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Description Notes	Alvin L. Young filed these documents together with others under the label, "Agent Orange Exposure Project."

January 8, 1986

Note to: Dr. James O. Mason

From : Daniel L. McGee, Ph.D., Director, AOP
Through: Vernon N. Houk, M.D., Director, CEH

Subject: Roles of Review Committees for CDC's Epidemiologic Studies of the Health of Vietnam Veterans

As you requested, we are providing an overview of the appropriate roles of the various review organizations.

OFFICE OF TECHNOLOGY ASSESSMENT (OTA)

- As specified in Public Law 96-151, these studies shall be conducted in accordance with a protocol approved by the Director of OTA and the Director shall monitor the conduct of the studies.

- OTA will approve/disapprove the exposure assessment methodology prior to the conduct of the Agent Orange Study component.

- CDC will keep OTA informed of major methodologic/study design changes.

- OTA will monitor the conduct/progress of the study with annual (more frequent if necessary) review meetings.

- OTA will not review interim data analyses or be part of the scientific review process for the publication of the study's seven major reports.

- OTA will be provided a briefing on final reports prior to public release.

AGENT ORANGE WORKING GROUP (AOWG) SCIENCE PANEL

- The AOWG Science Panel reviews the exposure assessment methodology and reports the results to the Chairman, AOWG.

- CDC will keep the Science Panel informed of major methodologic/study design changes.

- The Science Panel will monitor the overall progress of the study; CDC will provide updates on a regular basis.

- The Science Panel will not review interim data analyses or be part of the scientific review process for the publication of the study's seven major reports.

- The Science Panel will be provided a briefing on final reports prior to public release.

- The Science Panel as presently composed does not have the scientific expertise to function as a scientific review group. Additionally, since it contains predominantly CDC, DOD, and VA staff as members, it is inappropriate for this group to be reviewing and monitoring these studies. A more balanced representation is needed.

ADVISORY COMMITTEE ON SPECIAL STUDIES RELATING TO THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS

- This is the committee which CDC originally asked to function in an ongoing peer review capacity. The committee chairman said they could not assume this responsibility since the committee's members were already overextended in terms of professional commitments.

- This committee will provide scientific review and critique of the study's seven major reports as they desire and deem appropriate.

- Since this is a formal DHHS Advisory Committee, their meetings must be open to the public; therefore, their review of interim data is undesirable.

INSTITUTE OF MEDICINE (IOM)

- This review group was established to provide ongoing peer review and assistance to CDC in the conduct of the study.

- IOM's meetings will be closed to the public; therefore, interim review of data and methodologic issues is appropriate.

- CDC will discuss with IOM proposed methodologic/study design issues as they develop to assist CDC in determining necessary changes/additions to the studies.

- IOM will review interim data analyses to critique the analytic methods being used and discuss the inferences/decisions that should be drawn from these analyses.

- IOM will provide scientific review and critique of the study's seven major reports and other publications related to these studies.