MINUTES
HUMAN USE COMMITTEE MEETING
9 FEBRUARY 1978

ATTENDEES:

COL Francis Cadigan, Jr., Director, Biomedical Laboratories, Chemical Systems Laboratory
LTC F. M. Durel, Assistant Project Manager for Chemical Demilitarization, Office of the Project Manager for Chemical Demilitarization and Installation Restoration
Mr. David English, Collective Protection Branch, Physical Protection Division, Chemical Systems Laboratory
Mr. Wayne Davis, Collective Protection Branch, Physical Protection Division, Chemical Systems Laboratory

COMMITTEE MEMBERS PRESENT:

Dr. Hans Falk, National Institute of Environmental Health Sciences
Dr. Harry Hayes, USDA, National Program Staff
Mr. Joel Mangel, Department of Health, Education and Welfare
Mrs. Donna Spiegler, Department of Health, Education and Welfare
Chaplain LeRoy G. Kerney, National Institutes of Health
Mr. Mark Plakatoris, Postmaster, Bel Air Post Office
Mr. Frederick L. Conway, Office of the General Counsel, Veterans Administration

COMMITTEE MEMBERS ABSENT:

Mr. Nester B. Knoepfler, Textile Chemical Engineering Research, USDA, ARS
LT Kuchin, Atlantic Strike Team, USCG Air Base

The meeting of the Human Use Committee commenced at 1000 hours on 9 February 1978, and was held at the Biomedical Laboratory Conference Room, Aberdeen Proving Ground - Edgewood Area, Maryland.

PRESENTATION BY COL CADIGAN:

COL Cadigan began the meeting by informing committee members of guidelines for the human use review. He explained the channels of approval that the test protocol will go through if and when the protocol is approved by the Human Use Committee. COL Cadigan pointed out the

reason that a Human Use Committee was necessary for the approval of the protocol. He explained that the committee was formed so that it could objectively review and evaluate the test protocol, determining if the government's incentives were appropriate in testing the protective ensemble, if the gain would outweigh the risk, etc.

At this point, Mrs. Spiegler raised the question about the status of the committee's advice, i.e., does the committee have veto power. COL Cadigan answered by saying if the committee said "yes" to the protocol, it would be forwarded through the approval channels. However, if the committee said "no" to the protocol, then it would be back to the drawing board.

COL Cadigan asked the committee to ask itself questions such as: "Is there a need for what is to be done", "Is there a gain for science/ mankind", "Does the protocol appear to be proper", "Do the people volunteering for the tests really understand the risks associated with the tests".

Mr. Mangel asked if the protocol had ever been reviewed by someone other than a government employee. COL Cadigan explained that the protocol was reviewed by such a committee composed of mainly non-government employees, but that the committee's recommendation was not accepted because of procedural problems.

Chaplain Kerney stated that he assumed that his role in being a committee member was not that of a representative from his federal agency, but instead one of a private citizen. COL Cadigan explained that the committee members had been selected for their individual expertise in

various areas so as to provide a disinterested review and evaluation of the moral and ethical aspects of the test protocol, but that their purpose in being there was to provide a representative of the public.

Chaplain Kerney asked what options the committee had for their recommendations regarding the proposed testing. COL Cadigan answered by telling the committee members that they had four alternatives for their recommendations. They could (1) approve the test protocol as it now stands, (2) approve the test protocol and recommend specific changes be made before forwarding through approval channels, (3) approve the test protocol and recommend changes which would be incorporated into the protocol and then reviewed again by the committee to assure their satisfaction, or (4) disapprove the protocol.

Dr. Falk asked what would happen if the committee wanted changes made in the protocol. COL Cadigan explained that, depending on the changes, the protocol might go back to the developer or it might go back to the Medical Review Board for technical review and revision. Dr. Falk also questioned whether the committee members were responsible for all of the information contained in the documentation given to them. He felt that he had some reservations about small details contained in the material. COL Cadigan told the committee that they had the right to demand any changes they felt necessary to improve the protocol. A committee member may feel that there are areas in which he has no expertise or understanding. If the committee wishes to raise questions regarding the appropriateness of the study, then they have the right to do so. He explained that there are areas of the protocol which each individual might be unable to comprehend.

