House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol

A Joint Research Report of Academic and Research Institute, Pharmaceutical and Biotechnology Industry, Defense Contractor, and Inspection Veteran Brainstorming Groups

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Preface and Acknowledgments

This report is the product of a series of meetings that the Stimson Center's Chemical and Biological Weapons Nonproliferation Project convened to explore the technical prospects for monitoring the Biological and Toxin Weapons Convention (BWC). Discussion about how to monitor the BWC has been confined mostly to a small circle of government diplomats and security analysts, so the Stimson Center sought to tap nongovernmental expertise to invigorate the debate about the technical feasibility and costs of a BWC protocol. Therefore, the project was designed to draw technical insights from scientists who worked in the very facilities that would most likely fall under the purview of a BWC monitoring protocol: academic and research institutes, pharmaceutical and biotechnology companies, and defense contractors. In addition to those three groups, the project gathered a fourth group of technical specialists to distill the lessons from their participation in numerous monitoring activities during the early to mid-1990s that are relevant to a discussion of BWC monitoring.

Not only did the experts who participated in these brainstorming discussions have outstanding scientific qualifications, they repeatedly demonstrated an eye for pragmatism and a willingness to consider the issues associated with monitoring the BWC in an open-minded fashion. Prior to being contacted by the Stimson Center, many of these experts, particularly those from industry and academia, had given this subject little or no consideration. Tremendous credit and gratitude go to the more than thirty individuals who volunteered several days at a time from their already busy careers to ponder the intricacies of BWC monitoring. Without their willingness to make room for this project on their already packed agendas, this report would never have materialized.

A number of participants agreed to be named in the report and thus merit explicit acknowledgment here. Among the academic and research institute experts, thanks go to: Dr. Corrie Brown, Department of Veterinary Pathology, University of Georgia College of Veterinary Medicine; Dr. Nancy Connell, Department of Microbiology and Molecular Genetics, New Jersey Medical School; Dr. Jerry Goldstein, Botany/Microbiology Department, Ohio Wesleyan University; Dr. Jennie Hunter-Cevera of the University of Maryland Biotechnology Institute; Dr. Barry Kreiswirth of the Tuberculosis Center at the Public Health Research Institute; Theodore Myatt at the Harvard School of Public Health; Dr. Robert Shope, Department of Pathology, Center for Tropical Diseases, University of Texas Medical Branch at Galveston; and Dr. Anne Vidaver, Department of Plant Pathology, University of Nebraska-Lincoln.

Several members of the industry group can also be recognized. The Stimson Center expresses its appreciation to: Dr. Robert Hamilton, senior scientist and group leader at a large biotechnology company; Dr. Allen Laskin, president of Laskin/Larkin Associates; Dr. George Pierce, former manager of technology development and engineering, Cytec Industries, currently with the Applied and Environmental Microbiology Department, Georgia State University; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; and Dr. Robert Zagursky, distinguished research scientist for research and development, Wyeth-Lederle Vaccines.

In addition, thanks go to the remaining participants from the academic, industry, defense contractor, and inspection veteran groups who anonymously contributed their wisdom and time to this research effort. Identified in the report by their relevant experience and credentials, these individuals participated actively in their meetings, but wished not to be named to avoid any potential negative fallout that might result from their speaking out on these issues. Their willingness to participate in this research effort is nonetheless greatly appreciated.

The Stimson Center would also like to thank New York City's Public Health Research Institute (PHRI), in particular PHRI President Lewis Weinstein and Dr. Kreiswirth, who directs PHRI's Tuberculosis Center. During the first meeting of the academic and research institute brainstorming group, Kreiswirth volunteered his biosafety level 3 laboratories as a testbed for this group's proposed monitoring techniques. PHRI graciously welcomed Stimson "inspectors" for a one-day monitoring trial. Fellow academic group member Dr. Connell also helped to host the trial and deserves hearty thanks for her contributions and assistance. PHRI's enthusiastic participation in this exercise, which came at no small cost because of the disruption to the Tuberculosis Center's normal activities, is to be commended. The events of the trial, recounted in detail in the academic and research institute group's second meeting as well as in the body of this report, provided valuable empirical evidence to inform this group's discussions and recommendations.

The two inspectors for the PHRI trial were Lt. Col. Karen Jansen (USA, ret.) and Dr. David Franz, former commander of the US Army Research Institute of Infectious Diseases. In many other ways large and small, this pair's inspection experience and technical excellence enriched this research project. Both provided advice, helped to facilitate meetings, and offered feedback on the structure and progress of these sessions. Their deep biodefense and inspection expertise was extraordinarily helpful. The project also wishes to express its gratitude to another duo of bioweapons experts, Dr. P.C. Trexler and Dr. Ken Alibek, who provided crash course instruction to the brainstormers about the former US and Soviet bioweapons programs, respectively.

Behind the scenes, the project's staff also powered this research effort along from start to finish. Ms. Leslie-Anne Levy and Ms. Claudine McCarthy, both research associates, staffed the brainstorming sessions, diligently recording the participants' remarks on tables and charts that were used to aid discussions. In addition, they spent countless hours listening to the tapes of these meetings, pulling the key points of interest, convergence, and divergence from the transcripts. Also, Mr. Corwin Smidt, a project intern in the spring of 2001, pitched in with research and administrative assistance. Just before the report went out the door, Dr. William Durch, a senior associate at the Stimson Center, provided a constructive review of key parts of the text.

Finally, the Chemical and Biological Weapons Nonproliferation Project would not exist without the resources that foundations and individuals provide to bring various research efforts to life. This BWC

brainstorming effort was initiated by a grant from the John D. and Catherine T. MacArthur Foundation, with additional grant support from the Ploughshares Fund and Mrs. Margaret Spanel. Also, since its inception in January 1993, the project has enjoyed support from the Carnegie Corporation of New York.

A.E.S.
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Executive Summary

In 2001, the international community embarked on a push to conclude a monitoring protocol for the Biological and Toxin Weapons Convention (BWC). This 1972 treaty, which bans the development, testing, production, storage, and use of germ weapons, lacks provisions to verify compliance with its prohibitions. Given the USSR's systematic violation of the BWC spanning two decades, followed by the United Nations' unearthing of Iraq's bioweapons program, the behavioral norm that the BWC sought to establish was perceived as crumbling. Pressure was on to deliver a monitoring protocol that could detect programs illicitly perpetuating one of the most horrific warfare capabilities ever devised by man. So, international security and the viability of an industry essential to global health will rest partly on this protocol's performance.

Monitoring the BWC is an extremely difficult task because nature is the source of the microorganisms that are the basis of these weapons, and diseases must be studied if cures are to be found. Moreover, technical advances have given scientists the ability to engineer new disease strains and clean an entire manufacturing facility's fermenters and pipelines within minutes, capabilities that a government set on cheating could use to great advantage. The BWC protocol negotiators, in other words, would need to stretch the horizons of monitoring technologies and strategies if they were to succeed in creating a meaningful and feasible protocol.

The Stimson Center's Chemical and Biological Weapons Nonproliferation Project turned to nongovernmental technical expertise to explore the vexing technical challenges associated with monitoring compliance with the BWC. The Stimson Center recruited technical experts from three types of facilities likely to fall under the monitoring umbrella of a BWC protocol, namely research institutes and universities, pharmaceutical and biotechnology companies, and defense contracting firms. The Stimson Center asked these groups to "brainstorm" the technical aspects of BWC monitoring, showering them with questions to facilitate their discussions. A fourth group was composed of inspection veterans, who imparted the lessons they learned from US BWC trial and mock inspections, visits under the 1992 trilateral agreement to confirm the closure of the former Soviet biowarfare program, and United Nations Special Commission inspections. In the report, the short-hand reference of "inspection veterans" is used to describe this group. All totaled, thirty-five technical specialists, each a top expert in their respective disciplines, participated in these brainstorming sessions. This report reflects the findings and conclusions that each group reached, whether enthused or skeptical about the ability to monitor the treaty. The Stimson Center does not necessarily agree with their findings or recommendations.

Chapter 1 of the report explains how the brainstorming sessions were conducted, and chapter 2 summarizes the lifespan of the BWC, including major developments in the efforts to strengthen the treaty. Chapters 3 and 4 present in full the monitoring tools and strategies that the academic and industry brainstorming groups proposed for use in their respective settings. The insights from the defense contractors and inspection veterans are interspersed throughout the report to accentuate and contrast

points made by the academic and industry brainstormers. The report's final chapter highlights the similarities and differences between the draft BWC provisions and the ideas that emerged during the independent discussions of the four brainstorming groups.

On several issues, the brainstormers came out mostly in alignment with the technical substance and monitoring concepts in the draft BWC protocol. Both the industry and academic experts turned to the same monitoring tools—such as advance research on facilities to be inspected, visual observation, documentation review, interviews, and sampling and analysis—that those involved in efforts to strengthen the BWC have been contemplating since the early 1990s. With regard to the use of sampling and analysis, they observed that a great deal remains unsettled regarding the procedures for this important inspection tool and therefore called for additional technical research in this area. The monitoring strategies proposed by the academic and industry groups share common threads with what is known in arms control circles as "managed access" inspections, wherein inspectors and host officials work out compromises on the spot to satisfy inspection and host site needs. The industry and academic groups both estimated that their proposed monitoring strategies and tools would, for the most part, be effective. The defense contractors and inspection veterans groups, however, were quite dubious about the overall utility of BWC inspections. The defense contractors also noted that the activation of a BWC protocol would bring them to a crucial decision point, namely whether their companies should forsake defense contract work entirely.

On several important inspection parameters, the academic and industry experts differed with what the BWC's negotiators have envisioned. The inspectors must have sufficient manpower and time to be able to unravel the complexities that they would undoubtedly encounter in the field. The brainstormers' point about the need for specialized expertise on an inspection was driven home during the trial inspection that the Stimson Center conducted at a biosafety 3 level research laboratory to test the academic group's proposed monitoring tools and strategies. During this trial, which is fully described in at the end of chapter 3, two experienced inspectors resolved a few issues of monitoring concern but, lacking expertise in this laboratory's area of research concentration, did not pick up on the significance of clues that the laboratory's operators had planted to indicate possible foul play.

After reviewing summaries of the draft inspection terms in the BWC rolling text, the industry group gave the negotiators a "D" for their efforts. The inspection terms must provide ways to differentiate between the good guys and the bad guys, not leave question marks hanging over all facilities. In their view, such inspection terms were possible, but significant revisions of some of the draft protocol's technical nuts and bolts were in order.

All of the technical experts that participated in the brainstorming series believed that additional technical research and field trials, if well designed, would greatly serve the purposes of an eventual BWC

protocol. Such activities could stimulate technical improvements in the draft protocol and augmented political support from governments and the private sector. Since the US government has spoken perhaps loudest about the seriousness of the biological warfare threat, the United States bears a special responsibility to see that all possible efforts are made to secure a technically sound BWC monitoring protocol. What is called for is a technical research and field testing program worthy of the momentous proliferation problem that is being addressed. The US pharmaceutical and biotechnology industries need to become a true partner in this endeavor. The Pharmaceutical Research and Manufacturers of America long ago offered expert technical assistance, but there have been no industry field trials of prospective monitoring procedures. Therefore, it is incumbent upon both US industry and the US government to mount good faith efforts to test fully the assorted permutations of BWC monitoring technologies and strategies.

After more than five years at the negotiating table, the effort to reach a BWC compliance protocol appears to be at the proverbial crossroads. Some participating governments seem poised to drive for the approval of a technically weak agreement. Others seem content to make such a superficial show of participation that the process could wander fruitlessly for years on end. Either outcome risks consigning the BWC to a "house of cards" existence. An impotent monitoring protocol would implode sooner or later, and absent the political will to conduct the requisite research, field trials, and tough negotiation, the BWC would remain a nice international behavioral norm, violated at will and possibly with impunity. The governments negotiating a BWC monitoring protocol surely owe their citizens better outcomes than those that destine the international community's principal mechanism for biological weapons nonproliferation and arms control for insolvency.

Chapter 1
Introduction

A common practice in arms control talks, indeed in many negotiations, is to reach agreement on overarching principles and leave many of the bothersome technical details to be settled later. This practice is reinforced by the widespread belief that technology and ingenuity can overcome even the most monumental challenges. "If they can put a man on the moon," goes the frequent refrain of this faith, "then surely they can find a way to do [fill in the blank]." More often than not that faith is rewarded as cures are found for crippling diseases, tunnels are built beneath seas, and people on opposite sides of the globe communicate instantaneously through cyberspace. Until the drug is discovered and passes extensive clinical trials, until the underwater tunnel withstands immense pressure and dike-plugging maintenance procedures are proven, and until computers mature from card-programmed behemoths to handheld thinkpads with microchip modems, there is reason to hope for the technical miracle, but there is also reason to doubt that it will materialize. Time, diligent effort, and out-of-the-box thinking may yield the desired objectives. Until that occurs, prudence should predominate, especially when a great deal is at stake.

Such were the circumstances in 2001 as the international community embarked on a push to conclude a monitoring protocol for the Biological and Toxin Weapons Convention (BWC). This 1972 treaty bans the development, testing, production, storage, and use of germ weapons. Chapter 2, which provides a summary of this treaty's lifespan, explains that the BWC lacks provisions to verify compliance with its prohibitions.[1] In 1995, members of the BWC set out to strengthen the treaty with an awful lot riding on their efforts. First, there was pressure to deliver a protocol that could detect programs illicitly perpetuating one of the most horrific warfare capabilities ever devised by man.[2] Given the USSR's systematic violation of the BWC spanning two decades, followed by the United Nations Special Commission's unearthing of Iraq's bioweapons program, the behavioral norm that the BWC sought to establish was perceived as crumbling.[3] Hope that a monitoring protocol could be fashioned could be

[1] Note that while the BWC includes a provision to refer matters to the United Nations Security Council, it is otherwise devoid of on-site inspection tools.

[2] Biological weapons can be used against humans, livestock, and crops to devastating effect. For more detail on the effects of various biological agents, see *Textbook of Military Medicine: Medical Aspects of Chemical and Biological Warfare, Part I: Warfare, Weaponry, and the Casualty*, ed. Frederick R. Sidell, Ernest T. Takafuji, and David R. Franz (Washington, DC: Office of the Surgeon General, US Department of the Army, 1997); and US Congress, Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks* (Washington, DC: US Government Printing Office, 1993).

[3] Suspicions that the Soviet Union was violating the BWC arose in 1979 following an unusual outbreak of anthrax at Sverdlovsk and continued throughout the 1980s. US Arms Control and Disarmament Agency, *Soviet Noncompliance with Arms Control Agreements* (Washington, DC: US Arms Control and Disarmament Agency, 1 February 1986); US Arms Control and Disarmament Agency, *Soviet Noncompliance with Arms Control Agreements* (Washington, DC: US Arms Control and Disarmament Agency, 2 February 1988). Uncertainties about Soviet BWC implementation were confirmed in 1992 when Russian President Boris Yeltsin admitted that the Soviet Union had maintained an offensive biological weapons program. John-Thor Dahlburg, "Russia Admits It Violated Pact on Biological Warfare," *Los Angeles Times*, 15 September 1992; Michael Gordon, "Russia and West Reach Accord on Monitoring Germ Weapon Ban," *New York Times*, 15 September 1992. The United Nations Special Commission on Iraq uncovered the details of Iraq's biological weapons program. For accounts of the scope of

drawn from the 1993 Chemical Weapons Convention (CWC), which contained intricate monitoring procedures to oversee the destruction of chemical weapons arsenals and production facilities, as well as to safeguard against a hidden offensive weapons program within commercial chemical plants.[4] Monitoring the BWC would prove an even tougher challenge, however, because nature is the source of the microorganisms that are the basis of these weapons, and diseases must be studied if cures are to be found. Moreover, technical advances have given scientists the ability to engineer new disease strains and clean an entire manufacturing facility's fermenters and pipelines within minutes, capabilities that a government set on cheating could use to great advantage. The BWC protocol negotiators, in other words, would need to stretch the horizons of monitoring technologies and strategies if they were to succeed in creating a meaningful and feasible protocol.

