June 30, 1997. VA received one comment from a concerned individual.

The commenter stated that the extension of the presumptive period for disabilities due to undiagnosed illnesses is inconsistent with the Secretary's responsibilities under the law.

Section 103(1) of Pub. L. 103–446 establishes that the first purpose of the legislation is to provide compensation to Persian Gulf War veterans who suffer disabilities resulting from illnesses that cannot now be diagnosed or defined, and for which other causes cannot be identified. The Secretary determined that in order to accomplish this purpose it was necessary to extend the presumptive period. That action clearly was consistent with his responsibilities under the law and we make no change based on this comment.

The commenter stated that it is unfair to make a decision to extend the presumptive period without supporting data regarding the latency period of the illnesses at issue.

Pub. L. 103–446 requires the Secretary to prescribe the period of time following Persian Gulf War service appropriate for the presumption of service connection for disabilities due to undiagnosed illnesses after reviewing, among other things, any available credible medical or scientific evidence.

Despite a broad federal research effort, there is still insufficient data about the nature and causes of the undiagnosed illnesses to establish a specific latency period. What is clear, however, is that a two-year presumptive period prevented VA from compensating certain veterans with disabilities due to undiagnosed illnesses that may have resulted from their service in the Persian Gulf War. The Secretary therefore decided to extend the presumptive period until a time when it is reasonable to anticipate that the results of ongoing research may have shed enough light on these issues to guide future policies. For these reasons, we make no change based on this comment.

This commenter also stated that the extension of the presumptive period for disabilities due to undiagnosed illnesses is unfair since we are still within the Persian Gulf War time period and veterans will, therefore, have significantly different presumptive periods.

Once it became clear that a significant number of veterans were developing disabilities due to undiagnosed illnesses more than two years after the date that they last served in the Persian Gulf, the Secretary determined that the most equitable way to address this issue was to extend the presumptive period in such a manner that no Persian Gulf veterans with qualifying disabilities would be denied compensation. If the results of ongoing research eventually identify a latency period, VA will revise the presumptive period accordingly. In the meantime, no one should be denied benefits unfairly because of a presumptive period that, based on VA's experience with claims from Persian Gulf veterans, is too short. The department, therefore, makes no change based on this comment.

Based on the rationale set forth in the interim final rule and this document, the interim final rule amending 38 CFR part 3 which was published at 62 FR 23138 on April 29, 1997, is adopted as a final rule without change.

Approved: February 27, 1998.

Togo D. West, Jr.,

Acting Secretary.

[FR Doc. 98–5841 Filed 3–5–98; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AH68

Treatment of Research-Related Injuries to Human Subjects

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Veterans Affairs (VA) medical regulations to provide (or to pay for the provision of) necessary medical treatment to certain human subjects injured as a result of participation in VA research. Under the final rule all participants in research approved by a VA Research and Development Committee (regardless of source of funding), and conducted under the supervision of one or more VA employees, are eligible for treatment unless injuries are due to noncompliance by a research subject with study procedures. VA will provide medical care in those circumstances where VA has some responsibility for the need for medical care.

DATES: Effective Date: April 6, 1998.

FOR FURTHER INFORMATION CONTACT: David Thomas, Office of Research and Development (12B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8284.

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on September 9, 1996 (61 FR 47469), VA proposed to provide (or to pay for the provision of) necessary medical treatment to certain human subjects injured as a result of participation in VA research. Based on the rationale set forth in the proposed rule and in this final rule, the provisions of the proposed rule are adopted as a final rule with changes discussed in this document.

VA requested comments to be submitted on or before November 8, 1996. Comments were received from six sources. These comments are discussed below.

One commenter suggested that VA set forth the text of this final rule in a place in 38 CFR other than part 16. Part 16 consists of common rules applicable to a number of agencies. It was asserted that the provisions of the proposed rule are different because they are unique to VA. We agree with the suggestion and have included the text of the final rule in 38 CFR part 17.

Proposed § 16.125 (renumbered in the final rule as § 17.85) provided, in part, that VA medical facilities shall provide necessary medical treatment to research subjects who are injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted by VA employees. One commenter asserted that the term ''VA employee'' should be narrowly construed and noted that this would lessen the amount of treatment that would need to be provided by VA. Another commenter asserted that medical treatment should be provided for injured subjects even if non-VA employees conducted the research. We believe VA should provide medical treatment to injured research subjects when individuals acting within their appointment as VA employees have supervisory responsibility over the conduct of the research. Consistent with this principle, the regulations are clarified to state that research subjects are eligible for medical treatment if injured during research conducted under the supervision of one or more VA employees. Further, to avoid confusion regarding who would be considered a VA employee, we have included in the final rule a definition of ''employee,'' which provides that '' 'VA employee' means any person acting within an appointment by VA as an officer or employee.''

