ADDRESSES: Embraer Service Bulletin No. 110-27-076, Revision 01, dated July 2, 1985, applicable to the AD, may be obtained from Empresa Brasileira de Aeronautica S.A. (Embraer) Post Office Box 343-CEP 12.200 Sao Jose dos Campos, Sao Paulo, Brazil. Copies of the Service Bulletin are contained in the Rules Docket, FAA, Office of the Regional Counsel, Attention: Rules Docket No. 85-CE-30-AD, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106, and in the Central File Room, Atlanta Aircraft Certification Office, 1075 Inner Loop Road, College Park, Georgia 30337.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis A. Jackson, ACE-120A, Atlanta Aircraft Certification Office, Central Region, Federal Aviation Administration, 1075 Inner Loop Road, College Park, Georgia 30337; Telephone (404) 763-7407.

SUPPLEMENTARY INFORMATION: There have been two reports of failure of the elevator control rod tube on Embraer Models EMB-110P1 and EMB-110P2 airplanes which could result in loss of control of the airplane. One failure was caused by corrosion and the other by vibration induced by a failed elevator trim tab rod. As a result, Embraer has issued Service Bulletin 110-27-076, Revision 01, which provides instructions for the inspection and replacement of the elevator control rod tubes. The Centro Tecnico Aeroespacial (CTA) who has responsibility and authority to maintain the continuing airworthiness of these airplanes in Brazil has classified this Service Bulletin and the actions recommended therein by the manufacturer as mandatory to assure the continued airworthiness of the affected airplanes. On airplanes operated under Brazilian registration, this action has the same effect as an AD on airplanes certified for operation in the United States. The FAA relies upon the certification of the CTA combined with FAA review of pertinent documentation in finding compliance of the design of these airplanes with the applicable United States airworthiness requirements and the airworthiness and conformity of products of this design certificated for operation in the United States.

The FAA has examined the available information related to the issuance of Service Bulletin No. 110-27-076, Revision 01, and the mandatory classification of this Service Bulletin by the CTA. Based on the foregoing, the FAA has determined that the condition described therein is unsafe and may exist on all Embraer Models EMB-110P1 and EMB-110P2 airplanes certificated for operation in the United States.

Therefore, an AD is being issued requiring inspection and replacement of the elevator control rod tubes on these airplanes.

Because an emergency condition exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impractical and contrary to the public interest, and good cause exists for making this amendment effective in less than 30 days.

The FAA has determined that this regulation is an emergency regulation that is not major under Section 8 of Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it, when filed, may be obtained by contacting the Rules Docket under the caption "ADDRESSES" at the location identified.

List of Subjects in 14 CFR Part 39

Air transportation, Aviation safety, Aircraft, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the FAR as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By adding the following new AD:

Empresa Brasileria De Aeronautica S.A. (Embraer): Applies to Models EMB-110P1 and EMB-110P2 (all serial numbers) airplanes certificated in any category which have aluminum elevator control rod tubes installed.

Compliance: Required as indicated, unless already accomplished.

To prevent failure of the elevator control rod tube, accomplish the following:

(a) Within the next 50 hours time-in-service after the effective date of this AD, visually inspect the elevator control rod tubes, P/N 4A-500-10-09-01, for evidence of corrosion or cracks. If corrosion or cracks are found, prior to further flight replace the control rod tube in accordance with Embraer Service Bulletin (S/B) No. 110-27-076, Revision 01, dated July 2, 1985.

(b) Within 150 hours time-in-service or 30 (thirty) days, whichever occurs first, after the effective date of this AD, replace both left and right elevator aluminum control rod tubes P/N 4A-500-10-09-01 with steel control rod tubes P/N 110-500-10-00-04-01. Reidentify the elevator control rod assembly with the new P/N 110-500-10-00-09.

(c) Airplanes may be flown in accordance with Federal Aviation Regulation 21.197 to a location where the Ad may be accomplished.

(d) An equivalent method of compliance with this AD may be used if approved by the Manager, Atlanta Aircraft Certification Office, FAA, 1075 Inner Loop Road, College Park, Georgia 30337; Telephone (404) 763-7428.

All persons affected by this directive may obtain copies of the documents referred to herein upon request to Embraer, Post Office Box 343 CEP 12.200 Sao Jose Dos Campos, Sao Paulo, Brazil, or FAA, Office of Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

This amendment becomes effective on August 30, 1985.

Issued in Kansas City, Missouri, on August 16, 1985.

Edwin S. Harris,

Director, Central Region.

[FR Doc. 85-20263 Filed 8-23-85; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 76-CE-6-AD; Amdt. 39-5124]

Airworthiness Directives; Cessna Models 210, 210A, 210B, 210C, 210D, 210E, 210F, 210G, 210H, 210J, T210F, T210G, T210H, and T210J Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment revises Airworthiness Directive (AD) 76-14-07 Amendment 39-2778 applicable to Cessna Models 210, 210A, 210B, 210C, 210D, 210E, 210F, 210G, 210H, 210J, T210F, T210G, T210H, and T210J airplanes to permit the use of newly designed main landing gear saddles on certain models. This revision will thus provide an alternate means of compliance with AD 76-14-07.

DATE: *Effective Date:* September 27, 1985.

Compliance: As prescribed in the body of the AD.

ADDRESS: Parts availability information may be obtained from the Cessna

Aircraft Corporation Customer Service, P.O. Box 1521, Wichita, Kansas 67201.

FOR FURTHER INFORMATION CONTACT:
Mr. Douglas W. Haig, Aerospace Engineer, FAA, ACE-120W, 1801 Airport Road, Room 100, Wichita, Kansas 67209; Telephone 316-946-4409.

SUPPLEMENTARY INFORMATION:
Airworthiness Directive 76-14-07 Amendment No. 39-2778 applicable to certain Cessna Model 210 series airplanes requires inspection and/or replacement of the mail landing gear saddle. Subsequent to the issuance of this AD, the manufacturer designed new main landing gear saddles identified by part numbers 1294151-1 and 1294151-2 applicable to the Models 210B, 210C, 210D, 210E, 210F, 210G, 210H, 210J, T210F, T210G, T210H, and T210J airplanes. Therefore, the FAA is revising AD 76-14-07 to allow the use of the new style main landing gear saddles.

This amendment updates the AD by incorporating presently available information or corrective action, providing an equivalent level of safety which was not available to the FAA at the time of original issuance. It imposes no additional burden on any person. Therefore, notice and public procedure hereon are unnecessary and contrary to the public interest.

The FAA has determined that this document involves an amendment which provides an alternative means of compliance consistent with current improved parts replacement. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291 and (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation is not required). A copy of it when filed, may be obtained by contacting the Rules Docket under the caption "ADDRESSES" at the location identified.

List of Subjects in 14 CFR Part 39

Air transportation, Aviation safety, Aircraft, Safety.

Adoption of the Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the FAR as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

2. By revising AD 76-14-07 as follows:

Revise paragraph F. to read as follows:

An equivalent means of compliance with this AD may be used if approved by the Manager, Aircraft Certification Office, Federal Aviation Administration, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; Telephone (316) 946-4400.

Add paragraph G. as follows:

Installation of main landing gear saddles part numbers 1294151-1 and 1294151-2 in lieu of part numbers 1241423-1 and 1241423-2 constitutes an equivalent means of compliance for this AD.

This amendment revises AD 76-14-07, Amendment 39-2778.

This amendment becomes effective September 27, 1985.

Issued in Kansas City, Missouri, on August 13, 1985.