Also riding on the outcome of the negotiations, according to the US industry's main trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), was the viability of an industry responsible for discovering and manufacturing medications. Because medicines not yet on the market lack patent protection for many years, PhRMA asserted that BWC inspections could result in the loss of proprietary business data and have significant cost implications.[5] While the CWC's negotiators were able to find technical and procedural balances that would enable the inspectors to fulfill their monitoring goals and the host facilities to protect sensitive business data, PhRMA remained unconvinced that similar balances could be crafted for the BWC protocol, despite trial field inspections

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Iraq's germ warfare efforts, see Robin Wright, "Iraqis Admit to Broad, Virulent Germ War Plan," *Los Angeles Times*, 6 September 1995; R. Jeffrey Smith, "UN Says Iraqis Prepared Germ Weapons in Gulf War," *Washington Post*, 26 August 1995; Barbara Crossette, "Germ War Plan Underreported, Iraq Tells UN," *New York Times*, 23 August 1995.

[4] The CWC's articles consume forty-six pages, while the annexes detailing how to implement the treaty run over 140 pages. Underpinning the obligations that states take to destroy chemical weapons capabilities and forsake future weapons production, the CWC's verification annex specifies the inspection methods and procedures to be employed during routine inspections of chemical weapons defense, storage, production, and destruction facilities as well as at a variety of industrial facilities. Challenge inspection procedures are also spelled out in this annex, as are the safeguards that host facilities can employ to protect sensitive data unrelated to the treaty compliance. A separate annex lays out procedures to be used to protect confidential information. Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction.

[5] According to a PhRMA position paper on a BWC protocol, "The provision of information about some of our facilities and the possibility of opening these facilities to inspections under some circumstances will need to be elements to the strengthening of the treaty. However, these elements also entail risks to commercial facilities including the potential loss of proprietary information, risks to commercial reputations, and added regulatory expenses that ultimately affect the cost and availability of medicines and other widely-used products." Pharmaceutical Research and Manufacturers of America, "Summary of PhRMA's Position on a Compliance Protocol to the Biological Weapons Convention," July 1998. Available at http://srpub.phrma.org/phrma/Jul98.PhRMA.bwc.html. From 1974–1994, the US pharmaceutical industry was responsible for nearly half the new major global drugs. See Gillian Woollett, "Industry's Role, Concerns, and Interests in the Negotiation of a BWC Compliance Protocol," in *Biological Weapons Proliferation: Reasons for Concern, Courses of Action* (Washington, DC: Henry L. Stimson Center, January 1998), 42.

abroad that gave some evidence to the contrary.[6] Thus, the stakes riding on a BWC protocol were very high indeed.

Given the situation, it would be reasonable to assume that both the US government and the pharmaceutical industry would put forth considerable effort to ascertain the technical feasibility of monitoring the BWC and the possible costs attendant to such monitoring. While a procession of high-ranking US officials repeatedly stated that the conclusion of a BWC compliance protocol was a top nonproliferation goal and PhRMA reiterated support of efforts to strengthen the BWC,[7] little in the way of field research to put monitoring techniques and concepts to the true test followed. The US government held two full-scale field trials in the mid-1990s, but both produced indeterminate results indicating that inspectors may not be able to discriminate between legitimate and cheating facilities.[8] With only two inchoate data points upon which to base negotiating policy, again the reasonable assumption would be that the US government and industry would redouble their efforts to determine whether it was possible to monitor the BWC. Yet, neither the US government nor PhRMA moved forward with such field tests, despite 1999 legislation requiring them.[9]

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[6] Several countries have hosted trial inspections during the course of the protocol negotiations and submitted working papers on their outcomes. For example, the United Kingdom, Canada, Spain, Germany, Switzerland, Denmark, Finland, Iceland, Norway, Sweden, Austria, and Iran held trial inspections at a variety of facilities, including pharmaceutical research and production, biodefense, and vaccine production. Summaries of these exercises are available online at http://www.brad.ac.uk/acad/sbtwc/adhocgrp/wpindex.htm. Before the launch of BWC monitoring protocol talks, the United Kingdom held four "practice compliance inspections" at different facilities. Basic findings from these efforts and a discussion of the value of conducting trial inspections are contained in a Canadian report to the opening session of the Ad Hoc Group negotiators. United Nations, *Working Paper by Canada: The Role of Trial Inspections in Informing Arms Control Negotiations and Implementation, With Particular Emphasis on the Biological and Toxin Weapons Convention*, BWC/Ad Hoc Group/WP.1, 4 January 1995, 9–14.

[7] For official statements on the priority given the BWC protocol negotiations, see White House, Office of the Press Secretary, "Remarks by the President in Address to the 51st General Assembly of the United Nations," 24 September 1996; White House, Office of the Press Secretary, "State of the Union Address By the President," 27 January 1998; White House, Office of the Press Secretary, "Fact Sheet on the Biological Weapons Convention," 27 January 1998; Alexander Higgins, "Germ-Warfare Chairman Claims Progress Toward Tougher Treaty," *Associated Press*, 22 January 1999; Remarks by Samuel R. Berger, Assistant to the President for National Security Affairs, to the Carnegie International Non-Proliferation Conference, Washington, DC, 12 January 1999; Pharmaceutical Research and Manufacturers of America, "Summary of PhRMA's Position on a Compliance Protocol to the Biological Weapons Convention," July 1998. Available at http://srpub.phrma.org/phrma/Jul98.PhRMA.bwc.html.

[8] A three-day trial challenge visit occurred at a US vaccine plant in October 1995. The following March, a non-challenge exercise took place at a Department of Energy national laboratory. For the report of the latter, see *DOE Exercise to Determine the Potential Impact of a Legally Binding BTWC Regime on DOE Sites* (US Department of Energy, Pacific Northwest National Laboratories, June 1998). Both exercises are briefly described in Amy E. Smithson, "Man Versus Microbe: The Negotiations to Strengthen the Biological Weapons Convention," in *Biological Weapons Proliferation: Reasons for Concern, Courses of Action* (Washington, DC: Henry L. Stimson Center, January 1998), 120–1.

[9] The National Security and Corporate Fairness under the Biological Weapons Convention Act required the US government to conduct trial investigations and visits at a variety of government and private sector facilities. See Public Law 106-113, 29 November 1999. The Defense Department began training exercises in March 2001, none of which has approached the scale of full-fledged monitoring trials. Gail Kaufman, "Pentagon Conducts Biological Weapons Convention Training," *Stars and Stripes*, 23 March 2001.

Meanwhile, the inertia of several negotiating annual sessions propelled the draft protocol text forward to what some participating governments and outside observers have depicted as a window of opportunity not to be missed.[10] The articulated deadline for conclusion of the protocol text is November 2001, the occasion of the Fifth Review Conference of the BWC's membership. Before anyone puts pen to parchment, however, all should pause to appreciate not only the stakes riding on this agreement but the two elements essential to any success in arms control. First, participating nations must have the political will to negotiate, implement fully, and enforce compliance with the accord in question. Second, those charged with implementing the treaty's provisions, the inspectors, must have the technical means to do so reliably and effectively. With political will and a sound technical foundation, arms control can be a valuable mechanism to enhance national and international security. Absent either essential pillar, however, arms control can be a hollow endeavor.

No matter how worthy the goal, inertia is the wrong reason to wrap up a BWC protocol prematurely. With reflection should come the recognition that the necessary technical underpinnings of a BWC protocol are arguably lacking. Regrets would surely follow if the job were done fast, but in such a manner that the new protocol collapsed upon implementation. Just as surely, lamenting that sorry state of affairs would be poor cover for those who did not exercise patience when warranted and those who sat on the sidelines, not even expending the effort to craft a workable, meaningful accord.

PURPOSE AND METHODOLOGY OF THE REPORT

In the absence of US government-sponsored in-depth technical research, the Stimson Center's Chemical and Biological Weapons Nonproliferation Project turned to nongovernmental technical expertise to explore the vexing technical challenges associated with monitoring compliance with the BWC. With a grant from the John D. and Catherine T. MacArthur Foundation and additional support from the Ploughshares Fund and Mrs. Margaret Spanel, the Stimson Center invited some thirty-five scientists to a series of meetings to brainstorm the technical aspects of on-site monitoring of the BWC. As the resumes contained in the appendix attest, the people who gathered around the Stimson conference table are top experts in their respective fields.

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[10] Richard Norton-Taylor, "Britain Urges New Bio-Weapons Deal," *Guardian (London)*, 27 March 2000; Address by H E Leslie Luck, Ambassador and Permanent Representative to the United Nations and the Conference on Disarmament during the 19th Session of the BWC Ad Hoc Group, Geneva, Switzerland, 27 March 2000; "Political Decisions Needed Soon on Germ-Warfare Treaty: Chairman," *Associated Press*, 31 March 2000; "European Union Moves to Break Logjam on Anti-Germ Warfare Treaty," *Associated Press*, 29 June 1999. As one analyst noted, "Taken as a whole, it is evident that such outstanding issues are indeed soluble in such a way that different states-parties' concerns can be met while still achieving the goal of a protocol that strengthens the convention. It is simply a display of political will that is needed to go the final distance, and the window of opportunity for completion is indeed now." Graham Pearson, "The Protocol to the Biological Weapons Convention Is Within Reach," *Arms Control Today* (June 2000). Available online at: http://www.armscontrol.org/ACT/june00/bwcjun.htm.

The Stimson Center drew three groups of technical experts from the very types of facilities that would probably be subject to BWC monitoring: academic and research institutes, pharmaceutical and biotechnology companies, and defense contractors. The Stimson Center actively sought out arms control novices for the industry and academic and research institute groups.[11] Participants who were largely unaware of the BWC's verification dilemmas aside from any news they might have seen about the Soviet and Iraqi biological weapons programs were essential for the exercise's objective of securing assessments about BWC monitoring that were extremely well informed technically but not biased by preconceptions about whether a BWC protocol was a good or bad idea. In a fourth group, the Stimson Center sought the voice of experience from individuals who had taken part in several types of inspections in the early 1990s that were germane to a prospective BWC protocol. In the body of the report, the short-hand reference of "inspection veterans" is used to describe this group.

The Stimson Center's role throughout the project was that of convener and discussion facilitator. Two individuals seasoned by inspections in Iraq and the former Soviet Union, Lt.Col. Karen Jansen (USA, ret.) and Dr. David Franz, former commander of the US Army Research Institute of Infectious Diseases, provided technical expertise for the project.[12] Not only did Stimson opinions not matter one iota, Stimson personnel were explicitly barred from even entering the fray. Otherwise, the main ground rule was that the floor was wide open for the brainstormers to sort through the issues, identifying problems and developing solutions. This report reflects the conclusions each group reached, whether enthused or skeptical about the ability to monitor the treaty. The Stimson Center does not necessarily agree with their findings or recommendations.

The academic and industry participants each met twice during 2000.[13] Since these participants knew little about the specifics of running a bioweapons program, their first meetings began with "biological weapons 101" briefings about the former US germ warfare program, as well as the Iraqi and Soviet weapons efforts. After a brief review of the BWC's prohibitions, the brainstormers gained insight into how facilities like the ones they worked in were relevant to BWC monitoring. For example, the academic and research group learned from Dr. P.C. Trexler, a scientist at the University of Notre Dame during the 1940s and 1950s, about the crucial role US universities played in the US offensive program.[14]

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[11] Those in the veterans group had, of course, been exposed to the debate for and against a protocol. Given their interactions with US government officials, several individuals in the defense contractors group were also well aware of the debate surrounding the protocol negotiations.

[12] Jansen participated in six United Nations Special Commission on Iraq inspections, leading four of those teams. Franz had field experience in both Iraq and the former Soviet Union. The appendix contains their biographies.

[13] The academic group met on 6–7 January 2000 and 16–17 August 2000. The industry group's first meeting was 29–30 June 2000, and the second was 23–24 August 2000.

[14] Dr. Trexler explained candidly the nature of the research his laboratory conducted and how agents were actually produced there. He also regaled the group with harrowing tales of how he and his colleagues hauled batches of tularemia in the back of a Nash Rambler station wagon from Notre Dame to the Ft. Detrick, Maryland, where the US offensive weapons program was located.

Likewise, Dr. Ken Alibek briefed industry participants about how the Soviet Union masked much of its massive offensive biological weapons program behind an extensive network of front companies known as Biopreparat.[15]

Proceeding with an appreciation that governments have utilized facilities like their own to research, develop, test, and produce biological weapons, participants began to progressively work through a series of thought exercises, led by Stimson personnel. The general flow of the exercises can be understood from the sample questions in box 1.1, although during the meetings Stimson facilitators formulated many permutations of these questions to make sure that individual and group viewpoints were clear and that consensus statements indeed represented the position of all present. The participants' first chore was to contemplate on-site inspection activities from the vantage point of an inspector. They were invited to express what would catch their attention, what would make them as inspectors ask questions about the equipment or activities at a facility similar to their own.

As chapters 3 and 4 relate, the brainstormers cited worries about such things as equipment and waste treatment practices that did not correspond to a facility's stated purposes. Then, the participants were asked to mull over the monitoring techniques and steps they would take as inspectors to clarify ambiguities, to figure out whether a site was engaged in legitimate or prohibited activities. They suggested monitoring tools, usually employed in combination.

Having tackled the problem as inspectors, the brainstormers were then asked to explain how they would react if the very monitoring tools and strategies that they had proposed were employed at their own facilities. High on the participants' list of concerns, for example, was loss of confidential data and productivity. After the academic and industry brainstorming groups had created their own monitoring frameworks, they returned for a second set of meetings in which the Stimson staff pressed them harder on all fronts. Functioning as inspectors, they were asked to debate the strengths and weaknesses of each monitoring tool in given situations and ultimately to assess the technique's expected level of effectiveness. Stimson facilitators then instructed the participants to elaborate the impact that each of the techniques would have at their sites during the inspection itself and perhaps afterward. During this phase of the exercise, participants in both groups reflexively worked from their lengthy experience with all manner of regulatory inspections, pragmatically and creatively devising ways to meet an inspector's need for clarification while still averting the compromise of sensitive data and equipment.

The Stimson staff conducted a one-day trial inspection at a biosafety level 3 laboratory using the group's proposed monitoring techniques, which informed the views of the academic and research institute group about monitoring effectiveness, burdens, and possible work-arounds. Franz and Jansen conducted

[15] Dr. Alibek, who rose to the rank of deputy director of Biopreparat, illustrated vividly how a full-fledged weapons program can be hidden within the supposedly civilian sector. Dr. Alibek's account can be found in the book he co-authored with Stephen Handelman, *Biohazard* (New York: Random House, 1999).

Box 1.1: Example Questions Posed to Brainstormers During Meetings

Identifying Concerns On-Site

- What are the distinct differences between legitimate work and offensive bioweapons work?
- What would be done in a parallel setting with an offensive inclination?
- What would be considered inappropriate or unjustifiable work with pathogens?
- Which concerns should the inspectors know about before reaching the facility?

The Inspector Perspective

- How can the inspectors ascertain whether a particular item's use is legitimate, consistent with its stated purpose, or offensive in nature?
- What would that monitoring technique show the inspectors? What does it not show inspectors?
- Could other monitoring techniques be used instead or in combination?
- How would inspectors verify equipment is being used for its stated purpose?

