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DOD's Risk Assessment and Safeguards  
Management of Chemical and Biological  
Warfare Research and Development Facilities

Statement for the Record by  
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Before the  
Subcommittee on Oversight of Government  
Management  
Committee on Governmental Affairs  
United States Senate



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## SUMMARY

The Subcommittee requested that we: (1) identify the factors, standards, and methodology DOD employs in evaluating the safety and security of its chemical and biological warfare research and development contractor facilities; (2) determine whether these risk assessments are adequately documented; (3) review their technical quality and the extent to which they conform to generally accepted scientific standards and practices; and (4) provide possible recommendations for improving them.

For chemical contractors, DOD has developed and implemented a reasonably systematic and comprehensive approach for evaluating and managing risks. This approach consists of a contract proposal review, formal requirements for safety, security, and emergency preparedness, a pre-award inspection, and a post-award inspection system. DOD has also conducted "maximum credible event" analyses which provide a useful tool for estimating the effectiveness of existing safeguards against selected accidents or incidents. We recommend, however, that DOD devote additional effort to addressing other possible situations that could result in hazardous events at chemical contractor facilities.

In the biological defense program, DOD has not developed its own safeguard requirements or conducted regular, formal evaluations of contractor facilities. DOD relies instead on an existing safeguards system that was developed by the biomedical and microbiological research establishment and that is implemented individually by research investigators and institutions. DOD's current risk assessment and safeguards management process for biological defense contractors is one in which safeguards are only indirectly reviewed through the contract proposal review process, intermittent site visits, and contract monitoring by DOD contracting office representatives.

The lack of a formal DOD risk assessment and safeguards management process in the biological area makes it difficult to determine whether contractors are using recommended safeguard guidelines; whether safeguards are being used properly; and whether the existing safeguards are, in fact, effective in reducing the risks associated with biological warfare research and development efforts. We recommend that DOD take a more active role by developing and establishing a process to evaluate safeguards at contractor facilities. A more systematic, centralized evaluation process for contractor facilities would provide useful information to address concerns about risks. The evaluations conducted may well demonstrate that existing safeguards at contractor facilities are adequate. However, until such evaluations are completed, there is no way to determine this empirically, and uncertainties will persist about the adequacy of existing safeguards governing biological research and development.

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to be here today to discuss our review of the risk assessment and safeguards management activities of the Department of Defense. In February of this year, the Subcommittee requested that we: (1) identify the factors, standards, and methodology DOD employs in evaluating the safety and security of its chemical and biological warfare (CBW) research facilities; (2) determine whether these risk assessments are adequately documented; (3) review their technical quality and the extent to which they conform to generally accepted scientific standards and practices; and (4) provide possible recommendations for improving them.

#### INTRODUCTION

The United States has consistently proclaimed a policy that renounces the use of chemical weapons except in retaliation to an attack. Other than the binary weapons program, U.S. military research and development (R&D) efforts have focused on defensive capabilities since 1969. The main objectives of DOD's current chemical warfare research program are to develop protective clothing and equipment, techniques to identify and detect chemical weapons that hostile forces might employ, decontamination methods, and medical treatments.

With respect to biological weapons, the United States renounces any use of such weapons and, as a signatory to the 1972 Biological Weapons Convention, is prohibited from stocking them or conducting research and development work except for "prophylactic, protective, or other peaceful purposes." The main objectives of DOD's biological warfare research program are to develop measures for detection, decontamination, treatment, and protection, with particular emphasis on developing medical vaccines and drugs to protect against selected biological warfare agents.

The Department of Defense has pursued an active chemical and biological warfare research and development program over the past several years. In fiscal year 1987, DOD obligated \$334 million to this effort as compared to about \$64 million in fiscal year 1980.<sup>1</sup> Major portions of the program, however, do not use chemical and biological warfare agents per se.

In the chemical program, approximately \$34 million was obligated according to DOD officials in fiscal year 1987 for extramural contract work that involves the use of chemical agents either for testing and evaluating protective materials or in developing medical treatments. DOD defines a chemical agent "as

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<sup>1</sup> Funding information is reported from the Department of Defense Annual Reports on Chemical Warfare and Biological Defense Research Program Obligations, FY80 and FY87.

a chemical compound for use in military operations to kill, seriously injure, or incapacitate persons through its chemical properties." About 20 different chemical warfare agents are used in DOD's research and development program. They are usually categorized by their physiological properties or effects -- nerve, blister, and blood agents -- and are used in both undilute (called neat) and dilute form. Examples of chemical agents include GB (Sarin), GD (Soman), HD (Distilled Mustard), and VX.

