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DEPARTMENT OF THE ARMY
HEADQUARTERS, EDGEWOOD ARSENAL
ABERDEEN PROVING GROUND, MARYLAND 21010

File

12 Jul 76

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MEMORANDUM FOR: DIRECTOR OF BIOMEDICAL LABORATORY

SUBJECT: DPE Protocols

1. The Technical Program Manager of the DPE Program recently withdrew a protocol to conduct dynamic pressure tests in the DPE. During these tests certain characteristics of the suit are to be tested while a person is in the suit. He felt that a protocol was unnecessary because: (1) no data were to be collected from the individual, (2) no hazardous conditions would exist, and (3) only mechanical data on the suit would be gathered.

2. According to guidance we currently have, risk or no-risk is not a criterion for a protocol for tests involving humans. Therefore we can ignore reason number (2).

3. While I disagree with his ideas and reasons we should perhaps examine the concept he proposes more carefully. In the studies he proposes man is inside the suit and the tests are to be performed measuring characteristics of the suit. In this concept, man is merely a vehicle, not a test object.

4. There is a similar protocol proposed by the DPE Program Technical Program Manager. Under this proposal man would wear the suit into GB vapor and measurements would be made of the GB vapor within the suit. The protocol states the following:

a. "The detection of 0.01 mg/cu.m.- of agent in the in the outer-garment will result in immediate termination of the test."

b. "In the event of any leakage into the outergarment, the subject will be removed when the concentration reaches 0.01 mg/cu.m..."

c. "Any subject who accumulates a count of 10 mg/cu.m. is automatically eliminated from the test program."

The protocol does not state that the subject will be removed and the test terminated when he exhibits effects from GB, although this of course will

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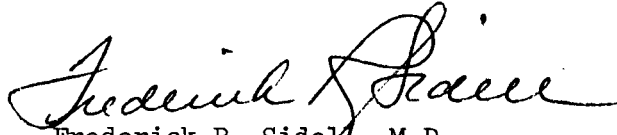
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be done by the medical officer. There is nothing in the protocol that states that these effects are to be considered data. The only data taken from the subject during or after the test will be a cholinesterase; this requirement is in the "medical screening" section of the protocol and was placed there by the medical staff, not the investigator. Although this information might now be used by the investigator, it is not an integral part of the test and was not in the original protocol as submitted as being a test measure (nor is it in the present protocol as a test measure).

5. The point to be made is that the principle of this proposal is exactly the same as that of the proposal for dynamic pressure testing, namely that (1) no data are to be collected from the individual (except that required by the medical staff for safety) and (2) only data on the suit are to be gathered (instead of pressures within the suit it would be GB within the suit).

6. I disagree with these reasons. However, if these are the reasons they chose to apply then the same reasons must be applied to both protocols and they should withdraw the GB test protocol as well.



Frederick R. Sidell, M.D.
Chief, Medical Volunteer Office

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