The Host Perspective

- How could a host facility show an inspector that a given activity is consistent with the stated purpose?
- What items or activities might be misinterpreted as possibly offensive in nature?
- How can compliance be demonstrated?
- Does the use of certain monitoring techniques pose problems? How so?
- How could that problem be resolved?
- What area of work or of a facility should be considered off limits?

Debating Effectiveness and Burdens

- If facilities were trying to evade a particular monitoring technique, what would they do? How could this be detected?
- What is the technical feasibility of these monitoring techniques?
- What would be the burden to host facilities if these techniques were used?
- How would BWC inspections differ from what other regulatory/oversight inspections?

Big Picture

- Is there an acceptable monitoring strategy that would contribute meaningfully to compliance verification?
- What would be the key essentials of such a strategy?
- What is the likelihood that such a strategy would arrive at an unambiguous assessment of the activities taking place at a given site?
- What is the likelihood that such a strategy would uncover violations of the BWC?
- To what degree would such a strategy provide conclusive proof that a site was not engaged in prohibited offensive activities?
- If a site is determined to be compliant, how quickly could that change?
- What is the likelihood that the monitoring strategy would risk national security? Proprietary information? Professional reputation?
- Is the burden or risk of BWC monitoring acceptable?

this trial, described in detail at the end of chapter 2, at the Tuberculosis Center at the Public Health Research Institute in New York City. For their part, the industry brainstormers agreed that real-world field tests of BWC monitoring techniques were certainly necessary, and some were quite amenable to assisting with such exercises. A full-scale field trial at a manufacturing plant outstripped the project's resources.

The final three chapters of this report were compiled from verbatim transcripts of the brainstorming meetings and extensive notes taken during the trial inspection. Participants in the academic and industry groups reviewed the pertinent draft segments of the report for accuracy, after which they were given the choice of being identified by name and affiliation or by a general characterization of their skills and work history. The handful who declined to be identified by name fully agreed that the report accurately reflects the proceedings and their specific views, but cited worries about a possible backlash from their employers or the media. All brainstormers, it should be noted, volunteered their time for this project.

The insights from the defense contractors and inspection veterans are interspersed throughout the report to accentuate and contrast points made by the academic and industry brainstorming groups. The defense contractors and inspection veterans each met for one day.[16] Stimson personnel jump-started the discussion of the defense contractors by showing them charts summarizing the monitoring tools and strategies proposed by the industry and academic groups. Their reactions to the feasibility of employing these monitoring techniques at their sites, the problems that might result, and their overall assessment of the possible utility of such monitoring appear in chapters 3, 4, and 5.[17]

All members of the inspection veterans group had under their belt at least one of the two full-scale BWC trial inspections that unfolded in the United States in the mid-1990s, not to mention experience with the inspections that took place under the 1992 trilateral agreement, United Nations Special Commission on Iraq inspections, or a series of mock visits at US defense facilities.[18] The Stimson Center assembled this unique corps to glean the technical lessons from their varied but extensive

[16] The inspection veterans and defense contractor meetings occurred on 27 April 2000 and 28 August 2000, respectively.

[17] Given the nature of biodefense work, the group did not need introductory briefings on biological weapons and the relevance of their facilities to BWC monitoring. Although this group's discussion was abbreviated in comparison to the industry and academic and research institute groups, their deliberations on monitoring effectiveness and impact were nonetheless thorough.

[18] The US, United Kingdom, and Russia concluded the trilateral agreement in September 1992 to improve confidence that Russia's offensive biological weapons program had indeed been mothballed and that it was living up to the terms of the BWC. The text of the Joint Statement on Biological Weapons by the Governments of the United Kingdom, the United States and the Russian Federation is available at http://www.stimson.org/cwc/trilats.htm.

inspection histories. The participants analyzed eight different categories of on-site activities,[19] discussing the problems they encountered in different locations, resolutions they worked out on-site to deal with those problems, and the lessons they took away from their experiences that could be applied to future inspection activities.

The report's final chapter highlights the similarities and differences with the draft BWC provisions that emerged during the independent discussions of the four brainstorming groups. Since the monitoring techniques themselves are not the only facet of BWC monitoring pertinent to the success of such efforts, this chapter also presents the brainstormers' thoughts on such matters as the qualifications that should be required of inspectors, the size of the inspection team, and the timeframe for inspection activities. Only after the groups had hashed out consensus positions on monitoring tools and strategies, as well as on these associated issues, did Stimson personnel show the academic and industry groups the corresponding proposals contained in the twelfth version of the BWC protocol rolling text.[20] Indicating a need for more technical research, development, and testing of monitoring techniques and strategies, the brainstormers' recommendations at times diverged significantly from the provisions contained in the composite text of the BWC protocol, which was the basis for the twenty-third round of negotiations, held from 23 April to 11 May 2001.[21]

[19] The eight categories were: 1) introductory briefings; 2) examining records; 3) access to certain areas or buildings at facility; 4) photography, video cameras, tape recorders; 5) interviewing facility personnel; 6) examining individual pieces of equipment; 7) viewing capabilities of facility (e.g., fermenter capacity, safety and containment set-up); and, 8) sampling.

[20] The draft BWC protocol provisions shown the brainstormers were roughly equivalent to those contained in the March 2001 composite text of the protocol.

[21] Ambassador Tibor Toth, the Chairman of the BWC protocol negotiations being held under the auspices of the Ad Hoc Group of the States Parties to the BWC, unveiled a compromise composite or "chairman's" text on 30 March 2001, a move that usually indicates that negotiations are entering their final phase. United Nations, *Draft Composite Text: Protocol to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, BWC/Ad Hoc Group/CRP.8 (Future), 30 March 2001.

Chapter 2
An Overview of International Efforts to Prohibit Biological Weapons

Only in recent years have biological weapons been widely recognized as being of the ominous rank as nuclear weapons. A single munition from either class of weapons can slay inconceivably large numbers of humans and lay waste to plants and animals. Perhaps the belated appreciation of the devastating character of biological weapons explains why in comparison to the nearly continuous efforts to rein in nuclear arms in the last century, the international community has attempted only sporadically to restrain the spread of germ weapons. This chapter provides an overview of international arms control efforts concerning biological weapons.

The 1925 Geneva Protocol banned the use of biological, toxin, and chemical weapons, but nearly a half-century passed before the international community developed a more comprehensive prohibition against the production and possession of germ weapons. Opened for signature on 10 April 1972, the Biological and Toxin Weapons Convention (BWC) contains a sweeping prohibition against germ weapons. The linchpin of this treaty is Article I, which mandates:

> [E]ach State Party. . .undertakes never in any circumstances to develop, produce, stockpile, or otherwise acquire or retain (1) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes; (2) weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.[1]

In addition, the BWC enjoins participating states not to transfer any of those agents, toxins, weapons, equipment, or means of delivery to any recipient for non-peaceful purposes and not to otherwise abet the proliferation or acquisition of biological agents or weapons. The BWC also requires states that possess biological weapons to destroy them within nine months of the treaty's activation.[2]

Since the BWC entered into force on 26 March 1975, it has been ratified by 143 countries and signed by an additional eighteen. To the extent that membership is an indicator of success, the world's nations view the BWC as a significant arms control agreement with the potential to enhance international security. However, this accord lacks what many see as a fundamental component of any arms control treaty—the means to verify compliance or to detect noncompliance.

The absence of cooperative verification provisions is typical of arms control treaties negotiated during the Cold War. The BWC was crafted in the early 1970s, a time when the type of highly intrusive on-site inspections needed for effective verification were widely viewed as politically unacceptable,

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[1] Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons, Article I. Hereinafter referred to as the Biological and Toxin Weapons Convention.

[2] Biological and Toxin Weapons Convention, Articles II, III, and IV.

infeasible, or unnecessary. Moreover, the negotiators were not pressed to include verification measures in the BWC because at that time policy makers viewed biological weapons as lacking military utility. As noted, that perception has changed significantly over the last twenty-five years due to violations of the BWC and to advances in biotechnology.[3] In an example of the former, the USSR, one of the BWC's co-depositaries, maintained a significant covert biological weapons program for decades.[4] Some observers first realized that the Soviet Union was cheating on the BWC in 1979, when a suspicious outbreak of anthrax occurred in the city of Sverdlovsk. The source of this outbreak was eventually traced to an accidental release from a Soviet biological weapons facility.[5] This incident raised concerns about the strength of the treaty and underscored the shortcomings of its mechanisms for resolving compliance problems. The BWC allows participating states to raise compliance "complaints" with the United Nations (UN) Security Council and requires an accused state to cooperate with efforts to ascertain the validity of a complaint. The Security Council would initiate any non-compliance investigation.[6] The drawback of this approach is that any permanent member of the Security Council can veto the launch of an investigation.

In addition to blatant indications that some states were not adhering to their obligations under the BWC, the field of biotechnology underwent something of a technical revolution in the latter part of twentieth century. Technical advances amplified the potential military utility of biological weapons. For example, genetic engineering has made it possible to alter some biological agents so that they are resistant to environmental stresses and not susceptible to vaccines or antibiotics.[7] Thus, experts began to worry that advancements in biotechnology, microbiology, genetic engineering, and related scientific disciplines would make circumvention of the BWC's prohibitions easier to accomplish and more difficult to catch.

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[3] Jonathan B. Tucker, "Strengthening the Biological Weapons Convention," *Arms Control Today* 25, no. 3 (April 1995): 9.

[4] For an insider's account of this program, see Ken Alibek and Stephen Handelman, *Biohazard* (New York: Random House, 1999). More briefly, see Milton Leitenberg, "The Conversion of Biological Warfare Research and Development Facilities to Peaceful Uses," in Erhard Geissler and John P. Woodall, eds., *Control of Dual-Threat Agents: The Vaccines for Peace Programme*, Stockholm International Peace Research Institute Chemical and Biological Warfare Studies 15 (London: Oxford University Press, 1994), 77–105; Anthony Rimmington, "From Military to Industrial Complex? The Conversion of Biological Weapons Facilities in the Russian Federation," *Contemporary Security Policy* 17, no. 1 (April 1996): 80–112.

[5] Although Soviet authorities initially claimed that the more than sixty deaths resulted from the consumption of contaminated meat, an independent group of scientists concluded that an accidental release of *Bacillus anthracis* was indeed the cause of the Sverdlovsk anthrax outbreak. Matthew Meselson et al., "The Sverdlovsk Anthrax Outbreak of 1979," *Science* 226, no. 5188 (18 November 1994): 1202–8. For more on the Soviet/Russian biological weapons program, see Milton Leitenberg, *Biological Weapons Arms Control*, Project on Rethinking Arms Control, Report No. 16 (University of Maryland, College Park: May 1996), 3–16.

[6] Biological and Toxin Weapons Convention, Article VI.

[7] US Congress, Office of Technology Assessment, *Technologies Underlying Weapons of Mass Destruction* (Washington, DC: Government Printing Office, December 1993), 114–5. The USSR, for example, made several of its bioagents resistant to multiple antibiotics. Alibek, *Biohazard*, 155–6, 160, 167, 261, 281.

Given these circumstances, the BWC's members decided that the treaty needed to be strengthened with a legally binding verification protocol. The feasibility of strengthening the BWC and the appropriate means of doing so are, however, strongly debated within the international community. Briefly, proponents of creating a verification protocol argue that it would increase the cost and difficulty of a clandestine weapons program, enhance confidence among compliant states, provide a legal framework for challenge inspections, and ultimately decrease the number of sites of proliferation concern. They cite the 1993 Chemical Weapons Convention (CWC) as a model of a verifiable arms control agreement. Critics, on the other hand, argue that the BWC cannot be effectively verified. They point to obstacles such as the dual-use nature of biological production facilities, the likelihood that a verification protocol would generate false confidence in compliance, and the possibility that inspections would expose facilities to foreign espionage. Opponents to a verification protocol also note that the BWC has a loophole because it does not directly prohibit research with biological agents.[8]

THE ONSET OF EFFORTS TO STRENGTHEN THE BWC

The BWC requires all member states to participate in review conferences to be held at five-year intervals. The objective of these meetings is to undertake an article-by-article review of the BWC's operation, ascertaining whether the purposes of the treaty's preamble and main articles are being achieved. Each such review should "take into account any new scientific and technological developments relevant to the" BWC.[9] The culmination of each review conference is a final declaration that "can also serve as a basis for further strengthening of the Convention."[10]

The First Review Conference was held in March 1980. As the meeting unfolded, participating countries raised concerns about verification and compliance, but a majority finally agreed that the existing international procedures for consultation and cooperation would be adequate to resolve any problems that might arise concerning the BWC. In the Final Declaration, the participants thus reaffirmed their support

[8] For a variety of opinions about the ability to verify the BWC, see S.J. Lundin, ed., *Views on Possible Verification Measures for the Biological Weapons Convention*, Stockholm International Peace Research Institute, Chemical and Biological Warfare Studies, Report No. 12 (London: Oxford University Press, 1991); Joseph Finder, "Biological Warfare, Genetic Engineering, and the Treaty That Failed," *Washington Quarterly* 9, no. 2 (Spring 1986): 5–14; Douglas J. Feith, "Biological Weapons and the Limits of Arms Control," *National Interest* (Winter 1986/87): 80–4; and Federation of American Scientists, "Progress in Identifying Effective and Acceptable Measures for a Compliance Protocol for the Biological Weapons Convention," Working Group on Biological and Toxin Weapons Verification, Working Paper (Washington, DC: May 1993).

[9] Biological and Toxin Weapons Convention, Article XII.

[10] United Nations, *Third Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Final Declaration,* Document BWC/CONF.III/23, Part II, 1991, 10.

for the treaty and found that Article I of the BWC "had proved sufficiently comprehensive to cover recent scientific and technological developments relevant to the Convention."[11]

The Second Review Conference took place in September 1986 amid a surge in concern about the "adequacy of the Convention in light of advances in genetic engineering and biotechnology…and allegations of breaches of the Convention."[12] The BWC's members were faced with the challenge of restoring confidence in the treaty's viability. This gathering coincided with the growing recognition of the value of confidence-building measures (CBMs), which encompass a variety of measures that states in regions of tension can undertake to promote openness in military matters and to build a climate of trust among nations.[13] The BWC's members sought to incorporate these mechanisms into the treaty regime. In the Final Declaration, the participants agreed to implement data exchanges concerning biological activities permitted under the treaty. An ad hoc meeting of scientific and technical experts therefore assembled in the spring of 1987 to design procedures for annual data exchanges among the BWC's members.[14] Beginning that year, states were asked to voluntarily submit pertinent data to the UN. Among the data to be declared annually was information on outbreaks of infectious diseases, the publication of scientific research results, and biological research laboratories that specialize in permitted protective, prophylactic, and other peaceful biological activities that are directly related to the BWC.[15]

Not long after these CBMs were instituted, members of the BWC arrived at a consensus that their non-legally binding nature was insufficient to produce meaningful results. The agreed CBMs did not authorize the UN to demand that states make declarations, and states that failed to submit data did not incur any penalty. Whether they were suspected of having covert biological weapons programs or not, most countries simply neglected to provide the information requested in the CBMs. For example, during the initial ten years after the CBMs were agreed upon, only fifty-two nations provided data at least once,

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[11] Aida Luisa Levin, "Historical Outline," in *Strengthening the Biological Weapons Convention by Confidence-Building Measures*, Erhard Geissler, ed., Stockholm International Peace Research Institute, Chemical and Biological Warfare Studies, Report No. 10 (London: Oxford University Press, 1990), 8. For more on the early years of the BWC, see also Nicholas A. Sims, *The Diplomacy of Biological Disarmament: Vicissitudes of a Treaty in Force, 1975–85* (London: MacMillan Press, 1988); and Barend ter Haar, *The Future of Biological Weapons* (New York: Praeger, 1991), 1–53.

[12] Levin, "Historical Outline," 9.

