

Originally Processed With FOIA(s):
2005-0336-F

FOIA Number:
2005-0336-F

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Series: O'Neil, John F., Files
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OA/ID Number: 62104
Folder ID Number: 62104-004

Folder Title:
Biological Warfare [1 of 4]

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Biological Weapons Treaty Review

In the Gulf War aftermath, scientists and ethicists anticipate complex negotiations this fall in Geneva

MELISSA HENDRICKS

Since the cease-fire in the Persian Gulf, anxieties over imminent biological weapons (BW) attacks have faded. But serious questions about biological weapons in the Middle East and other parts of the world remain. Moreover, this issue will draw renewed attention in September when delegates from 136 nations are invited to meet in Geneva, Switzerland, to review the Biological Weapons Convention (BWC). The 1972 treaty bans the development, production, and stockpiling of biological agents for nonpeaceful purposes. However, it does not prohibit research for defense against BW. Earlier review conferences on the Convention were held in 1980 and 1986.

BW negotiations have both direct and indirect bearing on microbiologists. To comply with the treaty, nations may decide to ban the import or export of certain biological agents as well as certain technologies used in biological research, thus perhaps slowing the pace of research, especially collaborative projects between countries. On the other hand, some signatory states may decide to promote exchanges of researchers to show they have nothing to hide. More abstractly, many microbiologists are faced with deciding whether they feel morally comfortable working on projects sponsored by the military or that have potential to be used by the military for BW purposes.

Scientists, historians, ethicists, and defense experts addressed these and related issues at "The Microbiologist and Biological Defense Research: Ethics, Politics and International Security," an April conference funded by a National Science Foundation grant and sponsored by ASM Archives, the Maryland Biotechnology Institute, the University of Maryland Baltimore County, and Physicians for Human Rights. Meeting participants repeatedly referred to the status of BW negotiations, gaps in the treaty, and possible outcomes of the next international review conference scheduled for September.

Review Issues Will Be Complex and Controversial

At the impending review conference, delegates are expected to examine whether the scope of the 1972 BW treaty is sufficient. Weaknesses in the Convention became evident soon after it was signed. High on the list of criticisms is the fact that the treaty lacks a formal verification policy, as events surrounding the war with Iraq illustrated. Though a signatory to the treaty, Iraq was rumored to have stockpiled BW. No formal mechanism to confirm or disprove such allegations exists under the treaty. Another issue—new since the treaty was drafted—is recombinant DNA technology. It prompts serious concerns about how to regulate containment of novel infectious organisms.

At the most recent treaty review conference in 1986, delegates adopted four "confidence-building measures." They called for signatory states to exchange information on laboratories working with biological agents under high safety standards, to promote interaction between scientists across international boundaries (for example, through conferences and research collaborations), to encourage publication of relevant research, and to report all outbreaks of strange diseases. While the measures opened the door to verification, they are voluntary and are not part of a formal verification protocol.

While confidence-building measures opened the door to verification, they are voluntary and not part of a formal verification protocol.

Verification means that signatories look for evidence confirming compliance. A formidable task, verification protocols could make thousands of laborato-

Melissa Hendricks writes for The Johns Hopkins Magazine in Baltimore, Md.

Scientists Grapple with the Ethics of BW

The microbiologist's role is to protect and save lives, not to develop weapons. By itself, however, science is value free. Moreover, scientists often feel they cannot be deemed responsible for how the results of their work are applied by others.

These arguments have been used by scientists and ethicists to explain why they ignore the ethical issues raised when considering the contemporary development and use of BW. The truth is that biologists and germ weapons share a long, sordid history. As early as 300 B.C., says James Poupard, director of the ASM Archives, Greeks were throwing animal and human corpses into wells to pollute the water of their enemies. Much more recently but prior to the BWC, even the United States developed BW. In the early 1940s, for instance, researchers in the United States worked on anthrax bombs and botulism weapons. The ASM Archives and the Center for the History of Microbiology serve as a depository of history on BW.

Much of the history of BW is only recently coming to light, including the story of Japan's BW experiments on civilians during World War II. Historian Sheldon Harris of California State University in Northridge revealed some of this troubling story at

the conference held in Maryland during April. Japanese microbiologists conducted experiments on men, women, and children (most of whom were Chinese), says Harris. They tested many pathogens, including anthrax, yellow fever, typhoid, smallpox, scarlet fever, and venereal diseases. "They injected pathogens of different strengths to get the right dose necessary to kill," he notes. More than 10,000 individuals died or were killed during the course of this BW effort.

Nearly every major Japanese university was involved in the project, according to Harris. "The vast majority [of scientists] serving were willing participants," he points out. "Some said they were being humanitarians, finding cures for illnesses. These scientists rarely expressed remorse in the postwar years. Extreme nationalism and ethnocentricity accounted for [a lack of] ethical concern over biological weapons."

On the other hand, history is also full of unproven allegations of BW use. During the Korean War, Korea accused the United States of BW use. After in-depth study, historian John Ellis van Courtland Moom of Fitchburg State College in Fitchburg, Mass., concluded that there is no definitive evidence confirming the allegation. However, he points out, "Once

an allegation is made, it is impossible to disprove it conclusively. Doubt is never totally exorcised."

Ethicists and historians urged other participants at the April gathering to learn from history. Although one speaker handed out an ethical road map for microbiologists, all urged them and others to keep open a broader dialogue on the subject. Several participants asked that ASM and other scientific and professional organizations become more involved in BW-related issues. ASM might help dispel some of the misconceptions and false allegations that arise periodically, such as reports speculating that Iraq was producing anthrax bombs. Raymond Zilinskas says, "That was an information and technically wrong," he asserts. "So why not have the ASM coming out saying 'this is technically wrong?' That effort would help to set the record straight and dispel unnecessary fears."

"Scientists have to be immersed in the real world and preserve autonomy over science," notes Douglas MacLean, a professor of philosophy at the University of Maryland. "But scientists should not have the responsibility to oversee this. The main focus should be not on the individual scientist but on the institutions."

ries liable to mandatory on-site inspections or surprise inspections. It could also mean that governments would be required to release import and export records for biological agents and certain other research materials. A strict protocol might even require researchers to make available data books, purchase records, and visitor lists. Some observers deem such measures necessary because inspectors cannot spot violations by satellite as they can for some nuclear treaty violations. Naturally, some nations and many individual researchers are likely to resist such intrusions.

Verification would probably involve amending the treaty, says Thomas Dashiell, a consultant to the Arms Control and Disarmament Agency who attended the April conference in Maryland. According to Dashiell, who will represent the United States at the upcoming review conference, and to other informed sources, delegates in September will evaluate each of the confidence-building measures. Ultimately any of the measures can be adopted within the context of the treaty's charters. "I do not think verification will be an issue," he predicted.

At the top of the list of confidence-building issues is the requirement that signatory states identify all research facilities dealing with high-risk biological materials. Signatories are to report the locations and relevant research activities of all such labs. Since 1986, that measure has met with limited compliance on a voluntary basis. Thus, of the 136 parties to the Convention, only 27, including the United States, filed reports.

Delegates this fall are expected to discuss how compliance with this measure could be improved. Part of the problem may be that states disagree on which biological agents pose identifiable BW risks. Also, the measure asks only for reports of laboratories conducting such high-risk work. Nations claiming no such facilities may have filed no reports. "All nations should make a report, even if it is 'we have none,'" suggests Dashiell. "I think our level of openness and transparency should serve as a model for other countries."

Another meeting participant, Charles Flowerree, proposes that a nongovernment organization coordinate the exchange of lab and other related information

covered by the Convention's Article 10. Flowerree, a consultant to the State Department and a former representative to the Conference on Disarmament, suggests that the International Organization of Scientific Unions, a branch of the United Nations (UN) Educational, Scientific, and Cultural Organization, play this role. Governments themselves are "not likely to give force to the provisions of Article 10," he says. "We need an organization to take the lead, to keep informed about facilities, who is doing what and with how much. There has to be agreement on an overall authority and a means of financing it." Admitting that these are daunting tasks, Flowerree adds, "However, I think there will be more discussion on verification at the next conference."

Defensive versus Offensive BW Research

Complicating verification proceedings is a long-running debate over what separates offensive BW research, which BWC prohibits, from defensive BW research, which the treaty allows. Administrators of the U.S. Biological Defense Research Program (BDRP), run out of Fort Detrick in Frederick, Md., say program investigators conduct research that is clearly only for defensive purposes. BDRP labs are open to public scrutiny, the administrators emphasize. (However, some aspects of the program are classified for national security reasons.)

Critics contend that the boundary separating offensive and defensive research is poorly defined.

Critics of BDRP contend that the boundary separating offensive and defensive research is poorly defined. Under BDRP auspices, for example, an investigator developing a vaccine to protect against anthrax might spend time looking for ways to optimize growing conditions for the bacterial pathogen. However, that knowledge might be applied to grow large amounts of the bacteria for use in bombs. Genetic engineering complicates the issue even further. For instance, an investigator might attempt to engineer a particular pathogenic virus to develop an innocuous strain for use as a vaccine. But similar efforts, say skeptics, might also be applied to create a more pathogenic virus.

"What is legitimate defensive research? What should be banned? How do you know what the threat is?" asks Flowerree. These and other questions concerning the distinction between defensive and offensive research will undoubtedly come up at the Third Review Conference this fall.

"The only means of distinguishing defensive from offensive research may be 'intent,'" says David Huxsoll, a former commander in BDRP and a delegate to

the Second Review Conference who is currently a faculty member in the School of Veterinary Medicine, Louisiana State University, Baton Rouge. "A bacillus culture in a tube of agar is just a bacillus culture in a tube of agar. A large culture is just a large culture. A biological weapon is a biological agent that has been developed and produced with 'intent' of weaponization."

How do observers assess intent? According to Huxsoll, certain endeavors clearly signal offensive BW research. Projects that seek to stabilize a pathogen in an aerosol, for example, or to improve its virulence indicate research for offense purposes, while ones that lead to methods of detecting and decontaminating agents are legitimate research for defense.

But some critics would like to seek a more precise means of dividing offense from defensive work. Flowerree suggests that BW negotiators explore the possibility of restricting the quantities of biological agents that may be produced in the course of peaceful research activities. The current BWC does not stipulate such permissible quantities.

Few Investigative or Punitive Measures

Neither does the BWC treaty outline procedures for investigating violations or for punishing proven transgressors. It says only: "The States [party] to this Convention undertake to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention."

Already, several allegations of BW use of possession have gone unanswered, including claims that the Soviet Union in 1979 accidentally released anthrax spores from a research facility in Sverdlovsk. The Soviets were suspected of conducting research at the facility in violation of BWC. Instead of admitting to an accident, the Soviets said that anthrax, a disease indigenous to that region, arose naturally and was spread by meat sold on the black market. "Had we been able to send a team to Sverdlovsk," says Flowerree, "lingering suspicions could have been avoided."