Research and development in the biological warfare defense program that pertains to detection, decontamination, and protective clothing and equipment is largely incorporated within the chemical defense program. DOD's stated purpose for combining these efforts is to develop defensive measures and products that are effective against both chemical and biological agents.

In the biological warfare defense program, about \$34 million was obligated in fiscal year 1987 for extramural R&D contracts involving the use of biological agents to investigate medical protective measures (vaccines, drugs, and other treatments). DOD defines biological agents as "natural and enhanced or modified pathogenic microorganisms, toxins, venoms, and active subfractions such as psychological and physiological bioregulators which are intended for use in warfare."<sup>2</sup> Potential

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<sup>2</sup> Toxins are poisonous chemical compounds produced by living organisms such as bacteria, fungi, reptiles, and algae. In the United States, they are generally classified with biological rather

agents include several different kinds of bacteria, viruses, toxins, and rickettsia. DOD has identified a number of these agents as possible threats and has focused R&D efforts on developing defenses against them. Examples of biological agents from this group are anthrax, Q fever, ricin, Venezuelan equine encephalitis, and botulinum toxin.

DOD delegates the roles and responsibilities for its research and development programs among several agencies and offices. The Department of the Army is the lead Service for coordinating chemical and biological defense requirements for the joint Services and for planning and executing research and development. Within the Army, the primary R&D facilities actively conducting and supporting contract work with chemical warfare agents are the Chemical Research, Development and Engineering Center (CRDEC) of the Armament, Munitions and Chemical Command and the Army Medical Research Institute of Chemical Defense (USAMRICD), which is part of the Army Medical Research and Development Command. Also under this command is the key center for the biological defense program -- the Army Medical Research Institute of Infectious Diseases (USAMRIID).

These three facilities conduct in-house research and development studies and fund numerous contracts at universities, research laboratories, and private industrial companies around  

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than chemical agents.

the country and overseas. The number of chemical agent contractors funded by CRDEC and USAMRICD is approximately 12 and 40 respectively, and the number of biological contractors funded by USAMRIID is about 100.<sup>3</sup>

### SCOPE AND METHODOLOGY

We focused our efforts on contractors conducting chemical and/or biological warfare research and development work for the Department of Defense. We collected information for our review of DOD's policies, practices, and programs for conducting its risk assessment and safeguards management of chemical and biological contractor facilities from multiple sources: technical literature, interviews with DOD officials, agency documents, and case studies of a small sample of selected contractor facilities.<sup>4</sup> We reviewed the literature to gain an understanding of CBW research and development efforts, risk assessment methods, and laboratory safeguard practices, and to develop criteria for our analysis. We identified and interviewed DOD officials who have oversight responsibilities for the CBW research and

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<sup>3</sup> Of the current chemical agent contractors, 10 of the CRDEC contractors and 3 of the USAMRICD contractors use neat chemical agents; the rest use only dilute chemical agents.

<sup>4</sup> We define risk assessment as a process or method of identifying, estimating, and evaluating the hazards (possible loss or injury) from a particular activity such as chemical or biological warfare research and development work.

development programs as well as those who are responsible for assessing and implementing contractor safeguard requirements. We requested and reviewed various documents from DOD such as relevant agency directives and regulations; contractor program requirements or guidelines; risk assessments and other inspections, surveys, or evaluations of contractor facilities; and contractor safeguard plans and standard operating procedures.

To determine the technical quality of DOD's risk assessments we reviewed the technical literature and prior GAO work in this area. We looked for evidence supporting the appropriateness, reliability, and validity of the methods, data, and analyses employed in the DOD assessments that we found. In addition, we talked with DOD officials and other knowledgeable individuals regarding the organization, completeness, and extent to which the assessments had been or could be verified.

