allowed to speak after those who have been scheduled. We will end the
hearing after all persons scheduled to speak and persons present in the
audience who wish to speak have been heard.
If you are disabled and need a special accommodation to attend a public
hearing, contact the person listed under FOR FURTHER INFORMATION CONTACT.
Public Meeting: If only one person requests an opportunity to speak at a
hearing, a public meeting, rather than a public hearing, may be held. If you wish
to meet with us to discuss the proposed amendment, you may request a meeting
by contacting the person listed under FOR FURTHER INFORMATION CONTACT. All
such meetings are open to the public and, if possible, we will post notices of
meetings at the locations listed under ADDRESSES. We will also make a written
summary of each meeting a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulations.

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to “establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.” Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be “in accordance with” the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations “consistent with” regulations issued by the Secretary under SMCRA.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that a decision on a proposed State regulatory program provision does not constitute a major Federal action within the meaning of section 102(2)(C) of the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(C)). A determination has been made that such decisions are categorically excluded from the NEPA process (516 DM 8.4.A).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3507 et seq.).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic impact upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million.
b. Will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions.
c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S. based enterprises to compete with foreign-based enterprises.
This determination is based upon the fact that the State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates
This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 914
Intergovernmental relations, Surface mining, Underground mining.

Richard J. Seibel,
Acting Regional Director, Mid-Continent Regional Coordinating Center.

BILLING CODE 4310–05–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3
RIN 2900–AK63

Disease Associated With Exposure to Certain Herbicide Agents: Type 2 Diabetes

AGENCY: Department of Veterans Affairs.
ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its adjudication regulations concerning presumptive service connection for certain diseases for which there is no record during service. This proposed amendment is necessary to implement a decision of the Secretary of Veterans Affairs under the authority granted by the Agent Orange Act of 1991 that there is a positive association between exposure to herbicides used in the Republic of Vietnam during the Vietnam era and the subsequent development of Type 2 diabetes. The intended effect of this proposed amendment is to establish presumptive service connection for that condition based on herbicide exposure.
humans to an herbicide agent (association) exists between exposure of credible evidence against the association is equal to or outweighs the evidence, that a positive association whenever the Secretary determines, period. 

Supplementary Information: Section 3 of Pub. L. 102±4 also required the diseases on the presumptive list defined as January 9, 1962 through May 7, 1975, for the purposes of such presumptions. 38 U.S.C. 1116.) Under current law, the Vietnam Era is codified at 38 CFR 3.309(e), is presumed to have been exposed to herbicides. Under current law, the Vietnam Era is defined as January 9, 1962 through May 7, 1975, for the purposes of such presumptions. 38 U.S.C. 1116.) Although Pub. L. 102±4 does not define “credible,” it does instruct the Secretary to “take into consideration whether the results [of any study] are statistically significant, are capable of replication, and withstand peer review.” Simply comparing the number of studies which report a positive relative risk to the number of studies which report a negative relative risk for a particular condition is not a valid method for determining whether the weight of evidence overall supports a finding that there is or is not a positive association between herbicide exposure and the subsequent development of the particular condition. Because of differences in statistical significance, confidence levels, control for confounding factors, bias, and other pertinent characteristics, some studies are clearly more credible than others, and the Secretary has given the more credible studies more weight in evaluating the overall weight of the evidence concerning specific diseases. II. History of NAS Review of Type 2 Diabetes In VAO, Update 1996, and Update 1998, NAS placed metabolic and digestive disorders (including Type 2 diabetes) in the category labeled "Inadequate/Insufficient Evidence to Determine Whether an Association Exists." According to NAS, this means that the available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association. For example, studies fail to chemical in an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the Vietnam era) and a disease, the Secretary will publish regulations establishing a presumptive service connection for that disease. Presumptive service connection relaxes the evidentiary burden, so that the claimant need not provide direct evidence of a link between his or her disease and the claimant’s exposure to Agent Orange. Instead, such a link is presumed and may be rebutted only if there is affirmative evidence to the contrary. If the Secretary determines that a presumption of service connection is not warranted, he is to publish a notice of that determination, including an explanation of the scientific basis for that determination. The Secretary’s determination must be based on consideration of the NAS reports and all other sound medical and scientific information and analysis available to the Secretary. (Under Section 2 of Pub. L. 102±4, any veteran who served in Vietnam during the Vietnam Era and has one of the diseases on the presumptive list codified at 38 CFR 3.309(e), is presumed to have been exposed to herbicides. Under current law, the Vietnam Era is defined as January 9, 1962 through May 7, 1975, for the purposes of such presumptions. 38 U.S.C. 1116.)
control for confounding factors, have inadequate exposure assessments, or fail to address latency.