[13] For more on the origin, art, and practice of CBMs in a variety of contexts, see Johan Jorgen Holst and Karen Melander, "European Security and Confidence Building Measures," in *Arms Control and Military Force*, Christoph Bertram, ed. (London: International Institute for Strategic Studies, 1980): 223–31; Richard E. Darilek, "The Future of Conventional Arms Control in Europe—A Tale of Two Cities: Stockholm, Vienna," *Survival* 29, no. 1 (January/February 1987): 5–19; and Michael Krepon, ed., *A Handbook of Confidence-building Measures for Regional Security* (Washington, DC: Henry L. Stimson Center, January 1995).

[14] US Arms Control and Disarmament Agency, *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, DC: Government Printing Office, 1990), 132.

[15] Erhard Geissler, "Agreed Measures and Proposals to Strengthen the Convention," in *Strengthening the Biological Weapons Convention by Confidence-Building Measures*, 44–7.

and only eleven participated every year.[16] Prior to the Third Review Conference in September 1991, most countries thus recognized the inadequacy of relying solely upon voluntary CBMs for enhancing confidence in the compliance with the BWC.

In addition, other developments contributed to widening concerns about the BWC's weakness. A number of reports alleged that as many as ten countries possessed or were in the process of acquiring biological weapons.[17] Moreover, after the 1991 Gulf War, the UN Special Commission on Iraq uncovered evidence that Iraq, a signatory of the BWC, had a biological weapons program. The extent of this program—encompassing weaponization of several agents and deployment of germ-filled missiles and other munitions during the war—is still being investigated.[18] The situation in Iraq again highlighted the lack of an independent inspectorate to monitor the BWC's prohibitions. Aside from the difficulty of dealing with the proliferation of biological weapons at the state level, one 1991 report maintained that "an increased risk now exists that the acquisition and use of biological weapons is being contemplated not only by nations but by subnational groups."[19] Later underscoring this point, the Japanese cult Aum Shinrikyo, infamous for its use of poison gas in a March 1995 terrorist attack in Tokyo, also endeavored but failed to develop a biological weapons capability.[20]

Thus, the 1991 Review Conference authorized a group of governmental experts to identify and examine potential BWC verification measures from a scientific and technical standpoint. This Ad Hoc

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[16] Another notable problem is that the international community did not set aside resources to analyze the data. Marie Chevrier, "Doubts About Confidence: The Potential and Limits of Confidence-Building Measures for the Biological Weapons Convention," in *Biological Weapons Proliferation: Reasons for Concern, Courses of Action* (Washington, DC: Henry L. Stimson Center, January 1998), 5–6.

[17] Lundin, "Introduction," in *Views on Possible Verification Measures for the Biological Weapons Convention*, 9; US Congress, Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks* (Washington, DC: Government Printing Office, August 1993), 14–5, 63–6; Testimony of James Woolsey, US Congress, Senate Committee on Governmental Affairs, *Proliferation Threats of the 1990's*, 103d Cong., 1st sess., S. Hrg. 103–208 (Washington, DC: Government Printing Office, 24 February 1993), 8–18; Office of the Secretary of Defense, *Proliferation: Threat and Response* (Washington, DC: Government Printing Office, November 1997).

[18] UN Security Council, "Note by the Secretary-General," Document S/1997/774, 6 October 1997. See also, R. Jeffrey Smith, "Iraq's Drive for a Biological Arsenal: US Pursuing 25 Germ Warheads It Believes Are Still Loaded With Deadly Toxin," *Washington Post*, 21 November 1997. UN inspections in Iraq were aborted in 1998, when Iraq insisted that the Special Commission leave the country. Barbara Crossette, "Iraqis Break Off All Cooperation with Inspectors," *New York Times*, 6 August 1998. In December 1999, a new inspection agency called UNMOVIC—the United Nations Monitoring, Verification and Inspection Commission—was created. "Security Council Establishes New Monitoring Commission for Iraq," UN Press Release SC/6775, 17 December 1999. However, as of this printing UNMOVIC inspectors had yet to set foot in Iraq.

[19] Lundin, "Introduction," in *Views on Possible Verification Measures for the Biological Weapons Convention*, 7. For a more comprehensive look at attempts to use biological agents for terrorist purposes, see Jonathan B. Tucker, "Historical Trends Related to Bioterrorism: An Empirical Analysis," *Emerging Infectious Diseases* 5, no. 4 (July/August 1999): 498–504; W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents in the 20th Century*, Working Paper, Center for Counterproliferation Research (Washington, DC: National Defense University, July 1999).

[20] Many press reports have erroneously credited the cult with the successful dissemination of anthrax and botulinum toxin. Aum's attempts to develop a biological weapons program were extensive, but ultimately unsuccessful. See Amy E. Smithson and Leslie-Anne Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the US Response* (Washington, DC: Henry L. Stimson Center, October 2000), 72–111.

Group of Verification Experts, known as VEREX, examined and evaluated twenty-one measures that ranged from off-site surveillance of publications to on-site monitoring and inspections. VEREX evaluated each proposed verification measure according to the amount of data it could or could not provide; its ability to differentiate between activities that are prohibited and permitted under the BWC; its capability to clarify ambiguities concerning compliance; its requirements for manpower, technology, equipment, or other material; its implications for the protection of confidential business information and for the development of permitted research and scientific activities; and its financial, legal, organizational, and safety ramifications.[21] In all, VEREX met four times from March 1992 to September 1993. In its final report, VEREX concluded that no single approach could adequately monitor the BWC. Rather, VEREX recommended a combination of means—including off-site and on-site measures—to make the BWC a more effective instrument. Off-site measures included national declarations of biological weapons defense programs, vaccines, and facilities handling specific organisms and toxins; on-site measures included short-notice inspections and information visits to declared facilities.[22]

In April 1992, Russian President Boris Yeltsin conceded that the Soviet Union had violated the BWC and issued a decree outlawing the continuation of the biological weapons program.[23] Acknowledging international concern, Moscow decided to work with the BWC's two other co-depositary nations to try to establish some confidence that Russia was no longer operating an offensive program. A trilateral process, formally initiated in September 1992, involved visits to military and non-military facilities of possible compliance concern.[24] US and British officials visited several Russian facilities and vice versa, but the trilateral process gradually lost momentum and did not completely alleviate remaining compliance concerns about Russia's biological facilities.[25] Although collaborative research grant programs have brought numerous scientists and other visitors to many of the institutes involved in the

[21] US Arms Control and Disarmament Agency, "Fact Sheet: The Biological Weapons Convention," Office of Public Affairs (Washington, DC: 18 August 1993): 1–2.

[22] United Nations, *Special Conference of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Final Report*, Document BWC/SPCONF/1, 19–30 September 1994, 14–5.

[23] R. Jeffrey Smith, "Yeltsin Blames '79 Anthrax on Germ Warfare Efforts," *Washington Post*, 16 June 1992; J. Dahlburg, "Russia Admits It Violated Pact on Biological Warfare," *Los Angeles Times*, 15 September 1992; "Decree of the Russian Federation on Fulfilling International Obligations with Regard to Biological Weapons," Moscow, 11 April 1992.

[24] Among other steps taken to end the offensive program, Russia stated that it had cut personnel in the program by fifty percent and reduced research funding by 30 percent. US Department of State, "Joint US/UK/Russian Statement on Biological Weapons," Press Release, Office of Public Affairs (Washington, DC: 14 September 1992). See also, "Proprietary Agreement: Procedures for Respecting Proprietary Information During Visits to Non-Military Biological Sites Pursuant to Paragraph 4(A) of the Joint US/UK/Russian Statement on Biological Weapons," Moscow, 12 May 1993.

[25] R. Jeffrey Smith, "US Wary of Russian Germ Arms; Despite Assurances from Yeltsin, Effort May Be Continuing," *Washington Post*, 8 April 1994; R. Jeffrey Smith, "US to Press Moscow on Alleged Arms Violations," *Washington Post*, 9 May 1994; US Arms Control and Disarmament Agency, *Threat Control Through Arms Control: 1994 Report to Congress,* (Washington, DC: US Arms Control and Disarmament Agency, 13 July 1995): 70; US Department of Defense, *Proliferation: Threat and Response*, 46.

former Soviet biowarfare program, no outsiders have ever been to the four military facilities at the core of this program.[26]

In September 1994, a Special Conference of BWC members convened in Geneva to discuss the findings of VEREX. This Special Conference called for the formation of the Ad Hoc Group to draft verification measures to be incorporated into a legally binding protocol to the BWC. The Ad Hoc Group was also to address the creation of measures to investigate the alleged use of biological weapons, as well as the following issues:

- the definition of terms and objective criteria (e.g., lists of biological warfare agents and possible threshold quantities);
- the possible incorporation of existing and additional enhanced CBMs into the verification regime;
- the development of a system of measures to promote compliance with the BWC; and,
- the delineation of a program for technical cooperation in the field of biotechnology for peaceful purposes.[27]

The Ad Hoc Group, which is open to all states parties to the BWC, began negotiations in 1995. Twenty-two rounds of negotiations were held through March 2001, with well over sixty member countries participating and additional countries observing. Upon completion, the Ad Hoc Group is to present its draft text to a Special Conference of the BWC's members and then to the UN General Assembly for approval. Once a completed monitoring protocol is endorsed by these two bodies, it must then be ratified by all of the BWC's members, taking effect for each participating state as it completes the ratification process.

Late in 1996, the Fourth Review Conference was held. An Iranian proposal to amend Article I by adding a prohibition against the use of biological weapons did not receive widespread support. Instead, seeking to reinforce the broad scope of the BWC's Article I prohibitions, the Final Declaration emphasized that those prohibitions apply to the emerging fields of molecular biology and genome studies. The Final Declaration called for the enactment of national penal legislation to criminalize individuals engaged in biological weapons activities.[28] Although the Final Declaration stated the importance of

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[26] The four military sites are Sergiyev Posad, Kirov, Yekaterinburg, and Strizhi. For more on the collaborative research grant programs that are helping to transform the weapons institutes to peaceful, commercial research centers, see Amy E. Smithson, *Toxic Archipelago: Preventing Proliferation from the Former Soviet Chemical and Biological Weapons Complexes* (Washington, DC: Henry L. Stimson Center, December 1999).

[27] United Nations, *Special Conference of the States*, Document BWC/SPCONF/1, 10.

[28] From the outset, the Harvard-Sussex project has advocated this laudable concept. For more details, see Matthew Meselson, "Averting the Hostile Exploitation of Biotechnology," *CBW Conventions Bulletin* 48 (June 2000): 16–19; "Draft Convention on the Prevention and Punishment of the Crime of Developing, Producing, Acquiring, Stockpiling, Retaining, Transferring or Using Biological or Chemical Weapons," *CBW Conventions Bulletin* 42 (December 1998): 2–5.

adherence to the BWC's provisions, it made no specific reference to the Soviet/Russian and Iraqi biological weapons programs, the existence of which by that time was well-known.[29] This omission, indicative of the political sensitivity of directly naming BWC violators, was perhaps a harbinger of how challenging it would be to conclude a verification protocol. Despite the difficult nature of this task, however, the Final Declaration mandated that the Ad Hoc Group "intensify its work with a view to completing it as soon as possible before the commencement of the Fifth Review Conference."[30]

Since the onset of negotiations, the Ad Hoc Group has made incremental progress. In the July 1997 negotiating session, the series of papers that had been produced in previous meetings was presented as a rolling text. This 246-page document consisted of twenty-three articles, seven annexes, and five appendices.[31] Virtually every line of this initial draft protocol was bracketed, indicating a lack of agreement on the proposed measure or language.

Over the intervening years of quarterly group meetings, however, the negotiators have found some compromise language. Activities began shifting in 1998 as the negotiators began submitting fewer working papers and focusing more keenly on working with the wording already in the rolling text. The amount of bracketed language decreased by mid-2000,[32] but the remaining brackets were in intensely disputed sections of the draft protocol.

Notably, opinions are most divergent about some of the Ad Hoc Group's main taskings—definition of terms and objective criteria; incorporation of enhanced CBMs into a regime; measures to promote compliance with the BWC; and a program for cooperation in biotechnology for peaceful purposes. For example, brackets in the August 2000 rolling text showed some declaration thresholds that were powers of ten apart from one another.[33] In March 2001, Ad Hoc Group Chairman Tibor Toth placed

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[29] For more, see Malcolm R. Dando and Graham S. Pearson, "The Fourth Review Conference of the Biological and Toxin Weapons Convention: Issues, Outcomes, and Unfinished Business," *Politics and the Life Sciences* 16, no. 1 (March 1997): 105–26.

[30] United Nations, *Fourth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction: Final Declaration*, Document BWC/CONF.IV/9, 25 November–6 December 1996.

[31] United Nations, *Procedural Report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, Document BWC/AD Hoc Group/38, 6 October 1997.

[32] Graham S. Pearson, "Progress in Geneva: Strengthening the Biological and Toxin Weapons Convention," *CBW Conventions Bulletin* 51 (June 2000): 33–8.

[33] For facilities working with listed agents and toxins that exceeded specific thresholds in the previous year, the range of production capacities that would trigger declarations included:

(i) Any fermenter(s)/bioreactor(s) with a total internal volume of **[10] [25] [50] [100]** litres or more; or

(ii) Continuous or perfusion fermenters/bioreactors with a flow rate capable of exceeding [2] litres an hour; or

(iii) A chemical reaction vessel or equipment used for recovery with a total internal volume of **[10] [50] [100]** litres or more; or

compromise language on the table with what is known as the chairman's text. The tabling of such a text usually signals the onset of a negotiating endgame.[34]

With the Fifth Review Conference slated for 19 November through 7 December 2001, the Ad Hoc Group has relatively little time to conclude its work. Not long before tabling his composite text, however, Ambassador Toth did not appear all that certain that a protocol could be completed by the fall of 2001: "The question is whether we can make it, or not. It's a tough agenda and there are big differences there to be cracked."[35] If indeed the Ad Hoc Group does complete a text by November 2001, it will have done so in far less time than was required to draft the Chemical Weapons Convention, which was the product of negotiations stretching over twenty-four years.

(iv) More than **[1,000] [2,000]** embryonated eggs on an annual basis; or

(v) More than **[100] [1,000] [2,500]** litres of tissue culture or other medium on an annual basis. [Emphasis added.]

United Nations, *Procedural Report and Rolling Text of the Ad Hoc Group*, BWC/Ad Hoc Group/52, 11 August 2000, Article III (D)(1)(h).

[34] A chairman's text for the Chemical Weapons Convention was tabled in March 1992, setting off a furious pace of negotiations over the summer and conclusion of the text by August 1992.

[35] John Zarocostas, "Gaps Remain in Weapons Ban Talks," *United Press International*, 23 February 2001.

Chapter 3
By the Book: Academic and Research Institute Perspectives on BWC Monitoring

The academic and research institute experts who accepted the Stimson Center's invitation to brainstorm the technical feasibility of monitoring the Biological and Toxin Weapons Convention (BWC) covered a wide spectrum of expertise and brought ample years of experience to the table. Among the participants were Dr. Robert Shope, an infectious disease epidemiologist of world renown, Dr. Barry Kreiswirth, the director of the Public Health Research Institute's tuberculosis research laboratories, Dr. Corrie Brown, a veterinary pathologist specializing in the diagnosis and pathogenesis of foreign animal diseases, and Dr. Anne Vidaver, a plant pathologist who alone has more than thirty years of teaching experience. This group's credentials included degrees in microbiology, zoology, bacterial genetics, virology, and veterinary medicine, as well as extensive experience in high containment laboratories handling dangerous pathogens. As the full resumes in the appendix attest, the attendees hold several patents and have authored literally hundreds of peer reviewed journal articles. Two of the ten participants in this group opted to remain anonymous.

