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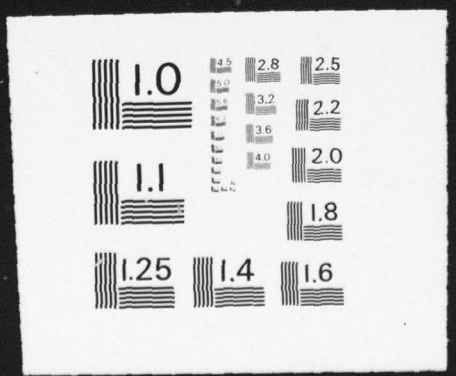

DEPARTMENT OF THE ARMY
OFFICE OF THE DEPUTY CHIEF OF STAFF FOR
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WASHINGTON, D. C. 20310

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REPORT OF THE

ARMY SCIENTIFIC ADVISORY PANEL

AD HOC GROUP

ON

BIOLOGICAL AND TOXIN SAMPLES

APRIL 1976

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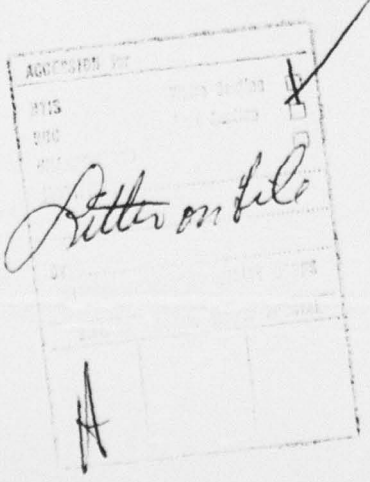

Final Report
Army Scientific Advisory Panel
Ad Hoc Group on Biological and Toxin Samples

1. Introduction:

An Ad Hoc Group of the Army Scientific Advisory Panel was convened to review current holdings of biological and toxin samples retained within the Army Material Development and Readiness Command and the Army Medical Research and Development Command to evaluate the appropriateness of the number and size of these holding in terms of the biological defense and ecologic programs currently approved. The Terms of Reference (TOR) for the review are attached as Appendix A, and the membership of the Ad Hoc Group, as Appendix B. All of the members of the Ad Hoc Group, with the exception of Dr. Steinfeld, participated in the full schedule of visits listed below. Dr. Steinfeld participated only in the visit to the U. S. Army Medical Research Institute of Infectious Diseases (USAMRIID) but reviewed all of the briefing materials supplied to the Ad Hoc Group, and participated fully in the discussions leading to the preparation of this report. Because his role was that of a consultant to the Ad Hoc Group, Dr. Steinfeld did not participate in the actual writing or review of the report.

2. Installations Visited:

On the basis of a review conducted by the Office of the Secretary of Defense in September 1975, only three installations within the Department of the Army held samples of biologicals and toxins. All three of these installations were visited on the dates specified in the schedule below:

a. Dugway Proving Ground, Dugway, Utah, on 13 January 1976
b. Edgewood Arsenal, Edgewood, Maryland, on 14 January 1976
c. U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Frederick, Maryland, on 15 January 1976.

3. Administrative Summary:

On the basis of the review conducted, the Ad Hoc Group finds that the number and size of the present holdings of biological and toxin samples are appropriate for the Army responsibilities for the biological defense and ecologic programs currently approved. On site inspections of material, to the extent permitted by the lack of immunization of the group, revealed that existing inventories of

samples held accurately reflect the holdings of biological and toxin samples. The current research and development programs of the three installations visited, as presented in the briefings of the Group, appear to be appropriate for the biological defense and ecological survey responsibilities of the Department of the Army (DA). In addition, the Ad Hoc Group has provided recommendations for changes in safety and surety programs concerned with biological and toxin samples retained within DA for discharge of its responsibilities.