One measure adopted by the last review conference—that signatory nations report unexplained disease epidemics—might help decrease or eliminate such suspicions in the future. States were asked to report unusual disease outbreaks to the UN. But since 1986, only one nation has complied with this measure. In 1989, the United Kingdom reported 100 cases of Q fever. "I think this confidence-building measure is likely to be dropped," says Barbara Rosenberg of the Federation of American Scientists (FAS). Nations cannot afford to run extensive disease surveillance systems, she says, and some are worried about scaring off tourists in the aftermath of such announcements.

Global Disease Monitoring and Other Plans

Several scientists and public health officials have developed more rigorous plans for global monitoring of disease. At the April meeting in Maryland, Raymond

Zilinskas unveiled a proposal for a biological hazards early-warning program (BHP). Zilinskas, of the Maryland Biotechnology Institute and the Johns Hopkins School of Public Health, called for the establishment of medical field teams around the world whose members would investigate new epidemics of infectious diseases.

The teams of doctors, parasitologists, bacteriologists, immunologists, virologists, and other medical professionals would seek the source of unusual disease outbreaks or rumors of outbreaks. The teams would examine both diseases due to BW, says Zilinskas, and those stemming from natural causes. Since many stations would be in poor or isolated regions, BHP would also help to improve health standards in many countries.

Zilinskas modelled the program after the U.S. Navy Medical Research Units, a group containing both permanent and roving clinics around the world that monitor disease epidemics. The Navy's teams have investigated outbreaks of malaria, cholera, AIDS, and other diseases. BHP teams, Zilinskas suggests, would report to a central civilian agency such as the World Health Organization. The international network of disease sleuths thus might deter potential developers of BW, he says.

Funding the labs and training of professional staff to run them will be difficult, Zilinskas acknowledges. Participating countries will have to share the financial burden, he notes, adding that BHP "requires active and direct participation of scientists and professional organizations."

FAS would like to broaden the authority of the UN secretary general in investigating BW allegations. The secretary now has authority to investigate only alleged use of BW. FAS proposes that the authority of

the secretary be broadened to investigate alleged possession of BW as well. The organization is submitting this proposal to the Review Conference, along with several other suggestions for implementing verification. Another item is on the FAS wish list: a request that a permanent group of experts be established to oversee BWC.

Several defense analysts say that BWC verification should wait until the chemical warfare (CW) treaty is completed and then follow verification procedures already outlined in the CW treaty. A drawback is that CW negotiations are at a stalemate. Furthermore, says Dashiell, a delegate to the CW proceedings, "it is going to be very difficult to just 'adapt' procedures. The problem of biological weapons verification is very different from [that of] CW verification." CW negotiators have identified chemical companies that will need to be inspected. But verification of biological agent research would involve reports from industries, research institutes, and even hospital labs. "I hate to say a chemical weapons treaty will be a model," he says, "but it will serve as a useful guide."

Weary of waiting for a chemical weapons treaty, FAS is trying to jumpstart verification. To test its verification proposals, the group is conducting trial inspections of biological research facilities in the United States. FAS's Rosenberg hopes to submit preliminary results of those tests to an expert committee if one is established by the Review Conference.

"Everyone agrees that the subject of verification cannot be resolved at a review conference," says Rosenberg. "But there is an interest in verification." An expert committee and strengthening of the last confidence-building measures may pave the way toward acceptable verification procedures. □

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Collection:

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Office: Science and Technology Policy, Office of (OSTP)
Series: O'Neil, John F., Files
Subseries: Reports and Publications Files
WHORM Cat.:
File Location: Biological Warfare [1 of 4]

Date Closed: 6/1/2010	OA/ID Number: 62104-004
FOIA/SYS Case #: 2005-0336-F	Appeal Case #:
Re-review Case #:	Appeal Disposition:
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02. Memorandum	To: D.A. Henderson Re: GAO Report [50 USC 403g, Sec. 6] (1 pp.)	3/25/91	(b)(1), (b)(3)	

Collection:

Record Group: Bush Presidential Records
Office: Science and Technology Policy, Office of (OSTP)
Series: O'Neil, John F., Files
Subseries: Reports and Publications Files
WHORM Cat.:
File Location: Biological Warfare [1 of 4]

Date Closed: 6/1/2010	OA/ID Number: 62104-004
FOIA/SYS Case #: 2005-0336-F	Appeal Case #:
Re-review Case #:	Appeal Disposition:
P-2/P-5 Review Case #:	Disposition Date:
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December 1990

BIOLOGICAL WARFARE

Better Controls in DOD's Research Could Prevent Unneeded Expenditures





United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

B-241869

December 27, 1990

The Honorable John Glenn
Chairman, Committee on Governmental Affairs
United States Senate

Dear Mr. Chairman:

This report responds to your request that we review the medical component of the Department of Defense's Biological Defense Research Program. It discusses, among other things, the need for the Department to implement better program controls to ensure that all medical research and development efforts are directed toward validated biological warfare threat agents. It contains recommendations to the Secretary of the Army aimed at improving the management of the program.

Unless you publicly announce its contents earlier, we plan no further distribution of this report for 30 days. At that time, we will send copies to the Secretaries of Defense and the Army, the Director of the Office of Management and Budget, and other interested parties.

This report was prepared under the direction of Richard Davis, Director, Army Issues, who may be reached on (202) 275-4141. Other major contributors are listed in appendix III.

Sincerely yours,

A handwritten signature in dark ink that reads "Frank C. Conahan". The signature is written in a cursive style with a large, stylized "F" and "C".

Frank C. Conahan
Assistant Comptroller General

Executive Summary

Purpose

In 1972, over 100 countries signed the Biological and Toxin Weapons Convention, which prohibits the development, production, and stockpiling of biological and toxin weapons. Since 1972, however, the number of nations having or suspected of having offensive biological warfare programs has increased from 4 to 10, with some of these countries being located in the Middle East, according to the Army's senior biological warfare analyst. U.S. military forces facing the threat of biological warfare must have medical countermeasures to defend against a biological weapons attack. The Department of Defense, through its Biological Defense Research Program, is responsible for developing these countermeasures, and the Congress has appropriated about \$370 million since fiscal year 1984 for this purpose.

The Chairman of the Senate Committee on Governmental Affairs requested that GAO determine whether the program's medical research and development projects were (1) directed at validated biological warfare threat agents, (2) used to develop medical products for the defense of U.S. forces, and (3) coordinated with other federal research organizations to avoid unnecessary duplication.

Background

The mission of the medical component of the research program is to develop medical defenses, such as vaccines and drugs, to defend against biological warfare. The Department of Defense defines a "biological warfare threat" as a biological agent that the intelligence community has assessed as being developed or produced as a weapon. The Armed Forces Medical Intelligence Center, in conjunction with other intelligence agencies, validates the biological agents that present a bonafide threat to U.S. forces. The Academy of Health Sciences, a component of the Army's Health Services Command, determines the requirements for drugs and vaccines needed to counter these validated threats. The Army's Medical Research and Development Command, at Fort Detrick, Maryland, executes the medical component of the research program through research and development projects. The Command reports to the Army Surgeon General.

Results in Brief

The Army, because it did not have adequate internal controls in its medical research program, unnecessarily expended funds on research and development efforts that did not address validated threats and may have duplicated research efforts of other federal agencies. GAO's review showed that

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- 49 research projects, valued at about \$47 million, were directed at biological agents that the Armed Forces Medical Intelligence Center had not assessed as warfare threat agents;
 - an additional 57 projects, valued at about \$48 million, were questionable because neither GAO nor the Army could readily determine whether these projects addressed validated biological threat agents;
 - research projects were not independently reviewed by the Academy or the Intelligence Center to ensure that the research addressed validated threat agents;
 - 3 of the 10 medical products already developed for the defense of U.S. forces and 2 of the 6 products under development do not address validated warfare threat agents; and
 - the Army and at least two other federal agencies were conducting medical research on many of the same agents.
-

Principal Findings

Millions Allocated for Research on Agents Not Validated as Threats

The Army's medical research program included research on biological agents that had not been assessed by the Armed Forces Medical Intelligence Center as warfare threats. In April 1990, GAO reviewed 218 ongoing or recently completed medical research projects, valued at about \$239 million. GAO determined, with the assistance of the Academy and the Intelligence Center, that 49 projects were not directed at validated threat agents. Neither GAO nor the Army could readily determine whether an additional 57 projects addressed validated threat agents because the Army project summaries did not contain sufficient information. The combined cost of the 106 projects was about \$95.3 million of the \$239 million, or about 40 percent.

The U.S. Army Medical Research and Development Command officials acknowledged that some research projects did not address validated threat agents. These officials believed that the Intelligence Center's interpretation of threat agents was too narrow because it did not include agents that were (1) highly infectious by aerosol or other means, (2) stable in the environment, and (3) of low to moderate communicability. Using this broad criteria, the Medical Command could conduct research on virtually all biological agents.

All proposed research projects are reviewed by Medical Command personnel for methodology, scientific merit, and military need. However,

neither the Command nor independent organizations such as the Academy or the Intelligence Center assessed projects to ensure that they were directed at validated biological warfare threat agents.

Some Medical Products Do Not Address Validated Threat Agents

Since 1965, nearly one third of the medical products that the Army has developed or is developing address agents not validated as warfare threats. Three of 10 products already developed and 2 of 6 products under development fall into this category. Of the \$45 million the Army spent on all 16 products by the end of fiscal year 1990, \$19 million, or 43 percent, was spent on the 5 products not addressing validated threat agents. In addition, the Army plans to continue to spend funds for the 2 products under development that do not address validated threats.

Some Medical Command Research May Duplicate Research of Other Agencies

The Medical Command may unnecessarily duplicate medical research, either in whole or in part, that is being performed by federal civilian agencies. Army regulations require a search of the Department of Defense's technical data base before a research project is initiated to prevent unnecessary duplication of effort but do not require Command personnel to search other federal research data bases. Command personnel responsible for conducting these searches told GAO that they did not access other federal data bases.

GAO's search of the Federal Research in Progress data bases disclosed that both the Army and the National Institutes of Health or the Centers for Disease Control were conducting medical research on about 23 of the same agents. For example, both the Army and the National Institutes of Health were conducting research to develop an improved anthrax vaccine. In addition, the Army, the National Institutes of Health, and the Centers for Disease Control were researching dengue fever. While GAO recognizes that duplication of research is not always inappropriate, the Army, to get the most from its research, needs to coordinate its research projects with those of other federal agencies.

Recommendations

GAO recommends that the Secretary of the Army direct the Medical Research and Development Command to

- review all ongoing medical research projects to determine whether they address validated warfare threat agents, and discontinue all projects that do not;

-
- arrange for independent reviews of all proposed research projects by officials from the Armed Forces Medical Intelligence Center and the Academy of Health Sciences to ensure that all future projects address validated warfare agents, and report the results of each review to the Army Surgeon General; and
 - discontinue development of all products that do not address a validated threat.