Edwin S. Harris,

Director, Central Region.

[FR Doc. 85-20363 Filed 8-23-85; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 84F-0040]

Indirect Food Additives: Paper and Paperboard Components

Correction

In FR Doc. 85-18181 appearing on page 31165 in the issue of Thursday, August 1, 1985, make the following correction:

In the third column, in the "**Authority**", first line, "202" should read "201".

BILLING CODE 1505-01-M

VETERANS ADMINISTRATION

38 CFR Parts 1 and 3

Adjudication of Claims Based on Exposure to Dioxin or Ionizing Radiation

AGENCY: Veterans Administration.

ACTION: Final rules.

SUMMARY: The Veterans Administration (VA) has adopted the following regulations to implement the "Veterans' Dioxin and Radiation Exposure Compensation Standards Act," Pub. L. 98-542 (Oct. 24, 1984). The Act required that the VA conduct rulemaking regarding its guidelines for the adjudication of compensation claims based upon disabilities or deaths of certain veterans who, while in military service, were exposed to ionizing radiation or herbicides containing dioxin. The stated purpose of the Act is to ensure compensation for "veterans who were exposed during service in the Armed Forces in the Republic of Vietnam to a herbicide containing dioxin or to ionizing radiation in connection with atmospheric nuclear tests or in connection with the American occupation of Hiroshima or Nagasaki, Japan, for all disabilities arising after that service that are connected, based on sound scientific and medical evidence, to such service."

DATES: These rules are effective September 25, 1985, with the exception of § 3.813 which is effective October 1, 1984, as required by law.

FOR FURTHER INFORMATION CONTACT:
Robert M. White, Chief, Regulations Staff, Compensation and Pension Service, Department of Veterans Benefits (202) 389-3005.

SUPPLEMENTARY INFORMATION: On pages 15848 through 15855 of the **Federal Register** of April 22, 1985, the VA published proposed amendments to title 38, Code of Federal Regulations, on the adjudication of claims based on exposure to dioxin or ionizing radiation. Included in those proposed amendments were a new § 1.17 on evaluation of studies relating to health effects of dioxin and radiation exposure, a revision of § 3.102 giving the benefit of reasonable doubt to claimants, and new §§ 3.311a, 3.311b and 3.813 dealing with claims based on dioxin exposure, claims based on radiation exposure and claims for interim benefit. Interested persons were given until July 22, 1985, to submit comments, suggestions or objections to the proposed rules.

The VA received a number of comments on these proposed rules from a variety of sources. The commenters included the Chairman and the Ranking Minority Member of the House Veterans' Affairs Committee, the Ranking Minority Member of the Senate Veterans' Affairs Committee, the junior Senator from Massachusetts, the Congressman from the Eighth District of Georgia, the Congressman from the Fourth District of Massachusetts, the U.S. Army and Joint Services Environmental Support Group, the Department of Justice, the Defense Nuclear Agency, the Environmental

Protection Agency, the Federal Emergency Management Agency, the Nuclear Regulatory Commission, the Department of the Navy, The Public Health Service, The Cabinet Council Agent Orange Working Group, Paralyzed Veterans of America, American Veterans of World War II, Korea and Vietnam, Veterans of Foreign Wars of the United States, Disabled American Veterans, The American Legion, National Association of Radiation Survivors, National Association of Atomic Veterans, Vietnam Veterans of America, American Ex-Prisoners of War, Military Order of the Purple Heart, American College of Radiology, American Board of Health Physics, the Advisory Committee on Former Prisoners of War, an epidemiologist from the School of Public Health at the University of California, Berkeley, Office of Commissioner of Veterans Services for Massachusetts, and seven members of the general public.

The VA has also received recommendations from the Veterans' Advisory Committee on Environmental Hazards (and the Scientific Council thereof) with respect to the proposed rules. Because its first meeting could not be held until April 22, 1985, the Environmental Hazards Committee did not participate in development of the proposed rules. The Committee did, however, review the proposed rules after publication and has made recommendations which were considered together with other comments in development of the final rules as required by Pub. L. 98-542.

The comments and recommendations with respect to each proposed rule have been summarized and are set forth below together with the actions and/or responses of the VA.

Comments and Recommendations

Section 1.17 Study evaluations.

One commenter strongly urged that specific standards be established and published to "ensure that all diseases that may be associated with dioxin will be evaluated in a uniform, consistent manner," noting that "other federal agencies have been using specific standards to evaluate scientific evidence concerning the health risks associated with chemicals like dioxin." The commenter further recommended that the VA use such "risk assessment principles" rather than establishment of cause and effect in determining the relation between exposure to dioxin and diseases.

The concept of risk assessment does not intrinsically differ from a cause-and-effect analysis. Risk assessment allows for a quantification of the possibility or probability that a given effect is attributable to a past event, or that a present event will give rise to a future consequence. Hence we do not regard this comment as setting forth a useful distinction.

The proposed VA regulations are intended to be workable guidelines that fulfill the intent of Pub. L. 98-542, which deals with determining the connection between present disabilities and past exposures rather than regulation of future exposures. It is possible to be much more consistent in applying principles of risk assessment where the possible future consequences of current exposure are estimated, usually in order to appropriately reduce or eliminate the exposure and thereby to control its consequences. The two situations are roughly analogous to the court procedure that determines the relation between present consequences and past acts on the one hand and, on the other, the evaluation of a hazardous condition in order to eliminate it by law or regulation and so to avoid future harm.

The Environmental Hazards Committee recommended that the words "statistically and epidemiologically valid" be substituted for the words "statistically significant" in proposed § 1.17(b)(1). The Committee noted that a study may present statistically significant findings and still not be a valid study. In this regard the Committee believed that statistical and epidemiological validity provided a better guideline for use in evaluating scientific studies.

The VA understands the rationale of the Committee in making this recommendation but notes the language of section 5(b)(1)(A) of Pub. L. 98-542 which requires the Administrator, in evaluating scientific studies, to take into account whether study results are statistically significant. Because statistical and epidemiological validity is not synonymous with statistical significance, the VA cannot adopt the recommended substitution. However, the statistical and epidemiological validity of a study's findings can be included in the views of the appropriate panel of the Committee's Scientific Council and, in that way, receive consideration under § 1.17 as proposed.

The Committee noted that the words "statistically significant" were also contained in the definitions of "sound scientific evidence" in proposed §§ 3.311a(a)(3) and 3.311b(c)(3) and recommended the same substitution of the words "statistically and epidemiologically valid." Since the content of these definitions is not mandated by law, we have appropriately amended the affected sections to implement the Committee's recommendation.

One commenter suggested that the term "statistical significance" should be defined in this rule while others suggested that the terms "statistical significance" and "peer review" should not be used to evaluate adjudication procedures and that they were simply additional methods for denying claims. These terms apply to the evaluation of scientific and medical studies and not to the adjudication of individual claims. The terms are well-understood by the scientific and medical communities as well as by those charged with the responsibility for evaluating the results of studies. The meaning of these terms was discussed in the preamble of the proposed rule and need not be repeated here nor included in the final rule.

One comment was to the effect that the rules should set "specific standards for evaluating studies," and specify a formula against which results of studies can be measured in order to determine if evidence is sufficient to justify findings of service-connection. It was suggested this would lend credibility to the process, and that the law requires no less.

The new law requires that, in general, these regulations include "guidelines and (where appropriate) standards and criteria." More specifically, with respect to study evaluations, the law requires issuance of "guidelines." Specific standards are not required, and would be inappropriate.