Stimson facilitators walked this group of technical experts through a progressive mental exercise that required them to consider a broad list of monitoring issues, thinking alternately as BWC inspectors and as hosts of BWC inspections. Box 1.1 shows the type of questions that Stimson facilitators posed iteratively to the brainstormers. The group's concerns, work-arounds, and overall reflections are the basis of this chapter.

The academic and research institute experts were no strangers to the concepts and realities of inspections. Activities at their facilities are overseen by an assortment of internal and external entities, any one of which could put the brakes on their work. Within their organizations, internal research, animal care, fire safety, and biosafety committees review projects. At various times, outside regulatory entities such as the Food and Drug Administration, the Occupational Health and Safety Administration, state and federal environmental protection agencies, fire inspectors, the US Department of Agriculture, and the Nuclear Regulatory Commission troop through their laboratories and wade through their records.[1] If an

[1] Chemical surety inspectors also oversee some sites, noted one individual from the veterans group, who said that the Food and Drug Administration was at his facility for thirty days in 1999. Inspection Veteran 3, trial inspection observer and mock inspection participant, 27 April 2001. Inspection Veteran 3, who holds a DVM and a PhD, observed the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and participated in the mock trilateral inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. If a laboratory is affiliated with a hospital, the Joint Commission on Accreditation of Healthcare Organizations would also have an oversight role. These inspections can be quite harrowing for the recipients. One academic participant cited a case where supplementary records were not readily available when Nuclear Regulatory Commission inspectors came through a facility. The inspectors began to press site personnel very hard. "They asked and asked and asked and made the staff feel horrible." The laboratory in question was almost fined $5,000 for momentarily leaving a freezer containing radioactive material unlocked. Dr. Nancy Connell recounted the Nuclear Regulatory Commission inspection. Dr. Nancy Connell, PhD in bacterial genetics, works in the Department of Microbiology and Molecular Genetics at the New Jersey Medical School, where she also serves as the director of molecular mycobacteriology at the National Tuberculosis Center. Note that commercial organizations that sponsor research also have an oversight role. On other oversight

accident occurs in a research laboratory, the Centers for Disease Control and Prevention enters the picture to investigate the problem, which one participant described as "your worst nightmare. They will stay until they are done. They are asked to come in because there is an outbreak problem. . . . They are trying to figure out what happened as opposed to did it happen or not. They have almost full carte blanche."[2]

While the presence of inspectors site can be unnerving and inconvenient, members of this group explained that inspections can also prompt beneficial changes in the way a laboratory is run (e.g., safety, operational practices).[3] Having inspectors in their midst can, in other words, be a positive learning experience. Such was the case for the two brainstormers who hosted an inspection that the Stimson Center mounted to test this group's monitoring concepts, an exercise described at length in box 3.1 at the end of this chapter.

Encounters with inspectors aside, the participants had all spent considerable time in laboratories replete with the very equipment and skilled personnel that they believed would be of concern to an inspectorate charged with monitoring the BWC. Research laboratories are inherently fungible places. Scientists could be studying innocuous strains one moment, but in the next they could place a super virulent strain under the microscope. Given that reality, one participant simply stated that "an overarching aspect of this is that it is going to be very easy to hide" improper activity at research institutes.[4] Consequently, the group concluded that it would be extremely hard to uncover prohibited activity in research laboratories. The difficulty of the task did not dissuade their efforts, however, to pull

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and inspections: Dr. Corrie Brown, DVM and PhD in comparative pathology; Dr. Barry Kreiswirth, PhD in microbiology; Academic Expert 1, PhD in microbiology; and Academic Expert 2, MD, 6 January 2000 and 16 August 2000. Dr. Corrie Brown, DVM and PhD in comparative pathology, heads the Department of Veterinary Pathology at the University of Georgia College of Veterinary Medicine. Dr. Barry Kreiswirth, PhD in microbiology, is the director of the Tuberculosis Center at the Public Health Research Institute. Academic Expert 1 is a virologist with a PhD in microbiology currently working in a microbiology and immunology department at a large US university. Academic Expert 2, MD, is a pathology professor at a major US medical school and the director of a tissue typing laboratory.

[2] Dr. Barry Kreiswirth described the Centers for Disease Control and Prevention's approach to inspections. Next in the nightmare category might be the Internal Revenue Service, which one participant recalled roosting at a university for three years. Academic Expert 1, PhD in microbiology, 16 August 2000.

[3] Dr. Robert Shope noted on 16 August 2000 that inspectors from the Centers for Disease Control were very helpful when they came to a laboratory at Yale University, including their efforts to explain matters to the media. Dr. Robert Shope, MD and epidemiologist, is a professor of pathology in the Center for Tropical Diseases at the University of Texas Medical Branch at Galveston. In the 6 January 2000 meeting, Dr. Corrie Brown noted another possible upside to hosting inspections in that they would broaden the horizons of workers and therefore possibly increase their productivity.

[4] Dr. Robert Shope, MD and epidemiologist, 16 August 2000. Some in the group pondered the likelihood that a chain of research laboratories would communally engage in bioweapons development, with each laboratory specializing in different areas. They surmised that such an approach would be even harder for inspectors to detect. Theodore Myatt, doctoral candidate, former biosafety officer; Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000. Theodore Myatt was previously a biosafety officer and currently serves in the Division of Epidemiology and Immunization at the Massachusetts Department of Public Health. Editor's note: The former Soviet Union took exactly that approach, nesting weapons research activities in a web of research laboratories. For more on the history of this vast weapons program, see Ken Alibek with Stephen Handleman, *Biohazard* (New York: Random House, 1999). On efforts to transform these bioweapons research institutes into peaceful research centers: Amy E. Smithson, *Toxic Archipelago: Preventing Proliferation from the Former Soviet Chemical and Biological Weapons Complexes* (Washington, DC: Henry L. Stimson Center, December 1999).

together a monitoring approach that they believed would be fair to legitimate research institutes and instill the fear of discovery in those involved in weapons research.

Early in their discussions, the academic and research institute experts differentiated between two kinds of monitoring concerns. The first category encompassed matters that the inspectors would know about ahead of time due to some sort of declaration process or information gathered from other outside sources; the second, matters that the inspectors found once on site. The group came to consensus that the essential features that should qualify research laboratories automatically for BWC monitoring were the presence of: 1) bioweapons agents, and 2) biosafety level 3 or 4 capabilities. Any defensive research activities in these settings, they presumed, would be declared. Other capabilities with weaponization potential (e.g., aerosolization, milling, encapsulation), they observed, would elevate a facility up the inspectors' target list. Such capabilities should be declared but should not in and of themselves automatically draw an inspection because of their ubiquitous use for legitimate research purposes.[5] Based on these criteria alone, it was noted with a mixture of apprehension and irony, that most collegiate laboratories would not be subject to BWC monitoring. Some in the group worried that not casting the inspection net wider would make it easier for cheaters, but others said that catching a violator red-handed in the laboratory setting would be a tremendous feat. Violations, they reasoned, would be more readily detected at the other sites involved in a full-scale bioweapons program (e.g., manufacturing plants, large test facilities).[6]

Other tenets that the group adopted early and reconfirmed continually included the need for inspections at academic and research institutes to proceed from a presumption of legitimacy and for inspectors to evaluate the big picture at a facility as opposed to a single item or capability located there. Essentially, few, if any, of the matters that concerned them could alone clearly signal to inspectors that something unsavory was taking place at a given research site. Simply having a primate facility or fermentation and aerosolization capabilities could not be viewed as conclusive of involvement in offensive weapons work, since these very capacities are also essential to vindicable research.[7] Certainly, such features would constitute a "flag" of possible concern, but the inspectors would need to assess such features in combination and in context to determine whether a laboratory's work constituted a genuine

[5] "Labs working with these agents by definition are going to be under some suspicion, so I think that monitoring comes with the territory." Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000. Dr. Nancy Connell, PhD in bacterial genetics; Dr. Corrie Brown, DVM and PhD in comparative pathology; Dr. Robert Shope, MD and epidemiologist; and Academic Expert 1, PhD in microbiology, expressed similar views about the importance of agents as well as biosafety levels and key equipment, to which the group concurred.

[6] Dr. Barry Kreiswirth, PhD in microbiology; Dr. Robert Shope, MD and epidemiologist; Dr. Nancy Connell, PhD in bacterial genetics; and Academic Expert 1, PhD in microbiology, expressed such sentiments.

[7] For example, some may consider aerosolization capabilities indicative of possible offensive work, but it is not uncommon for university laboratories to have some aerosol capacity, for instance those working on plant diseases. Dr. Anne Vidaver, PhD in bacteriology, 6 January 2000. Dr. Anne Vidaver heads the Department of Plant Pathology at the University of Nebraska-Lincoln. Also on this point, Theodore Myatt, doctoral candidate, former biosafety officer.

BWC violation.[8] Thus, the group designed a "dig deeper and deeper" monitoring approach, but only if necessary given the presumption of legitimacy. They concocted a tri-level inspection scheme, with an inspection team getting increasingly intrusive if inspectors unearthed signs of possible foul play.

PRE-INSPECTION ACTIVITIES

Working from declarations, the academic and research institute experts believed that the inspectorate could perform several literature searches to help prepare inspectors for their work on site. This group advised pulling up the publication records and presentation activities of a laboratory's staff. Universities in most countries operate under a time-honored "publish-or-perish" rule, and there is considerable pressure at research institutes to air research results as well. One would expect laboratory personnel to leave a wake of scientific publications and presentations commensurate with their tenure in the field.[9] Therefore, scanning publications and conference presentations offers the inspectors a quick gauge of legitimacy. "They have all this money, all this equipment, all these people, and they haven't published in a decade. That's a tipoff."[10] These data searches would also give inspectors an idea of what organizations have been funding a laboratory's work and who has been interacting with its scientists.[11] Rarely are research institutes islands. Their work is very collaborative, so a facility with few or no outside ties would definitely be atypical. Finally, a review of newspaper and other media sources might reveal if there had been any unusual disease outbreaks among humans, livestock, or crops in the vicinity of the laboratory. News to that effect should certainly forewarn inspectors to be on their toes. While helpful for a quick assessment and for the assignment of suitably skilled individuals to the inspection

[8] As one participant put it, "There are various flags, but it takes several flags to turn them red." Academic Expert 1, PhD in microbiology, 6 January 2000. Another brainstormer labeled this approach "multiple variant analysis." Academic Expert 2, MD, 6 January 2000.

[9] The group noted that such data may be hard to come by in some countries, such as Iran and North Korea. However, scientific journals exist in virtually all of the world's languages, and professional conferences are routinely held on a national, regional, and international basis. Total lack of publications and presentations would therefore be most unusual. To the group's agreement, Dr. Jerry Goldstein voiced these observations about the importance of looking into the publication track record of facility scientists. Dr. Jerry Goldstein, PhD in microbiology, is a professor of microbiology and chairman of the Botany/Microbiology Department at Ohio Wesleyan University.

[10] Academic Expert 1, PhD in microbiology, 16 August 2000. Dr. Barry Kreiswirth also noted the utility of a literature search to reveal gaps in time where scientists did not publish, which would necessitate an explanation. Dr. Corrie Brown added that literature searches would be "especially important in those countries that only publish in-country" because their scientists are therefore unlikely to have much of a profile internationally. Some in the defense contractors group also agreed that it would be somewhat useful to examine resumes, papers published, membership in professional societies, attendance at professional meetings, and whatever data was available about a site's activities. Defense Contractor 3, senior technical adviser; Defense Contractor 5, director of microbiology and special government projects; Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000. Defense Contractor 3, employed at a large, nonprofit research organization, holds a PhD in physics. Defense Contractor 5, working at a small defense contracting research company, has a PhD in microbiology. Defense Contractor 7 has a PhD in microbiology.

[11] Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000.

team, these off-site data searches, the academic and research institute group decided, were of low utility in comparison to on-site monitoring activities.[12]

ON-SITE MONITORING ACTIVITIES: LEVEL 1 INSPECTION

Once on site, the inspectors must contend with the daunting task of trying to determine whether laboratories that have declared possession of biological agents of concern and/or have a biosafety level 3 or 4 capability are engaging in illicit offensive research and development activities. Should a laboratory have a scale of capabilities that could contribute to weaponization work (e.g., media, serum, concentrators, fermenters, milling and aerosolization equipment) and that surpassed the laboratory's needs, academic and research institute experts argued that the excess scale should quickly elicit concern on the part of the inspectors.[13] A facility also engaged in studies targeting increased virulence, resistance to therapeutics, stability, and human or animal toxic dosage should make the inspectors chafe even more.[14] With regard to biosafety matters, this group advised inspectors to be alerted by a physically isolated facility, one that employed unusual clean-up protocols or waste treatment procedures, one that had non-standard biosafety oversight arrangements, or one that experienced an inordinately high level of infectious illness among its staff.[15] Another oddity that should heighten inspectors' suspicions would be if the facility's staff were not open to inquiry. Personnel in universities and research institutes normally thrive on interaction with other scientists. To encounter individuals who were closed, who refused to reveal how many people worked in their laboratory, to explain their work, or to show their working environment would be an unlikely occurrence in the scientific research community. Aside from inappropriate reactions to questions and requests, the inspectors could be tipped off by personnel telling conflicting stories.

Inspectors, they instructed, should also look askance at a facility that had few or no records, or that had overly organized records. While universities and research institutes certainly adhere to regulations and scientific standards, the atmosphere in a research facility is not the same as in the

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[12] Theodore Myatt made a statement about the low monitoring utility of the data searches, which elicited nods of agreement from other participants. The need to send appropriately skilled inspectors is discussed subsequently. Since the inspectors would track down such data on their own, the institutes being monitored would not be inconvenienced at all. Dr. Nancy Connell, PhD in bacterial genetics, 16 August 2000.

[13] Dr. Jennie Hunter-Cevera, PhD in microbiology; Dr. Nancy Connell, PhD in bacterial genetics; Academic Expert 2, MD, 6 January 2000. Dr. Jennie Hunter-Cevera, PhD in microbiology, is president of the University of Maryland Biotechnology Institute.

[14] Dr. Corrie Brown, DVM and PhD in comparative pathology; Dr. Anne Vidaver, PhD in bacteriology; Academic Expert 2, MD, 6 January 2000.

[15] The group reasoned that a proliferator might want to take the extra precaution of isolating a bioweapons research facility, although that might not always be the case. Odd cleanup or waste treatment procedures might indicate that personnel were working with more dangerous microorganisms than the one(s) declared. A research institute that lacked a biosafety oversight committee or biosafety officer(s) would be quite uncommon, as would overkill in the biosafety department. Biosafety oversight should fit the stated research work. Finally, sick leave due to infectious illness would warrant investigation.

manufacturing sector, where every "i" must be dotted, every "t" crossed. In an academic setting, logbooks devoid of erasures or mistakes and other perfectly lined-up records could be a giveaway to cooked books. Summing up the group's views on this point, one participant stated: "Lab books are supposed to be messy."[16] That same too-good-to-be-true principle could apply to the appearance of the laboratory as a whole. Some of the brainstormers asserted that a laboratory that was too tidy, too organized, or otherwise presented as if "tied up in a bow" would stand out sorely from the normal university or research laboratory. However, an immaculate high-containment laboratory could also simply be a matter of good biosafety practices.[17]

As for other matters that this group thought might be worrisome, no sooner had one participant identified why something might warrant concern than did another give a reason why it should not. For instance, a large number of sub-types in a culture collection could be consistent with vaccine research or it might indicate that the laboratory was performing comparative research on disease strains, a step on the road to improving a disease strain for weapons purposes.[18] Whereas one school of thought held that large animal handling capabilities in a high-level containment infectious disease laboratory should raise hackles, particularly if primates were involved, another held that such capabilities could be found in most agricultural and veterinary colleges.[19] Similarly, the group batted back and forth whether the inspectors should fret about research on diseases not endemic to a region.[20] For some, military funding or affiliation with other entities conducting defense research would be troublesome, but eventually the group coalesced on the view that monies for offensive research could be channeled through any number of other government departments. The inspectors' evaluation of funding and affiliations, they decided, should be guided by whether a facility tried to hide its funders or stated the nature of their affiliations openly and subsequently explained and documented them.[21] Finally, the group was of the opinion that the inspectors

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[16] Academic Expert 1, PhD in microbiology, 16 August 2000.