To avoid unnecessary duplication of effort and improve coordination, GAO also recommends that the Army amend its regulations to require the systematic coordination of its medical biological research projects with those of other federal research agencies.

Agency Comments

As requested, GAO did not obtain official agency comments on this report. However, it discussed information obtained during the review with agency officials and included their views where appropriate.

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Abbreviations

BDRP	Biological Defense Research Program
DOD	Department of Defense
GAO	General Accounting Office

Introduction

The Biological Defense Research Program (BDRP) is aimed at ensuring the sustained effectiveness of U.S. military forces in biological warfare by providing medical countermeasures that deter, constrain, or defeat biological warfare threats. The Department of Defense (DOD) defines a “biological warfare threat” as a biological agent that is assessed by the intelligence community as being developed or produced as a weapon. Medical defenses against these threats include preventive vaccines, drugs, therapeutic measures, and patient treatment and management procedures. The Department of the Army, serving as DOD’s executive agent, executes the medical component of the BDRP through research and development projects.

Program Funding History

In response to DOD’s information about the growing number of countries having or suspected of having offensive biological warfare capability, the Congress steadily increased funding for medical biological defense research from \$29.2 million in fiscal year 1984 to a high of \$69.9 million in fiscal year 1989. The fiscal year 1990 appropriation declined slightly to \$66.4 million. This appropriation included \$55.4 million for technology base funding categories—basic, exploratory, and advanced (non-systems) research projects—and \$11 million for product development and testing.¹ (Appendix I describes the research program categories.) Total program funding allocated to medical research for fiscal years 1984 through 1990 was \$369.7 million, as shown in table 1.1.

Table 1.1: Program Funding for the BDRP Medical Component

Dollars in millions	
Fiscal year	Funding appropriated
1984	\$29.206
1985	36.463
1986	52.031
1987	56.976
1988	58.798
1989	69.857
1990	66.398
Total	\$369.729

The Army’s fiscal year 1991 budget request totaled \$66.3 million.

¹ Advanced nonsystems development includes preparation for full-scale production and advanced testing of a medical product.

Management Structure of the BDRP Medical Component

The U.S. Army Medical Research and Development Command, at Fort Detrick in Frederick, Maryland, manages the medical component of the BDRP, directing the research and development of drugs and vaccines needed to defend against biological warfare agents. The Commander of the Medical Command reports to the Army Surgeon General. Within the Command, the U.S. Army Medical Research Institute of Infectious Diseases, also at Fort Detrick, serves as the lead medical laboratory for the BDRP.

Other organizations play a vital role in the BDRP. The Academy of Health Sciences, a subordinate command of the U.S. Army Health Services Command, has responsibility for preparing requirements documents for medical research against biological warfare threat agents for the U.S. Army Training and Doctrine Command. Under a memorandum of understanding with the Training and Doctrine Command, the Academy establishes the requirements for medical products (drugs and vaccines) that are needed to counter biological warfare threats.

The Armed Forces Medical Intelligence Center, a tri-service organization at Fort Detrick, is responsible, in conjunction with other intelligence agencies, for analyzing and validating information on biological agents that present a warfare threat to U.S. forces. This intelligence information is intended for use by the Academy of Health Sciences in setting requirements needed to counter the threats.

Objectives, Scope, and Methodology

The Chairman of the Senate Committee on Governmental Affairs asked us to evaluate DOD's Biological Defense Research Program. As arranged with the Committee, our work included only the medical component of the program because the Army has allocated the majority of BDRP funds to this component since 1984. Our objectives were to determine whether the program's medical research and development projects were (1) directed at validated biological warfare threat agents, (2) coordinated with other federal research organizations to avoid unnecessary duplication, and (3) used to develop medical vaccines, drugs, and other products for the defense of U.S. forces.

We reviewed 218 ongoing or recently completed BDRP projects, as of April 1990, to determine whether the Army's policies and procedures, including internal controls, were adequate to ensure that research and development was directed at only biological warfare threats. Because of the technical nature of the projects, the Academy of Health Sciences, with the help of the Armed Forces Medical Intelligence Center, assisted

us in determining which projects involved research on agents identified by the Intelligence Center as warfare threats. We did not, nor did the Academy, attempt to assess the scientific merit or value of the research.

To evaluate the adequacy of the Army's coordination with civilian agencies, we obtained information on the program's use of data bases for federal civilian research on the same biological agents. Through a limited literature search, we determined whether other federal agencies, such as the National Institutes of Health and the Centers for Disease Control, were conducting research on the same biological agents being researched by the Army. In addition, we obtained and analyzed documentation and interviewed officials from the Centers for Disease Control in Atlanta, Georgia, and from the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the National Institute of Neurological Disorders and Stroke, all in Bethesda, Maryland, to determine whether these agencies had an interest in the same biological agents as did the BDRP.

Further, we examined the Army's use of independent reviews for research proposals, discussed the use of independent reviews with program officials, and reviewed applicable Army regulations.

To determine the number of medical products produced for the defense of U.S. forces against biological warfare, we obtained and reviewed Army documentation from 1965 to the present. We discussed this information with officials from the Army and the Department of Health and Human Services' Food and Drug Administration, in Rockville, Maryland, which approves the Army's use of new drugs and vaccines. Given the expense and sometimes long-term nature of medical research, we did not attempt to assess the adequacy of the number of medical products developed by the Army relative to the resources invested.

To accomplish our objectives, we interviewed officials from the Department of the Army and the Army's Training and Doctrine Command, Fort Monroe, Norfolk, Virginia, and the Army's Academy of Health Sciences, Fort Sam Houston, San Antonio, Texas. We also obtained and analyzed documentation and interviewed officials from the following military activities at Fort Detrick, in Frederick, Maryland:

- U.S. Army Medical Research and Development Command,
- U.S. Army Medical Research Institute of Infectious Diseases,
- U.S. Army Medical Material Development Activity, and
- DOD's Armed Forces Medical Intelligence Center.

We reviewed Financial Integrity Act reports submitted by the Army to the Secretary of Defense for fiscal years 1987 through 1989 to determine whether any management control weaknesses were identified concerning the Army's implementation of the program.

We conducted our review from September 1989 to October 1990 in accordance with generally accepted government auditing standards. Because of the technical nature of the program, our Chief Medical Adviser assisted us in this review. As requested, we did not obtain official agency comments, but we discussed the information in this report with agency officials. Their views are included in the report where appropriate.

Army Management of the Medical BDRP Can Be Improved

The Army, because it did not have adequate internal controls in the BDRP’s medical component, allocated at least \$47 million to research and development that did not address validated biological warfare threat agents. Further, the Army’s review of proposed research did not include an assessment of whether the research was directed at validated warfare threats. Moreover, some of the Army’s research may duplicate research of federal civilian agencies because Medical Command personnel were not required to conduct searches of those agencies’ data bases.

Funds Allocated for Research of Agents Not Validated as Warfare Threats

The Army was conducting research on biological agents that were not assessed by the Intelligence Center as warfare threats. In April 1990, the Army had 218 ongoing or recently completed BDRP research projects valued at about \$239 million. We determined that 49 projects, valued at \$47.4 million, or about 20 percent of the total funds, were not directed at validated biological threats. For another 57 projects, valued at about \$48 million (another 20 percent of the total funds), we could not determine whether the projects were directed at validated biological threats because the Army project summaries did not contain sufficient information. Table 2.1 shows the results of this analysis.

Table 2.1: BDRP Funding by Threat and Non-Validated Threat Projects

Type of projects	Number of projects	Percentage of total projects	Dollar value	Percentage of total dollars
Non-threat	49	22.5	\$47,390,468	19.8
Unknown	57	26.1	47,966,716	20.1
Threat-related	112	51.4	143,633,474	60.1
Total	218	100.0	\$238,990,658	100.0

The U.S. Army Medical Research and Development Command acknowledged that it was conducting research on biological agents that have not been validated by the Intelligence Center as warfare threats. Medical Command officials told us that they believed that the Intelligence Center’s interpretation of threat agents was too narrow because the Intelligence Center identifies only those biological threat agents that are being developed or produced as weapons. In addition to the biological agents assessed by the Intelligence Center as potential warfare agents, the Medical Command believed that other agents must be researched if they were (1) highly infectious by aerosol or other means, (2) stable in the environment, and (3) of low to moderate communicability. Using this

broad criteria, the Medical Command could conduct research on virtually all biological agents.

The Medical Command's interpretation of what constitutes a threat agent contradicts DOD's definition—that is, an agent assessed by the intelligence community as being developed or produced as a weapon.¹

Technical Review Did Not Ensure That Proposed Research Addressed Validated Threat Agents

The Medical Command's in-house review of proposed projects did not require that research be directed at validated warfare threats. All projects are subject to an in-house technical review by Medical Command personnel for methodology, scientific merit, and military need. However, neither the Command nor independent organizations such as the Academy or the Intelligence Center assessed projects to ensure that they were directed at validated threat agents.

Medical Command Does Not Search Other Federal Research Data Bases to Prevent Duplication

Army regulations require a search of the Defense Technical Information Center's data bank prior to initiating a research project in order to prevent unnecessary duplication of effort. However, there is no similar requirement for the Medical Command to search other federal research data bases, and we found that it did not perform such searches. Accordingly, the Medical Command was unaware of research being done that could benefit the BDRP.

Army regulation 70-9, "Research Information Systems and Reports," dated May 1981, requires a thorough search of the Defense Technical Information Center data base before new research is started to prevent unnecessary duplication among DOD components. We found that these searches were generally conducted. The personnel responsible for conducting the search of the Defense Technical Information Center's data base told us that they do not access other data bases. Medical Command officials told us that BDRP scientists are experts in the field, who keep abreast of the latest scientific developments by attending seminars and reading professional publications pertaining to their areas of expertise.

Our literature search of the Federal Research in Progress data bases disclosed that both the Army and the National Institutes of Health or the Centers for Disease Control were conducting research or had an interest

¹The Assistant to the Secretary of Defense for Atomic Energy provided DOD's definition to the Senate Committee on Governmental Affairs in a written response to questions raised during a May 17, 1989, congressional hearing.

in the detection, treatment, or prevention of about 23 of the same diseases.² For instance, both the Army and the National Institutes of Health were conducting research to develop an improved anthrax vaccine. Also, the Army, the National Institutes of Health, and the Centers for Disease Control were researching dengue fever. Appendix II contains a list of the agents we identified for which both the Army and the National Institutes of Health or the Centers for Disease Control had one or more research projects underway involving the same biological agents. While the research methods and goals may differ, the list shows that civilian health agencies are concerned about many of the same biological agents as the Army.

Further, our literature search disclosed that other federal agencies, such as the U.S. Department of Agriculture and the National Science Foundation, also had ongoing research on some of the same agents as the Army. For instance, both the Army and the Department of Agriculture were conducting research on botulism and Venezuelan equine encephalitis. We recognize that duplication of research is not always inappropriate. However, the Army, because it does not coordinate its research with federal civilian agencies, cannot ensure that its research is not unnecessarily duplicating other agencies' research on the same agents.