However, after NAS released Update 1998 the National Institute of Occupational Safety and Health (NIOSH) published a report that detects an association, though not a strong association, between Type 2 diabetes and dioxin exposure. The study does suggest a dose response relationship because of excess cases of Type 2 diabetes found in workers having the highest serum-lipid levels of dioxin (Calveret GM, Sweeney MH, Deddens J, Wall DK. 1999. Evaluation of Type 2 diabetes, Serum Glucose and Thyroid Function Among U.S. Workers Exposed to 2,3,7,8 tetrachlorodibenzo-p-dioxin. Occupational and Environmental Medicine 56:270±276). The Secretary concluded that the NIOSH study was potentially important enough that it warranted a full review by NAS as soon as possible, and he directed VA to amend its contract with NAS for the third biennial update to require a special report on herbicide exposure and Type 2 diabetes, as a separate deliverable.


III. October 2000 NAS Review of Type 2 Diabetes

NAS issued its report, “Veterans and Agent Orange: Herbicide/Dioxin Exposure and Type 2 Diabetes” (VAO: Diabetes) on October 11, 2000. NAS concluded that “there is limited/ suggestive evidence of an association between exposure to the herbicides used in Vietnam or the contaminant dioxin and Type 2 diabetes.” (“Type 2 diabetes” is also referred to as “Type II diabetes mellitus” or “adult-onset diabetes.”) The term “limited/suggestive evidence” means “evidence is suggestive of an association between herbicides and the outcome, but limited because of small numbers, and confounding could not be ruled out with confidence.” NAS based its conclusion on the totality of the scientific evidence on this issue, not one particular study. (VAO: Diabetes).

Mortality Studies on Type 2 Diabetes

In VAO: Diabetes, NAS noted that positive associations between herbicides and Type 2 diabetes are reported in many mortality studies. NAS stated that these may underestimate the incidence of Type 2 diabetes because: (1) It is not typically fatal; (2) its known complications, as opposed to Type 2 diabetes itself, may be more likely to be listed as the cause of death on the death certificate; and (3) contributory causes of death are not routinely recorded on death certificates. In one mortality study reviewed by NAS, people living near the site of a 1976 industrial accident involving dioxin were found to have a higher risk of death from Type 2 diabetes than a reference population, in all exposure zones in which deaths were recorded. (Pesatori AC, Zocchetti C, Guercilena S, Consonni D, Turrini D, Bertazzi, PA. Exposure and non-malignant health effects: a mortality study. Occupational and Environmental Medicine. 55:126–131.) Two studies of a group of workers exposed to TCDD at 12 U.S. plants found positive, but non-statistically significant associations between measures of exposure and notations of Type 2 diabetes on death certificates, although the later paper also found a significant negative trend between Type 2 diabetes mortality and cumulative TCDD exposure. (Steenland K, Nowlin S, Ryan B, Adams S. 1992. Use of multiple-cause mortality data in epidemiological analyses: US rate and proportion files developed by the National Institute for Occupational Safety and Health and the National Cancer Institute. American Journal of Epidemiology 136(7):855–862; Steenland K, Placetelli L, Deddens J, Fingerhut M, Chang LI. 1999. Cancer, heart disease and diabetes in workers exposed to 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin. Journal of the National Cancer Institute 91(9):779–786.) Another study, which examined who produced or sprayed phenoxy herbicides and chlorophenols, reported an elevated relative risk of mortality from Type 2 diabetes in exposed workers versus non-exposed referents. (Vena J, Boffetta P, Becher H, Benn T, Bueno-de-Mesquita HB, Coggon D, Colin D, Flesch-Jany D, Green L, Kauppinen T, Littorin M, Lyne E, Mathews JD, Neuberger M, Pearce N, Pesatori AC, Saracci R, Steenland K, Kogevinas M. 1998. Exposure to dioxin and nonneoplastic mortality in the IARC international cohort study of phenoxy herbicide and chlorophenol production and workers and sprayers. Environmental Health Perspectives 106 (Supplement 2):645–653.) In addition, earlier studies previously reviewed by NAS in and VAO, Update 1996, and Update 1998 showed an inconsistent but weakly positive association between exposure measures and Type 2 diabetes.

Morbidity Studies on Type 2 Diabetes

In VAO: Diabetes, NAS noted that, “Positive associations are reported in most of the morbidity studies identified by the [NAS Committee to Review the Evidence Regarding the Link Between Exposure to Agent Orange and Diabetes].” NAS discussed a number of epidemiological studies. In a study of a population near an Arkansas plant that manufactured pesticides, researchers found that insulin levels were significantly higher in the group with high dioxin levels. The study authors concluded that this was evidence that dioxin may cause insulin resistance. (Cramer M, Louie S, Kennedy RH, Kern PA, Fonseca VA. 2000. Exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) is associated with hyperinsulinemia and insulin resistance. Toxicological Sciences 56(2): 431–436.) A survey of Australian Vietnam veterans found a statistically significant excess of self-reported Type 2 diabetes—2,391 cases were reported when 1,780 were expected. (Commonwealth Department of Veterans Affairs. 1998a. Morbidity of Vietnam Veterans: A Study of the Health of Australia’s Vietnam Veteran Community. Volume 1: Male Vietnam Veterans Survey and Community Comparison Outcomes. Canberra: Commonwealth Department of Veterans Affairs.)

