration (VHA), to consolidate information about mustard gas testing as it becomes known into a central source. VHA officials have visited several locations where testing is known to have been conducted and/or where records might be found. The information resulting from these visits is available to VA regional offices as they attempt to establish the exposures of veterans who have filed claims.

There is an additional protection for veterans elsewhere in VA's regulations. If a claim is disallowed because exposure cannot be established but new evidence establishing exposure later becomes available from service

department records, VA will reopen the claim and authorize benefits based on the date of the original claim. (See 38 CFR 3.400(q)(2)).

One commenter suggested that the regulation should apply to oral ingestion of vesicants; another suggested that exposure via drop or patch testing should also be covered. A third commenter, a medical doctor, agreed with VA that the presumption should apply only to full-body exposures.

As explained in the preamble to the proposed rule, the literature upon which the NAS report is based covered animal studies and two types of human studies: (1) Industrial studies of workers in chemical factories which manufactured mustard gas; and (2) studies of soldiers exposed to mustard gas in warfare, primarily during World War I. The subjects of these studies were subjected to full-body exposure and NAS determined that the exposures of participants in chamber and field tests were equivalent to the full-body exposure of soldiers in World War I. Since the NAS report addressed only full-body exposures, in our judgment there is no basis for applying the presumption of service connection to those who received less extensive exposures.

Another commenter questioned why VA is restricting the presumption that acute nonlymphocytic leukemia is service-connected only to those veterans exposed to nitrogen mustard.

The NAS report found that the evidence indicated a causal relationship between the development of acute nonlymphocytic leukemia and exposure to nitrogen mustard only (See Table 12-1, Summary of Findings Regarding Specific Health Problems, Veterans at Risk: The Health Effects of Mustard Gas and Lewisite, NAS). Because of the use of nitrogen mustard in cancer chemotherapy, there is an extensive body of literature concerning the effects of nitrogen mustard in humans after systematic administration. This literature documents an increased incidence of acute nonlymphocytic leukemia in patients who were treated with nitrogen mustard as a chemotherapeutic agent. NAS noted, however, that as a therapeutic agent nitrogen mustard has a different systemic pharmacology than sulfur mustard, and that it is difficult to make quantitative extrapolations to the carcinogenicity of sulfur mustard or to which tumors sulfur mustard would be expected to produce. For those reasons, we have limited the presumption that acute nonlymphocytic leukemia is service connected to only those veterans exposed to nitrogen mustard.

Another commenter stated that the NAS report outlined and underscored a list of compelling ethical questions regarding the WWII tests of clothing and equipment that are now being ignored: why there was no formal long-term follow-up and medical monitoring in spite of clear evidence (as early as 1933) regarding delayed onsets of debilitating disease; why these subjects were treated so disrespectfully when they gave so much; and how many additional soldiers were physically harmed and morally abused from the end of World War II to 1975? The commenter decried the fact that these questions were not addressed by formal recommendations in the NAS report, although they caused the problems that have given rise to VA's efforts to expand compensation eligibility.

It is unquestionably beyond VA's ability to modify historical events by regulation; however, we believe that this regulation is an appropriate government response to these issues. VA recognizes that because the tests were secret and no follow-up examinations were conducted, veterans who took part in them are at a disadvantage when attempting to establish entitlement to compensation. This regulation addresses that situation by establishing a regulatory framework which recognizes that specific conditions are likely to result from exposure to vesicant agents and relieves veterans of the burden of submitting evidence to establish those associations in individual claims.

VA appreciates the comments submitted in response to the proposed rule which is now adopted with the corrections noted above, as corrected at 59 FR 10675, and with the following change to the effective date.

The proposed rule stated that the amendment would be effective on the date of publication of the final rule. In a letter of May 12, 1994, the Honorable John D. Rockefeller IV, Chairman of the Senate Committee on Veterans' Affairs, expressed his concern over the delay in publishing the final regulation as well as his belief that VA could establish an earlier effective date for the amendments. We share Senator Rockefeller's concern over the delay in the rulemaking process, and have therefore determined that it would be both appropriate and more equitable for this amendment to be effective January 6, 1993, the date of the decision to modify 38 CFR 3.316.

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory

Flexibility Act (RFA), 5 U.S.C. 601-612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604. This regulatory action has been reviewed by the Office of Management and Budget under Executive Order 12866.

The Catalog of Federal Domestic Assistance program numbers are 64.109 and 64.110.

#### List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Handicapped, Health care, Pensions, Veterans.

Approved: July 15, 1994.

Jesse Brown,  
Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 3 is amended as set forth below:

#### PART 3—ADJUDICATION

##### Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A, continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. Section 3.316 is revised to read as follows:

##### § 3.316 Claims based on chronic effects of exposure to mustard gas and Lewisite.

(a) Except as provided in paragraph (b) of this section, exposure to the specified vesicant agents during active military service under the circumstances described below together with the subsequent development of any of the indicated conditions is sufficient to establish service connection for that condition:

(1) Full-body exposure to nitrogen or sulfur mustard during active military service together with the subsequent development of chronic conjunctivitis, keratitis, corneal opacities, scar formation, or the following cancers: Nasopharyngeal; laryngeal; lung (except mesothelioma); or squamous cell carcinoma of the skin.

(2) Full-body exposure to nitrogen or sulfur mustard or Lewisite during active military service together with the subsequent development of a chronic form of laryngitis, bronchitis, emphysema, asthma or chronic obstructive pulmonary disease.