Because we worked within a relatively short time frame (March-May 1988), we limited our case studies to four facilities that the Subcommittee staff selected for us -- two chemical and two biological defense contractors. The chemical contractor case study sites include one private industry contractor funded by CRDEC that uses neat chemical agents in testing various protective clothing and materials. The other site is a university contractor funded by USAMRICD that uses dilute chemical agents in examining the effects of chemical blistering



on cellular compounds. The two biological contractors, funded by USAMRIID, include a nonprofit laboratory institute that produces developmental vaccines and reagents and a university research center that tests antiviral drug compounds against selected viruses and also produces reagents.

At these facilities, we conducted semistructured interviews with the officials directly involved in conducting DOD research and development work (the principal investigators, research staff, and laboratory technicians) and also those responsible for management and oversight of safety, security, and emergency preparedness (administrators, safety committee members, and institutional safety officers). We used an open-ended interview guide to obtain information from these officials. In addition, we requested and reviewed available documentation on safeguard plans, programs, and procedures; risk assessment studies; and other risk management activities. Because our sample was small and judgmentally selected, it is not representative of all DOD chemical and biological warfare contractor sites; therefore, our findings are not generalizable to other sites.

In the following sections, we summarize information available on DOD's risk assessment and safeguards management processes and how they have been applied at four selected contractor sites. Since we found that DOD has established very different safeguard structures for chemical and biological

contractors, we present our findings separately for each.

DOD'S RISK ASSESSMENT AND SAFEGUARDS MANAGEMENT AT CHEMICAL  
CONTRACTOR FACILITIES

Many of the chemical warfare agents used in DOD's research and development program trace back to the developmental work on weapons during World Wars I and II. Since then, DOD has gained a significant amount of experience with respect to the hazards associated with the handling, storage, and use of these chemical agents. Their basic lethal characteristics, such as their toxicity and physiological effects, as well as their physical properties, such as their reactivity and flammability, are well documented.<sup>5</sup> Potential exposure to even small concentrations of many of these agents can be life-threatening. Based on this awareness and understanding of chemical agent hazards, and the lack of a preexisting set of industry or research safeguard standards in the nondefense sector for hazardous chemical materials, DOD established a formal set of safety, security, and

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<sup>5</sup> Although there is a general understanding of the basic hazards, some gaps persist in scientific information about the possible adverse health effects of some chemical agents, particularly prolonged exposure to low-level doses. The Army Surgeon General has established permissible exposure limits for personnel working with chemical agents and for non-work-related personnel, including the general public. A working group of scientists convened by the Centers for Disease Control (CDC) recently reviewed these limits and determined that adverse health effects would be unlikely at the recommended exposure limits.

emergency preparedness standards and rules for all military activities involving the use of chemical warfare agents.

DOD's approach to reducing the risks associated with chemical agent R&D work relies on a strategy of containment and controls that incorporates physical design and construction criteria, personnel protection equipment, operating procedures, safeguard redundancies, monitoring capabilities, emergency response plans, and limits on the amount of chemical agent material allowed at any one time in a laboratory facility (currently a maximum of 1 liter). According to DOD officials, safety, security, and emergency preparedness requirements have been designed with the objectives of both controlling a potential release of chemical agents during normal laboratory operations and protecting against a potential release due to accidents or incidents in the laboratory.

#### Assessing Safeguards: Maximum Credible Events

As part of its overall assessment process, DOD has conducted some analyses to estimate the effectiveness of existing safeguards against unplanned events such as accidents that might occur in a typical laboratory facility. These analyses, which it calls "maximum credible event" analyses, are generic to all DOD contractor laboratory facilities and focus on selected events that have a reasonable possibility of occurring. A maximum

credible event scenario, defined by DOD for contractor facilities, is one in which a quantity of chemical agent representative of the amounts used in laboratory tests is spilled or leaked during normal operations. Analysts estimate the likely area beyond the accident location where there would be harmful effects. They base these estimates on factors such as the quantity of agent involved, the physical characteristics of the agent such as evaporation rates, and the physical containment measures of the facility (particularly the ventilation and filtration systems). DOD has concluded from these analyses that no harmful release of chemical agent material would occur outside the laboratory containment area.

