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Title 38, Parts 0, 1, 2, 12, 14-16,
18-20, 25-26, 38-45, 48-49, 74-75

General

Veterans Benefits Administration

Supplement No. 93

Covering period of *Federal Register* issues
through May 5, 2010

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GENERAL INSTRUCTIONS

Custom Federal Regulations Service™

Supplemental Materials for *Book A*

Code of Federal Regulations

Title 38, Parts 0, 1, 2, 12, 14-16, 18-20, 25-26, 38-45, 48-49, 74-75

General

Veterans Benefits Administration

Supplement No. 93

5 May 2010

Covering the period of Federal Register issues
through May 5, 2010

When **Book A** was originally prepared, it was current through final regulations published in the *Federal Register* of 21 April 1992. These supplemental materials are designed to keep your regulations up to date. You should file the attached pages immediately, and record the fact that you did so on the *Supplement Filing Record* which begins on page A-8 of Book A, *General*.

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FILING INSTRUCTIONS

**Book A, Supplement No. 93
May 5, 2010**

<i>Remove these old pages</i>	<i>Add these new pages</i>	<i>Section(s) Affected</i>
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HIGHLIGHTS

Book A, Supplement No. 93
May 5, 2010

Supplement Highlights references: Where substantive changes are made in the text of regulations, the paragraphs of *Highlights* sections are cited at the end of the relevant section of text. Thus, if you are reading §3.263, you will see a note at the end of that section which reads: “Supplement *Highlights* references—6(2).” This means that paragraph 2 of the *Highlights* section in Supplement No. 6 contains information about the changes made in §3.263. By keeping and filing the *Highlights* sections, you will have a reference source explaining all substantive changes in the text of the regulations.

Supplement frequency: This Book A (*General*) was originally supplemented twice a year, in April and October. Beginning 1 August 1995, supplements will be issued *every month* during which a final rule addition or modification is made to the parts of Title 38 covered by this book. Supplements will be numbered consecutively as issued.

Modifications in this supplement include the following:

1. On 8 April 2010, the VA published a final rule, effective that same date, to amend its regulation concerning evaluation of studies relating to the health effects of exposure to herbicides containing dioxin and radiation in order to remove the obsolete references to herbicides containing dioxin. Changes:

- In §1.17, revised the section heading, and paragraphs (a), (c), (d), and (f).



Pagination System

Page numbers have three parts: (1) the section number, (2) a hyphen, and (3) the page number within that section—e.g., 25.71-2.

This looseleaf book has two indices.

- **Index 1** (by section number)begins on this page
- **Index 2** (alphabetical by section title) appears with each Part

The first index is arranged by *section number* and presents the contents of the parts in this book in the order in which they appear in the *Code of Federal Regulations*. The second is arranged by *section title*, and presents the titles of all sections in each part in alphabetical order. These *section title* indices appear at the beginning of their respective parts.

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

(a) From time to time, the Secretary shall publish evaluations of scientific or medical studies relating to the adverse health effects of exposure to 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.

(c) When the Secretary determines, based on the evaluation of scientific or medical studies and after receiving the advice of the Veterans' Advisory Committee on Environmental Hazards and applying the reasonable doubt doctrine as set forth in paragraph (d)(1) of this section, that a significant statistical association exists between any disease and exposure to ionizing radiation, §3.311 of this chapter, as appropriate, shall be amended to provide guidelines for the establishment of service connection.

(d) (1) For purposes of paragraph (c) of this section a *significant statistical association* shall be deemed to exist when the relative weights of valid positive and negative studies permit the conclusion that it is at least as likely as not that the purported relationship between exposure to ionizing radiation and a specific adverse health effect exists.

(2) For purposes of this paragraph a valid study is one which:

(i) Has adequately described the study design and methods of data collection, verification and analysis;

(ii) Is reasonably free of biases, such as selection, observation and participation biases; however, if biases exist, the investigator has acknowledged them and so stated the study's conclusions that the biases do not intrude upon those conclusions; and

(iii) Has satisfactorily accounted for known confounding factors.

(3) For purposes of this paragraph a valid positive study is one which satisfies the criteria in paragraph (d)(2) of this section and whose findings are statistically significant at a

probability level of .05 or less with proper accounting for multiple comparisons and subgroup analyses.

(4) For purposes of this paragraph a valid negative study is one which satisfies the criteria in paragraph (d)(2) of this section and has sufficient statistical power to detect an association between exposure to ionizing radiation and a specific adverse health effect if such an association were to exist.

(e) For purposes of assessing the relative weights of valid positive and negative studies, other studies affecting epidemiological assessments including case series, correlational studies and studies with insufficient statistical power as well as key mechanistic and animal studies which are found to have particular relevance to an effect on human organ systems may also be considered.

(f) Notwithstanding the provisions of paragraph (d) of this section, a *significant statistical association* may be deemed to exist between exposure to ionizing radiation and a specific disease if, in the Secretary's judgment, scientific and medical evidence on the whole supports such a decision. (Authority: 38 U.S.C. 501; Pub. L. 98-542, as amended by Pub. L. 102-4)

[54 FR 40391, Oct. 2, 1989; 54 FR 46187, Nov. 1, 1989; 75 FR 17859, Apr. 8, 2010]

Supplement *Highlights* reference: 93(1)

Next Section is §1.200