The 1999 NIOSH study (Calvert et al., 1999) reported an elevated incidence of Type 2 diabetes in individuals who had high levels of serum dioxin relative to others examined in that study. A study of the Ranch Hand comparison group, reported in 1999 and published in 2000, showed similar findings. (Longnecker MP, Michalek JE. 2000. Serum dioxin level in relation to Type 2 diabetes among Air Force veterans with background levels of exposure. Epidemiology 11(4):44–48.) The Air Force’s subsequent analysis of Ranch Hand data (AFHS, 2000) showed almost identical Type 2 diabetes incidence in Ranch Hand and the matched comparison group. However, this study did show significant dose-response relationships between dioxin levels and Type 2 diabetes incidence, controlling for confounding variables.
Biological Plausibility


IV. The Secretary’s Determination on Diabetes

NAS reviewed all known relevant scientific and medical articles published since Update 1998, and prior studies, as an integral part of the process that resulted in VAO: Diabetes. In VAO: Diabetes, NAS observed that, “Although some of the risk estimates in the studies examined by the committee are not statistically significant and, individually, studies can be faulted for various methodological reasons, the accumulation of positive evidence is suggestive.”

After considering all of the evidence, the Secretary has determined that there is a positive association between exposure to herbicides and Type 2 diabetes and, therefore, a presumption of service connection is warranted.

V. Compliance With the Congressional Review Act, the Regulatory Flexibility Act, and Executive Order 12866

We estimate that the five-year cost of this proposed rule from appropriated funds would be $3 billion in benefits costs and $62 million in government operating expenses. Since it is likely that the adoption of the proposed rule may have an annual effect on the economy of $100 million or more, the Office of Management and Budget has designated this proposed rule as a major rule under the Congressional Review Act, 5 U.S.C. 802, and a significant regulatory action under Executive Order 12866, Regulatory Planning and Review. The following information is provided pursuant to E.O. 12866.

This proposed rule is necessary to comply with the Agent Orange Act of 1991, which requires VA to establish a presumption of service connection if the Secretary finds that there is a positive association between exposure to herbicides used in the Republic of Vietnam during the Vietnam era and the subsequent development of any particular disease. As explained above, the Acting Secretary has found that there is such an association regarding Type 2 diabetes. There are no feasible alternatives to this proposed rule, since the Agent Orange Act of 1991 requires the Secretary to promulgate it once he finds the positive association described above. The adoption of the proposed rule would not interfere with state, local or tribal governments in the exercise of their governmental functions.

Benefits Costs

Historical statistics indicate that the total number of veterans who served in the Republic of Vietnam or its surrounding waters was about 2.6 million. We estimate that about 2.3 million of these veterans are alive today. Using information gained from VAO: Diabetes and VA’s Office of Planning and Analysis, VA applied a prevalence rate of 9% to the current population to determine the number of veterans who might have Type 2 diabetes today. VA assumes that over five years, about 90% of some veterans who would file a diabetes-related claim. We expect that 8 out of 10 claims will be made by first time applicants (original) and that 2 out of 10 will come from veterans already service connected for some other issue (reopened). The average monthly award made on account of diabetes or its ancillary conditions for original or reopened claims is estimated to be $462 and $786, respectively. These figures are based on average benefits to current beneficiaries for all conditions and include dependents’ benefits and unemployability benefits where applicable. A moderate number of DIC and burial claims have also been factored into this estimate.

VA estimates the cumulative totals of benefits awards to claimants for years 2001–2005 as follows: 10,199, 80,526, 129,988, 159,198 and 178,356. Benefits costs (in $ million) for years 2001–2005 are as follows: $6.4, $18.6, $16.5, $11.9, and $8.2, for a total GOE cost of $62 million over five years.

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, 5 U.S.C. 601–612. The reason for this certification is that these amendments would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), these amendments are exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance program numbers are 64.100, 64.101, 64.104, 64.105, 64.106, 64.109, and 64.110.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Veterans, Vietnam.

Approved: December 6, 2000.

Hershel W. Gober,
Acting Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is proposed to be amended as follows:

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. In § 3.309, paragraph (e), the listing of diseases is amended by adding “Type 2 diabetes (also known as Type II diabetes mellitus or adult-onset diabetes)” between “Chloracne or other acneform disease consistent with chloracne” and “Hodgkin’s disease” to read as follows:
§ 3.309 Diseases subject to presumptive service connection.