#### Evaluating Safeguard Standards: Contractor Inspections

DOD's process for evaluating the safety and security of individual chemical contractor facilities comprises a number of activities that it undertakes prior to awarding a contract and during the contract period when chemical agents are in use.<sup>6</sup> Before it approves a contract, DOD reviews proposals for their scientific and technical merits. At this point, it also reviews proposals for safety, security, and emergency planning concerns. DOD determines if particular aspects of the proposed research and development work might create additional risks. When a proposal

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<sup>6</sup> The safeguard standards and evaluation process established by both CRDEC and USAMRICD are modeled after the Department of Army's Chemical Surety Program regulations (AR 50-6).

is accepted as a candidate for award, DOD conducts a pre-award survey of the laboratory facility. An inspection team of DOD safety, security, and surety staff visits the facility and evaluates the safeguard elements that DOD requires. Some elements it examines are facility design, storage containment, laboratory worker training, safety program management, chemical monitoring and detection procedures, chemical accident or incident emergency response plans, access control measures, decontamination and disposal methods, ventilation systems, and protective clothing and other equipment.

DOD's pre-award survey does not include a review of site-related factors or environmental conditions at laboratory sites. Proximity to residential areas or public facilities, for example, is not a formal consideration in the survey. According to DOD officials, this is largely because the laboratory containment measures and controls have met the maximum credible event analysis requirements. That is, DOD has already determined that the containment measures are sufficient for protecting against any possible harmful release of chemical agents into the surrounding environment.

The Department of Defense requires contractors to develop a facility safety and security plan, which it reviews and approves. DOD then conducts regular safety inspections after the contract is awarded and chemical agents are being used (semiannual

inspections for neat contracts and annual ones for dilute contracts). The program elements it reviews are similar to those reviewed in the pre-award surveys. In addition, as part of these inspections, DOD conducts a chemical accident or incident response plan exercise to assess the contractor's emergency response capabilities. This exercise involves a scenario similar to that used in the maximum credible event analyses. The major elements DOD reviews include notification and reporting procedures, containment measures, first aid, decontamination, and cleanup. DOD also conducts a decertification inspection when a contract is completed and further chemical agent contract work is no longer expected at a facility.<sup>7</sup>

At the two chemical research and development facilities that we visited, DOD had conducted the required inspections and reviews of contractor work and found that contractors were generally in compliance with program requirements. In a recent inspection at the neat contractor facility, DOD noted some safety-related problems such as incomplete training records, failure to use protective mask-fitting and leak-testing procedures, and lack of a required chemical detection kit. In addition, this inspection identified numerous deficiencies in the

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<sup>7</sup> The Army Materiel Command also conducts an annual inspection to review the CRDEC and USAMRICD chemical programs. The command evaluates how CRDEC and USAMRICD implement their respective contractor inspection programs. As part of the evaluation, an inspection of a selected contractor facility is also conducted.

chemical accident or incident emergency plan exercise. DOD did not consider these problems serious enough to halt contract work, but brought them to the attention of the contractor for corrective action. To ensure that noted deficiencies were resolved, DOD scheduled a follow-up site inspection later in the year. At the other site, DOD identified a small number of safety and security infractions in a recent inspection, such as a lock combination that had not been changed annually.

#### Federal, State, and Local Safeguard Requirements

In addition to DOD's formal set of safeguard requirements, we found other federal, state, or local government regulations and guidelines that pertained to safety, security, and emergency preparedness at the chemical contractor facilities. The key federal regulations include Occupational Safety and Health Administration (OSHA) work place safety standards, Environmental Protection Agency (EPA) hazardous waste disposal and clean air and water standards, and Nuclear Regulatory Commission (NRC) rules on the use of radioactive materials. DOD does not address these standards in its own regulatory process, however some of its requirements are similar to the OSHA standards and the EPA disposal regulations. Officials at the contractor sites indicated that they incorporate these government standards into their facility safety plans. However, the federal agencies responsible for setting the standards either have not conducted

onsite inspections or conduct them infrequently.