Mr. Mangel stated that he had no understanding of the science involved in the study. He questioned what was expected of the committee if they had no understanding in this area. COL Cadigan pointed out that, although Mr. Mangel may have no understanding of the technical aspects of the test protocol, he would as a lawyer have some understanding of the legal implications involved in the testing. COL Cadigan went on to say that it was desirable to have at least one lawyer on the committee so that there would be someone present who would understand these implications. The chaplain would be present to present views regarding the welfare of the individuals who will be volunteers in the testing. As a whole, the committee should be able to evaluate the moral, ethical, legal and safety aspects of the protocol.

Mrs. Spiegler had a question regarding the final decision of the committee; should there be a majority vote in favor of the protocol? COL Cadigan stated that the committee would be selecting a chairman and from there would decide what would constitute approval of the protocol, whether the decision should be majority, unanimous, etc. All of these details would be left up to the committee itself. He pointed out though that a unanimous vote in favor of approving the testing might be a bit unexpected. COL Cadigan explained that in making recommendations, a committee member may choose to be mentioned by name if he has reservations about the testing. All of these details concerning any decision the committee may reach are left entirely up to the committee.

Mr. Conway asked if the committee would be allowed to review any changes made in the protocol by approving authorities, assuming the

committee approved the testing and recommended that it be forwarded through the approval channels. COL Cadigan explained that, according to changes made in the protocol as it went through approval channels (major or minor), the committee would have the opportunity to once again review the protocol, i.e., if the changes appear to be major ones, the committee will review the protocol again. However, if the changes are of a minor nature, there will be no need for a further review by the committee.

At this point in the discussions, COL Cadigan asked each committee member to introduce himself and give a brief background on his profession.

PRESENTATION BY MR. ENGLISH:

Mr. English gave a background of the new protective ensemble manufactured for use in the proposed testing. He explained the Army's interest in developing a protective ensemble that would afford the workers the ultimate in protection when working in a GB environment. Mr. English had mannequins dressed in the M3 suit (the former protective ensemble) and the demilitarization protective ensemble (the new proposed protective ensemble). He explained the shortcomings of the M3 suit and why it had been determined that the M3 suit was inadequate for personnel protection. He went on to say that an extensive survey had been performed to determine if there was a suit already developed which would provide the protection to workers which is required by current regulations. It was found that a number of various pieces of equipment were available, but there was no complete ensemble available which could be used to provide adequate protection to the worker. Mr. English then proceeded to point out advantages the

new protective ensemble possessed and how it provided better personnel protection. He also explained that the suit could be manufactured cheaply enough that it could be thrown away after a single use instead of going through costly and length decontamination procedures before reuse (the current process which is used now for the M3 suit).

Mr. English next covered the testing which had been done to date with mannequins in toxic environments and with humans in simulant environments. He explained monitoring procedures employed to assure that no leakage was found when mannequins wore the suit in a toxic environment.

Mr. Mangel asked if similar tests had been performed using the M3 suit and if any agent penetration had been found during these tests. Mr. English stated that tests had been done using the M3 suit and that agent leakage had been detected. He pointed out that the M3 suit was not originally designed for work to be performed in enclosed toxic areas. The M3 suit was not satisfactory for the purposes of agent operations.

At 1230 hours, the committee recessed for lunch.

TOUR OF THE TEST FACILITY/CHAMBER:

After lunch, the committee members, accompanied by the other attendees of the meeting, were taken on a tour of the test facility and chamber. Mr. English took charge of explaining the procedures involved in donning the demilitarization protective ensemble and the process by which the suit was examined for any leakage before the volunteer entered the test chamber. A question was raised by one committee member as to how many times a leak had been detected once the volunteer was heat sealed

in the protective ensemble. Mr. English replied that a leak had never been detected when examining the suit for leakage. The committee members were then taken to the actual testing chamber where Mr. English explained procedures employed in testing. Mr. English also discussed the procedures used in the event of an emergency situation during testing.

After an extensive tour of the test facility, the members resumed their meeting in the Biomedical Laboratory Conference Room approximately at 1400 hours.

PRESENTATION BY LTC DUREL:

LTC Durel gave a brief background on the use of the demilitarization protective ensemble in demilitarization operations, i.e., the CAMDS facility located at Tooele Army Depot, Utah. He explained the actual demilitarization process and the operational schedule for the CAMDS facility.