The proposed rule lists 5 factors to be considered in evaluating studies. To convert these to hard standards would require assignment of both rigid tolerance limits and specific relative weights to each factor. Such an all-purpose formula would not permit the necessary flexibility that reasoned policy-making requires. For example, in certain cases it may be extremely important that the differences between study and control groups are "statistically significant," but in others less so if, for example, the findings are not particularly "applicable to the veteran population of interest." Also, creating a hard formula in an informational vacuum would be extremely unwise. If, for example, a decision were now made to recognize as service-connected any diseases which studies show appear with a 10 percent greater frequency among veterans exposed to certain herbicides, should a decision to award benefits be foreclosed if evidence eventually shows only an 8 or 9 percent greater incidence? Certainly

other factors, including the severity of the resulting disablement, must come into play in making those sorts of policy choices.

It was recommended that VA apply its "reasonable doubt" policy to the evaluation of studies. The reasonable doubt policy, discussed in the next section, has always been a rule of claims adjudication. While we consider that sound scientific findings should be applied in the manner most beneficial to claimants, it would not be appropriate to assess the soundness of data in the manner proposed.

Section 3.102 Reasonable doubt policy.

We also received several comments on the proposed reformulation of the "reasonable doubt" rule, 38 CFR 3.102. One comment expressed concern that the revision would tend to shift the burden of proof to the claimant, especially in view of certain deletions. Another requested retention of the current characterization of the term "reasonable doubt." Several objected to the deletion of a reference to the rule's applicability in cases where official records cannot be located. Most of these commenters urge complete retention of the rule's current text so as not to impair the "working understanding" of the reasonable doubt rule that has developed over time. With one minor clarifying modification, we have decided to retain the current text of § 3.102 as urged by these commenters.

As observed in the Notice of Proposed Rulemaking, restatement of the "reasonable doubt" policy was proposed in keeping with the congressional reformulation of section 2(13) of Pub. L. 98–542. Review of the regulatory history of the "reasonable doubt" policy confirms our view that section 2(13) is a precise and coherent statement of this policy. The "reasonable doubt" policy goes back to the post-Civil War era when determining the extent of a veteran's disability—today called "rating"—was done on a case-by-case basis by Bureau of Pension physicians without reference to uniform guidelines such as now appear in the Rating Schedule (38 CFR Part 4). For example, in an 1899 Bureau of Pension report, this statement appears: "[s]o far as it was permissible under the laws as they exist and the established practice of the Bureau, the benefit of any doubt has been resolved in favor of the claimant." Report of Medicine Division, Bureau of Pensions, July 26, 1899.

Following World War I, rating schedules were promulgated. The earliest schedule of which we have record is dated September 22, 1921, and its preface contains this statement: "The law must be administered by its broadest interpretation and ratings of disability should be made as generous as possible in consistency with the facts. Wherever a question of doubt arises the benefit of such doubt must be given to the claimant." The preface goes on to explain the policy's application in two situations, rating and determining service connection. In rating, if the medical evidence points to two possible ratings, the higher should be assigned until it is clearly shown not to be justified. (We continue this rule today, *see* 38 CFR 4.7.) In determining service-connection, even though a disability is not clearly established as of service origin, it should be so considered if this would be reasonable in the light of medical experience and judgment.

In 1924, the foundation for the present text of § 3.102 was laid in a Veterans Bureau General Counsel opinion involving a World War I veteran who has applied for compensation for a psychoneurotic disability. There was credible evidence for and against the claim. The General Counsel outlined the "benefit of the doubt" policy and explained it was not to be applied if the truth could be established by a preponderance of the evidence; on the other hand, proof "beyond a reasonable doubt" was never required. In 1930, the policy statement appearing in the schedule for Rating Disabilities for that year was revised to reflect the General Counsel opinion. As so revised, it was the predecessor of 38 CFR 3.102.

These commenters suggest that, because Congress did not specifically mandate this revision, it should not be made. Section 5(a)(2) of Pub. L. 98–542 requires these new regulations to include provisions that ensure, with respect to exposure claims, that "the policy of the United States described in section 2(13) (of Pub. L. 98–542) is carried out." This is an express directive to include in the new regulations assurance that this policy applies to these claims. This could be accomplished either by restating the policy in the new regulations or providing a cross-reference to 38 CFR 3.102. The latter means, being simpler, was selected. To avoid two separate formulas for the same policy, revision of § 3.102 was proposed. No substantive change in the policy was intended. Rather, we hoped that simplifying the rule's text would help to avoid misconception and misuse. Among other matters, § 3.102 states that information in support of a claim must be sufficient to persuade an impartial person of its validity. This is a common-sense rule of thumb that differs sharply from the degree of evidence required for a criminal conviction. When claims are denied, however, the Agency is sometimes wrongly charged with requiring proof "beyond a reasonable doubt." Other times the claimant, on appeal, urges application of the reasonable doubt policy to his or her claim even though the claim was denied for a clear lack of sufficient evidence to support it.

As indicated above, we have determined to retain § 3.102's present text with one clarification. This clarification provides a guideline as to when the reasonable doubt policy is to be followed. In situations where the evidence for or against the claim is clearly preponderant, this policy does not apply. It should be carefully adhered to, however, when there is credible evidence on both sides of a material issue.

This modification should not be interpreted as "shifting the burden of proof" to the claimant.

The adjudication process at the VA is a truth-finding process in which both the claimant and the Agency have responsibility for locating and developing evidence pertinent to the claim, *see* 38 CFR 3.103(a). The concept of "burden of proof" in the courtroom sense is inconsistent with the nonadversarial, *ex parte* nature of VA adjudicatory proceedings.

One commenter objected to the revised rule and also proposed certain additions to the current text. First, it was suggested adjudicators should be required to accept a veteran's testimony as evidence. Second, it was contended that a veteran's unsupported testimony, if credible, should be accepted as dispositive if there is no "credible, contradictory, authenticated documentary" evidence in opposition. Neither suggestion requires changes in current regulations. Under VA rules, claimants' testimony is considered evidence and is part of the evidentiary record under 38 CFR 3.103(c). Second, nothing in current VA rules precludes the awarding of benefits based upon credible testimonial evidence.

Section 3.311a Dioxin rule

One commenter stated that "sufficient data exists for the identification of veterans exposed to dioxin" and that requests for certification of dioxin exposure should be forwarded to the Department of Defense in a manner similar to the procedures for requesting radiation dose information. The VA's longstanding policy of presuming dioxin exposure in the cases of veterans who served in the Republic of Vietnam

during the Vietnam era is based on the many uncertainties associated with herbicide spraying during that period which are further confounded by lack of precise data on troop movements at the time. While it may be possible to approximate areas where herbicides were sprayed, it would be extremely difficult to determine with an acceptable degree of precision whether an individual veteran was exposed to dioxin. Accordingly, the policy of presumed exposure as stated in § 3.311a(b) will remain unchanged.

Other commenters suggested that, in order to avoid misinterpretation by rating boards, the term "sound medical and scientific evidence" should be clarified relative to the term "sound medical principles" because the latter was a cornerstone of claims adjudication. While the term "sound medical principles" may have been used in other VA publications on claims adjudication, we have been unable to identify that precise term elsewhere in 38 CFR Part 3 (except in the limited context of tuberculosis cases). For that reason, and because the terms "sound medical evidence" and "sound scientific evidence" are clearly defined in §§ 3.311a and 3.311b, we do not believe that rating boards will misinterpret them.

One suggestion was made that a paragraph be added to make clear that service-connection is a temporal, rather than causal, relationship. However, there are both temporal and causal components of any finding of service-connection.

