

**Veterans
Administration**

**Research and Development
in Medicine
Rehabilitation Research and
Development Program**

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M-3, Part IV**

**Department of
Medicine and Surgery
Washington DC 20420**

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Veterans Administration
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CHAPTER 1. GENERAL**1.01 DEFINITIONS**

The Rehab R&D (Rehabilitation Research and Development) program consists of a broad range of investigations into the rehabilitation and support of disabled, handicapped, infirm or aged veterans in order to improve the quality of their lives and to enhance their functional independence. The Rehab R&D program expands the VA's historical role in prosthetics research into investigation of any device, technique, or concept for rehabilitation. Projects may relate to techniques for improving function after spinal cord injury, implants to improve locomotor functions, correction of sensory deprivation, means to increase the short distance mobility and long range transportation of the handicapped, physiological control systems, prosthetics, orthotics, cosmesis, and environmental, behavioral, and socioeconomic factors affecting rehabilitation. Rehab R&D projects tend to emphasize devices and prototype development. Such development and evaluation requires compliance with the medical device laws and regulations including those of the Food and Drug Administration and other Federal agencies concerned with other aspects of patient protection and safety.

1.02 PRINCIPLES AND OBJECTIVES

- a. The goal of the Rehab R&D program is to improve the quality of life and permit optimal functional independence of disabled, handicapped, and infirm or aged veterans through research and development.
- b. The Rehab R&D Service supports primarily intramural and, in some cases, extramural projects. To maintain the high quality of research and development, there is scientific and technical review by experts of all projects.
- c. The evaluation of new devices and concepts is effected by means of independent and objective preclinical and clinical trials, including cooperative and collaborative studies, preferably within VA health care facilities.
- d. To insure that veterans' and other patients effectively utilize technological advances, the Rehab R&D Service sponsors publication to disseminate research and development information; collaborates with the Offices of the Assistant Chief Medical Directors for Clinical Affairs and Academic Affairs in the VA, and with other Federal agencies in patient and staff education; and encourages private industry to introduce new devices.

1.03 POLICIES

- a. VA professional and technical staff conduct Rehab R&D studies, preferably within VA facilities. When this is not feasible, the VA, through contracts and interagency agreements, supports research and development by individuals, educational and other nonprofit institutions, Federal, State or local government agencies, and/or commercial organizations. Administrative and technical direction of these extramural activities usually is assigned to the staff of a VA health care facility. (See pt. 1, par. 3.02h.) When this is not feasible, they are directed from VA Central Office.
- b. Programs are planned to provide systematic progression through research, development, evaluation, procurement, and introduction into clinical use. The last step implies that a device becomes readily available; this generally requires commercial production by private enterprise. (See pt. I, par. 1.03m.)
- c. Rehab R&D patentable ideas and inventions by VA staff members must be reported to Central Office (See pt. 1, par. 1.03n.) The rights to patents developed under a Rehab R&D contract are stipulated in the agreement.
- d. Each Rehab R&D program must be submitted for approval of its scientific and technical merit by peer review, and must comply with existing laws, policies, and regulations concerning safety, research methods, and participation of human subjects. (See pt. 1, par. 9.02.)
- e. Evaluation of new products developed by the VA and by other includes suitable laboratory testing and determination of safety and efficacy in clinical use. Independent objective evaluations of new devices and concepts are conducted in VA health care facilities when practical.

f. Routine distribution of new and improved devices and techniques to eligible beneficiaries should occur only after the products have been tested, sources established, and personnel trained in their use. Once commercially available or approved to be marketed by the FDA, they cease to be the responsibility of the Rehab R&D Service.

g. The Rehab R&D staff, both in VA Central Office and in health care facilities, maintains close coordination and cooperation with other research, clinical, and education programs. This facilitates prompt, effective responses to clinical needs; improves clinical trials; ensures timely, informed decisions as to general distribution of new or improved devices and techniques; expedites their availability to patients; and educates and trains VA personnel in areas of rehabilitation R&D.

h. Increased emphasis will be given in the rehabilitation research and development program to the prevention of disabling conditions, and the restoration of function rather than compensation by adaptive devices and mobility aids. In some areas, development of compensatory devices is the chief goal, as in those cases involving sensory deprivation- of blind and minimally sighted patients, and individuals having hearing impairment or loss of peripheral sensation.

i. Reporting requirements for Rehab R&D programs are given in part 1, chapter 4, and guidance on publications in part 1, chapter 8; where a contract is involved, the requirements for part I, paragraph 5.02a(2)(e) also apply.