[17] Dr. Jennie Hunter-Cevera verbalized this point, to the agreement of other participants. Also noting that a real laboratory would have a "lived-in" look: Defense Contractor 5, director of microbiology and special government projects, 28 August 2000. In the same academic session, Dr. Robert Shope argued the dissenting view that a tidy laboratory should not prompt automatic concern.

[18] Academic Expert 1, PhD in microbiology; Dr. Jennie Hunter-Cevera, PhD in microbiology, 6 January 2000.

[19] In addition to primates, the animals specified were dogs, pigs, sheep, and cattle. Dr. Corrie Brown, DVM and PhD in comparative pathology; Dr. Jennie Hunter-Cevera, PhD in microbiology; and Academic Expert 2, MD, primarily waged this debate.

[20] "Doing rinderpest work in the US would seem more questionable than if it were being done in Africa. The same with foot and mouth." Academic Expert 2, MD, 6 January 2000. Academic Expert 1 provided the counterpoint that "We do foot and mouth work here, yet we don't have a foot and mouth problem." Academic Expert 1, PhD in microbiology, 6 January 2000. Dr. Corrie Brown noted that the research into particular diseases is indeed relevant if their introduction would unleash economic havoc. For example, US research into foot and mouth is based on the reality that the appearance of this disease could lay waste to livestock and wreak economic havoc. Research into the properties, behavior, and treatments for human, plant, and animal diseases is done as a safety measure against natural transmission of the disease into the country, as well as to guard against possible deliberate use in hostilities.

[21] Academic Expert 1 debated this matter with several other participants, eventually leading to agreement that military funding in and of itself should not be a concern.

should take note if the laboratory were heavily populated with post-doctoral or graduate students from countries thought to harbor bioweapons programs.

On this litany of possibly ambiguous matters, some of which the inspectors would have little or no way of knowing beforehand, the group suggested that by employing a variety of investigative tools, the inspectors should be able to figure out whether a facility was part of an offensive weapons program. According to the group, the inspectors' first pass at the facility should include a facility tour, a review of select records, and interviews with certain staff members. Upon arrival, laboratory managers or key project leaders would be expected to acquaint the inspectors with the work being done there, as well as with the house safety rules. No particular time limit was specified for this introductory briefing because such overviews can provide a useful basis for the subsequent tour, review of records, and interviews. The academic and research institute group noted, however, that the inspectors should object if they thought the briefers were droning on to avoid giving the inspectors access. Also, the inspectors should ask about the laboratory's level of funding, sources of funding, and affiliations if such information is not volunteered during the briefing. In Box 3.2, the inspection veterans group culled its collective experience to guide facility managers through this first step of an inspection.

A guided tour of the premises should follow the briefing, with inspectors observing requisite safety precautions (e.g., wearing laboratory coats, booties, racal hoods).[22] Along the way, the inspectors should take careful notes on the general setup of the facility; the inventory of key supplies (e.g., media, personal protective equipment); the number and species of animals, if present; and the types and numbers of equipment (e.g., milling, aerosolizers, autoclaves).[23] They should also view key laboratory features, such as waste treatment and air handling systems. In small, cramped, or highly regulated areas, host officials should have the right to request that one or two inspectors be given access instead of the entire entourage. The site being inspected may also want to consider restricting the number of host government escorts that enter tight quarters, as Insights 3.1 explains. The appropriate vaccinations should be a pre-requisite for inspectors' entry into some high-level containment areas.[24] Ideally, the tour would be

[22] If house biosafety rules are not followed, laboratories working with dangerous pathogens would have to undergo weeks of decontamination and biosafety checks, essentially shutting the facility down prior to the inspections. Such an interruption would not only be burdensome, touring a sanitized laboratory would disadvantage inspectors, who could learn more from seeing the normal work setting. Academic Expert 1, PhD in microbiology, 16 August 2000. Also Dr. Nancy Connell, PhD in bacterial genetics; Dr. Barry Kreiswirth, PhD in microbiology; Dr. Corrie Brown, DVM and PhD in comparative pathology. Agreeing that inspectors must abide by all host facility safety rules: Defense Contractor 2, principal research scientist; Defense Contractor 5, director of microbiology and special government projects, 28 August 2000. Defense Contractor 2, a scientist at a medical research facility, is a veterinarian and a PhD microbiologist.

[23] A facility tour would include the relevant laboratories, all equipment therein, growth chambers, associated storage areas, animal holding pens, greenhouses, and administrative areas, as applicable depending on the type of site inspected. While this group specified that the inspectors take notes, they did not mention that the inspectors should use any other methods, such as photographs or videos, to record what they saw.

[24] Agreeing that inspectors would have to be vaccinated for the agents that the facilities declare, or, as a much less desirable alternative, sign a liability waiver for the host facility: Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company; Defense Contractor 7, president and founder of a small sensor development

Box 3.2: Cliffs Notes on the Opening Moves as the Host of an Inspection

The inspection veterans could not emphasize enough the need to prepare carefully for an inspection.[1] They sought to dispel the impression that there was "such a thing as a collegial visit" since the host site would be trying to protect its equities and government escorts might have agendas of their own.[2] Government bureaucrats and sometimes a company's own senior managers do not have an adequate understanding of the technical issues underpinning a site's operation and the inspection.[3] They counseled site managers to agree from the outset on their strategy to host an inspection, beginning with the contents of the introductory briefing.[4] Some inspection veterans said that from the host's viewpoint, the less said in the opening briefing, the better. Inspectors, however, should be expected to probe deeper after a perfunctory briefing. Also, taking the opposite tack and giving a briefing that reasonably reviews the activities known to be of interest to the inspectors could "de-fang" them.[5] The trick is to find common ground between hosts and inspectors who are somewhat at cross purposes. "Typically, one assumes that the task is to rattle off a list of facts about the facility—square footage, number of light bulbs, number of class 3 hoods. Really, however, the inspection team wants something very different from that or in addition to that. A least common denominator approach to the introductory briefing is almost destined to result in disappointment."[6] The straightest route to finding that common ground, according to one participant who spoke from the added experience of regulatory inspections, was to let the inspectors brief the host officials *first* on what they want so that facility managers can figure out how to address their agenda and requirements.[7] Moreover, facility managers should decide from the start what records, equipment, or areas of the site are proprietary so that an overeager, inexperienced, or nervous briefer does not inadvertently blurt out such information. Designating a chief spokesperson ahead of time who will call the shots for the host facility is crucial.[8]

NOTES

[1] During one BWC trial, "the team walked into the first lab and, despite months of preparation, there was a glaring declaratory malfeasance." When it came to interviews, "the inspection team picked a random person, and it was like hogs looking at wristwatches—absolutely no understanding of what the team was doing there." Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000. Inspection Veteran 9, who has an MD and a PhD, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. *(continued, next page)*

accomplished with as little disruption as possible to ongoing work.[25] Also, site personnel should accompany inspectors every step of the way.[26]

The inspectors should walk through with an eye toward whether containment precautions, equipment, and supplies are in line with the demands of the research described. "If they went into a laboratory that said it was working with a harmless bug and yet they had an inordinate number of

company; Defense Contractor 5, director of microbiology and special government projects, 28 August 2000. Defense Contractor 6 has over fifteen years of experience in molecular genetics.

[25] Academic Expert 1 argued that a tour would be disruptive, but Dr. Nancy Connell and Dr. Barry Kreiswirth stated that a walk-through would not be much of a bother. Everyone agreed that the inspectors should try to minimize their burden on the host facility while still accomplishing their mission.

[26] The group's stress on the perils of unescorted inspectors was expressed by Dr. Barry Kreiswirth, who said: "I don't think you'd want anyone just going around grabbing things willy nilly in your lab. You would want to be with the person and you would want to make sure *you* know what they are looking at and that *they* know what they're looking at."

Box 3.2: Cliffs Notes (continued)

[2] On this point, "Call it a confidence-building measure or whatever you want, but we had trouble with collegial visits with some of our allies." Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico.

[3] Inspection Veteran 2, trilateral and mock inspection participant, 27 April 2000. Inspection Veteran 2 participated in inspections under the 1992 trilateral agreement, took part in a series of round robin mock inspections at military facilities in the western United States, and engaged in background planning for the mock visit to the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[4] For some sites, just putting together the introductory briefing can be quite complex because the facility's direct management and headquarters personnel may differ on what can be said. Negotiating what can be said should not be left until the last minute because those talks can be quite time consuming. Inspection Veteran 2, trilateral and mock inspection participant; Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Some sites are accustomed to inspections (e.g., military and commercial facilities), but others may be unprepared for anything that goes beyond the superficial introductory briefing and tour one would give international visitors or high school students. Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000.

[5] Advocating a name-rank-and-serial-number philosophy for the opening briefing: Inspection Veteran 3, trial inspection observer and mock inspection participant; Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Pointing out that inspectors would "chew up" someone who took a perfunctory approach and that sometimes they come in with a certain piece of information to "nail" the site: Inspection Veteran 2, trilateral and mock inspection participant; Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Recalling an opening briefing that included a discussion of such sensitive data as particle sizes: Inspection Veteran 7, United Nations Inspection Commission inspector and mock inspection participant, 27 April 2000. Inspection Veteran 7, a PhD scientist, served on several United Nations Special Commission on Iraq missions, was on the host team during the mock inspection at Dugway Proving Ground, Utah, and took part in a follow-on round robin exercise. Editor's note: During one of the early trial inspections held at a US commercial chemical plant to explore the effectiveness and feasibility of Chemical Weapons Convention monitoring techniques, the introductory briefer showed a viewgraph that contained the single piece of information—a chemical formula—that the site's managers had determined must not be revealed.

[6] Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000.

[7] "Hardly a month goes by that I don't have some US organization inspecting my facility. . . . They come in with a target, so I usually have them give the opening presentation so they can say why they are there and what I can do to help them." Inspection Veteran 3, trial inspection observer and mock inspection participant, 27 April 2000. Inspection Veteran 3, who holds a DVM and a PhD, observed the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and participated in the mock trilateral inspection at the Edgewood Arsenal, Aberdeen Proving Ground. Agreeing that it is crucial to find out right away what is important to the inspectors: Inspection Veteran 8, trilateral and trial inspector, 27 April 2000.

[8] Inspection Veteran 3, trial inspection observer and mock inspection participant, 27 April 2000. Having just one spokesman or point of contact may be difficult unless that individual is intimately familiar with the entirety of a site's operations. Otherwise, detailed questions about certain programs will have to be referred to site experts who can answer them. Inspection Veteran 1, facility manager and US trial inspection host, 27 April 2000. Inspection Veteran 1, a facility manager, was a principal host of a US trial inspection held in late March 1996 at three facilities located in Albuquerque, New Mexico.

biosafety cabinets, the inspectors should be concerned."[27] Moreover, they should be alert to whether the laboratory is outfitted more richly than its visible funding level. Evaluating a facility's status, it was noted, would be even more complicated if the laboratory were not operating at its full biosafety level. Moreover, if excess equipment were sitting about, the inspectors should be wary of explanations that such equipment is no longer used, particularly if its condition does not indicate that to be the case.[28] In general, the inspectors should get a feel during the tour for whether they are in a working laboratory and what they see fits with the facility's declaration, other data gathered prior to the inspection, and the introductory briefing.

[27] Theodore Myatt, doctoral candidate, former biosafety officer, 16 August 2000.

[28] On housing lower level research in a high-level biosafety laboratory: Dr. Corrie Brown, DVM and PhD in comparative pathology, 6 January 2000. On the quick and dirty way to determine equipment use status: "We have old steel hoods that have crusty old lab tape over them. It's pretty obvious that we don't use them anymore." Theodore Myatt, doctoral candidate, former biosafety officer, 16 August 2000.

Insights 3.1

The issue here is not just the size of the inspection team, but the number of US government "minders" sent to accompany it. One defense contractor remembered that when his site received a Chemical Weapons Convention inspection, there were only four international inspectors, but the size of the group ballooned with at least eight additional US government escorts. Someone from the facility had to accompany each of the outsiders, which was quite a drain on personnel resources. The facility had difficulty accommodating a group of this size in some areas and in providing sufficient office space.[1]

NOTES

[1] The US government sent personnel from the Commerce Department, the Defense Security Service, the Federal Bureau of Investigation, and the Defense Threat Reduction Agency. Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000. The president of a company that provides consultant, technical, and materials evaluation support to government agencies and commercial clients, this individual received a PhD in chemical engineering but is also trained in physics and previously worked for almost a decade in the aerospace industry.

Next, the inspectors would undertake a first-level review of a site's records, requesting documents from the Institutional Animal Care and Use Committee, the institutional review board, and the biosafety committee.[29] These documents would provide a basis from which the inspectors can judge variance from what they have already heard and seen. Also, these records give the exact numbers for the items (e.g., animals and species, agents, recombinant deoxyribonucleic acid work) that are supposed to be in the laboratory. Biosafety documents compose a second important series of records that should correlate back to the baseline explanation of research activities. Here, the inspectors should examine the engineering control records for biosafety cabinets, autoclaves, high efficiency particulate air (HEPA) filters, and decontamination activities. They should also see biosafety protocols and records pertaining to personal protective equipment (e.g., suits, respirators) and administrative controls, such as those on personnel training and vaccinations.[30] Again, the inspectors' assignment is to consider whether these documents validate or refute the explanations provided about the facility's work. Other than the personnel costs to retrieve these documents, the academic and research institute experts did not describe this type of inspection activity as a burden to their facilities.[31]

Also in this first-level monitoring pass, the research institute and academic group experts recommended that inspectors interview biosafety officers and bench scientists, including graduate students. According to what the inspection veterans described in Insights 3.2, interviews can turn out to be a monitoring bonanza or a bust. The academic group perceived interviews with the biosafety officer(s) as being particularly useful since these individuals are outside of the laboratory and their outlook on its activities would be somewhat different. Biosafety officers would not only have a "big picture" perspective on the laboratory, they should certainly know what work was being done with dangerous

[29] In the 6 January 2000 meeting, Theodore Myatt noted that such oversight committees and documentation may not exist in other countries.

[30] Biosafety officers normally categorize things in terms of engineering, administration, and personal protective equipment. Ibid.

[31] Academic Expert 1 stated that these salary costs would accrue with personnel in other departments outside of this person's laboratory. Other participants noted personnel costs as well, but did not portray them as being heavy.

Insights 3.2

The inspection veterans group confirmed that interviewing scientists and technicians could be a goldmine, especially if done without supervision and in a social setting.[1] At a former Soviet biowarfare facility, said one inspection veteran, "I interviewed a junior person on video as he was explaining an aerosol capability, and we nailed him."[2] Thereafter, the Russians did not allow unsupervised interviews. If their bosses are present, technical staffers can find the experience petrifying.[3] Supervised interviews produced much less of monitoring value.