4. Sample Classifications on the Basis of Safety Considerations:

In the course of its review, the Ad Hoc Group concluded that biological and toxin samples could conveniently be subdivided into five classes, differing in degree of safety hazards. The safety and surety handling of these five classes of materials should differ, although at present such differences are not major. An outline of these five classes, in order of increasing safety precautions, follows:

a. Simulant organisms: Simulant microorganisms are used in the programs of Edgewood Arsenal. Although they are generally considered non-pathogenic for man, they may occasionally cause illness in infants and debilitated adults, and for this reason should be stored in secure areas. However, it does not appear necessary or desirable to include them in the inventories of hazardous substances.

b. Snake and insect venoms: Venoms of biological origin are available through commercial medical channels of supply, and for this reason unduely severe surety measures do not appear warranted. Venoms are potent chemicals and should be handled with respect, like many drugs handled in medical installations. It appears appropriate to include them in the inventories of biologicals and toxins, even though their main use in Department of the Army programs is for the preparation of protective serums used in treatment of snakebite in troops who may be stationed throughout the world. Inventory of venoms does not appear to be warranted more frequently than annually.

c. Pathogenic microbial samples: The current holdings of pathogenic bacteria, rickettsiae and viruses in the Department of the Army installations visited are comparable to similar holdings, both in terms of variety and quantities, in research laboratories and institutes in the civilian sector in the United States and abroad. Many of these microorganisms are capable of causing severe disease in man, and for this reason require unusual safety precautions for the

small quantities of these materials held in frozen storage and for the laboratory areas in which the work performed is concerned with the prevention or treatment of the diseases which these organisms cause. It therefore appears appropriate that these microbial samples be included in inventories and be subjected to appropriate safety precautions. Because frozen stock strains of these microorganisms may be killed if subjected to frequent changes in temperature, inventories of such samples should be at appropriate intervals, preferably on an annual basis. It should be emphasized that microbial samples comparable to those held within DA are readily available from research laboratories and institutes in the civilian sector.

d. Low risk microbial toxins: There are a number of "low risk" microbial toxins in the present holdings, e.g., enterotoxins and shellfish toxins. These materials, although toxic when administered by the appropriate routes, are of a lower level of toxicity than the next class. The low risk toxins are appropriately included in inventories and subjected to secure storage.

e. High risk microbial toxins: The high risk toxin derived from the organism causing botulism is extremely potent and for this reason deserves maximum safety and surety precautions. It should be included in inventories and stored under maximum security conditions.

5. Definition of "Reasonable Quantity" for Research:

The Ad Hoc Group considered the question of whether it was possible to define a "reasonable quantity" of biological or toxin without reference to toxicity, cost or research mission, and concluded that all of these factors influenced the judgment of what constituted a reasonable quantity. To adequately perform its responsibilities for biological defense, it is necessary that the DA installations responsible for research in this field have sufficient supplies of biologicals and toxins to test appropriately protective equipment and alarm systems for effectiveness. Such testing includes initial testing with simulants, but cannot omit carefully controlled testing with active biologicals or toxins that potentially might be utilized against the United States. It is therefore essential that an appropriate sample of biologicals or toxins be available for this purpose. Similarly, if protective vaccines are to be developed, samples of the microorganisms are necessary to prepare such vaccines. Present samples of biologicals and toxins held within

DA are considered by the Ad Hoc Group to represent reasonable quantities for defensive research.

Two specific areas that received special consideration were the samples of enterotoxin held by USAMRIID and botulinum toxin held by Edgewood Arsenal. In the first instance, the enterotoxin in the inventory at USAMRIID was initially prepared for conversion into toxoid. Because of contractural problems, it was not possible to convert the enterotoxin into toxoid which would be utilized for immunization. Until a suitable contractor can be identified, it appears appropriate to hold the enterotoxin under secure storage. In the second instance, the amount of botulinum toxin held at Edgewood is appropriate for testing of pretective equipment and alarm systems. There is a discretionary question of whether a portion of that sample of botulinum toxin might be converted to the non-toxic toxoid, but appropriate testing of the comparability of test results with toxin and toxoid has not yet been done, and, until it is, the decision of what amount might be converted to toxoid cannot be made.