Contractor officials also identified state and local regulations and guidelines that apply to environmental protection, the use and disposal of hazardous materials, and emergency response coordination. At the neat chemical agent contractor facility we visited, a state environmental agency and local emergency response departments had conducted periodic inspections. The chemical contractors themselves, or their parent organizations, also imposed certain safety oversight and management activities. For example, at the university we visited where dilute chemical agent was being used, a separate department of occupational safety and environmental health was responsible for establishing overall safety guidelines and had conducted regular inspections of the chemical laboratory facilities on campus. These inspections, which were forwarded to DOD, reviewed chemical storage procedures, emergency response equipment and procedures, and general laboratory practices. At the other contractor site, officials were responsible for safety and security management and had conducted informal reviews of facility operations to assess fire protection and other safety and security considerations.

#### Documentation

DOD uses a formal set of internal operating procedures and



methods for conducting facility inspections and reviews of contractor safety and security plans. Inspection teams consist of staff trained in the safety, security, and surety management of chemical agent materials. They use a standard safeguard checklist, interview contractor officials, and review contractor records and lab procedures on site.

We found that detailed documentation was available for the various activities performed by DOD in its evaluation of the safeguards at contractor facilities. DOD has developed and provided to the contractors written safeguard requirements and material data safety sheets that describe the hazards associated with the chemical agents they intend to use. The two contractors we visited had completed and filed facility safety and security plans with DOD. In addition, DOD safety, security, and surety teams had completed inspection reports on both sites. The two contractors had also written standard operating procedures for conducting contract work and maintained records for various equipment performance tests, staff training, and certifications.

### Technical Quality

With regard to the technical quality of DOD's risk assessments, we found that the maximum credible event analysis provides a useful tool for identifying necessary facility safeguards and estimating their effectiveness. The analyses that

we reviewed for a hypothetical chemical laboratory incident are based on a mathematical diffusion model that appears to be an appropriate method for calculating the dispersion of materials. As reported in a 1984 National Academy of Sciences study on the disposal of chemical munitions, this model is a relatively standard scientific approach that is widely used to calculate the dispersion of atmospheric pollutants.<sup>8</sup> The above study identified some of the model's limitations, particularly with respect to estimating dispersion over large areas. Such limitations, however, did not apply to DOD's use of the model for a laboratory incident where environmental conditions are largely controlled.

In our technical review of DOD's maximum credible event analysis, we found that many of the assumptions specified in the model were reasonable. For example, DOD used a particular chemical agent in the model which is known to be more volatile than other agents and therefore would be expected to disseminate more quickly. Also, the quantity of chemical agent used in the model was larger than what DOD indicates is typically used in laboratory procedures.

From available information, we could not verify the accuracy

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<sup>8</sup> Committee on Demilitarizing Chemical Munitions and Agents, Board on Army Science and Technology, National Research Council. Disposal of Chemical Munitions and Agents, Washington, D.C.:National Academy Press, 1984.

of some of the assumptions specified in the model or establish what factual basis supported their use. For example, one assumption was an estimate of the evaporation time for the chemical agent spilled. This covers the time from when the spill occurs to when emergency procedures (containment and decontamination) are enacted. The value for evaporation is based on DOD's estimate of how long it would take laboratory workers to respond to a spill if standard operating procedures are followed. DOD's estimate for this may be reasonable, but supporting information (derived perhaps from the contractor accident/incident emergency plan exercises) is needed to determine this.

The outcomes of any model should be considered approximations of what outcomes might be expected in a real situation. Determining how close these approximations are to real outcomes is usually referred to as "validating" the model. Although we found that the model was generally accepted in the research community and technically accurate, DOD was unable to provide any evidence to indicate that the model had been systematically validated. Comparing the model results with, for example, results from an empirical test such as a controlled spill or with other data that might be available from accident or incident reports would provide additional evidence for evaluating whether the model is an accurate representation in this case. Lack of validating efforts makes such an assessment more

difficult and can detract from the confidence one might have in the analysis.

The maximum credible event scenarios for contractor facilities focus only on selected incidents. There are other possible incidents (equipment malfunctions, security breaches, or natural disaster events) that DOD has not addressed in a formal analysis that could nonetheless result in the release of chemical agent materials. The potential consequences of a low-probability accident such as a fire or explosion, for example, have not been systematically assessed. DOD officials have indicated that chemical agents would detoxify if subjected to the high temperatures of a fire. Yet, as described in DOD's recent environmental impact statement on the Chemical Stockpile Disposal Program, toxic gases could be released by accidental fire or explosion. The fact that DOD restricts the quantity of agent material allowed at a contractor site greatly reduces the consequences of any incidents that could result. However, the toxic nature of certain chemical agents requires that the accidental release of even small quantities of these should not occur.