A question was raised by the committee as to whether the workers in the actual operations would be monitored for leakage in their protective ensembles. LTC Durel explained that there was no monitoring system within the suit itself during actual toxic operations.

Mr. Mangel expressed concern that, in testing operations, should an emergency situation occur within the test chamber, rescue workers would be wearing the M3 suit for protection instead of the demilitarization protective ensemble. He pointed out that if the M3 suit had already been determined as inadequate protection for workers, why should they be sent into a toxic area wearing the suit? Mr. English explained that, although the M3 suit was not as adequate as the demilitarization protective ensemble for personnel protection, it was not as bulky to wear and afforded the

worker greater mobility which would be required to rescue a worker wearing the demilitarization protective ensemble. He went on to explain that the time a rescue worker would actually spend in the toxic environment would be of short duration (several minutes).

At this time, a videotape was shown to the committee which depicted a simulated emergency situation and procedures involved in rescuing a worker wearing the demilitarization protective ensemble. An additional videotape was played for the committee showing normal operations involved in the testing.

At this point, the committee was left alone for deliberations.

COMMITTEE DELIBERATIONS:

The first issue resolved by the committee concerned selection of their chairman. It was concluded that Mrs. Donna Spiegler would act as chairman for the committee.

Chairman Spiegler brought up the question of whether toxic tests would be necessary at all. It seemed that the committee had been shown the advantages in using the demilitarization protective ensemble and it had been proven that the ensemble was definitely more than adequate for use in toxic environments. After some discussion, the committee concluded that the testing requirement had been imposed on the Army and they could not recommend that testing not be performed at all. The Army was obligated to perform these tests before the suit could be certified for human use.

Dr. Falk suggested that the addendum to the consent document be incorporated as part of that document to assure that a volunteer had read all information before volunteering for the testing. He felt that the addendum

contained important information which the volunteer should be aware of before signing a consent statement.

Dr. Falk next raised the question of why the testing had to be performed at the 100 mg/m^3 level of concentration in addition to testing at the 10 mg/m^3 level. At this point, Mr. English was brought back in the room to answer this question. Mr. English explained that in actual demilitarization operations it is believed that the level of concentration will exceed the 10 mg/m^3 level. It would be conceivable that in actual operations the concentration of agent might even be as high as 1,000 mg/m^3, but that 100 mg/m^3 seemed to be a good medium. In addition, Mr. English explained that the Army had already committed itself to The Surgeon General to perform testing at both the 10 mg/m^3 and 100 mg/m^3 levels. The Army agreed to perform testing at reasonable concentrations which would be encountered in actual operations.

Mr. Mangel asked if anything scientifically significant would be added by testing at the 100 mg/m^3 level as well as the 10 mg/m^3 level. Mr. English agreed that there was no significant addition to the data package.

At this point, COL Cadigan entered the discussion. He explained that, to a large extent, testing in a range of 100 mg/m^3 would reassure the people working in actual demilitarization operations that the suit could successfully be worn in a lethal environment.

Chaplain Kerney asked how the risks changed from 10 mg/m^3 to 100 mg/m^3. Mr. English explained that the risks were the same, but that a worker completely unprotected in a toxic environment would not receive a lethal

dose until after a 7 minute period at the 10 mg/m^3 level. At the 100 mg/m^3 level, the same worker would have approximately 45 seconds before receiving a lethal dose. Mr. English also said that before testing at the 100 mg/m^3 level, the testing which had been done at the 10 mg/m^3 level would be thoroughly reviewed and evaluated.

At this time, it was decided that the meeting should be continued at a later date. Several of the committee members had questions they wished to have answered and felt that further deliberations would be necessary before a recommendation could be made.

COL Cadigan was able to obtain authority to continue the meeting in lieu of beginning a new meeting which would require posting in the Federal Register again.

It was concluded that the meeting would resume on 16 February 1978 in Bethesda, Maryland, at 0930 hours. The exact location was yet to be determined.

Minutes of this portion of the meeting were recorded and transcribed by Deborah L. Mullins, Office of the DA Project Manager for Chemical Demilitarization and Installation Restoration.

FOR THE CHAIRMAN:

Mark S. Plakatoris

MARK S. PLAKATORIS
Committee Member