Conclusions

The Army's medical BDRP program unnecessarily expended millions of dollars on research projects that did not address validated biological warfare threat agents. The Medical Command was aware of the Armed Forces Medical Intelligence Center's validated list of warfare threat agents, but believed that this information was interpreted too narrowly. Therefore, the Medical Command researched biological agents that it assessed as threats, in addition to those validated by the Intelligence Center. Further, the Command did not determine whether proposed research projects addressed validated threat agents. Moreover, the Command did not systematically query the data bases of federal civilian agencies involved in similar research to avoid duplication. The Army and at least two other agencies were conducting medical research on as many as 23 agents.

Recommendations

We recommend that the Secretary of the Army direct the Medical Research and Development Command to (1) review all ongoing medical

²Federal Research in Progress data bases provide access to information about ongoing federally-funded research projects in the fields of physical sciences, engineering, and life sciences.

research projects to determine whether they address validated warfare threat agents, and discontinue all projects that do not; and (2) arrange for independent reviews of all proposed research projects by officials from the Armed Forces Medical Intelligence Center and the Academy of Health Sciences to ensure that all future projects address validated warfare agents, and report the results of each review to the Army Surgeon General.

We also recommend that the Army amend its regulations to require the systematic coordination of its medical biological research projects with those of other federal research data bases.

Some of the Army's Medical Products Do Not Address Validated Threat Agents

The Army has developed and is developing several biological vaccines and drugs for U.S. military forces who might encounter biological warfare. However, nearly one third of these products did not address validated biological warfare threat agents. Since 1965, the Army invested about \$45 million in development and initial production costs for about 16 medical products. Of the \$45 million, over \$19 million, or 43 percent, was spent for 5 medical products that did not address validated threats. Moreover, the Army continues to develop medical products that do not address validated threats.

Medical Products Developed Since 1965

Over the past 25 years, the Army completed the development of 10 medical products, costing about \$24.6 million. However, 3 of the 10 products did not address validated biological warfare threats. Of the \$24.6 million, about \$17.1 million, or 70 percent, was spent to develop the 3 products that did not address validated threats. Table 3.1 shows the 10 products developed since 1965.

Table 3.1: BDRP Products Developed Since 1965

Dollars in millions

Product	Fiscal year	Development and initial production costs	Directed at validated threat
Vaccine, Venezuelan equine encephalitis	1965	\$0.234	Yes
Vaccine, tularemia	1966	0.242	Yes
Vaccine, eastern equine encephalitis	1968	0.437	Yes
Vaccine, rift valley fever ^a	1969	12.351	No
Vaccine, Venezuelan equine encephalitis	1975	1.138	Yes
Drug, ribavirin	1979	2.702	Yes
Vaccine western equine encephalitis	1984	0.243	Yes
Vaccine, Argentine hemorrhagic fever ^a	1986	4.086	No
Vaccine, chikungunya	1986	0.722	No
Vaccine, Q fever	1989	2.479	Yes
Total		\$24.634	

^aThe Army used BDRP funds to develop this product, even though this disease is not a biological threat agent but a naturally-occurring, or "infectious," disease that affects large numbers of people in various parts of the world.

Medical Products Under Development

The Army's six additional medical products under development are for either the identification of, protection against, or treatment for various biological agents.¹ These include four products for use against validated warfare agents and two products for agents that are not validated by the intelligence community as threats. The two products not directed at validated threats accounted for \$2.1 million of the total developmental costs, or about 10 percent. The products under development are shown in table 3.2.

Table 3.2: BDRP Products Under Development

Dollars in millions		
Product	Development cost ^a	Directed at validated threat
Toxoid, botulinal polyvalent	\$3.006	Yes
Immune globulin, lassa fever	1.915	No
Vaccine, anthrax recombinant DNA	0.015	Yes
Vaccine, vaccinia vectored Venezuelan equine encephalitis	0.737	Yes
Vaccine, vaccinia vectored Korean hemorrhagic fever	0.190	No
System, rapid identification	14.492	Yes
Total	\$20.355	

^aThese costs are as of the end of fiscal year 1990.

Conclusions

The Army has developed several medical countermeasures against biological warfare since 1965. However, of the \$45 million invested in the development of 16 products, about 43 percent of this amount has been spent on products that do not address valid biological threat agents. So far, the Army has spent about \$2 million on products still being developed that do not address valid threats.

Recommendation

We recommend that the Secretary of the Army direct the Medical Research and Development Command to discontinue development of the two products that do not address validated threats.

¹Products selected for development, but not funded, were excluded from this analysis.

Medical Research and Development Program Categories

Technology Base Research

Basic research (funding category 6.1):

- identification and isolation of infecting agents and
- characterization of agents.

Exploratory development (funding category 6.2):

- definition of animal models,
- preparation of vaccine and drug candidates,
- improvement of disease diagnosis and agent identification, and
- epidemiological studies.

Advanced nonsystems development (funding category 6.3A):

- scale-up production and
- advanced testing.

Product Development

Advanced systems development (funding category 6.3B):

- safety and efficacy testing.

Engineering development (funding category 6.4):

- large-scale field trials and
- initial purchase of product.

Research Conducted by the Army and Other Agencies Involving the Same Biological Agents

Biological agent	Agencies involved	
	National Institutes of Health	Centers for Disease Control
Anthrax	X	
Venezuelan equine encephalitis	X	X
Lassa fever		X
Ebola virus		X
Hemorrhagic fever with renal syndrome		X
Congo Crimean hemorrhagic fever		X
Dengue fever	X	X
Yellow fever	X	
Alphaviruses	X	
Eastern equine encephalitis	X	
Arboviruses	X	X
Q fever	X	
Tetanus	X	
Plague	X	
Tetrodotoxin	X	
Saxitoxin	X	
Ricin	X	
Brevetoxins	X	
Enterotoxins	X	
Hantaan virus	X	
Arenaviruses	X	
Vaccinia virus	X	
Botulism	X	

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February 4, 1991

Dear Colleague:

Attached you will find a report by the FAS Working Group on Toxin and Biological Weapons verification entitled "Implementation of the Proposals for a Verification Protocol to the Biological Weapons Convention." This is a follow-up to the Group's previous report of September/October 1990, "Proposals for the Third Review Conference of the Biological Weapons Convention," which you should have already received.

We hope that you will find this document of interest and request that you bring this, and the former report, to the attention of your government's foreign ministry so that they might influence the Review Conference in September.

Please feel free to copy and distribute the report as you see fit. If you need further copies of either this or the September/October 1990 report, please contact FAS at the above address.

Thank you for your help.

Sincerely,

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and Toxin Weapons Verification

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IMPLEMENTATION OF THE PROPOSALS FOR A VERIFICATION PROTOCOL TO THE BIOLOGICAL WEAPONS CONVENTION

Report of the

Federation of American Scientists
Working Group on Biological and
Toxin Weapons Verification

February 1991

The Federation of American Scientists (FAS) is a non-profit civic organization, comprised of 4,000 physical and social scientists and engineers who are concerned with science and society issues in general, and in particular with matters of international security. Democratically organized with an elected National Council and Officers, FAS was first established in 1945 as the Federation of Atomic Scientists and has functioned as a conscience for the scientific community for over forty years.

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IMPLEMENTATION OF THE PROPOSALS FOR A VERIFICATION PROTOCOL TO THE BIOLOGICAL WEAPONS CONVENTION

The Federation of American Scientists
Working Group on Biological and Toxin Weapons Verification

OVERVIEW

This report is intended to elaborate the proposals for a Verification Protocol included in the FAS Working Group's previous report, entitled "Proposals for the Third Review Conference of the Biological Weapons Convention" (October 1990). That report, which should be used as a reference in reading this one, outlines both short-term, voluntary measures and a legally-binding verification regime that includes annual declaration of sensitive categories of facilities, sites and activities; control of certain categories of biological and toxin agents; targeted inspection mechanisms; and other measures relevant to compliance with the Biological Weapons Convention (BWC).

This report carries the long-term verification proposals a step farther. It specifies the collateral information that should accompany annual declarations* so that they will be both effective in providing reassurance about the purpose of the declared item and adequate as a basis for the interpretation of subsequent inspection results. The report also lists the documentation that could be maintained at declared sites for access during inspection, and outlines inspection procedures; and it lists and discusses the significance of the information that can be obtained by inspection. Sections of the report on "Inspection Results" (p. 11) and "Effectiveness of On-site Inspection for Verification" (p. 16) discuss the effectiveness of inspections together with annual declarations in verifying compliance with the BWC. The final section proposes several additional measures to enhance the efficacy of a Verification Protocol.

This and the previous report are not meant to constitute a complete model for a Verification Protocol, but rather to focus on particular features important to biological verification and to give a sense of the degree to which it could be effective. The object is to show that a workable, legally-binding biological verification regime (or confidence-building regime, as some prefer to call it) can be devised. In this endeavor we have tried to set forth the wealth of relevant information potentially available, rather than to select the critical or most essential sources. The latter task will have to be addressed during the actual drafting of a Verification Protocol. It is assumed here that the procedural and administrative aspects of a biological regime will borrow heavily from the Chemical Weapons Convention (CWC), which must be completed first. But there are many unique features that can be addressed separately, and it is not too soon to begin the process.

A verification regime would provide States Parties with a means of demonstrating that they do not intend to develop a biological warfare capacity; it would provide a mechanism for resolving any doubts about the intentions of other States Parties and a forewarning of any possible danger so that timely political action could be taken. By opening their facilities to international inspection, States Parties would enhance their credibility and encourage other States to participate in the treaty regime. Confidence and mutual trust would gradually increase as the information provided in annual declarations was consistently confirmed by on-site inspection. The experience amassed over a period of time would reassure States that they and their neighbors were not statistically outside the norm, and this would tend to overcome the arms race mentality.

No verification regime can provide total assurance, especially when intrusiveness and expenditures must be limited. But the authors are confident that a scheme similar to the one outlined in these two reports would provide a high degree of confidence among States Parties that the BWC was working effectively, and it could do so with relatively little intrusion and at reasonable cost. Because of the

* Some of the specified information would also be applicable as an extension of the current voluntary information exchange.

targeted type of inspection proposed for declared facilities/sites in the previous report,* a large number of inspections per year would not be necessary. Most declared facilities, activities or events would probably be inspected or monitored very infrequently, if ever; but the possibility of inspection would always be present as a deterrent. The limited list of controlled pathogenic agents would also keep the regime within bounds. Specification of the agents to be controlled should be one of the first orders of business in drafting a Verification Protocol.