DOD'S RISK ASSESSMENT AND SAFEGUARDS MANAGEMENT AT BIOLOGICAL  
CONTRACTOR FACILITIES

In the biological warfare defense program, DOD risk assessment and safeguards management activities for contractors are structurally different from those developed and implemented in the chemical program. DOD has not developed its own safeguard standards or regulatory assessment and inspection system but instead relies on an existing safeguard system largely established by the biomedical research community. This consists of:(1) various federal and state government regulations and guidelines related to environmental and health protection, (2) requirements and oversight activities promulgated by research institutions, and (3) safety procedures and practices established by professional research organizations and individual research investigators.

The main responsibility for risk assessment and safeguards management, however, has been left to the research contractors themselves. DOD has not perceived a need for developing its own systematic, centralized regulatory approach because DOD officials do not see a distinction between the type of research and development taking place in the biological warfare defense program and non-DOD biomedical research on pathogenic microorganisms.

#### Health and Environmental Risks of Biological Agents

All the agents used in the biological defense program are considered harmful, however the hazards of some are greater than others. Differences in the agents themselves, in the research procedures using the agents, and in the availability of medical protective measures against the agents make the assessment of risks complex. Factors that are characteristic of agents such as pathogenicity, virulence, infectiveness, method of transmission, and environmental stability pose different risks to lab workers, the environment, and the general public. For example, arthropod-borne viruses, which were a key focus of the contract work at the two facilities we reviewed, require a living host (cell) to survive and a specific kind of vector (mosquitos, ticks) for transmission to occur. The likelihood of these viruses being transmitted from human to human is considered remote.

Other factors that mitigate the likelihood of infections taking place are the quantity and concentration of agent material and the susceptibility of the host organism. With some biological agents, for example, scientific evidence seems to indicate that only a small number of organisms may cause infection and possibly result in disease. For other agents, much larger quantities of organisms are usually needed for infections and disease to occur. Different environmental conditions also affect the ability of the agents to survive. Temperature, humidity, and lighting, for example, if not strictly controlled in a laboratory setting, will reduce the infectiveness and

virulence of certain agents and thereby reduce the risks.

In addition to characteristics of the agents, the type of procedures or manipulations being carried out in the research laboratory also contribute to different health and environmental risks. Aerosolization, propagation of agent materials, and the use of animals are examples of laboratory procedures that are likely to increase risks. Medical protection such as vaccines and drug treatments are available for several of the agents under study and vaccines were used at the two facilities we visited to reduce work-related risks. For other agents in use, no such protection is currently available and reliance is placed on physical containment measures.

Approximately 10 percent of the biological defense program contracts involve genetic engineering techniques to study disease processes. The use of genetic engineering and recombinant DNA molecules has been a subject of concern because of the risks associated with the possible creation of modified agents and their potential release into the environment. Recognition of these risks led to the establishment of regulatory controls for recombinant DNA research by the National Institutes of Health (NIH). The guidelines provide a formal process for reviewing recombinant DNA research work and establish both biological and physical containment safeguard standards. NIH developed the guidelines for its research contractors, and DOD has adopted them

and required contractors using genetic engineering techniques to comply with them.

#### DOD's Assessment of Safeguard Measures

DOD's management and oversight of the biological defense contractors focuses principally on the scientific aspects of the contract work. DOD officials, with input from an external peer review committee of scientists, evaluate contract proposals for their scientific feasibility and merit and for their relevance to program objectives. Laboratory safeguards are addressed as part of this review, according to DOD officials. The type of agents and procedures proposed are reviewed as well as the qualifications of the research contractors and their experience in working with pathogenic microorganisms. DOD officials reported that pre-award site visits to survey safety and security measures have been conducted at selected contractor facilities, particularly those where contractors had limited experience with high-risk agents. However, such visits are not required prior to contract approval, nor are they performed regularly.