Also, the proposed rule excluded the provision of medical treatment by VA for subjects injured as a result of research conducted for VA under a contract with a non-VA institution. One commenter argued against this exclusion. VA has retained the exclusion. The obligation to provide treatment under such circumstances

should rest with the contractor rather than VA because the contractor would have control over the actions of individuals involved in the research. Also, VA has clarified the exclusion to state that the exclusion covers contracts with individuals as well as non-VA institutions. The exclusion was intended to cover all contract research conducted by non-VA employees whether the contract was with an individual or an institution.

The law directs VA to conduct a program of medical research in connection with caring for veterans. 38 U.S.C. 7303. VA includes nonveterans in VA research projects if there are not enough suitable veteran-patients and cares for them in VA hospitals as part of the research. 38 CFR 17.45 (1996). This final rule further implements § 7303 to specify when and how VA gives free medical treatment to research subjects if their participation in the research adversely affects their health.

Congress gives money to VA in appropriation accounts and restricts how VA may use the money in these accounts. VA pays for medical care and research out of different appropriation accounts. The law requires that, if VA medical care funds pay for the care of research subjects who are not otherwise eligible for VA care, VA research appropriation must reimburse VA medical care appropriation. 38 CFR 17.101(g).

The Secretary hereby certifies that this final rule 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. This rule concerns individuals. It does not make changes applicable to small entities. Therefore, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analyses requirements of §§ 603–604.

There is no Catalogue of Federal Domestic Assistance Program Number.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: February 26, 1998.

Togo D. West, Jr.,

Acting Secretary.

For the reasons set out in the preamble, 38 CFR part 17 is amended as set forth below:

PART 17—MEDICAL

1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

2. Section 17.85 and an undesignated center heading are added to read as follows:

Research-Related Injuries

§ 17.85 Treatment of research-related injuries to human subjects.

(a) VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This section does not apply to:

(1) Treatment for injuries due to noncompliance by a subject with study procedures, or

(2) Research conducted for VA under a contract with an individual or a non-VA institution.

Note to § 17.85(a)(1) and (a)(2): Veterans who are injured as a result of participation in such research may be eligible for care from VA under other provisions of this part.

(b) Except in the following situations, care for VA research subjects under this section shall be provided in VA medical facilities.

(1) If VA medical facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required, VA medical facility directors shall contract for the needed care.

(2) If inpatient care must be provided to a non-veteran under this section, VA medical facility directors may contract for such care.

(3) If a research subject needs treatment in a medical emergency for a condition covered by this section, VA medical facility directors shall provide reasonable reimbursement for the emergency treatment in a non-VA facility.

(c) For purposes of this section, ''VA employee'' means any person appointed by VA as an officer or employee and acting within the scope of his or her appointment (VA appoints officers and employees under title 5 and title 38 of the United States Code).

(Authority: 38 U.S.C. 501, 7303)

[FR Doc. 98–5840 Filed 3–5–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 264 and 265

[FRL–5973–3]

Project XL Site-specific Rulemaking for OSi Specialties, Inc., Sistersville, WV

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is implementing a project under the Project XL program for the OSi Specialties, Inc. plant, a wholly owned subsidiary of Witco Corporation, located near Sistersville, West Virginia (the ''Sistersville Plant''). The terms of the XL project are defined in a Final Project Agreement (''FPA'') which was made available for public review and comment. See 62 FR 34748, June 27, 1997. Following a review of the public comments, the FPA was signed by delegates from the EPA, the West Virginia Division of Environmental Protection (''WVDEP'') and Witco Corporation on October 17, 1997. The EPA is today publishing a direct final rule, applicable only to the Sistersville Plant, to facilitate implementation of the XL project.

Today's action is a site-specific regulatory deferral from the Resource Conservation and Recovery Act (RCRA) organic air emission standards, commonly known as RCRA Subpart CC. The applicability of this site-specific deferral is limited to two existing hazardous waste surface impoundments, and is conditioned on the Sistersville Plant's compliance with air emission and waste management requirements that have been developed under this XL project. The air emission and waste management requirements are set forth in today's rulemaking. Today's action is intended to provide site-specific regulatory changes to implement this XL project. The agency expects this XL project to result in superior environmental performance at the Sistersville Plant, while deferring significant capital expenditures, and thus providing cost savings for the Sistersville Plant.

DATES: This direct final rule is effective on April 1, 1998, unless relevant adverse comments are received by March 27, 1998. If such comments are received, EPA will publish timely notice