The temporal relationship which must be shown is that injury or disease was incurred or aggravated coincident in time with a veteran's military service. (Statutory presumptions make this literally unnecessary in certain cases.) There must, however, also be a showing that disability or death resulted from—was caused by—such an injury or disease. Strictly speaking, it is not injuries or diseases which are service-connected, but the disabilities or deaths resulting therefrom.

Thus, where it is shown that a veteran was exposed to potentially injurious radiation in service, and it is contended cellular injury sustained at that time gave rise to development of cancer after a latent period of perhaps 10 years, the question of causation of the disease and resulting disability or death by the insult or injury becomes the central issue. Accordingly, this suggestion has not been adopted.

Additional comments indicated a preference for affirmative wording in §§ 3.311a(c) and (d) with regard to diseases which may or may not result from dioxin exposure in order to avoid confusion and to eliminate the necessity for § 3.311a(g). While we endeavor to couch our regulatory amendments in positive terms, where appropriate, there are instances when negative language is more desirable. For example, sound medical and scientific evidence has not established a relationship between porphyria cutanea tarda (PCT) and dioxin exposure. That is a negative fact and should be stated in the negative. This does not mean that service connection cannot be established for PCT on other grounds, and it is precisely for that reason that § 3.311a(g) was proposed. The thrust of this comment was that rating boards should be alert to other rules by which service-connection can be established. We are in complete agreement and will include a cross-reference to paragraph (g) at the end of paragraph (c). For additional emphasis we will include a specific paragraph on this subject in the transmittal sheet that will accompany these regulations when they are sent to adjudication personnel.

In this same vein three commenters and the Veteran's Advisory Committee on Environmental Hazards were concerned that some claims of service-connection for chloracne may be prejudiced by an initial misdiagnosis within the applicable three-month period. This situation is already covered by 38 CFR 3.307(c) which provides authority to reconsider earlier manifestations of a disease once a definite diagnosis is established. To further emphasize this point, however, a cross-reference to § 3.307(c) will be included in § 3.311a(c), and details will be provided in the regulations transmittal sheet to alert adjudication personnel to the existing regulatory provisions that permit a skin condition, initially misdiagnosed, to be considered as a *manifestation* of a later diagnosed case of confirmed chloracne.

One commenter suggested the three-month period should be extended to one year because of the in-service diagnostic uncertainties. A veteran incurring chloracne within one year of departure from Vietnam would be eligible for interim benefits under new § 3.813, if disabled. We will take this comment under advisement pending a review of our claims experience under § 3.813.

A commenter who is a scientist, and others who are not, objected that the **Federal Register** notice of proposed rulemaking did not report fully all information and scientific investigations of the possible relationship between phenoxy herbicide exposure and soft tissue sarcomas. They imply that a cause-and-effect relationship has been demonstrated. In addition, these commenters would add malignant lymphoma to the list of conditions they believe can result from phenoxy herbicide exposure, as well as soft-tissue sarcomas developing within 20 years of exposure.

Although not all the investigations mentioned by these commenters were discussed in the Preamble to the notice of proposed rulemaking, all published studies bearing on the issues of concern and other information were carefully considered in the development of the proposed regulations. In addition, the Environmental Hazards Advisory Committee agrees with the Administration's conclusion that the "jury is still out" concerning a causal association between dioxin exposure and cancer such as soft tissue sarcomas and malignant lymphoma.

Review by the Advisory Committee and the Administration of studies like those referred to by the commenters will continue. If, at a later time, sound medical and scientific evidence supports inclusion of soft tissue sarcomas and/or malignant lymphoma, amendment of these regulations will promptly follow.

Four commenters also recommended that porphyria cutanea tarda be included among diseases caused by dioxin, but advert to no evidence not previously considered. Review of the available information does not now disclose sound medical and scientific evidence sufficient to justify that inclusion. As with the malignancies, later information will be carefully evaluated and these regulations amended as warranted.

Section 3.311b Radiation rule.

Comments were received indicating that the VA was proposing a more restrictive rule with regard to radiation dose estimates than that previously in effect. Whereas the prior rule specified a policy of conceding the highest exposure level reported by the Department of Defense when a range of doses was supplied or estimated for the veteran's unit or when the overall estimated exposure level of the veteran's unit exceeded the documented reading for the veteran, proposed § 3.311b(a) provides simply that dose data will be obtained from the Department of Defense.

VA's proposed rule was published before it was known how the Defense Nuclear Agency (DNA) would modify its procedures for reporting exposure and dose information to the VA. Pub. L. 98-542 required DNA to issue regulations containing requirements for the uniform reporting of dose estimates to the VA. Under regulations proposed on May 9,

1984 (50 FR 19538–39), DNA will report to the VA upon request a veteran's recorded radiation exposure or, if recorded dosimetry data is unavailable or incomplete, the dose reconstruction for the most probable dose, with error limits, if available. In most cases, therefore, under DNA's proposal a single value for a veteran's radiation exposure level will be reported. There will, however, be situations where information sufficient for dose reconstruction cannot be obtained and DNA will furnish the VA a range of doses to which the veteran may have been exposed given the circumstances of the exposure which can be ascertained. In such cases the VA will maintain its present policy of presuming exposure at the highest level of any dose range reported by DNA. Accordingly, we have amended proposed § 3.311b(a) to incorporate this policy.

Objections were also raised with regard to the provisions of proposed § 3.311b(b) which call for review, by the Chief Medical Director of radiation claims meeting the initial review criteria. This referral was said to be tantamount to a transfer of rating jurisdiction from the Department of Veterans Benefits to the Department of Medicine and Surgery.

While no such transfer of jurisdiction was contemplated, we recognize a need to prevent any such misunderstanding. Accordingly, paragraphs (b), (c), (d) and (f) of § 3.311b have been appropriately amended to provide for referral of all claims meeting the initial review criteria to the Chief Benefits Director for further consideration with the option of requesting an advisory medical opinion from the Chief Medical Director. These changes will leave no doubt as to the jurisidiction of the Department of Veterans Benefits over service-connection determinations.

Two commenters pointed out that it cannot be assumed a veteran was not exposed in service just because a DD Form 1141 does not exist. We agree, and have revised § 3.311b(a)(2)(iii) to make clear that a search should be made for any records that may evidence exposure.

Comments were also received which questioned the periods of time in § 3.311b(b)(4) (i) and (ii) during which certain cancers must have become manifest in order to be further considered as having resulted from prior exposure to ionizing radiation. It was noted that under 38 U.S.C. 301 and 312, service-connection may be established for cancers which become manifest within one year of discharge from active duty and that under the proposed rule service-connection for leukemias and bone cancer could be denied if a veteran were discharged immediately following radiation exposure and developed one of those cancers more than one but less than two year later.

In addition, the Environmental Hazards Committee reviewed the epidemiologic basis for these time periods and, while it generally agreed they were adequate for most cases, recommended that further consideration of service-connection be accorded to leukemias (other than chronic lymphatic leukemia) and bone cancer which become manifest more than one year but less than thirty years after exposure, and that further consideration of service-connection be accorded to other radiogenic cancers (as defined in § 3.311b(b)(2)) which became manifest more than five years after exposure. Based on these comments and recommendations we have amended § 3.311b(b)(4) (i) and (ii) to provide further consideration of service-connection for leukemias (except chronic lymphatic leukemia) and bone cancer which become manifest within 30 years after radiation exposure and for other forms of radiogenic cancer which become manifest 5 years or more after exposure.