6. Records and Inventories:

As indicated in paragraph 4., above, it does not appear that any useful purpose is served by maintaining the simulant organisms in the inventories. The remaining four classes of biologicals or toxins are appropriately subjected to inventory. The records obtained as a result of inventories should be supplemented by additional records of materials removed from inventory because of research use or destruction so that the records may be reconciled periodically.

The Ad Hoc Group found that inventories and records were being maintained appropriately by all three installations, although the system in use at USAMRIID was exemplary.

The Ad Hoc Group recommends that the inventory procedure be continued at all three installations, and that consideration be given to the development of a standard procedure of inventory of biological and toxin samples on an Army wide basis, taking into consideration the fact that the periodicity of inventory may vary for the class of material involved.

In the opinion of the Ad Hoc Group, consideration should also be given to a modification of the current method of inventory that would make a representative of the Inspector General (IG), supported by a civilian scientific consultant, participants in the installation

inventories. Both the IG representative and the scientific consultant should be immunized, as appropriate, so that they could participate in actual physical verification of such inventories, where appropriate.

Such inventories might also be available for review at DA or Department of Defense (DOD) levels for review by appropriate advisory groups.

7. Safety and Security Measures:

In terms of safety precautions, all three installations were following acceptable procedures, although the measures in use at USAMRIID were exemplary. Particular practices at USAMRIID that could be applied at the other installations, where appropriate, include the subdivision of a particular batch or lot of material into smaller lots, the storage of infectious materials in sealed glass ampules, and the use of sealed plastic bags within larger metal containers or cans for physical containment of samples of infectious and toxic materials and for greater protection of persons handling such samples.

In terms of security measures, all installations were practicing a high degree of security precautions. In some instances the level of security was deemed excessive, as for the simulant organisms already mentioned. In other instances, the paperwork associated with entry into certain buildings required so much time to complete that the question was raised whether the system was interfering with the conduct of normal operations. There is no question that the high risk microbial toxins require require maximum levels of security, but the level of security afforded to the remaining four classes of biologicals and toxins should, in the opinion of the Ad Hoc Group, be graded on the basis of the safety risk involved.

8. Disposition or Detoxification of Certain Materials:

In the opinion of the Ad Hoc Group, standard microbial samples lacking an adequate passage history or identification should be discarded from the inventory.

Similarly, samples of enterotoxin not of the purity of the material held at USAMRIID should be destroyed, and the USAMRIID supply utilized for research investigations.

The question of possible detoxification of a portion of the sample of botulinum toxin was discussed in paragraph 5. Information available at the time of the visits was not sufficient to permit the Ad Hoc Group to arrive at a definite recommendation of whether such steps should be taken and, if so, what proportion of the sample should be detoxified. This question should be addressed by a detailed internal review of the planned testing requirements involving this sample.

All three of the installations visited had developed their own procedures for recording destruction or detoxification of biological or toxin samples. Although all were judged satisfactory, it appeared that a uniform method of recording such actions including utilization of a witness might be developed by DA. Such records are necessary for the reconciliation of inventories conducted on a periodic basis, as discussed in paragraph 6.

9. Review of Associated Programs:

The time available for the visit of the Ad Hoc Group to these three installations was limited so that it was not possible to review the associated programs in depth. A full review of program and budget documents for the three installations visited would easily have taken a number of days for each installation. As a practical matter, the Ad Hoc Group was briefed verbally on the programs of each of the installations. This, in the time available to the Group, provided a reasonable picture of the programs of the three installations.

However, because biological science advances and changes with time, the Ad Hoc Group strongly endorses a continuing review of both programs and inventories at each of the installations to insure that both are consistent with the requirements for defensive research assigned to DA. On the basis of the material presented to the Ad Hoc Group, the programs of all three installations are appropriate to the defensive missions assigned to each. In particular, the Group commends the installations for their continuing involvement with the civilian scientific community in the form of scientific advisory committees, and in the supplying of research quantities of the biological and toxin samples to appropriate civilian biomedical research laboratories. Such involvement with the civilian scientific community provides a commendable link with the scientific public and utilizes the advice of appropriate experts to assure that the ongoing scientific programs of the three installations are scientifically sound and current.