The international inspection costs of a biological Verification Protocol would be considerably less than current estimates for verification of the CWC⁺ based on the rolling text as it now stands (even after the period of chemical weapons destruction). The studies cited provide data that are helpful in estimating the cost of biological inspection, as well.[#]

The proposed verification regime is based on the following principles:

1. The regime should borrow as extensively as possible from the draft CWC, which is already under negotiation and has many similarities.
2. Because of the very substantial civilian-military overlap in relevant biological activities, the regime should rely on openness rather than prohibitions. In order to avoid circumvention of verification measures by the use of civilian facilities as covers for military activities, *both* must be subject to the regime. This will necessitate some intrusion into civilian matters. Where needed, confidentiality should be safeguarded.
3. Everything objectively verifiable that could give rise to suspicions or might be useful for prohibited purposes should be declared and thereby opened to the possibility of routine inspection. Because stockpiles of weapons agents could be produced relatively quickly, the potential for development and production of weapons agents, as well as their actual development and production, must be included. Most of the declared facilities will be civilian and unquestionably peaceful; but, in order to make sure that any illegitimate activities that may occur anywhere (regardless of the level of prudence or technological sophistication) are covered, universal declaration by all nations of certain normal civilian operations is necessary. These should include the kinds of basic facilities that a militarily weak nation under pressure might be tempted to utilize for biological weapons purposes.
4. Annual declarations should be routine and the requirements should be defined closely, avoiding matters of judgment or matters of intent or purpose, which are too subjective to be reliable.
5. The declaration requirements should be such that complete and accurate compliance with them would provide the transparency in relevant activities that is needed to inspire confidence in compliance with the BWC. Verification would consist of demonstrating the accuracy of the declarations. This would be the aim of all inspections. (In the case of challenge inspection of an undeclared site, compliance would be verified by the absence of declarable items.)
6. The regime should be acceptable to all affected, including the scientific community, industry, and the military.

* See "Proposals for the Third Review Conference of the Biological Weapons Convention," October 1990 [hereafter referred to as "October 1990 FAS report"], p. 13. In brief, a fixed number of inspections of declared facilities/sites would be carried out each year, with each State Party choosing a certain number and the Inspectorate choosing the rest. The choices of the States Parties could be communicated in confidence to the Inspectorate. Such an inspection would in no way imply non-compliance. Special monitoring of declared activities or events is also proposed.

⁺ *The Chemical Weapons Convention and the International Inspectorate: A Quantitative Study* (Canada, August, 1990); *Inspection Costs for a Multilateral Chemical Weapons Convention*, (J. Grotte, S. Leibbrandt, D. Schultz, Institute for Defense Analyses, June 1990); *Verifying the Projected Chemical Weapons Convention: A Cost Analysis* (Herbert Beck, AFES Press Report No. 13, Mosbach, FRG, 1989).

[#] See B.H. Rosenberg, *Disarmament*, Vol. XIV No. 2, in press (United Nation, 1991).

With the proposed verification regime, the major hurdle (which must be left to the national intelligence of the States Parties) is the discovery of clandestine sites and activities so that they can be inspected or monitored. Fortunately, the number of declarable facilities is in general relatively low in the parts of the world where possession of biological weapons would be of greatest advantage. It is the purpose of this report to show that, once opened for routine or challenge inspection, illicit activities on any significant scale could not be covered up with any likelihood of success. They would be exposed as, at the least, questionable. However, this is not the same thing as proof of violation of the BWC; it would still be up to the States Parties to judge whether or not the situation could be justified for peaceful purposes. This uncertainty is intrinsic to biological verification, but it does not preclude operational conclusions regarding the trustworthiness and responsibility of States Parties.

DEFINITIONS OF TERMS IN THIS REPORT

Facility: A room or rooms containing controlled agents (whether active or inactivated), aerosol equipment and/or chambers, or structural features or equipment for containment; or room(s) in which research, development, testing, production or other activities directly related to the Biological Weapons Convention* are conducted. One or an ensemble of such rooms, under the same administration, constitute a facility. Also included are the associated support facilities (see the draft Chemical Weapons convention (CWC), 21 September 1990, Appendix II: "Models for Agreements"), including: service areas for sterilization, glassware washing and preparation, media preparation, animal maintenance, cage washing, stock rooms, cold rooms, hot rooms, etc; administrative offices, documentation and record locations, effluent and waste handling and treatment areas, control/analytical bioassay laboratories, storage areas, medical facilities, transportation facilities, all associated and interconnecting pipework and ductwork, electric, water and gas lines, surface and underground storage tanks and storage facilities of all kinds, open-air areas for field work.

Outbreak of Disease: A single case or a cluster of cases. When outbreaks regularly occur more than three times a year, it will suffice to make a single annual report for the affected area stating that there have been many separate outbreaks and that this occurs regularly.

Open-Air Release of Controlled Agents:⁺ Includes open-air release of live and killed pathogens, attenuated strains and derivatives with low toxicity.

I. INFORMATION TO BE PROVIDED IN CONJUNCTION WITH ANNUAL OR AD HOC DECLARATIONS

Annual declarations are to be filed with the international Inspectorate by all States Parties, which must enact and implement national legislation in order to compile the necessary information from governmental and private sources under their jurisdiction or control. As proposed for the CWC, a National Authority could be established by each Party to identify and assist all institutions under its jurisdiction that have declarable facilities or activities in drawing up the required information, and to collect and report it. The National Authority could also assist in preparations for possible inspections, including the negotiation of Facility Agreements, and could be responsible for facilitating and observing any inspections at sites under its jurisdiction.

The required information is straightforward, easy to compile and would not ordinarily change much from year to year, with the exception of the detailed tracking of biologicals. Most of the tracking information, however, is likely to be included in normal record-keeping by facilities handling controlled pathogens and related biologicals. The ready availability of most of the required information in some relevant facilities, at least, has been confirmed in preliminary results of a trial inspection program being conducted by the FAS Working Group.

* It would be desirable for the Review Conference to define the expression "permitted biological activities directly related to the Biological Weapons Convention," as used in the Final Declaration of the Second Review Conference with respect to the information exchange under Article V.

⁺ A specific list of controlled agents will have to be negotiated. The agent categories that should be controlled are listed in Appendix A of the October 1990 FAS report.

Declarations should cover the preceding year and should specify any changes since the previous declaration. To facilitate future inspections, any foreseeable plans for significant change in activities, output, equipment or physical plant in the coming year should be stated.

The information listed below should be supplied for *all* activities, equipment, personnel, projects, etc. carried out in whole or in part at the declared facility or site, whether or not related to controlled agents, aerosols or other reportable features.

Analytical facilities and techniques available for use during inspection should be listed.

Any requirements for confidentiality of declared information should be stated (and the reasons supplied for the Inspectorate only). Confidential declared information should be handled according to the procedures that will be adopted for the CWC. It may be advisable for the Inspectorate to withhold certain confidential details before releasing the declarations to States Parties. The Inspectorate should make all declarations (in expurgated form, if necessary) available to all States Parties. The Parties should treat any confidential information with appropriate precautions.

Records for declarations should be kept up to date at each site so that current data could be made available to inspectors without delay, when requested.

States Parties would be free to provide voluntary, *ad hoc* reports between annual declarations, and/or to invite immediate inspection, whenever they judge that such action would contribute to international confidence.

Facilities to be Declared*

1. Facilities containing controlled agents in reportable quantities.+
2. Facilities containing equipment for the production of aerosols under BL2 or higher containment.
3. Facilities with BL3 or BL4 containment. For BL3 facilities that do not fall into any other category to be declared, an abbreviated reporting scheme should be developed so as not to discourage the use of higher containment than required, in cases where extra precautions may be desired. This would also help to control the amount of paperwork for the Inspectorate and the declaring State.
4. Facilities conducting research, development, testing, production or other permitted activities for the purpose of protection against the hostile use of biological agents or toxins. (Facilities engaged simply in the manufacturing of protective equipment, according to received specifications, should be exempted.)
5. Sites for permitted open-air field release of controlled plant pathogens (under controlled conditions, for civilian purposes).

Information Concerning Declared Facilities:

1. Name of the facility, its location (including any distant sites or mobile units used by the facility); name and sphere of activity of the responsible public or private parent organization or company and any relations it may have with national defense or military organizations.
2. Description of the facility, including distant sites and mobile units, overall size, major equipment, capabilities of relevance to the BWC (whether or not in use) and the amount of space and equipment

* These are defined in more detail in the October 1990 FAS report. For reasons of practical necessity, certain groups or classes of facilities (e.g., medical diagnostic laboratories or teaching facilities) cannot be included.

+ The agent categories to be controlled are outlined in Appendix A of the October 1990 FAS report. For infectious agents, any quantity is reportable because only small amounts are required for weaponization studies and because such stocks could be readily magnified.

available for each, and whether that capability was utilized during the reported year.

Capabilities Checklist:

- a. Microbial, cell culture or virus production (give maximum capacity* if limited to a single controlled agent or its precursor).
 - b. Vaccine, toxoid, antitoxin or antiserum production (maximum capacity* if limited to a single product).
 - c. Plant or animal (including primates and arthropods) cultivation, breeding, or maintenance (list species).
 - d. Animal or plant testing (test types, species).
 - e. Germ-free animal work (species).
 - f. Egg incubation (scale of operation).
 - g. Tissue culture and non-cellular in vitro test systems.
 - h. Associated medical, veterinary or public health facilities.
 - i. Microencapsulation.
 - j. Aerosol generation.
 - k. Freeze drying, spray drying.
 - l. Sterilization (capacity).
 - m. Field work (where and what type).
 - n. Storage of microbial agents, viruses or toxins (method and capacity for each type of storage).
 - o. Genetic and protein engineering techniques, including biological active site modeling.
 - p. Other (specify).
3. Number and size of any containment units; level of containment and description of containment equipment, structural features and required practices for each unit.
 4. Availability of encapsulating and/or air-supplied protective clothing.
 5. Aerosol generating equipment, including capacity; arrangements, if any, for containment of aerosols; size of aerosol chamber(s); controlled agents aerosolized in the year reported; purpose and general description of projects.
 6. Description of any construction or alteration of the facility that affects its relevant capabilities (see checklist) and that was instituted, continued or completed since the last report.
 7. A confidential list (to be retained by the Inspectorate) of all biological agents and toxins (whether controlled or not) handled in each declared facility.

* A checklist with a series of broad ranges should be provided from which to choose the best indicator of maximum capacity.

8. A list of the controlled agents (if any) handled in the facility and associated sites during the year reported; the total quantity of each handled during the year; whether live or inactivated; the sources of each, including production; their disposition (give quantities), including whether destroyed (how), whether stored, sold or distributed (to what destination and for what general purpose); and all available data on the properties of any controlled agents handled that have not been fully described in internationally available publications. (The specifics of some of this information could be designated as confidential, for the use of the Inspectorate only.)
9. Purpose(s) of the facility or site and general description of all activities, projects and programs; indicate any that involve controlled agents (specify which) and any that are carried out at the request of, in collaboration with, under the direction of or funded in whole or in part by the military, a national defense agency or any governmental or private, national or international agency or organization (of the same or another State or States) whose sphere of activity includes military concerns; state the amount of these funds and give a breakdown of their use according to program and project.
10. Total number of all professional and non-professional personnel and of all visiting professionals and consultants.
11. List any infections or intoxications caused by controlled agents among personnel during the year reported, including pathogen involved or possibly involved, probable mode of infection or intoxication, any spread or suspected spread of the infection within or outside the facility.
12. Types of animals and plants handled, and their purpose; number of humans and primates used in testing, and nature of the tests.
13. Whether toxoids, antitoxins, vaccines or antisera have been handled during the year reported and, if so, the quantities, sources, and disposition (i.e., whether used, stored, sold or distributed; in the case of the latter, to whom (categories to be provided as a checklist) and for what purpose).
14. Types of security arrangements: fences, gates, guards, identity cards, locks, etc., and any restrictions on visitors. (The specific data would be retained as confidential by the Inspectorate.)
15. Waste and effluent treatment; sterilization, decontamination and cleanup arrangements.
16. Any national or other inspection to which the facility is subject, and its purpose.
17. The means by which materials are transported into and out of the facility.