The period of 30 years after exposure within which leukemias must become manifest in order to be considered due to that exposure has been questioned. Data on the Japanese survivors indicate a pronounced decrease in the excess deaths from leukemia among the Japanese survivors by the end of the first decade after the nuclear bomb exposures. The rate fell further during the next decade, and thereafter the death rate was less than one per million person-year rad above that in the comparable Japanese population. The 30-year limit, therefore, seems reasonable, but the Advisory Committee will be asked to review this information.

Several commenters questioned the omission of polycythemia vera from the list of radiogenic diseases. Review of the reports from test "Smokey" and from Japan has been judged not to present sufficient evidence to warrant a conclusion that exposure to radiation encountered by American veterans resulted in the later development of polycythemia vera. The preliminary "letter" regarding the condition in British veterans contains incomplete information in a form that does not provide grounds for a sound decision. A second letter (E.G. Knox et al. Lancet, Oct. 8, 1983, pp. 856–857) by the same authors cautions, in the light of further data, "There is no longer an excess of reported deaths of RES neoplasms." Further information about these observations or other studies will be reviewed by the Advisory Committee and the Administration. These regulations will be amended promptly if the review establishes that this can be done on the basis of sound medical and scientific evidence.

Several recommendations were made to include other cancers as well as some non-cancerous diseases. On recommendation of the Advisory Committee, the Administrator has expanded the list of radiogenic cancers in the proposed regulation of April 22 (§ 3.311b(b)(2)) to include cancers of the esophagus, stomach, colon, pancreas, kidney, urinary bladder and salivary gland. The Committee did not advise expanding further the list of "radiogenic diseases" at present.

In light of the continuing study of nuclear blast survivors in Japan, however, multiple myeloma has also been included. The Advisory Committee will be asked to consider the addition of non-malignant thyroid nodular disease, posterior subcapsular cataracts and premature aging as radiogenic.

The Committee and the Administration will consider new information and the Administrator will amend the regulations to include additional diseases when sound medical and scientific evidence to do so is available.

A total of eight commenters urged the VA to consider individuals certified in the field of health physics as "credible sources" from whom claimants could obtain independent radiation dose estimates in support of their claims. One commenter also suggested that certifying groups would not describe themselves as "governing bodies." We concur with these comments and have appropriately amended § 3.311b(a)(3)(ii) to define "credible sources" as persons certified by an appropriate professional body in the field of health physics, nuclear medicine or radiology.

One commenter indicated that some individuals who are highly qualified to calculate dose estimates may not be certified by any group but should not be excluded from consideration as a "credible source." It was suggested that certification could be a qualifying factor but not a necessary one. Because the law requires independent dose estimates to be calculated by credible individuals, there is clearly a requirement that some restrictions be placed on the acceptability of the evidence that would automatically trigger referral to an independent expert selected by the Director of the National Institutes of Health. Nothing in the proposed rule precludes VA from

referring other estimates for reconciliation if that appears to be warranted, and we believe the definition, as amended, provides a wide variety of sources which claimants may employ to challenge official dose estimates.

Two comments were received which recommended that provision be made for permitting DoD to comment on the dose estimate from a claimant's "credible source" before the matter is submitted to NIH to reconcile material differences. The proposed rule also does not preclude that, and we believe it is unnecessary to make it a routine requirement. If it is clear from the two estimates that significantly different data or assumptions were employed, VA may request clarification from the estimator (either DoD or the unofficial source) of the underlying information. These differences are then to be reviewed by an independent expert. While the DoD estimate is always available to a claimant, and VA may request DoD's appraisal of the estimate supplied by the claimant's source, we believe it is unnecessary to routinely require review of either estimate.

The Scientific Council of the Veterans' Advisory Committee on Environmental Hazards recommended that the radioepidemiological tables developed by the Department of Health and Human Services be used as a starting point in considering claims but, in view of the uncertainties associated with the tables, should not be the final determinative in granting or denying service-connection. Use of the tables was supported by one other commenter.

The VA has formally requested the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) of the Federal Coordinating Council for Science, Engineering and Technology (FCCSET) to assess the utility of employing the tables in some fashion to adjudicate compensation claims. That assessment is expected to take several months. In addition, comments were received from veterans' groups and others expressing serious reservations about the formal adoption of the tables by VA, and some advocates for individuals exposed to ionizing radiation have recently testified strongly before Congress against use of the tables in adjudicating claims. We have decided to withhold final judgment on use of the tables until CIRRPC has made its assessment.

Several comments were received which were critical of the radiation dose data supplied to VA by the military services. Some even suggested it was so unreliable, in terms of underestimating the doses sustained, that it should not be used at all.

As the official repository for Government records concerning the military's participation in the atmospheric tests and occupation of postwar Japan, the Department of Defense (DoD) is in possession of invaluable dosimetry data of direct relevance to the issue of exposure. For several years, the Defense Nuclear Agency has been DoD's executive agent for the Nuclear Test Personnel Review program, a major function of which is to assist VA in verifying claimants' participation in the tests and supplying either film badge readings for them or estimates of doses when the former do not exist. The "NTPR" effort has also included a detailed research program to recover all data pertaining to possible exposure of the occupation forces.

VA would certainly be remiss if it did not routinely draw upon this storehouse of data in weighing the merits of claims filed by former participants. The Congress has tacitly acknowledged the propriety of this practice, and has specified in Pub. L. 98-542 what form the reported dose estimates from DoD should assume. The VA's proposed rule specifies that "known limitations in the dosimetry devices employed or the methodologies employed" in the dose estimation shall be taken into account, as will be dose estimates from other, credible sources. Thus, VA has not revised its proposed rule in response to these particular comments.

One commenter suggested that specific weights should be assigned to the factors for consideration in evaluating claims, and that the officials responsible for the initial review of the claims should be indentified. The former is not possible to do in any way that would be scientifically valid and afford VA the flexibility necessary to take into account facts unique to each claim. Also, because adjudication personnel at VA regional offices have responsibility for all initial reviews of claims for veterans' or survivors' compensation benefits, it is not necessary to specify that fact in this context.

Another commenter asked that VA refer claims to outside consultants for opinions even if it determines there is no reasonable possibility of a relationship between disability and exposure. This is unnecessary and would only tend to delay the disposition of clearly undeserving claims.

Another suggestion was made that more guidance is required with respect to the "willful misconduct" and "supervening cause" provisos in paragraph (g) of this rule. The former is already defined at 38 CFR 3.1(n), and the latter concept is also one with which adjudication personnel are already familiar (see 38 CFR 3.307(d)). Finally, the same commenter suggested that strict guidelines be established regarding claims-processing time. Because no two claims are alike, and the needs for evidentiary development and analysis vary so widely, this simply is not feasible for this or any other class of disability claims.

Another suggestion was made that VA require all claimants to be on a "radiation registry." VA has for some time maintained statistics with respect to all claims decided in which it has been contended that radiation exposure in service resulted in disability or death.

Two commenters suggested the rules should make clear that a claimant can appeal an adverse determination. The appeals process is already addressed elsewhere in VA regulations (see 38 CFR Part 19) which specify that all claimants are to be advised of their appellate rights.

Finally, with regard to the provisions for referral to outside consultants for additional medical opinions in some cases, it was suggested that the regulations be specific as to who shall pay such consultants, out of which appropriations payments will be made and how much the payments shall be. In addition, one agency expressed concern as to how the experts were to be compensated. These administrative details are covered by current budgetary procedures and are not appropriate for inclusion in adjudication regulations.