During the term of a contract, a DOD contracting officer's representative is responsible for monitoring the progress of the contractor's work. The contracting officer's representative, who is typically a DOD scientist with expertise in the relevant field of research, maintains contact with the contractor through



periodic site visits and other forms of communication. DOD does not conduct regular inspections or evaluations to ensure that contractor facilities have adequate safeguards, but during site visits it does informally review them, according to DOD contract officers. Officials at the two facilities we visited confirmed that the DOD contract officers had conducted periodic site visits in which laboratory safeguards were discussed.

### Contractor Safeguards Management

At these two sites, we found that contractors had organized and implemented a risk management process. We did not find that they had conducted any formal risk assessments, however the site officials we interviewed were knowledgeable about the risks associated with the agents and procedures they were using.<sup>9</sup> At the university research center we visited, the principal investigators were in fact leading experts in the fields of virology and epidemiology and had made significant scientific contributions to what is currently known about several of the viral agents under study. Officials from both biological contractor sites indicated that certain risk information on viruses along with recommendations on biosafety containment levels had been compiled by a group of scientists -- the

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<sup>9</sup> Officials at the vaccine and drug development site had completed and recently updated an environmental assessment that discussed mitigation measures for the handling and disposal of infectious material.

Subcommittee on Arbovirus Laboratory Safety (SALS) of the American Committee on Arthropod-Borne Viruses -- and was used to guide risk management decisions.<sup>10</sup>

Officials at the contractor sites identified the following federal agencies and regulations that pertained to their research and development efforts: OSHA work place safety standards, EPA hazardous waste disposal and clean air and water standards, Department of Agriculture (USDA) restrictions on the use of certain animal pathogens, and Food and Drug Administration (FDA) "good laboratory and manufacturing practices" for developmental drugs and vaccines. Officials pointed out that USDA had conducted periodic inspections but the other agencies had not.

The principal laboratory biosafety guidelines used by the research contractors we interviewed were those published jointly by the Centers for Disease Control and the National Institutes of Health in 1984.<sup>11</sup> The guidelines describe four biosafety levels that incorporate different laboratory practices and techniques, physical containment measures, safety equipment, and facility

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<sup>10</sup> This evaluation of risks was based on a survey of arbovirus research facilities throughout the world. Information was collected on the use of viruses in research labs, the incidence of laboratory infections, and current and past biosafety practices.

<sup>11</sup> U.S. Department of Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories, 1st ed., Department of Health and Human Services pub. no. (CDC) 84-8395 (Washington, D.C.: U.S. Government Printing Office, March 1984). These guidelines are similar to those produced by NIH for work with recombinant DNA.

design characteristics for use in working with infectious agents. These guidelines along with other relevant federal and state government safety, health, and environmental regulations were incorporated into facility safety plans and operating procedures at the two sites.

We found that each of the contractor sites had established a process for setting safeguard policies, developing safety, security, and emergency preparedness procedures, and conducting oversight activities. The structure of the process was somewhat different at each of the sites, largely reflecting differences in the type of institution and the nature of their research and development efforts. At the university research center, contractors were required to obtain approval on contract proposals from a biosafety committee that met regularly to review contract work and other research safeguard issues. In addition, a separate biosafety office was set up to conduct employee training and periodic inspections of all laboratory facilities. At the laboratory institute, where vaccine and drug development work was underway, certain staff were assigned responsibilities for developing the written standard operating procedures for safety and for reviewing laboratory procedures and any accidents or incidents that occurred. These staff also had conducted some audits to check on compliance with safety procedures and the FDA "good manufacturing practices" requirements.

## Documentation and Technical Quality

DOD had very limited documentation available on its risk management activities. Examples of contract reports and site visit reports that we looked at provided only cursory attention to contractor safeguards. At the two sites we visited, most of the contractor officials felt that the DOD contracting office representatives were technically knowledgeable and generally familiar with the safeguards being used in the contract work. One principal investigator indicated some concern, however, that the contract representatives might be less qualified than some research contractors about certain laboratory safety procedures. The contractors did not believe that more formal safety reviews or inspections were needed.

DOD published a draft environmental impact statement on the biological warfare defense program on May 12, 1988, which provides the first reasonably comprehensive assessment of possible environmental impacts and health and safety risks. In developing the statement, DOD reviewed safeguards at a sample of contractor facilities and also looked at likely maximum credible events that might occur. These included possible infections of laboratory personnel and the unintentional release of agents into the environment. DOD concluded from its assessment that there is a very low probability of such incidents occurring, and if they were to occur, existing control measures would provide adequate

containment. We found, however, that the available information and data in the report itself were not sufficient to allow us to assess DOD's review of contractor facilities.