Information Concerning Outbreaks of Human, Animal or Plant Disease Caused, or Possibly Caused, by Controlled Agents:

1. Agent or suspected agents
2. Their suspected source.
3. Route of contact or intake; any vectors that may be involved.
4. Species and approximate numbers of primary and secondary victims.
5. Symptoms.
6. Location and area affected.
7. Time of first cognizance.
8. Measures taken.

9. Whether assistance is needed, and whether any assistance has been provided, and by whom.
10. Any available information on the endemic level of the disease (see proposal in Section V).
11. All available information should be provided within a fixed time* (e.g., five days after the outbreak is recognized), with more complete information provided as it becomes available.

Since there are various reasons why a State might not want to publicize this information, it could be supplied in confidence to the Inspectorate, which would release to States Parties only the essential facts, in confidence, after a specified delay (except in cases of urgency).

Information Concerning Military and Mass Civilian Immunization Programs:

1. Purpose
2. Whether military or civilian.
3. Agent immunized against.
4. Scale of program.
5. Locations.
6. Approximate dates.
7. Troop units or segment of population immunized.
8. Source of vaccines.
9. Sources of funding.

Information Concerning Military Programs for the Development and Usage of Vaccines:

1. Whether or not the State Party has a program for developing vaccines, antisera, toxoids or antitoxins financed by, or for the purposes of or any use by, the military, or is conducting part or all of such a program for another party; and whether the biologicals are for human or animal use.
2. All locations where any part (specify which) of the program is carried out.
3. Purpose.
4. Responsible agency(s) and sources of funding.

Information Concerning Sites for Open-Air Field Testing or Training for Protection Against BW:

1. Whether for testing protective measures and/or for training.
2. Location.
3. Size; facilities included.
4. Responsible organization(s).

* See definition of "outbreak of disease."

Information Concerning the Time and Site of Open-Air Field Testing or Training:

1. Purpose.
2. Scale.
3. Date and duration.
4. Whether aerosols will be used and, if so, of what materials.
5. Specific organization(s) carrying out the operation.
6. Number and designation of troops involved.
7. Name and address of local health authorities (the Inspectorate should make certain they are apprised of any potential hazards and of appropriate countermeasures and that the local public is informed.)
8. The above information to be provided at least six months in advance of the operation.

Information Concerning Publications Based on Work Done at Declared Facilities:

To be listed according to the declared facility where the work was done.

II. ADDITIONAL RECORDS TO BE MAINTAINED FOR IMMEDIATE ACCESS DURING INSPECTION

Records should be maintained by all declared sites and should be treated as confidential by inspectors. Facility Agreements on inspection should be drawn up to specify arrangements for the provision of needed information and the conditions under which any documents of particular interest could be copied for removal from the site, or stored under seal for future consultation. The principles and procedures should be based on those elaborated for the CWC (e.g., see Annex on the Protection of Confidential Information in the rolling text of September 1990). A standard form could be drawn up by the Inspectorate for the use of non-sensitive sites which do not consider it necessary to negotiate a specific Agreement.

The records should be kept current, maintained for at least three years and made available without delay for inspection, when requested. Insofar as possible, the relevant information should be organized so that it is readily separable from irrelevant information. Standard formats for recording some of the information could be drawn up by the Inspectorate to simplify the task and make inspection easier.

The following list, not necessarily exhaustive, contains records of various kinds that could be of use in an inspection. The requirements for record-keeping would depend on the nature of the declared site, and should of course be kept to a minimum.

1. Logs of the use of certain critical types of equipment, e.g., equipment for large-scale cultures, aerosol generation, freeze or spray drying, large-scale sterilization (including time and temperature), microencapsulation. Include dates, agents and amounts.
2. Logs of animal, plant and human tests, and other animal or plant usage, including dates, purpose, agents used, number and species of animals and their sources; logs of animal mortality from all causes.
3. Logs of infectious agent, nucleic acid, toxin, cell culture, vaccine, antiserum, toxoid and antitoxin production or acquisition and disposition, including name of the biological, date, source, quantity, activity titer, use, treatment (including inactivation, lysis or extraction), storage site, recipient and purpose for any transfers.
4. Logs of diagnostic and agent identification tests, virulence tests and all quality control tests carried out.

5. Logs of open-air release of controlled plant pathogens at each declared site.
6. Logs of open-air military field testing and training operations in BW defense at each declared site.
7. Purchase orders and receiving records for supplies and equipment costing more than \$1,000 and for *all* air filters, animals, eggs, chemicals, biologicals, microbiological and tissue culture media components, dry ice and liquid nitrogen, cloning vectors, enzymes and other reagents for genetic engineering technologies.
8. Shipping records.
9. Financial records, including income and expenditures, for any part of the budget of a facility/site that is derived directly or indirectly from government sources.
10. Personnel and visitor immunization records.
11. Names of all current personnel, visitors, and consultants; curriculum vitae (including training and experience) of all those with formal training or specialized experience; any security requirements or secret clearance and the reason therefore; any restrictions imposed (e.g., on movement or publication), and the reason; any prophylactic measures imposed during the person's tenure. Also, similar information for all personnel terminated during the previous three years, as well as their subsequent and present professional locations. These and all personnel records should be treated according to the confidentiality safeguards that will be adopted under the CWC.
12. Full health records of all the above personnel, including immunizations and other prophylactic treatments; infectious disease episodes and therapies received; any job-related illness or injury.
13. Names and addresses of contractors responsible for any construction or alteration of the site.
14. Current organizational chart, with all personnel and visitors listed by name, position, responsibility and location.
15. List of code names used in records or labels for all controlled and other biological agents and toxins, vaccines, toxoids, antitoxins and antisera possessed. This information should not be removed from the site.
16. A map for use during inspection (not to be removed from the site), drawn to scale, including the facility, the buildings that house it, and the surrounding area, interior and exterior, identifying all rooms containing any part of the facility as well as the locations of: major equipment and supplies; controlled agents and other biological agents; toxins and other biologicals; containment units; aerosol equipment and chambers; agent analysis facilities and equipment; various logs, records and other documentation; associated and inter-connecting pipework, duct work, utility lines, air and water intakes and outlets; effluent and waste treatment and disposition; packing, loading and unloading areas; etc.

III. INSPECTION PROCEDURES

In inspections of all kinds, the mandate of the inspectors would be to determine whether all declaration requirements have been met and whether declarations that have been made are accurate.

The formal and administrative procedures to be followed could be taken from the CWC (see, for example, "Protocol on Inspection Procedures" in the September 1990 rolling text), including the rights of inspectors and the inspected Party, the access and assistance to be provided, the importation and use of equipment, the taking and analysis of samples, the language to be used, the presence of observers, etc. Facility Agreements should be drawn up to provide an explicit understanding of the procedures, together with specific confidentiality arrangements. The protection of confidential information in general should be effected in accord with the provisions that will be adopted for the CWC (see the Annex on the Protection of Confidential Information, in the CWC rolling text of September 1990). Distinctions

between procedures for challenge inspections and other inspections could also be drawn from the CWC. Since these distinctions are already under negotiation, they are largely ignored in this document, which aims only to show that effective and acceptable inspection procedures can be devised.

Initial Inspections: Declared facilities and sites would be subject to familiarization visits soon after their first declaration, to verify the declarations and establish basic information to facilitate future inspections. The Inspectorate would choose which sites to visit, based on its sense of priority and on the available resources.

Before Inspection: The inspectors should be familiar with the declared information about the site, publications based on work done at the site, publicly-available information such as annual reports, and any national regulatory policies and requirements applicable to the site. Inspectorate staff should arrive within a specified time to secure the site (including attached buildings and grounds, as deemed relevant) and prevent or monitor all transport in and out.

When a challenge inspection is announced, the officials in charge of the inspected site should be required, if the site is undeclared, to record within [twenty-four] hours all the information required annually for declared sites; and then to marshal and make available to the inspectors, to the full extent possible, the additional records normally required during inspection of a declared site. If the site is considered vital to national security, means of protecting sensitive but irrelevant information should be undertaken immediately (i.e., "managed access" or other measures that will not impede the inspectors' determinations). Once the site is secured, the inspectors could allow a certain time for completion of these operations before commencing the inspection.

During Inspection: Inspection should be conducted in the least intrusive manner possible, consistent with the timely and effective accomplishment of the objectives. In particular, every effort should be made to avoid any disruption of large-scale production activities or of irrelevant activities in the same complex.

Inspection should begin with a briefing by the staff of the inspected site on the work carried out there, the physical layout and recommended safety precautions. Provisions for observers and for the conduct of the inspection should follow those that will be adopted for the CWC. In general, access should be provided to the entire facility, the entire building(s) in which any part of it is housed, any attached or adjacent structures and the immediately surrounding grounds, and to all personnel, documentation and records, as the inspectors may require. Knowledgeable guides (personnel with different kinds of expertise) should be available to answer questions, provide access to records, take samples and demonstrate the use of equipment, as needed.

All inspectors should be immunized to the full extent possible at all times. The Inspectorate should provide protective clothing, antisera, antitoxins, antidotes and other materials and equipment to permit the entry of inspectors, guides and observers into all parts of the site even under hazardous conditions. This would circumvent possible stalling tactics. The protective equipment must meet or exceed the safety requirements specified in the Annual Declaration for the site.

The kinds of information available through inspection are listed in Section IV. Inspectors should collect enough information of this kind to satisfy their concerns, with a minimum of intrusion.

Sampling and Analysis: Sampling for identification of agents present at a facility or site should follow protocols such as those outlined in the draft CWC. Samples could be taken from stored materials as well as from ongoing processes and from containers, instruments, equipment, filters, ground and surfaces of all kinds: they would include wipe samples, environmental and waste/effluent samples, as selected by the inspectors. A duplicate of each sample should be provided for the inspected Party. All tests and analyses should be carried out on site, if feasible, using equipment brought and operated by the inspectors. Parallel analyses could be carried out by the inspected Party using resident equipment and personnel. Whenever the inspectors or the inspected Party consider it necessary, especially in challenge inspections, replicate samples should be sealed in storage containers supplied by the Inspectorate and transported off site for analysis at two or more laboratories (designated and certified by the

Inspectorate), either accompanied by representatives of the inspected Party or with some other acceptable custody trail for sample security. Off-site analysis should be obligatory whenever analytical results obtained on site suggest any irregularity.