* * * * *

(e) * * * *

Type 2 diabetes (also known as Type II diabetes mellitus or adult-onset diabetes)

* * * * *

[FR Doc. 01–685 Filed 1–8–01; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6931–7]

National Priorities List for Uncontrolled Hazardous Waste Sites, Proposed Rule No. 35

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA" or "the Act"), requires that the National Oil and Hazardous Substances Pollution Contingency Plan ("NCP") include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List ("NPL") constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency ("EPA" or "the Agency") in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This proposed rule proposes to add five new sites to the NPL, all to the General Superfund Section of the NPL. (Please note that one of the sites is being reproposed to the NPL.)

DATES: Comments regarding any of these proposed listings must be submitted (postmarked) on or before March 12, 2001.

ADDRESSES: By Postal Mail: Mail original and three copies of comments (no facsimiles or tapes) to Docket Coordinator, Headquarters; U.S. Environmental Protection Agency; CERCLA Docket Office; 1235 Jefferson Davis Highway; Crystal Gateway #1, First Floor; Arlington, VA 22202. By E-mail: Comments in ASCII format only may be mailed directly to superfund.docket@epa.gov. E-mailed comments must be followed up by an original and three copies sent by mail or express mail.

For additional Docket addresses and further details on their contents, see section II, "Public Review/Public Comment," of the Supplementary Information portion of this preamble.

FOR FURTHER INFORMATION CONTACT: Yolanda Singer, phone (703) 603–8835, State, Tribal and Site Identification Center, Office of Emergency and Remedial Response (Mail Code 5204G); U.S. Environmental Protection Agency; 1200 Pennsylvania Avenue, NW., Washington, DC 20460; or the Superfund Hotline, Phone (800) 424–9346 or (703) 412–9810 in the Washington, DC metropolitan area.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
A. What are CERCLA and SARA?
B. What is the NCP?
C. What is the National Priorities List (NPL)?
D. How are Sites Listed on the NPL?
E. What Happens to Sites on the NPL?
F. How Are Site Boundaries Defined?
G. How Are Sites Removed From the NPL?
H. Can Portions of Sites Be Deleted from the NPL as They Are Cleaned Up?
I. What is the Construction Completion List (CCL)?
II. Public Review/Public Comment
A. Can I Review the Documents Relevant to This Proposed Rule?
B. How do I Access the Documents?
C. What Documents Are Available for Public Review at the Headquarters Docket?
D. What Documents Are Available for Public Review at the Regional Dockets?
E. How Do I Submit My Comments?
F. What Happens to My Comments?
G. What Should I Consider When Preparing My Comments?
H. Can I Submit Comments After the Public Comment Period Is Over?
I. Can I View Public Comments Submitted by Others?
J. Can I Submit Comments Regarding Sites Not Currently Proposed to the NPL?
III. Contents of This Proposed Rule
A. Proposed Additions to the NPL
B. Status of NPL
IV. Executive Order 12866
A. What is Executive Order 12866?
B. Is This Proposed Rule Subject to Executive Order 12866 Review?
V. Unfunded Mandates
A. What is the Unfunded Mandates Reform Act (UMRA)?
B. Does UMRA Apply to This Proposed Rule?
VI. Effect on Small Businesses
A. What is the Regulatory Flexibility Act?
B. Has EPA Conducted a Regulatory Flexibility Analysis for This Rule?
VII. National Technology Transfer and Advancement Act
A. What is the National Technology Transfer and Advancement Act?
B. Does the National Technology Transfer and Advancement Act Apply to This Proposed Rule?
VIII. Executive Order 12988
A. What is Executive Order 12988?
B. Does Executive Order 12988 Apply to this Proposed Rule?
IX. Executive Order 13045
A. What is Executive Order 13045?
B. Does Executive Order 13045 Apply to this Proposed Rule?
X. Paperwork Reduction Act
A. What is the Paperwork Reduction Act?
B. Does the Paperwork Reduction Act Apply to this Proposed Rule?
XI. Executive Orders on Federalism
A. What are the Executive Orders on Federalism and Are They Applicable to This Proposed Rule?
XII. Executive Order 13084
What is Executive Order 13084 and Is It Applicable to this Proposed Rule?

I. Background

A. What Are CERCLA and SARA?


B. What Is the NCP?

To implement CERCLA, EPA promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan ("NCP"), 40 CFR part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA section 105 and Executive Order 12316 (42 FR 42237, August 20, 1981). The NCP sets guidelines and procedures for responding to releases and threatened releases of hazardous substances, pollutants, or contaminants under CERCLA. EPA has revised the NCP on several occasions. The most recent comprehensive revision was on March 8, 1990 (55 FR 8666). As required under section 105(a)(8)(A) of CERCLA, the NCP also includes "criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practicable, taking into account the potential..."