(3) Full-body exposure to nitrogen mustard during active military service together with the subsequent development of acute nonlymphocytic leukemia.

(b) Service connection will not be established under this section if the claimed condition is due to the veteran's own willful misconduct (See § 3.301(c)) or there is affirmative evidence that establishes a nonservice-related supervening condition or event as the cause of the claimed condition (See § 3.303).

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[CO27-1-5754a; FRL-5012-6]

### Approval and Promulgation of Air Quality Implementation Plans; Colorado; New Source Review and Prevention of Significant Deterioration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rulemaking.

**SUMMARY:** In this document, EPA is partially approving revisions to the State Implementation Plan (SIP) submitted by the Governor of Colorado on January 14, 1993. The submittal included revisions to the State's new source review (NSR) and prevention of significant deterioration (PSD) regulations, which were made to bring the State's regulations up-to-date with the amended Clean Air Act (Act) and the Federal regulations. EPA finds that the revised State rules meet the Federal nonattainment NSR permitting requirements of the Act for the State's carbon monoxide and ozone nonattainment areas. EPA also finds that the State regulations only partially meet the nonattainment NSR requirements of the Act for the State's PM-10 nonattainment areas because the State has not addressed the NSR requirements for new and modified major sources of PM-10 precursors in some of the State's PM-10 nonattainment areas. Last, EPA finds that the other revisions submitted are consistent with the amended Act and the Federal regulations in 40 CFR 51, and that the revisions correct previous EPA disapprovals promulgated in 40 CFR 52, Subpart G—Colorado.

**DATES:** This action will become effective on October 17, 1994 unless adverse or critical comments are received by September 19, 1994. If the effective date

is delayed, timely notice will be published in the **Federal Register**.

**ADDRESSES:** Comments should be addressed to Vicki Stamper, 8ART-AP, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, suite 500, Denver, Colorado 80202-2466. Copies of the State's submittal and other relevant information are available for inspection during normal business hours at the following locations: Air Programs Branch, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, suite 500, Denver, Colorado 80202-2466; and Air Pollution Control Division, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado 80222-1530.

**FOR FURTHER INFORMATION CONTACT:** Vicki Stamper, (303) 293-1765.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### *A. Nonattainment NSR Requirements of the Amended Act*

The air quality planning requirements for nonattainment NSR are set out in part D of title I of the Act. The EPA has issued a "General Preamble" describing EPA's preliminary views on how EPA intends to review SIPs and SIP revisions submitted under part D, including those State submittals containing nonattainment area NSR SIP requirements (see 57 FR 13498 (April 16, 1992) and 57 FR 18070 (April 28, 1992)). Because EPA is describing its interpretations here only in broad terms, the reader should refer to the General Preamble for a more detailed discussion of the interpretations of part D advanced in this notice and the supporting rationale. A brief discussion of the specific elements required in a State's NSR program is also included in Section II.B. of this notice.

EPA is currently developing rule revisions to implement the changes under the 1990 Clean Air Act Amendments in the NSR provisions of parts C and D of title I of the Act. The EPA anticipates that the proposed rule will be published for public comment in the fall of 1994. If EPA has not taken final action on States' NSR submittals by that time, EPA may generally refer to the proposed rule as the most authoritative guidance available regarding the approvability of the submittals. EPA expects to take final action to promulgate the rule revisions to implement the part C and D changes sometime during 1995. Upon promulgation of those revised regulations, EPA will review NSR SIPs to determine whether additional SIP

revisions are necessary to satisfy the requirements of the rulemaking.

Prior to EPA approval of a State's NSR SIP submission, the State may continue permitting only in accordance with the new statutory requirements for permit applications completed after the relevant SIP submittal date. This policy was explained in transition guidance memoranda from John Seitz dated March 11, 1991 and September 3, 1992.

As explained in the March 11 memorandum, EPA does not believe Congress intended to mandate the more stringent title I NSR requirements during the time provided for SIP development. States were thus allowed to continue to issue permits consistent with requirements in their current NSR SIPs during that period, or to apply 40 CFR 51, Appendix S for newly designated areas that did not previously have NSR SIP requirements.

The September 3, 1992 memorandum also addressed the situation where States did not submit the part D NSR SIP revisions by the applicable statutory deadline. For permit applications complete by the SIP submittal deadline, States may issue final permits under the prior NSR rules, assuming certain conditions in the September 3 memorandum are met. However, for applications completed after the SIP submittal deadline, EPA will consider the source to be in compliance with the Act where the source obtains from the State a permit that is consistent with the substantive new NSR part D provisions in the amended Act. EPA believes this guidance continues to apply to permitting pending final action on Colorado's NSR SIP submittal.

##### *B. Correction of Deficiencies in Colorado's NSR/PSD Regulations*

Aside from the new provisions of the amended Act, EPA has previously identified many deficiencies in the State's NSR and PSD permitting regulations. On June 28, 1985, EPA disapproved certain provisions in the State's NSR rules (see 50 FR 26734), and on February 13, 1987, EPA disapproved specific provisions in the State's PSD rules (see 52 FR 4622). In addition, after completing a thorough evaluation of the State's NSR and PSD regulations, EPA notified the State on February 17, 1988, of various other deficiencies in Regulation No. 3 and the Common Provisions Regulation.

On May 26, 1988, EPA issued a SIP call to the State due to the failure of many areas to attain the national ambient air quality standards (NAAQS) for ozone and carbon monoxide (CO). Pursuant to the SIP call, EPA required the State to correct all of the