#### CONCLUSIONS AND RECOMMENDATIONS

Our brief review of DOD's process for assessing safeguards at chemical and biological defense contractor facilities is based on information we collected from DOD officials, available documents and technical literature we reviewed, and our visits to four case study sites. We found very different practices being followed for chemical and for biological defense contractors. One factor that may account for this is the fundamental difference between chemical and biological defense efforts. The chemical work involves the use of agents that were developed initially as weapons; the biological work involves the use of pathogenic microorganisms that for the most part occur naturally in various locations around the world but are thought to have potential as weapons. In the chemical area, DOD officials pointed out that a safeguards program for research and development work had to be developed and established early on because there was no preexisting system of safeguards. In the biological program, in contrast, DOD entered into an established field of research in which a safeguard system was perceived as already in place.

## Chemical Warfare Research and Development Contractors

DOD's approach for evaluating and managing the risks associated with chemical agent research and development efforts at contractor facilities appears to be reasonably systematic and comprehensive. DOD has developed and established requirements and imposed a formal review of contractors prior to contract award, a pre-award inspection, and a post-award inspection system to determine if contractors employ sufficient safety, security, and emergency preparedness measures. DOD has also conducted maximum credible event analyses, which provide a useful tool for estimating the effectiveness of existing safeguards. However, we believe that additional effort should be devoted to addressing other possible threats that could result in hazardous events at chemical contractor facilities. Thus, we recommend that DOD expand the scope of these analyses to incorporate other maximum credible event scenarios. Assessments that look at a broader range of threats, including instances of human failure, would result in more realistic assessments of risk and better response potential.

## Biological Warfare Research and Development Contractors

In the biological warfare defense program, DOD is relying on a system of safeguards that was largely developed by the

biomedical and microbiological research establishment and that is implemented individually by research investigators and institutions. DOD has not developed its own safeguard requirements or conducted regular, formal evaluations of contractor facilities. DOD's current risk assessment and safeguards management process for contractors is one in which safeguards are only indirectly reviewed through the contract proposal review process, intermittent site visits, and contract monitoring by DOD contracting office representatives. The process relies heavily on the expertise and experience of the research contractors and the technical capabilities of the DOD representatives.

The lack of a formal DOD risk assessment and safeguards management process in the biological area makes it difficult to determine whether contractors are using the CDC/NIH or other recommended guidelines; whether safeguards are being used properly; and whether the existing safeguards are, in fact, effective in reducing the risks associated with biological warfare agent research and development work. Intermittent and unsystematic site visits by contracting office representatives do not necessarily provide a reliable or credible overview of contractor safeguards. In addition, reliance on an existing fragmentary system of oversight, where responsibilities are shared among several different organizational entities, raises the question of whether coordination could become a problem. A

centralized approach affords the opportunity to coordinate and organize responsibilities more effectively and prevent possible gaps in safeguards from occurring.

Biological defense research and development poses recognized health and safety risks, thus adequate protective measures need to be implemented. We recommend that DOD take a more active role in the risk assessment and safeguards management of contractor facilities by developing and establishing a process to evaluate safeguards. A more systematic, centralized evaluation process for contractor facilities would provide useful information to address concerns about risks. The evaluations conducted may well demonstrate that existing safeguards at contractor facilities are adequate. However, until such evaluations are completed, there is no way to determine this empirically, and uncertainties will persist about the adequacy of existing safeguards governing biological research and development.

As we were preparing testimony for these hearings, DOD informed us that several new policy initiatives have recently been implemented since we began our review with respect to safeguards management in the biological defense program. One policy is a requirement now that research contractors follow the CDC/NIH biosafety guidelines. Research contractors will also be required to submit a safety and security plan to DOD, and those conducting work with particularly hazardous biological agents or



procedures will be regularly inspected by a DOD biosafety officer. As we have already stated, we believe that these initiatives are important steps toward establishing a more effective safeguards management and evaluation process, and we are pleased to see DOD undertake these new endeavors.

This concludes my prepared statement. I will be happy to respond to any questions you may have.