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Description Notes

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1. On 5 March 1982, the AOWG Science Panel approved a 4 December 1981 DOD/AAOTF concept paper on cohort selection. Specifically, what the Science Panel approved was the general principle of selecting battalion, and then company size, military units for exposure analysis, assigning the company A/O exposure score to each member of that company. If an individual was reported absent on a day when his company received an exposure, that individual's exposure score would be reduced accordingly. This is a departure from the approach suggested by UCLA, in which individual subjects were to be drawn at random and exposure scores developed for each subject individually.

2. On 5 March 1982, the Science Panel states: "The Science Panel will oversee this cohort selection process." The 4 December 1981 DOD/AAOTF concept paper was clearly not a scientifically rigorous methodological protocol. AOWG approval of that document should not have been construed as a signal to proceed with the actual selection of subjects without first developing a step-by-step protocol with the assistance of the Science Panel and other qualified scientists.

3. On 10 June 1982, the VA submitted to the AOWG Science Panel a memorandum (attached) concerning AAOTF cohort selection activities. That memo alerted members of the

Science Panel to the fact that inappropriate and unapproved decisions concerning cohort composition, exposure criteria, and selection methods had been made independently by DOD/AAOTF. It was the VA's belief that, if the AAOTF proceeded to select subjects as they proposed, their efforts would produce unusable cohorts and no useful data on the feasibility of conducting the larger study.

4. Between 4 December 1981 and 10 June 1982, meetings were held on the topics of Agent Orange exposure and cohort selection and some important progress occurred.

°It was generally agreed that a third cohort, roughly comparable to the two Vietnam cohorts could be assembled, if that were called for by the final study design.

°A general AAOTF cohort data automation contract was developed by AAOTF. It should be noted that general functional capabilities, not specific data elements, were approved by the VA.

°A Ranch Hand mission time/distance exposure matrix was developed.

°Methods of equating the different modes of exposure were proposed. Work on this problem continues.

°The AAOTF proceeded with work on an augmented "services" herbicide application record. This work also continues. The AAOTF was never asked by the AOWG or the VA to halt work on the documentation of herbicide use in Vietnam. This information is essential to any cohort selection process.

°On 8 April 1982, a letter was sent from VA Administrator Nimmo to Secretary Weinberger addressing the need for the support and cooperation of both agencies in this research effort. (attached)

°On 8 April 1982, a memo was sent by Secretary Scheiker^w to Secretary Weinberger. (attached) That memo recommended that DOD assume responsibility for cohort selection in support of the VA study.

°On 26 April 1982, Secretary Weinberger issued a tasking memo to the Secretaries of Army, Navy and Air Force authorizing full DOD support of this effort. (attached)

°The AOWG Science Panel created a subcommittee to 1. develop an acceptable Agent Orange exposure index 2. develop a cohort selection protocol for the AAOTF.

°On 8 September 1982, the Chairman of the Science Panel forwarded to DOD a draft protocol for cohort selection for DOD approval.

5. The AOWG and the VA can not provide the kind of continuous scientific supervision which is required for proper cohort selection. It has become clear that this important, complex and costly effort cannot be adequately supervised by a physiologist. The AAOTF should obtain the assistance of a qualified epidemiologist and/or biostatistician before proceeding with their cohort selection pilot work.