Section 3.813 Special interim benefits.

No comments, suggestions or objections were received with regard to this proposed rule.

Other Comments

One commenter expressed the opinion that some benefits should be available to the women and children who have suffered because of a veteran's exposure to dioxin or ionizing radiation. Public Law 98-542 does not, however, authorize direct benefits to the classes of persons about which the commenter was concerned. While there are no programs for compensating spouses and children directly because of a living veteran's service-connected disability, there is a program of dependency and indemnity compensation for surviving spouses and children of veterans who die as a result of service-connected disabilities, and there are additional allowances payable to living disabled veterans with eligible dependents.

All comments will be shared with the Veterans Advisory Committee on Environmental Hazards, including one relating to concerns about the committee's duties and functions.

We appreciate the comments and the suggestions of those concerned individuals and organizations that responded to publication of the proposed rules, and we acknowledge the significant contributions of the Veterans' Advisory Committee on Environmental Hazards in developing these final rules. The proposed rules are, therefore, adopted with the amendments noted above and minor conforming amendments of a technical nature. The final rules are set forth below.

Regulatory Evaluations

The Administrator hereby certifies that these regulations do not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Therefore, pursuant to 5 U.S.C. 605(b), these regulations are exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604. The reason for this certification is that these regulations impose no regulatory burdens on small entities, and only claimants for VA benefits will be directly affected.

In accordance with Executive Order 12291, Federal Regulation, the VA has determined that these proposed regulations are non-major for the following reasons:

(1) They will not have an effect on the economy of $100 million or more;

(2) They will not cause a major increase in costs or prices;

(3) They will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 38 CFR Part 3

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

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

Approved: August 20, 1985.

Harry N. Walters,

Administrator.

PART 1—[AMENDED]

1. Part 1 is amended by adding a new § 1.17 to read as follows:

§ 1.17 Evaluation of studies relating to health effects of dioxin and radiation exposure.

(a) From time to time, the Administrator shall publish evaluations of scientific or medical studies relating to the adverse health effects of exposure to 2,3,7,8 tetrachlorodibenzo-p-dioxin or ionizing radiation in the "Notices" section of the **Federal Register.**

(b) Factors to be considered in evaluating scientific studies include:

(1) Whether the study's findings are statistically significant and replicable.

(2) Whether the study and its findings have withstood peer review.

(3) Whether the study methodology has been sufficiently described to permit replication of the study.

(4) Whether the study's findings are applicable to the veteran population of interest.

(5) The views of the appropriate panel of the Scientific Council of the Veterans' Advisory Committee on Environmental Hazards.

(Pub. L. 98–542)

PART 3—[AMENDED]

2. Part 3 is amended by revising § 3.102, by removing and reserving § 3.311 and by adding new §§ 3.311a, 3.311b and 3.813 so that the new and revised material reads as follows:

§ 3.102 Reasonable doubt.

It is the defined and consistently applied policy of the Veterans Administration to administer the law under a broad interpretation, consistent, however, with the facts shown in every case. When, after careful consideration of all procurable and assembled data, a reasonable doubt arises regarding service origin, the degree of disability, or any other point, such doubt will be resolved in favor of the claimant. By reasonable doubt is meant one which exists because of an approximate balance of positive and negative evidence which does not satisfactorily prove or disprove the claim. It is a substantial doubt and one within the range of probability as distinguished from pure speculation or remote possibility. It is not a means of reconciling actual conflict or a contradiction in the evidence; the claimant is required to submit evidence sufficient to justify a belief in a fair and impartial mind that the claim is well grounded. Mere suspicion or doubt as to the truth of any statements submitted, as distinguished from impeachment or contradiction by evidence or known facts, is not justifiable basis for denying the application of the reasonable doubt doctrine if the entire, complete record otherwise warrants invoking this doctrine. The reasonable doubt doctrine is also applicable even in the absence of official records, particularly if the basic incident allegedly arose under combat, or similarly strenuous conditions, and is consistent with the probable results of such known hardships. (38 U.S.C. 210(c))

§ 3.311a Claims based on exposure to herbicides containing dioxin during service in the Republic of Vietnam.

(a) *Definitions.* For purposes of this section:

(1) "Service in the Republic of Vietnam" includes service in the waters offshore and service in other locations, if the conditions of service involved duty or visitation in the Republic of Vietnam.

(2) "Dioxin" means 2, 3, 7, 8 tetrachlorodibenzo-p-dioxin.

(3) "Sound scientific evidence" means observations, findings, or conclusions which are statistically and epidemiologically valid, are statistically significant, are capable of replication, and withstand peer review.

(4) "Sound medical evidence" means observations, findings, or conclusions which are consistent with current medical knowledge and are so reasonable and logical as to serve as the basis for management of a medical condition.

(b) *Presumption of exposure.* A veteran who served in the Republic of Vietnam during the Vietnam era shall be presumed to have been exposed to a herbicide containing dioxin while in Vietnam. The commencement date of any period specified in paragraph (c) of this section shall be the day of the veteran's latest departure from the Republic of Vietnam during such service.

(c) *Service-connection based on dioxin exposure.* Except as provided in paragraph (e) of this section, exposure to dioxin together with the development of the following disease within the period specified is sufficient to establish service-connection for resulting disability: Chloracne manifested not later than three months from the date of exposure. (See paragraph (g) of this section with regard to service-connection on other grounds and § 3.307(c) in cases where chloracne is initially misdiagnosed.)

(d) *Diseases not associated with dioxin exposure.* Sound scientific and medical evidence does not establish a cause and effect relationship between dioxin exposure and the following diseases:

(1) Porphyria cutanea tarda.

(2) Soft tissue sarcomas.

(3) Any other disease not specified in paragraph (c) of this section.

(e) *Exceptions.* Service-connection will not be established if the claimed disease is due to the veteran's own willful misconduct or there is affirmative evidence that establishes a nonservice-related supervening condition or event as the cause of the disease.

(f) *Study evaluations.* In the adjudication of individual claims, due consideration shall be given to the evaluations of study findings published pursuant to § 1.17 of this title.

(g) *Service-connection under other provisions.* Nothing in this section will be construed to prevent the establishment of service-connection for any disease or disorder shown by sound scientific or medical evidence to have been incurred or aggravated during active service.

(h) *Reasonable doubt doctrine.* With regard to any issue material to the determination of an individual claim, the provisions of § 3.102 of this title shall apply.

(Sec. 5(a)(2) of Pub. L. 98-542)

§ 3.311b Claims based on exposure to ionizing radiation.

(a) *Determinations of exposure and dose*—(1) *Dose assessment.* In all claims in which it is established that a radiogenic disease, listed in paragraph (b)(2) of this section, first became manifest after service and was not manifest to a compensable degree within any applicable presumptive period as specified in § 3.307, and it is contended the disease is a result of exposure to ionizing radiation in service, an assessment will be made as to the size and nature of the radiation dose or doses. When dose estimates provided pursuant to paragraph (a)(2) of this section are reported as a range of doses to which a veteran may have been exposed, exposure at the highest level of the dose range reported will be presumed.

(2) *Request for dose information.* Where necessary pursuant to paragraph (a)(1) of this section, dose information will be requested as follows:

(i) *Atmospheric nuclear weapons test participation claims.* In claims based upon participation in atmospheric nuclear testing, dose data will in all cases be requested from the appropriate office of the Department of Defense.

(ii) *Hiroshima and Nagasaki occupation claims.* In all claims based on participation in the American occupation of Hiroshima or Nagasaki, Japan, prior to July 1, 1946, dose data will be requested from the Department of Defense.