In addition to agent samples, blood samples would be taken at the discretion of the inspectors from personnel and experimental animals at the facility or site, for immunological analysis to determine their exposures to biological agents, toxins, toxoids, vaccines, antisera, etc. Provision would have to be made to allow the drawing of blood from personnel during an inspection, either in the national legislation to implement the Verification Protocol or in a Facility Agreement, requiring that assent by the personnel be made a condition of employment. Analytical results on individuals and all individual health data should be held confidential. Alternatively, a requirement for periodic collection and storage of serum samples from all personnel at declared facilities/sites could provide samples from which the inspectors could choose. However, there would be occasions, including challenge inspections, when it would be essential to collect the samples in the presence of the inspectors. Immunological analysis is such an important facet of biological verification that the development of provisions for the acquisition of authentic blood samples is essential.

Suggested procedures for on-site analysis of agent and blood serum samples are found in Appendix A.

After Inspection: As provided in the draft CWC, at the completion of an inspection the inspectors and representatives of the inspected party should meet to discuss the preliminary findings, eliminate any non-essential confidential information and try to clarify any remaining ambiguities. This might entail some repeat sampling, analyses or a decision to take some samples off site. Following the inspection, the inspectors could consult off-site information sources (see list below), and expedite any necessary off-site analyses.

The draft report would consist of factual material and a section on the cooperation of the inspected Party. It would be handled according to procedures determined for the CWC.* Except when relevant to a clear violation, the confidentiality of any sensitive portion of the report should be respected by the States Parties.

Inspection Results: The following conclusions could be drawn in the Inspection Report regarding compliance with the Verification Protocol. Insofar as possible, the aim would be to make the report objective and independent of questions of motive or purpose. Declaration requirements are assumed to include those in Section V. as well as those in the October 1990 FAS report.

- Evidence indicates full compliance with the requirements of the Protocol.
- Failure to comply or incomplete compliance with one or more declaration requirements; or
- Inconsistency or ambiguity of declared information, with respect to the observed facts regarding the capabilities of the site, the activities conducted there or the agents handled.
- Inability of the inspectors to verify some aspect of compliance.

Clearly, the more extensive and incisive the declaration requirements, the more meaningful these conclusions would be. Specification of the nature of the incompleteness, inconsistency, ambiguity or uncertainty in the Inspection Report would focus attention on the character of possible violations of the BWC that might be present at the inspected site. This would aid the States Parties in judging the significance of the inspection results.

* For example, the inspection report would be submitted to the chief of the Inspectorate who would transmit it to the inspected Party with a request for a written clarification of any remaining ambiguities and a time limit for reply. After receiving the reply the Inspectorate could revise the report, consult further or take any feasible steps to resolve remaining problems. The final reply would then be annexed to the report, and any sensitive information that was not essential would be removed before transmission to the Executive Council, which could then decide to release the report to all States Parties.

Under the proposed verification regime, the comprehensiveness of the coverage can be judged by a perusal of the annual declarations proposed in the FAS Working Group's October 1990 report, of the additional declaration proposals in Section V of this report, and the "Information to be Provided in Conjunction with Annual Declarations," proposed in Section I above.

With comprehensive declaration requirements and effective, targeted inspection of declared items, illicit activities would have to be clandestine; it would be difficult to find a plausible civilian cover that would not require declaration. The difficulties and risks of clandestine activities and the possibility of challenge would deter such operations; if undertaken, they could be verified by challenge inspection.

IV. ACCESSIBLE INFORMATION RELEVANT TO COMPLIANCE

This section is meant to illustrate the depth and variety of relevant information that is potentially available. Some of these information sources would be limited to challenge inspection; some would probably never be needed. In any single inspection, only a few would likely be called upon. Regulations for access to the various types of information by inspectors and Inspectorate staff would have to be included in the Verification Protocol.

Information Sources Potentially Available to Inspectors:

1. Declarations (information listed in Section I).
 - Verify the declarations and look for new operations or programs and changes in normal activities.
2. On-site records (information listed in Section II).
 - Look for deviations from normal routine and from declared information.
3. On-site inspection data (which should be documented insofar as possible by photographs, signed statements, samples, etc.), based on:
 - Visual inspection, including requested operation of equipment by personnel.
 - Personnel questioning. (For details see page 15.)
 - Sampling and analysis of agents, other biologicals and chemicals found at the site.
 - Waste and environmental sampling and analysis.
 - Blood sampling for immunological analysis of on-site animals and personnel.*
 - Environmental sampling, plant specimen sampling, and immunological testing of local inhabitants and domestic animals, when inspecting open-air sites for testing or training or release of controlled plant pathogens.*
 - Blood sampling from troops or civilians for immunological analysis, when monitoring military or civilian immunization programs.*
 - The examination of patients and records and the carrying out of analyses, when monitoring outbreaks caused, or possible caused, by controlled agents.*

* The authority and conditions for obtaining blood samples from the relevant military personnel, civilians, local inhabitants and domestic animals would have to be provided in the national instrument implementing the Verification Protocol. This instrument would also have to authorize the transport of blood samples, agent samples, chemical, environmental and waste samples and plant specimens to appropriate laboratories for analysis, when necessary, under agreed conditions; and would mandate the cooperation of local health authorities with inspectors monitoring relevant outbreaks. These arrangements would enable the State Party to take advantage of these valuable means of demonstrating the absence of violations.

4. Off-site sources.

Off-site Sources of Evidence or Suggestive Data:

1. Check shipping and receiving records for controlled agents against those declared for the recipients and suppliers or against any information voluntarily supplied by the latter upon request.
2. Look for slow-down in related industries or activities which might result from transfer of experienced workers or materials to a new weapons program. Information could be obtained from the annual declarations of other facilities and from news media and other publicly-available sources.
3. Look for increased activity of vaccine producers; increased production of vaccines would be needed if biological weapons were in production. Information could be obtained from annual declarations of other facilities and other publicly-available sources.
4. Check the literature for the topics of any unreported articles from the facility and past articles on work done elsewhere by its present or past personnel.
5. Request medical and veterinary data for the surrounding area.
6. Consult the possible sources of cultures or other significant materials regarding shipments to the facility in question.

Information Accessible Through On-site Inspection:

1. Biological agents:

- Examine data in on-site records and correspondence.
- Request samples for analysis of biological agents, vaccines, toxoids, antisera, etc. that are stored or in use.
- Take samples for analysis of trace quantities from equipment, air, ground (especially at field test sites and plant pathogen release sites), building walls, air exhaust and filters, other waste exit points, waste treatment systems, the perimeter of the entire site. Include some deep ground samples.
- Examine first aid and medical facilities, refrigerators, lab benches, etc. for antidotes and prophylactic agents. Note quantities and take samples.
- Examine processes, equipment, materials (types and quantities of media, disinfectants and other chemical reagents), safety precautions; deductions regarding agents can be drawn from these data.
- Carry out virulence or toxicity tests, where relevant.
- Look for hidden storage sites (e.g., power supply for freezers, compressors to make liquid nitrogen or dry ice, or other means of replenishing them).

2. Safety:

- Areas maintained under negative pressure (as opposed to positive pressure, normally used to protect a non-hazardous product).
- HEPA (high-efficiency particulate air) filters, air incinerators, air ducts, air locks. Note air flow and air velocity.
- Safety cabinets, glove ports.

- Showering and clothes change requirements and facilities.
- Water treatment at outlets.
- Hermetically-sealed areas.
- Antiseptic ports.
- Gas masks, air-supplied protective clothing.
- Double-ended autoclaves; other sterilization equipment and the conditions of operation.
- Laboratory practices.
- Isolation of facilities with regard to local population.
- Security features and their locations.

3. Materials:

- Media components - types and quantities (hundreds of kg per year would be required to maintain a strategic weapons stock).
- Eggs (purchase, production, use, e.g., in rickettsia production).
- Stockpiles of other key materials: decontaminants, materials for columns and other fractionation procedures, additives to prevent inactivation of biological materials (e.g., sugars, proteins), etc.
- Types and amounts of key reagents in use and on hand; take samples for analysis of these materials, as needed.
- Try to develop a materials balance.
- Examine waste outlet streams (visually and by sampling for analysis; e.g., eggshells or high calcium ash in solid waste would suggest rickettsia production).

4. Equipment:*

- Aerosol generators.
- Culture equipment, especially large-scale (more than 20 liters); continuous flow fermenters; modifications for tissue culture use; self-sterilization mechanisms; other procedures for sterilizing the equipment.
- Harvesting or concentrating equipment (including continuous flow centrifuges, filtering devices suitable for viruses, etc.; columns, etc.).
- Bioinactivation equipment.
- Lyophilization (freeze drying) equipment.
- Processing equipment (grinding, drying, fractionation, microencapsulation, etc.).
- Incubators (for eggs, cells or microorganisms) and related equipment.

* Note capacity and associated containment and safety features. Sample contents as needed.

- Sterilization equipment and procedures (note types).
- Refrigerators, freezers (note temperature), dry ice and liquid nitrogen containers, other storage equipment and materials.
- Biocontainment cabinets (number, size, types).
- Equipment for producing and analyzing genetic recombinants.
- Nucleic acid sequencing equipment.
- Containers for safe transport of dangerous pathogens.
- Storage tanks.
- Sealed containers (ask personnel to open randomly and take samples).
- Stockpiled equipment and parts.
- Request operation of equipment when necessary to determine its function.

5. Plants, animals, testing:

- Number and species of animals acquired, housed; number used in testing (what type of test); used for production of serum, antibody, toxin, other biologicals, eggs, etc., or for other purposes; how disposed of.
- Animal breeding (for what?).
- Germ free animal facilities; containment measures; isolation areas.
- Take blood samples from laboratory animals for immune testing to determine agent exposures.
- Vector organisms (note whether carrying pathogens; take samples). Note containment and safety measures.
- Plants: greenhouses, fields, breeding, testing, etc. Take samples for analysis of pathogen damage.
- Diagnosis and identification equipment and procedures.

6. Personnel:

- Interview individually (subject to the limitations and safeguards that will be provided under the CWC). Tape-recordings of the interviews should be made by the inspected Party and stored on site under appropriate safeguards for possible future reference. Personnel could be separately questioned on the purpose of equipment, materials, agents; about projects in which they participate; about goals, funding and auspices of programs, etc.
- Discuss operations with the personnel involved. Request demonstrations as needed. Watch for familiarity with procedures.
- From current and past employment records, note changes in key personnel: number and kind of personnel; sources of personnel (e.g., from vaccine industry?); expertise and experience; subsequent positions of past employees; turnover rate.