Inspectors should also be sensitive that to the likelihood that different strata of personnel—bosses versus technicians—could construe and possibly answer the same question differently. In some cases, the different answers result from varying perspectives and language barriers. In others, the variance could be much more meaningful, with one of the interviewees having revealed something they were not supposed to discuss. The inspectors' efforts to make this judgment call may be handicapped by poor interpretation and by disciplinary differences between the inspector and the interviewee. Such problems surfaced in Russia and Iraq, as well as during US BWC trial inspections.[4]

Despite the difficulties entailed in interviewing, one veteran inspector described interviews as "the only real place to mine for intent. Inspectors won't read or measure the smoking gun, but they can get at it through interviews. This is the eye of the tiger for success, it's where the vulnerabilities lie" because people do slip up in interviews.[5]

NOTES

[1] "The scientists wanted to blurt out everything they were doing." Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000. Inspection Veteran 9, who has an MD and a PhD, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. Inspection Veteran 1 made a virtually identical statement. Inspection Veteran 1, a facility manager, was a principal host of a US trial inspection held in late March 1996 at three facilities located in Albuquerque, New Mexico.

[2] Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico.

[3] For instance, when the Russians interviewed a US woman at an American biodefense facility, she started to cry. The situation was so stressful for another US staffer that the individual did not want to be interviewed at all. Inspection Veteran 2, trilateral and mock inspection participant, 27 April 2000. Inspection Veteran 2 participated in inspections under the 1992 trilateral agreement, took part in a series of round robin mock inspections at military facilities in the western United States, and engaged in background planning for the mock visit to the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. Also on this point, Inspection Veteran 8, trilateral and trial inspector, 27 April 2000.

[4] Inspection Veteran 9, participant in trial and one mock, 27 April 2000. Note that interpreters do not tend to be scientists, so they can inadvertently distort technical aspects of a conversation. An inspector who is a microbiologist would use terminology differently than an administrator trained in management.

[5] Inspection Veteran 8, trilateral and trial inspector, PhD microbiologist, 27 April 2000.

pathogens. Inspectors could query them about equipment, procedures, or other operational matters, probing for variance with what they had been told already.[32] What the biosafety officers have to say can also be checked against documentation and other interviews. By chatting with the scientists, inspectors who are experts in their own rights would know fairly quickly whether these individuals were really

[32] Note that the biosafety officers were seen as individuals who would really know what was going on in a laboratory but also as a possible source of both negative and positive information. In an academic setting, it would be unusual for the biosafety officer to be in cahoots with an individual principal investigator who was doing something wrong. Academic Expert 1, PhD in microbiology; Theodore Myatt, doctoral candidate, former biosafety officer; Dr. Barry Kreiswirth, PhD in microbiology; Dr. Robert Shope, MD and epidemiologist, 16 August 2000.

proficient at their work or might have been planted there, instructed to provide a cover story.[33] The main costs of interviewing to the host laboratory would include lost productivity and salaries for those being interviewed.[34]

When it came to costs to the host facility, group participants adamantly and unanimously stated their participation in BWC monitoring activities should not cost them anything. Cooperation with inspectors was one thing, lost productivity another entirely. The US government, they posited, should reimburse them for preparation costs (e.g., advance retrieval of supporting documents), salaries of employees called upon for interviews, recall of additional documents, escort functions, and any other costs associated with the inspection.[35] Indeed, as a defense contractor recounts in Insights 3.3, the tab for hosting an inspection can be high. If the cost issue was resolved, the academic and research institute group was quite amenable to occasional inspections, say on the order of every five years or so.[36] When the BWC inspectorate did want to send in a team, the academic and research institute scientists requested advance notice of up to two weeks and the leeway to negotiate when the inspectors would arrive to ensure that key personnel would be there to assist with the inspection.[37] Another guideline that would make the inspections more palatable is if they were held during normal business hours.[38] Finally, the commitment

[33] The group expected that the inspectors might find it easier to draw the scientists out in an informal setting, although how the inspectors should go about arranging such informal conversations over the course of a few days was left unspecified.

[34] Academic Expert 1, PhD in microbiology; Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000. Dr. Kreiswirth also had concerns that biosafety officers or scientists who had a gripe with one of their colleagues might provide the inspectors false information. "I guarantee that if there is one person there who's out to get you, they can make it really ugly," he stated. In addition, Dr. Kreiswirth worried about negative effects on the quality of the work environment and difficulty recruiting personnel if word got out that a facility's personnel were going to be routinely grilled about possible bioweapons research. Dr. Robert Shope cautioned against overplaying these and other concerns about interviews possibly creating dissension within the laboratory.

[35] The group heartily backed statements of Academic Expert 1 to this effect.

[36] Participants debated how frequently inspections should take place given the presumption of innocence and the need to deter ready use of supposedly legitimate research laboratories as fronts for offensive work. According to one view, sites should be selected randomly and an individual laboratory should not be inspected more frequently than every five years. Others held that given the need to check treaty compliance, the inspection rate ought to be not less than five years. Several agreed that the inspectorate would probably not employ enough inspectors to allow them to inspect laboratories so frequently, estimating that twenty-five years would pass between BWC inspections. Dr. Nancy Connell, PhD in bacterial genetics; Dr. Robert Shope, MD and epidemiologist; Dr. Barry Kreiswirth, PhD in microbiology; Academic Expert 1, PhD in microbiology, 16 August 2000.

[37] On this latter point, professional commitments are often made far in advance, and scientists slated to attend a conference elsewhere should not have to cancel their plans because of an incoming BWC inspection. A delay of one or a few days might allow everyone's schedules to be accommodated. Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000. Flexibility on the part of the inspectorate can be helpful, pointed out an expert from a defense contractor facility that had received a Chemical Weapons Convention (CWC) inspection, but it can also be frustrating when schedules slip. The date for their CWC inspection was apparently moved several times, which made it difficult to plan and execute regular laboratory activities. Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000. Defense Contractor 4 has a PhD in chemical engineering. On the need for advance notice: Academic Expert 1, PhD in microbiology; and Dr. Nancy Connell, PhD in bacterial genetics, 16 August 2000. The main reason given for wanting a week or more advance notice was the need to have other departments within the institution pull personnel, occupational health, and other supporting documents.

[38] This point of view was represented by Academic Expert 1, who said: "My concern is that I have people sitting around till 8 or 9 o'clock at night waiting to be interviewed. Although it could be advantageous to the host to just get it over with."

to accept BWC inspections would be much easier to make if the inspectors were obliged to go about their business quietly, with no blaring signs of their presence and no public announcements. A low-profile approach to the inspections would counteract the potential for the mere fact that this type of inspection was taking place to be misconstrued and equated to a facility's involvement in bioweapons research, which would deal a serious blow to a lawful laboratory.[39]

Insights 3.3

One commercial facility engaged in contract defense research that was inspected under the CWC estimated its costs at $100,000, including the time the inspectors were on site and the preparation requirements. Senior personnel devoted a considerable amount of time to preparing for the inspectors in the four days prior to their arrival, which meant that for all intents and purposes, laboratory operations were hampered, at times shut down, during this preparatory phase as well during the inspection itself.[1]

NOTES

[1] Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000. The president of a company that provides consultant, technical, and materials evaluation support to government agencies and commercial clients, this individual received a PhD in chemical engineering but is also trained in physics and previously worked for almost a decade in the aerospace industry.

The academic and research institute experts expected this first level of monitoring activity to be quite effective in identifying inconsistencies with a site's declaration, other background information, and what the inspectors saw, heard, or read once on site. They defined effectiveness as "being capable of distinguishing between legitimate and illegitimate activity as defined in the BWC."[40] As shown in table 3.1, the group quickly and universally rated a facility tour as having a high level of monitoring effectiveness, particularly given the ability to play off what was observed against paperwork and interviews. On the utility of reviewing project and biosafety documents, some in the group thought this activity would be highly effective, others were at the opposite end of the spectrum. Therefore, the group settled on a moderate rank for document reviews, but returned to rate what inspectors could determine from interviewing biosafety officers and bench scientists as high.[41]

[39] Academic Expert 1 was particularly worried about the "collateral" damage (e.g., student pickets, waning university support or outright cancellation of legitimate research programs underway) that could result from faulty media coverage of an inspection. Several other brainstormers agreed that a low profile would be helpful. However, others noted that the inspections would be conducted at many laboratories, just like other types of inspections, and that in time there would be few, if any, negative connotations to being on the BWC inspection list. Dr. Barry Kreiswirth, PhD in microbiology; Dr. Robert Shope, MD and epidemiologist, 16 August 2000. One participant in the defense contractor group was also terribly worried about adverse publicity. "Just the association . . . . We cannot tolerate that type of notoriety." Defense Contractor 3, senior technical adviser, 28 August 2000. Another remarked that the cat was already out of the bag, so to speak, due to the inspections they underwent to gain their licenses to work with these agents. Because their community was already aware that they "use these agents, I don't perceive that as a problem." Defense Contractor 2, principal research scientist, 28 August 2000.

[40] The group mulled over stipulating how to factor in size of capacities and ultimately decided that size was intrinsic to legitimate or illegitimate. Dr. Barry Kreiswirth, Dr. Robert Shope, and Academic Expert 1 also gave examples of how these monitoring techniques would not be effective against an individual terrorist. The goal was to detect fairly large-scale cheating, and the group believed the three-level approach could function effectively in that regard.

[41] Since the Institutional Animal Care and Use Committee and the institutional review board are outside of the laboratory itself, they offer some assurance that activities therein are being watched by other organizations. Put differently, were the laboratory involved in offensive research activities, it would indicate a more widespread conspiracy within the institution as a

Table 3.1: Anticipated Effectiveness of Level 1 Inspection Activities

Type of Inspection Activity	Expected Level of Effectiveness
Facility Tour	High
Review of Project Paperwork	Moderate
Review of Biosafety Documentation	Moderate
Interviews	High

The group decided three days, perhaps less depending on the size of the laboratory, would be needed to conduct a level 1 inspection.[42] At the conclusion of these initial monitoring activities, if the inspectors have found nothing suspicious or otherwise have no reason to believe that the laboratory is engaged in clandestine offensive bioweapons research, the academic group recommended that the inspection be curtailed, with legitimacy presumed. This approach would not impose an unreasonable burden on peaceful research facilities. Also, given the wafer-thinness of the dual-use line in the laboratory setting, this approach would go a long way toward calming the misgivings that legitimate research facilities have about false accusations resulting from a BWC inspection.[43]

ON-SITE MONITORING ACTIVITIES: LEVEL 2 INSPECTION

If, on the other hand, inspectors have heard conflicting stories, have seen records that do not match up, or otherwise have reason to believe that something is wrong, the inspection should proceed to a second level wherein mostly the same tools would be plied, but in a more intensive fashion. The objective of second-level monitoring would be to confirm or dispel suspicions raised earlier. Accomplishing this task would require an inspection of longer duration. Although the academic and research institute specialists did not agree on a time limit for this phase of the inspection, they obviously did not want the inspectors to camp out indefinitely in their midst. The situation would be serious enough that they believed the inspectors should nonetheless be allowed several additional days to conclude their work. [44]

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whole. The detail inherent in biosafety documents would offer reassurance that the facility was operating as stated or perhaps subtle signs that operations were not as portrayed.

[42] A one to three day time range was discussed, with Dr. Jerry Goldstein in particular expressing strong views that one day would not be sufficient time to tour, interview, and review paperwork. The job might be accomplished in two days in a smaller laboratory, and three days should be enough time for a large laboratory. Dr. Nancy Connell, PhD in bacterial genetics; Dr. Robert Shope, MD and epidemiologist, 16 August 2000.

[43] "That's actually really good, because that helps my feeling of being able to come out of one of these things with my skin on me." Academic Expert 1, PhD in microbiology, 16 August 2000. Dr. Barry Kreiswirth expressed similar thoughts.

[44] Academic Expert 1's comments about not wanting a "camp out" but still wanting to give the inspectors leeway to do their jobs was characteristic of the group's views on the time allotted for a phase two inspection. Some experts mentioned three days to a week of additional time on site as being reasonable, but others wanted to leave the timeframe open-ended.

The academic and research institute brainstormers recommended opening the second phase of an inspection with a monitoring tool commensurate with the gravity of having determined that a second level was necessary: sampling. Analysis of samples can cut straight through cover stories by identifying microorganisms. Because of its ability to provide definitive information about a facility's activities, some in the group advocated sampling in the first level of inspection. Weighing both the intrusiveness and cost of this tool against the presumption of innocence, however, the brainstormers ultimately decided that the appropriate placement of sampling and analysis was at the beginning of the second level of inspection.[45] After taking samples, the inspectors would go through another, deeper round of document reviews and interviews, which might prove sufficient.[46] The following paragraphs describe the group's rationale for this monitoring strategy as well as the qualms they would have if it were implemented in their laboratories.

Sampling, the academic and research institute group decided, was not a tool to be used sparingly or with hesitation. If a second phase of inspection has been triggered, a laboratory is out to clear its name and the inspectors would be hot on the trail of a possible cheater. Thus, at the outset of the second phase the inspectors should head straight toward the laboratory's HEPA filters. Historical data about what has occurred in a laboratory would most likely be distilled from HEPA filters in biosafety cabinets, racal hoods, and animal facilities, making these filters especially important sampling targets. The inspectors should also collect samples from freezer filters, gloves, drains, sewage, and animal feces. In addition, air and background environmental samples should be secured. These baseline samples are important because something could come out of the HEPA that does not reflect the work being done in the laboratory.[47]

The crux of sampling is to take a sample that would capture historical data, and the group acknowledged several of their recommended sampling locations would provide data only about activities that took place just before the inspection. They also conceded that a laboratory could rig or discard

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[45] Outside maintenance personnel might have to be called in to assist with taking some of the desired samples (e.g., HEPA filters). Theodore Myatt, doctoral candidate, former biosafety officer; Academic Expert 1, PhD in microbiology; Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000.

[46] During a CWC inspection of a commercial site conducting defense contract research, the inspectors did request samples, but did not push for them since the facility's records were clear and comprehensive. Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000.

[47] Academic Expert 1 brought up this last point, to widespread agreement among the group. Recommendations for sampling locations came from Dr. Robert Shope, MD and epidemiologist; Dr. Corrie Brown, DVM and PhD in comparative pathology; Theodore Myatt, doctoral candidate, former biosafety officer; Dr. Barry Kreiswirth, PhD in microbiology; Dr. Jennie Hunter-Cevera, PhD in microbiology; Dr. Nancy Connell, PhD in bacterial genetics; Academic Expert 1, PhD in microbiology, 6 January and 16 August 2000. As one of the participants in the inspection veterans group noted, "Absent characterization of collections taken from all over the world, it's hard to know what the sampling data from an individual inspection shows. Think of sampling in the BWC context as discovering fingerprinting, but not having the FBI's fingerprint database. Sure, we can fingerprint, but what does it mean? We could become less wise as a result of having more data." Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000. Inspection Veteran 9, who has an MD and a PhD, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

evidence from some of these sample areas.[48] While sampling from less obvious locations (e.g., air conditioning compressor fans, compressor radiators on freezers) might trip up a less adept cheater, the group favored establishing a guideline prohibiting laboratories from changing their HEPA filters upon receiving notice of an inspection. Filter change-outs would therefore be accomplished under the watchful eye of inspectors, with samples taken from the area(s) of the filter(s) most likely to provide the desired historical data.[49] The group debated the wisdom of getting on with sample analysis versus holding the samples to see if other inspection activities resolved suspicions. In the end, they sided with the former option. "If a sample is taken, it should always be analyzed. It seems to me, why take it if you aren't going to analyze it?"[50]

Sampling from some locations would not be that complicated of an exercise, but the group stated that taking HEPA samples would be an unprecedented act for most university or research laboratories. Therefore, they recommended that this aspect of the protocol be grounded in rigorous studies to pin down sampling and analysis strategies and techniques that would furnish optimum results. Among the factors to be clarified, for example, are the utility of sampling from the intake side versus other areas of the filter, the ideal size of the filter samples, and how many and which biosafety cabinets should be sampled in a multi-cabinet laboratory to gain confidence that the results accurately represent the laboratory's activities.[51] While the academic and research institute brainstormers identified several analytical techniques that could be employed (e.g., biochemical and biophysical assays, nucleic acid-based and immunologically-based assays, and classic clinical laboratory identification), studies should also rank the various techniques according to their ability to culture, separate, and identify background data from more unique data points on the filter.[52] The group's strong view that the accuracy of the results would be

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[48] Dr. Robert Shope, MD and epidemiologist; Theodore Myatt, doctoral candidate, former biosafety officer; and Academic Expert 1, PhD in microbiology, sustained this part of the discussion.