(iii) *Other exposure claims.* In all other claims involving radiation exposure, a request will be made for any available records concerning the veteran's exposure to radiation. These records normally include but may not be limited to the veteran's Record of Occupational Exposure to Ionizing Radiation (DD Form 1141), if maintained, service medical records, and other records which may contain information pertaining to the veteran's radiation dose in service. All such records will be forwarded to the Chief Medical Director, who will be responsible for preparation of a dose estimate, to the extent feasible, based on available methodologies.

(3) *Referral to independent expert.* When necessary to reconcile a material difference between an estimate of dose, from a credible source, submitted by or on behalf of a claimant, and dose data derived from official military records, the estimates and supporting documentation shall be referred to an independent expert, selected by the Director of the National Institutes of Health, who shall prepare a separate radiation dose estimate for consideration in adjudication of the claim. For purposes of this paragraph:

(i) The difference between the claimant's estimate and dose data derived from official military records shall ordinarily be considered material if one estimate is at least double the other estimate.

(ii) A dose estimate shall be considered from a "credible source" if prepared by a person or persons certified by an appropriate professional body in the field of health physics, nuclear medicine or radiology and if based on analysis of the facts and circumstances of the particular claim.

(4) *Exposure.* In cases described in paragraph (a)(2) (i) and (ii) of this section:

(i) If military records do not establish presence at or absence from a site at which exposure to radiation is claimed to have occurred, the veteran's presence at the site will be conceded.

(ii) Neither the veteran nor the veteran's survivors may be required to produce evidence substantiating exposure if the information in the veteran's service records or other records maintained by the Department of Defense is consistent with the claim that the veteran was present where and when the claimed exposure occurred.

(b) *Initial review of claims.* (1) When it is determined:

(i) A veteran was exposed to ionizing radiation as a result of participation in the atmospheric testing of nuclear weapons, the occupation of Hiroshima or Nagasaki, Japan, from September 1945 until July 1946, or other activities as claimed:

(ii) The veteran subsequently developed a radiogenic disease specified in paragraph (b)(2) of this section; and

(iii) Such disease first became manifest within the period specified in paragraph (b)(4) of this section; before its adjudication the claim will be referred to the Chief Benefits Director for further consideration in accordance with paragraph (c) of this section. If any of the foregoing 3 requirements has not been met, it shall not be determined that a disease has resulted from exposure to ionizing radiation under such circumstances. (But see paragraph (h) of this section.)

(2) For purposes of paragraphs (a)(1) and (b)(1) of this section, "radiogenic disease" shall include only the following:

(i) All forms of leukemia except chronic lymphatic leukemia;
(ii) Thyroid cancer;
(iii) Female breast cancer;
(iv) Lung cancer;
(v) Bone cancer;
(vi) Liver cancer;
(vii) Skin cancer;
(viii) Esophageal cancer;
(ix) Stomach cancer;
(x) Colon cancer;
(xi) Pancreatic cancer;
(xii) Kidney cancer;
(xiii) Urinary bladder cancer;
(xiv) Salivary gland cancer; and
(xv) Multiple myeloma.

(3) For purposes of paragraphs (a)(1) and (b)(1) of this section, "radiogenic disease" shall not include polycythemia vera.

(4) For purposes of paragraph (b)(1) of this section:

(i) Leukemias and bone cancer must become manifest within 30 years after exposure;

(ii) Other forms of cancer specified in paragraph (b)(2) of this section must become manifest 5 years or more after exposure.

(c) *Review by Chief Benefits Director.* (1) When a claim is forwarded for review pursuant to paragraph (b)(1) of this section, the Chief Benefits Director shall consider the claim with reference to the factors specified in paragraph (e) of this section and may request an advisory medical opinion from the Chief Medical Director.

(i) If after such consideration the Chief Benefits Director is convinced sound scientific and medical evidence supports the conclusion it is at least as likely as not the veteran's disease resulted from exposure to radiation in

service, the Chief Benefits Director shall so inform the regional office of jurisdiction in writing. The Chief Benefits Director shall set forth the rationale for this conclusion, including an evaluation of the claim under the applicable factors specified in paragraph (e) of this section.

(ii) If the Chief Benefits Director determines there is no reasonable possibility that the veteran's disease resulted from radiation exposure in service, the Chief Benefits Director shall so inform the regional office of jurisidiction in writing, setting forth the rationale for this conclusion.

(2) If the Chief Benefits Director, after considering any opinion of the Chief Medical Director, is unable to conclude whether it is at least as likely as not, or that there is no reasonable possibility, the veteran's disease resulted from radiation exposure in service, the Chief Benefits Director shall refer the matter to an outside consultant in accordance with paragraph (d) of this section.

(3) For purposes of paragraph (c)(1) of this section, "sound scientific evidence" means observations, findings, or conclusions which are statistically and epidemiologically valid, are statistically significant, are capable of replication, and withstand peer review, and "sound medical evidence" means observations, findings, or conclusions which are consistent with current medical knowledge and are so reasonable and logical as to serve as the basis of management of a medical condition.

(d) *Referral outside consultants.* (1) Referrals pursuant to paragraph (c) of this section shall be to consultants selected by the Chief Medical Director from outside the VA, upon the recommendation of the Director of the National Cancer Institute. The consultant will be asked to evaluate the claim and provide an opinion as to the likelihood the disease is a result of exposure as claimed.

(2) The request for opinion shall be in writing and shall include a description of:

(i) The disease, including the specific cell type and stage, if known, and when the disease first became manifest;

(ii) The circumstances, including date, of the veteran's exposure;

(iii) The veteran's age, gender, and pertinent family history;

(iv) The veteran's history of exposure to known carcinogens, occupationally or otherwise;

(v) Evidence of any other effects radiation exposure may have had on the veteran; and

(vi) Any other information relevant to determination of causation of the veteran's disease.

The Chief Benefits Director shall forward, with the request, copies of pertinent medical records and, where available, dose assessments from official sources, from credible sources as defined in paragraph (a)(3)(ii) of this section, and from an independent expert pursuant to paragraph (a)(3) of this section.

(3) The consultant shall evaluate the claim under the factors specified in paragraph (e) of this section and respond in writing, stating whether it is either likely, unlikely, or approximately as likely as not the veteran's disease resulted from exposure to ionizing radiation in service. The response shall set forth the rationale for the consultant's conclusion, including the consultant's evaluation under the applicable factors specified in paragraph (e) of this section. The Chief Benefits Director shall review the consultant's response and transmit it with any comments to the regional office of jurisdiction for use in adjudication of the claim.

(e) *Factors for consideration.* Factors to be considered in determining whether a veteran's disease resulted from exposure to ionizing radiation in service include:

(1) The probable dose, in terms of dose type, rate and duration as a factor in inducing the disease, taking into account any known limitations in the dosimetry devices employed in its measurement or the methodologies employed in its estimation;

(2) The relative sensitivity of the involved tissue to induction, by ionizing radiation, of the specific pathology;

(3) The veteran's gender and pertinent family history;

(4) The veteran's age at time of exposure;

(5) The time-lapse between exposure and onset of the disease; and

(6) The extent to which exposure to radiation, or other carcinogens, outside of service may have contributed to development of the disease.

(f) *Adjudication of claim.* The determination of service connection will be made under the generally applicable provisions of this part, giving due consideration to all evidence of record, including any opinion provided by the Chief Medical Director or an outside consultant, and to the evaluations published pursuant to § 1.17 of this title. With regard to any issue material to consideration of a claim, the provisions of § 3.102 of this title apply.