- Take blood samples for immunological analysis, as needed; also of surrounding population and domestic animals, especially at undeclared sites and field testing sites, with the permission of the inspected Party.
- In monitoring immunization programs or disease outbreaks, take blood samples at random from military personnel or civilians.
- Examine health records; carry out medical examination, if necessary.

Effectiveness of On-site Inspection for Verification. The above list shows that a great deal of information can be obtained by inspection. Much can be learned regarding what is being done at the inspected site and what could potentially be done there, by putting together various observations, like pieces of a puzzle. For example: the amount and kind of media components on hand; the size and type of production vessels, incubators, etc.; the size and type of centrifuges and fractionation equipment; the kinds and numbers of laboratory animals; the kinds of safety precautions; the past experience of key personnel -- all provide separate clues as to the nature of the undertaking, the agents produced or studied and their quantities. Medical records and available emergency medical treatments may give specific information regarding agents. Decontamination capacity gives evidence of the quantity of pathogens that may be present. Very large quantities of agents would be needed for even a single biological warfare attack, compared to the amounts involved in vaccine production, the most similar civilian activity. (Small amounts might suffice, however, for covert or terrorist usage.) Stockpiling would require storage under special conditions (since biological agents are easily inactivated): usually at very low temperature, often using liquid nitrogen, which must be replaced frequently. Stored samples may contain chemical stabilizers; stocks of these would be meaningful, as would freeze drying, microencapsulation and other processing equipment used for stabilization of agents. Bioinactivation equipment would suggest vaccines rather than live agents as the end product. Marked changes in these variables could be significant of program shifts; and so forth. This kind of approach would be especially relevant in an initial visit or a challenge inspection.

Although there are characteristic difficulties in biological weapons verification, there are also unique and extremely valuable facilitating factors compared to other weapon types: namely, the need for stringent safety precautions when handling human or animal pathogens, and the inevitable presence of specific antibodies in the blood of humans and animals either exposed to biological agents or immunized against them. The physical safety measures exceed and differ from those required even for chemical weapons, and it would be essentially impossible to hide them from inspectors. Antibodies can readily be detected in blood samples from any exposed mammal or bird, from laboratory mice to janitors, scientists and troops. Thus, antibodies are always there to bear witness to biological agents, even when agent stocks have been removed, hidden or destroyed before inspection. Traces of the agents may also be found in wastes, air filters etc.

A practiced inspector would be able to extrapolate from relatively few observations and could confirm his conclusions with a few more spot-checks. The relevant facts assembled by the inspector would then make possible an estimate of the nature and scale of potential or current operations at the inspected site, to be weighed against the capabilities and activities declared. The degree of openness evidenced, together with the appropriateness for peaceful purposes of the activities and facilities in their social and economic context, would enable other States Parties to evaluate the degree of confidence they should place in compliance with the BWC at the inspected site. This would be true regardless of whether or not any explicit, official judgment were passed. The availability of reliable facts would reduce misunderstanding, and the effectiveness of inspection would provide an additional incentive for States Parties to ensure that their own declarations were accurate.

The information listed above as accessible through on-site inspection is particularly indicative of the production, testing or stockpiling of controlled agents -- i.e., the later stages of biological weapons development. But, in like manner, much can also be learned through the inspection of research laboratories: the agents studied, the scale of the work and of the resources (human, physical and fiscal) devoted to it, whether there are military connections, the general type and level of research and its ostensible purpose, the potential for novel agent development, etc.

V. ADDITIONAL MEASURES

1. Annual declaration of compliance with the requirements and prohibitions contained in the October 1990 FAS report:

- Compliance during the preceding year with the specified levels of containment for all infectious agents.
- Compliance during the preceding year with the prohibition on the open-air release of controlled agents other than plant pathogens, and with the requirement that controlled plant pathogens be released in the open air only under controlled conditions and for civilian purposes.
- Compliance during the preceding year with the prohibition on transfer to non-Parties of any biological agents or toxins or any material, equipment or information relevant to prohibited or permitted biological activities directly related to the BWC (i.e., for hostile purposes or protection against hostile use), and on personnel transfer, cooperative activities or other collaboration with non-Parties relevant to such biological activities.

2. Annual declaration of all facilities containing large scale (25 liters or larger) bioprocessing equipment [types to be listed]. For those facilities not falling under any other declarable category, an abbreviated reporting scheme should be developed. This measure would increase confidence and help deter violations by making available for routine inspection the types of facilities most likely to become causes of concern in less-developed countries.

3. Surveillance of endemic levels of infectious diseases and intoxications and of the emergence of new epidemic/epizootic threats is urgently needed as a global public health measure.* Such a program would also have utility for verification in connection with the BWC⁺; unusual outbreaks of disease could be more accurately interpreted, and the detection of illicit testing, accidental escape or hostile use of controlled agents would be greatly facilitated. A program of this kind would ultimately provide the best possible means of deterrence and protection against the hostile use of biological agents or toxins. Such a program should include the training of local experts and should also aim at the internationalization of vaccine production and the establishment of a comprehensive international collection of strains and variants of controlled agents. Surveillance data would be reported annually to WHO or an international center established for this purpose. Participation could be limited to States Parties to the BWC and its Verification Protocol, thereby providing an incentive to ratify them.

Even in the absence of an established global surveillance program, it might be possible for the developed nations to provide resources for extending surveillance and improving the capabilities of the less-developed nations. Under a Verification Protocol, activities in this regard should be reported to the Inspectorate together with annual declarations. The Inspectorate could collect and collate the data available from States Parties, private sources, WHO, FAO, etc., and advise the Parties in developing an appropriate infrastructure for surveillance.

4. Personnel exchange, particularly between declared government facilities, should be encouraged on a bilateral basis among States Parties under a Verification Protocol, and a multilateral exchange program should be considered. This would provide an important means of reassurance and a valuable supplement to the verification regime.

* J.A. Miller, "Diseases for our future," *Bioscience* 39, 509 (1989); S.S. Morse, "Regulating viral traffic," *Issues in Sci. and Tech.*, 81 (Fall 1990).

+ M.L. Wheelis, "The role of epidemiology in strengthening the Biological Weapons Convention," in *Prevention of a Biological and Toxin Arms Race and the Responsibility of Scientists*, ed. E. Geissler and R. Haynes (in press).

Appendix A

On-site Analysis

For routine inspection of declared facilities/sites, the on-site analysis program would usually involve limited testing of personnel and animal sera (for antibodies) and of biological agents (for identity). For the first purpose, fresh blood should be collected by the inspection team in the presence of appropriate facility supervisory staff from selected, positively identified facility employees, when feasible, and from a random sampling of experimental animals in the facilities. If stored serum samples are available, selection of those to be tested would be made by the inspection team in consultation with the facility personnel. Selection of test antigens (agents to be tested for) would be made by the inspection team or the Inspectorate prior to the team's arrival and not revealed in advance. Sera or plasma can be tested for antibodies to most infectious or toxin agents by EIA/ELISA (enzyme immunoassay).*

The inspection team would need to bring each test antigen in appropriate form (e.g., immobilized on standard "Microtiter" plates; if the antigen is made from whole agent, it can be inactivated for biosafety), together with control sera and other necessary reagents and equipment. The host facility could perform the same test in parallel, using their own reagents on the same standards and test sera. Representatives of both host facility and inspection team would be present throughout (containers could be secured with seals during lengthy incubation steps). These tests typically require 4-6 hours; including time for sample set-up, the tests can be done by 1-2 competent technicians within a single working day.

Identification of agents themselves involves a greater potential diversity of procedures. Tests can easily be devised to identify agents by their antigenic characteristics (applicable to toxins, viruses or organisms) or genetic characteristics (applicable to viruses, organisms or DNA clones). In a routine inspection, usually only minimal confirmatory testing would be needed, using a random selection of agent samples. For many agents, antigenic identification by competitive EIA using a defined antibody standard can determine whether an agent is antigenically as declared. This test can be done in parallel with the serology (antibody) tests discussed above. Choice of agents to be tested for would generally be made before the visit, as for antibody testing.

For challenge inspections, more elaborate procedures may be necessary. In addition to the regular procedures outlined above, additional testing should focus on any agents that may be suspected in a challenge. Larger numbers of samples (perhaps five times as many as for routine inspection) would also need to be tested. Suspect agents should be subjected to more stringent testing, using specific DNA probes in, e.g., a dot-blot hybridization assay at crucial or unique segments of the genome, in order to establish genetic identity. The dot-blot assay can be carried out on site in about 6 hours or, if radioactive probes are used for greater sensitivity, in 24 hours. (Newer, but bulkier and more expensive equipment is available that would cut the time for radioactive assay considerably.) For very small or unknown samples or mixtures containing much interfering DNA, it might be necessary to use other, more sensitive (but touchier) methods such as PCR (polymerase chain reaction). This equipment is portable and the analysis can be done in 24 hours. It would be best to take replicates of difficult or questionable samples for off-site analysis as well.

It might be desirable on some occasions to conduct virulence or toxicity testing of agents that are listed in declarations as killed, attenuated (weakened) or otherwise altered. The test generally requires inoculating animals with samples and determining effects. Because of its complexity, virulence testing should be performed on site only when the inspection team, Inspectorate or inspected Party considers it unavoidably necessary (i.e., when there is cause for serious doubt as to the veracity of the declaration for a given agent). The on-site test could be performed, using standard protocols acceptable to all

* There are quicker and easier alternatives also worth considering, but standard EIA has the following advantages: it is widely available for a variety of agents, allows using the same general equipment for all assays, is the test most likely to be available at the majority of facilities so that the inspected party can most easily check results in parallel with the inspectors, and is generally the most straightforward to troubleshoot. It is also more readily modified for other purposes (such as in "reverse" (competition) format for identifying antigen). Dot-blot or latex agglutination methods are often faster and give a result which is easier to interpret qualitatively, but standardizing can be more difficult, and errors harder to detect. In all cases, the reagents and equipment are reasonably portable in a car or small van.

interested parties, in the presence of representatives of the host facility and the inspection team. The containers with the original samples should be appropriately marked, sealed and securely stored in case they are needed for subsequent re-analysis. After the assays are set up, the room or area containing the inoculated animals or cultures should be sealed, and opened only in the joint presence of designated representatives of the host facility and the inspection team for maintenance and at the termination of the assay. For most toxins, the assay should take about 24 hours; for viruses and bacteria, roughly 3-8 days, depending on the type.

On occasion, chemical analysis of materials, residues or wastes may be of interest as evidence for processes carried out at the inspected site. If anticipated, it might be possible to carry out some of these on-site, bringing reagents and standards and using resident or imported equipment for procedures such as mass spectrometry, flame photometry, spectroscopy, various chromatography techniques, and bioassays. Otherwise all analyses of such samples would have to be carried out off-site.

The technology referred to here is well established and currently available. Newer technologies are now under development that can be expected to decrease the amount of equipment and the time required for the necessary analyses.

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Appendix B

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Date Closed: 6/1/2010	OA/ID Number: 62104-004
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Date Closed: 6/1/2010	OA/ID Number: 62104-004
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