10. Conclusions and Recommendations:

a. On the basis of the review conducted, the Ad Hoc Group concludes that the number and quantity of the present holdings of biological and toxin samples are appropriate for the DA responsibilities for the biological defense and ecologic programs currently approved.

b. On site inspections of samples, to the extent permitted by the lack of immunization of the group, revealed that existing inventories of materials held accurately reflect the holdings of biological and toxin samples.

c. The current research and development programs of the three installations visited, as presented in briefings of the Ad Hoc Group, appear to be appropriate for the biological defense and ecologic survey responsibilities of DA.

d. Non-pathogenic simulant microorganisms should be stored in secure areas, but need not be retained in the inventories of hazardous samples.

e. Snake and insect venoms, being available through commercial medical channels, do not require unduely severe security measures. They should be stored in secure areas and included in the inventories of hazardous samples.

f. Pathogenic microorganism samples held within DA are comparable to similar holdings in research laboratories and institutes in the civilian community. These samples pose safety problems and should be stored in secure areas and included in the inventories of hazardous samples. Care should be exercised in the timing and nature of inventories so that these samples are not killed by exposure to adverse temperature conditions.

g. Low risk microbial toxins should be stored in secure areas and included in the inventories of hazardous samples.

h. High risk microbial toxins should be stored under maximum security conditions and included in the inventories of hazardous samples.

i. The sample inventory procedure should be continued on an appropriate periodic basis which could and should vary with the class

of sample being inventoried. The inventory procedure should be supplemented with appropriate reporting procedures to account for destruction or detoxification of samples so that inventories may be reconciled periodically.

j. Consideration should be given to the use of IG representatives and appropriate civilian scientific consultants for

(1) participation in inventories of samples at the installation level, as appropriate, and

(2) reviewing inventories and/or programs at the DA and DOD levels.

k. Safety procedures were generally satisfactory, but could be modified at both Dugway Proving Grounds and Edgewood Arsenal to include some of the refinements incorporated into the safety storage procedures at USAMRIID.

l. Standard microbial samples lacking an adequate passage history or identification should be destroyed and discarded from the inventory. Similarly, samples of enterotoxin not of the purity of the material held at USAMRIID should be destroyed and removed from the inventory.

m. Security measures were adequate at all installations visited, and probably excessive for the less hazardous categories of samples.

n. Methods of destruction of samples were appropriate and adequate for the class of sample.

Appendix A

Terms of Reference
ASAP Ad Hoc Group on
Biological and Toxin Samples within DA

24 November 1975

1. Background: As a result of assignment of responsibilities for biological defense and in connection with the biomedical and ecological programs within the AMC installations of Edgewood Arsenal and Dugway Proving Ground and the Medical Defense Against Biological Agents Program within the U.S. Army Medical Research and Development Command Institute of Infectious Diseases, a number of biological and toxin samples of varying size are in controlled holding. Commanders, AMC and Medical R&D Command have requested that an independent review be made of the number and size of these holdings to determine they are not excessive in view of assigned R&D responsibilities.

2. Terms of Reference: The Ad Hoc Group is requested to: (a) make on-site inspection (if appropriate) of the holdings, (b) review the associated programs and (c) recommend the appropriateness of the size and quantity in view of the intended usage.

3. Termination of Effort: The Chairman of the Ad Hoc Group is requested to conclude his efforts at the earliest possible date. A final report should be available not later than 30 January 1976.

Appendix B

DEPARTMENT OF THE ARMY
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Washington, D.C. 20310

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13. ABSTRACT

Ad Hoc Group reports findings of survey of Army installations made to determine and evaluate holdings of biological and toxin samples. Current holdings were found to be reasonable and consistent with defensive research needs.

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