(g) *Willful misconduct and supervening cause.* In no case will service connection be established if the disease is due to the veteran's own willful misconduct, or if there is affirmative evidence to establish that a supervening, nonservice-related condition or event is more likely the cause of the disease.

(h) *Service connection otherwise established.* Nothing in this section will be construed to prevent the establishment of service connection for any injury or disease otherwise shown by sound scientific or medical evidence to have been incurred or aggravated during active service.

(Pub. L. 98-542)

§ 3.813 Interim benefits for disability or death due to chloracne or porphyria cutanea tarda.

(a) *Disability benefits.* Except as provided in paragraph (c) of this section, a veteran who served in the active military, naval or air service in the Republic of Vietnam during the Vietnam era, and who suffers from chloracne or porphyria cutanea tarda which became manifest within one year after the date of the veteran's most recent departure from the Republic of Vietnam during such service, shall be paid interim disability benefits under this section in the same manner and to the same extent that compensation would be payable if such disabilities were service-connected.

(b) *Death benefits.* Except as provided in paragraph (c) of this section, if a veteran described in paragraph (a) of this section dies as a result of chloracne or porphyria cutanea tarda, the veteran's survivors shall be paid interim death benefits under this section based upon the same elgibility requirements and at the same rates that dependency and indemnity compensation would be payable if the death were service-connected.

(c) *Exceptions.* Benefits under this section are not payable for any month for which compensation or dependency and indemnity compensation is payable for the same disability or death, nor are benefits payable under this section (1) when there is affirmative evidence that the disease was not incurred by the veteran during service in the Republic of Vietnam during the Vietnam era, (2) when there is affirmative evidence to establish that an intercurrent injury or disease, which is a recognized cause of the disease for which benefits are being claimed, was suffered by the veteran between the date of the veteran's most recent departure from the Republic of Vietnam during active military, naval or air service and the onset of the claimed disease, or (3) if it is determined, based on evidence in the veteran's service records and other records provided by the Secretary of Defense, that the

veteran was not exposed to dioxin during active military, naval or air service in the Republic of Vietnam during the Vietnam era.

(d) *Similarity to service-connected benefits.* For purposes of all laws administered by the VA (except chapters 11 and 13 of Title 38, United States Code), a disease establishing eligibility for disability or death benefits under this section shall be treated as if it were service-connected, and the receipt of disability or death benefits shall be treated as if such benefits were compensation or dependency and indemnity compensation, respectively.

(e) *Effective dates.* Benefits under this section may not be paid for any period prior to October 1, 1984, nor for any period after September 30, 1986.

(Pub. L. 98-542) (Oct. 1, 1984)

[FR Doc. 85-20381 Filed 8-22-85; 10:55 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[AD-FRL-2887-6]

Review of Standards of Performance for New Stationary Sources; Sulfuric Acid Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Review of standards.

SUMMARY: The EPA is required to review standards of performance for new, modified, or reconstructed stationary sources every 4 years by the Clean Air Act. A review of the existing new source performance standards (NSPS) for sulfuric acid plants (40 CFR Part 60, Subpart H) has been completed to determine if changes are needed. The review indicates that no revision to the standards is necessary.

DATE: Comments must be received on or before October 25, 1985.

ADDRESSES: Send comments (in duplicate if possible) to: Central Docket Section (LE-131), Attention: Docket Number A-85-20, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

Review Document: The document summarizing information gathered during the review may be obtained from the EPA Library (MD-35), Research Triangle Park, North Carolina 27711, telephone number (919) 541-2777. Please refer to "Review of New Source Performance Standards for Sulfuric Acid Plants," EPA-450/3-85-012, March 1985.

Docket. Docket No. A-85-20, containing supporting information gathered during the review is available for public inspection and copying between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery 1, Waterside Mall, 401 M Street, SW., Washington, DC, 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. James Crowder, Industrial Studies Branch, Emission Standards and Engineering Division (MD-13) U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5601.

SUPPLEMENTARY INFORMATION:

Background

Emissions from sulfuric acid plants were among the first pollutants to be regulated by EPA under the Clean Air Act. The NSPS were promulgated for sulfuric acid plants on December 23, 1971 (40 CFR 60.80, Subpart H). The standards limit emissions of sulfur dioxide (SO_2), sulfuric acid mist, and opacity from new or modified sulfuric acid production units that have been constructed, modified, or reconstructed after the date of proposal (August 17, 1971). The promulgated standard limits SO_2 to 2 kg per metric ton of sulfuric acid (H_2SO_4) produced (4 lb/ton), sulfuric acid mist to 0.075 kg per metric ton of acid produced (0.15 lb per ton), and opacity to less than 10 percent. The acid produced is always expressed as 100 percent H_2SO_4, even though the acid is usually produced and marketed at lower concentrations.

Requirements were also included in the promulgated standards for continuous monitoring of SO_2 in the stack gas. Excess SO_2 emissions are required to be reported to the EPA (or the appropriate State regulatory agency) for all 3-hour periods of such emissions (or the arithmetic average of three consecutive 1-hour periods). Periods of excess emission are considered to occur when the average plant stack SO_2 emission exceeds the standard of 4 lb/ton of 100 percent H_2SO_4 produced.

Each sulfuric acid production unit (or "train") is the affected facility. The standards of performance apply to contact-process sulfuric acid and oleum facilities that burn elemental sulfur, alkylation acid, hydrogen sulfide, metallic sulfides, organic sulfides, mercaptans, or acid sludge. The NSPS does not apply to metallurgical plants that use acid plants as control systems, or to chamber process plants or acid concentrators.

The Clean Air Act Amendments of 1977 require that the Administrator review and, if appropriate, revise established standards of performance for new stationary sources at least every 4 years [Section 111(b)(1)(B)]. A review of the sulfuric acid plant standard was previously conducted in 1979 (44 FR 15742). However, no revisions to the NSPS were made as a result of the 1979 review. A second review has been conducted by contacting EPA regional offices, other Federal agencies, State agencies, and companies with plants subject to the NSPS. Information was collected on the number and location of all facilities subject to the NSPS, on control equipment performance and costs, and on the results of performance tests and continuous stack gas monitoring. From these sources, a background document (EPA-450/3-85-012) was prepared covering the current status of control technology, compliance test data, monitoring systems employed, cost, and cost effectiveness for representative control systems on different sizes of acid plants. This notice announces that the EPA has completed the review and invites comments on its results.

Findings

Industry Growth Rate

U.S. sulfuric acid production in 1971 was 29.0 million tons, and approximately 36.6 million tons in 1983. Production is expected to increase to 48.0 million tons by the year 1995. Over 77 percent of the sulfuric acid design capacity is located in the South, and over half of the NSPS plants are located in Florida.

In 1971, the EPA projected two new units to be coming on-line each year for the next several years. On the average, three to four new units have been completed each year since 1971, representing an annual growth in production averaging 2 percent.

Control Technology

Sulfur dioxide and acid mist are present in the tail gas from all contact process sulfuric acid production units. In modern four-stage contact process plants burning sulfur with approximately 8 percent SO_2 in the converter feed and producing 98 percent acid, SO_2 and acid mist emissions are generated at the rate of 26 to 56 lb/ton of 100 percent acid and 0.4 to 4 lb/ton of 100 percent acid, respectively. The dual absorption process is the best demonstrated control technology for SO_2 emissions from sulfuric acid plants, while the high efficiency acid mist