[49] Academic Expert 1 first expressed this concept, which the group later refined, when he said: "What you do is call three weeks ahead of time and say 'do not change out your HEPA filter. We will change it for you.'" On the advisability of having facility or regular contract maintenance personnel—who are very familiar with the site's safety protocols—pull the filter while the inspectors watch: Theodore Myatt, doctoral candidate, former biosafety officer; Dr. Barry Kreiswirth, PhD in microbiology; Dr. Robert Shope, MD and epidemiologist, 16 August 2000.

[50] Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000. The group agreed with this sentiment, and one participant—Academic Expert 1—commented that he would even be annoyed if samples were taken but not analyzed.

[51] Theodore Myatt, doctoral candidate, former biosafety officer, thought there would be so many problems with sampling that it would never be employed. Others voted for studies to resolve those problems. The tradeoffs between analytical results and safety factors such as whether decontamination of the HEPA filter precedes sampling should also be studied. In addition, the appropriate procedures to prevent contamination or compromise of the samples should be identified. Dr. Robert Shope, MD and epidemiologist; Academic Expert 1, PhD in microbiology; Dr. Barry Kreiswirth, PhD in microbiology; and Dr. Nancy Connell, PhD in bacterial genetics, discussed these points. On size of samples: Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000. Mr. Myatt, Dr. Connell, Dr. Shope, and Dr. Kreiswirth debated whether inspectors should by default sample all filters, only those that can be more easily accessed (e.g., racal filters) as opposed to other filter locations, or leave this matter to the judgment call of the inspectors. On the best sample location(s) on the filter surface: Academic Expert 1, PhD in microbiology, 16 August 2000.

[52] Such studies would define, for instance, the number and type of culture tests to be used to detect various microorganisms, as well as the polymerase chain reaction or other types of assays to be employed. Note that any declaration of

"absolutely critical" and that these activities were also costly underscored the need for sampling and analysis to be undertaken with deliberation.[53] The academic and research institute experts were willing to have the inspectors oversee analysis conducted on site or to send the samples to outside laboratories, as long as they were certified and appropriate precautions were taken to protect the integrity of the samples. What was most important was that the process yield accurate results.[54]

A second principal way to sort out uncertainties would be for inspectors to return to the paper chase. They should investigate their suspicions via project log books; computer records; additional project paperwork; purchasing, supply, and shipping records; and animal and plant pathology records. Logs in the laboratory would provide historical data on air pressure readings, temperatures, and use of key pieces of equipment (e.g., freeze driers). Extensive use of the autoclave(s) just prior to the inspection, for example, would be noteworthy. Facility personnel are normally required to initial their notations in these logs, which would enable inspectors to trace the working patterns of different individuals and identify personnel for further interviews. Computer records of laboratory activities are also kept, and while they can be edited, someone with computer expertise could track down the timing and pattern of such edits to determine whether a cover-up had been attempted. These log books and computer records can help straighten out or confirm inconsistencies and are usually at the fingertips of laboratory personnel.[55]

Additional project paperwork that the inspectors should seek would include project proposals, contracts, and reports—all of which should corroborate a site's described activities. This category of documents should also help answer questions about a laboratory's funding sources.[56] The complications in accessing these materials stem from confidentiality. Some data therein might be controlled by a laboratory's contractual arrangements with outside sponsors (e.g., commercial firms, government agencies). The defense contracting group shared this problem, as Insights 3.4 conveys. In addition, the

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infectious agents present in the laboratory would serve as a control for the analysis. The prospect of engineering around publicly announced analytical techniques was broached, which led to a suggestion that the inspectorate could rely on random primers and therefore make it more difficult for a laboratory to foil sampling and analysis. Dr. Barry Kreiswirth, PhD in microbiology; Academic Expert 1, PhD in microbiology; Dr. Jennie Hunter-Cevera, PhD in microbiology; Dr. Robert Shope, MD and epidemiologist, 16 August 2000.

[53] The group agreed with Academic Expert 1's statement that the analysis results must be accurate. Dr. Barry Kreiswirth stated that an emergency filter change in his laboratory would cost $1,800, but others estimated their costs at closer to $500.

[54] If an outside laboratory were employed, the group agreed that the results should be verified at a second certified laboratory. Academic Expert 1, PhD in microbiology; Dr. Barry Kreiswirth, PhD in microbiology; Dr. Nancy Connell, PhD in bacterial genetics; and Theodore Myatt, doctoral candidate, former biosafety officer, were the mainstays of this discussion.

[55] "It's right there in the top drawer because people are always asking for it." Dr. Nancy Connell, PhD in bacterial genetics, 6 January 2000. Seconding this point, Academic Expert 1, PhD in microbiology. On the importance of accessing such records to understand patterns of autoclave use and other inconsistencies observed: Dr. Jennie Hunter-Cevera, PhD in microbiology; Dr. Jerry Goldstein, PhD in microbiology, 6 January 2000.

[56] If these documents do not clarify funding sources, then the inspectors should request documents to provide a historical record of funding. Dr. Anne Vidaver and Dr. Jennie Hunter-Cevera emphasized the importance of gaining an overall understanding of funding sources, and the group agreed.

Insights 3.4

Defense contractors, it should be noted, faced similar quandaries about the need to protect the confidentiality of research being conducted for other government and commercial entities. They feared losing credibility with their clients if they were compelled to reveal contract data without the specific permission of clients. "We have an obligation to the clients not to tell and we just can't do that or we'd lose our credibility."[1]

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[1] Defense Contractor 5, director of microbiology and special government projects, 28 August 2000. Defense Contractor 5, works at a small defense contracting research company and has a PhD in microbiology. Defense Contractor 3 expressed a virtually identical opinion, noting that they were at liberty neither to describe their work nor name their clients. Defense Contractor 3, a senior technical adviser at a large, nonprofit research organization, holds a PhD in physics. For that matter, projects may be so tightly secured that people in the same building may be unaware of the work being done in the adjacent room. Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico.

research world can be highly competitive, so some laboratories also enforce policies to prevent others from getting an unwarranted glimpse of a laboratory's work. Both the laboratories and the outside sponsors are likely to require the inspectors to sign a confidentiality agreement to see these documents.[57]

A review of purchasing, supply, and shipping records should also prove useful to understanding the scale of a laboratory's activities and its interactions with outside entities. Paperwork for media, serum, animal supplies, and personal protective equipment would verify that a laboratory's purchases were qualitatively and quantitatively in line with the research supposedly underway.[58] Unusual types or quantities of media purchased might indicate a different type of research was actually being performed.[59] Shipping data would tell inspectors more about the pace and nature of the laboratory's work with outside organizations (e.g., routine culture supplier versus infrequent exchanges). Pathology records would validate or refute facility staffers' explanations for studies in increased virulence or other work that teeters on the fine line between offensive and legitimate research. Normally, such records would be maintained by individuals outside of the laboratory itself (e.g., purchasing, administrative, or pathology departments), so pulling this set of records would begin to spread the burden of the inspection outside of the laboratory's immediate staff. In Insights 3.5, members of the inspection veterans group explain the difficulties a facility can have in tracking down some documents. Also, turning

[57] The laboratories themselves are subject to penalties if they breech the confidentiality arrangements in their contracts with outside sponsors. At the very least, the laboratory would have to get permission from outside sponsors to show inspectors these documents. Dr. Barry Kreiswirth, PhD in microbiology; Dr. Nancy Connell, PhD in bacterial genetics; Academic Expert 1, PhD in microbiology, 16 August 2000.

[58] Defense contractors agreed that inspectors should question unusual quantities or combinations of supplies, agent, or other materials that appear out of kilter with a facility's stated purpose. "Well, if this solution is made and added on top of that one, they they've got a great media for those type of organisms." Defense Contractor 1, staff scientist in biotechnology, 28 August 2000. Defense Contractor 1, a scientist at a large research contractor, has an MA in cellular and molecular biology. Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company, made a similar comment.

[59] Dr. Barry Kreiswirth, PhD in microbiology, made this comment, which the group thought was sound.

over pathology records brought up concerns among the academic experts about compromising intellectual property.[60]

A final aspect of a second-level paper chase would be for the inspectors to cross-check the information in all of the previously accessed documents with two additional key sources of data. In this regard, laboratory notebooks can function somewhat like a polygraph. Scientists record each step of their work, the problems encountered, and the results in these notebooks. Their authenticity should be readily apparent to an experienced inspector who should recognize whether the blow-by-blow notes back up or contradict the research that has been described.[61] Laboratories also maintain inventories of the contents of their freezers, and these inventory lists can be compared against the media supplies and laboratory setup. Culture collection items, equipment, other physical laboratory features, and laboratory biosafety protocols should all correspond to the stated research program(s).

Insights 3.5

During one US BWC trial and a trilateral inspection of a US defense facility, locating some of the supporting documentation was described an "onerous" task because the items of interest were intermingled with so many other records. Also, some documents were not necessarily centrally filed, others had been destroyed long ago or placed who knows where by a staffer long since retired, and some ancient activities were not even documented.[1] Most sites have no cultural experience with international inspections and do not have their record keeping system set up to support quick document retrieval.[2]

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[1] Inspection Veteran 1, facility manager and US trial inspection host; Inspection Veteran 2, trilateral and mock inspection participant, 27 April 2000. Inspection Veteran 1, a facility manager, was a principal host of a US trial inspection held in late March 1996 at three facilities located in Albuquerque, New Mexico. Inspection Veteran 2 participated in inspections under the 1992 trilateral agreement, took part in a series of round robin mock inspections at military facilities in the western United States, and engaged in background planning for the mock visit to the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. Agreeing that trying to round up the records for any type of inspection is the "biggest headache," Inspection Veteran 3, trial inspection observer and mock inspection participant, 27 April 2000. Inspection Veteran 3, who holds a DVM and a PhD, observed the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and participated in the mock trilateral inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[2] Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000. Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000. Inspection Veteran 9, who has an MD and a PhD, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

While examining documents, the inspectors may turn up additional scientists that they should interview. Even if that is not so, the academic and research institute experts suggested that the inspectors broaden the scope of their interviews to include personnel who support the laboratory's operation. Unless well coached, animal caretakers, janitors, administrators, and bookkeepers would all have difficulty

[60] On negatively affecting the productivity of other personnel at the institution: Dr. Barry Kreiswirth, PhD in microbiology; Academic Expert 1, PhD in microbiology; Dr. Nancy Connell, PhD in bacterial genetics, 16 August 2000. The group would provide pathology records, but preferred that the inspectors sign a confidentiality agreement beforehand.

[61] Dr. Robert Shope, MD and epidemiologist; Academic Expert 1, PhD in microbiology, 16 August 2000. Should log books or other documents of interest be in a high containment facility, inspectors can suit up and examine them there, scan documents out, or tape desired records to the window for review.

Table 3.2: Anticipated Effectiveness of Level 2 Monitoring Activities

Type of Inspection Activity	Expected Level of Effectiveness
Sampling and Analysis	High
Review of Additional Project Paperwork	Moderate
Review of Purchasing, Supply Records	Moderate
Review of Project Log Books, Computer Records	Moderate
Review of Animal, Plant Pathology Records	Moderate
Additional Interviews	High
Correlating Laboratory Notebooks, Freezer Inventories with Other Documentation	High

sustaining a cover story convincingly.[62] Consequently, the group ranked interviews as one of a trio of second-tier inspection activities that should be highly effective. Other monitoring activities that rated highly were correlation of documents and sampling and analysis. The latter was described as being able to provide the proverbial smoking gun or clean bill of health. As table 3.2 shows, the group expected the four other monitoring activities that delve into laboratory paperwork to be moderately effective in determining a facility's true status.

ON-SITE MONITORING ACTIVITIES: LEVEL 3 INSPECTION

Should suspicions of illegitimate activity persist throughout the second phase of an inspection, the group concurred that a third level of inspection should be initiated to try to determine the specific violation. The objective in level three would be, in the words of one participant, "to finger point," and the time needed to complete this phase of the investigation should be left "to the discretion of the inspectors."[63] The group concluded that in addition to the results of the analysis from samples taken previously, finger pointing was most likely to be accomplished through examining freezer contents and taking additional samples.[64]

Investigating the contents of facility freezers is an activity with possible high inspection payoffs and high costs to the inspected site, which is why the group placed this monitoring tool in the third level. The academic brainstormers believed that the freezers would be where evidence of illegitimate activity could be found. Cultures might be marked accurately, ambiguously, or with some type of code. In the first instance, laboratory scientists would have erred on the side of safety and any undeclared biowarfare

[62] While a covert facility might rehearse its laboratory scientists and managers with mock interviews, thorough preparations might not occur with support personnel. Inspectors might also catch some of these people off guard. Conversely, inspectors would notice if all of these individuals gave the same rote answers to questions.

[63] "If they get to level three, then I think it should be up to the discretion of the inspectors, because then they're obviously on to something. At that point it's an investigation." Academic Expert 1, PhD in microbiology, 16 August 2000.

[64] Note that the results of sample analysis would probably not be available prior to the onset of level three inspection activities. Running the appropriate tests could take four weeks or longer, a time lag that did not bother the group.

agents could be identified. By observing the distribution of freezer crystals on the surfaces of items, inspectors would also note if certain cultures had been handled just prior to the inspection. The Stimson inspectors who conducted a trial of a biosafety level 3 laboratory to facilitate this group's discussion scrutinized the freezer crystals on the vials in this laboratory's culture collection, as box 3.1 describes at the end of this chapter. Should more recently handled cultures have strange labels that host officials cannot reasonably explain, then those cultures should be examined.[65]

From the host facility's perspective, rummaging through the freezer presents potential biosafety problems and could damage invaluable culture collections. "Your catalogue is priceless. Without that, I can just go home."[66] Therefore, the group agreed that guidelines should be stipulated for searches of freezer contents.[67] After taking inventory of the freezer contents, the group recommended returning to the documentation to match inventory results with associated documents (e.g., inventory list). Throughout this process, the inspectors would be asking the host officials to explain anomalies. However, if the hosts juggle for answers and the contents and documentation do not jibe, then the academic experts recommended that some strains be pulled randomly for sampling as another cross-check.[68]

Finally, another type of sample could be taken to ferret out what is really happening at a laboratory, namely collecting blood samples from laboratory personnel or animals. The group viewed blood samples as another smoking gun tool because they would reveal antibodies in the donors.[69] Not surprisingly, members of the group were concerned about confidentiality and the aftershocks that could

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[65] Some organisms can be seen readily under the microscope, but others need tissue culture and specialzed techniques for viewing. An electron microscope might also be needed for certain organisms. Even then, a simple visual examination might not tell the inspectors what they need to know because many rod-shaped bacteria look alike. Genetic or serological techniques would be required for specific identification, perhaps even animal or plant tests. Dr. Anne Vidaver, PhD in bacteriology, 6 January 2000.

[66] Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000. Academic Expert 1 chimed in on the possible harm to culture collections, noting that some microorganisms are quite delicate. "Some things are sensitive to warming up even if they don't thaw. The temperature goes up and down even though they remain frozen." Academic Expert 1, PhD in microbiology. A biosafety hazard could occur if a freezer located in a biosafety level 2 area actually had dangerous pathogens. Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000. Other participants agreed with both points.

[67] Among the guidelines advocated were the necessity of having host personnel present during a freezer search, of limiting the time that freezer doors could remain open, and of establishing who should be allowed to retrieve items from freezers for further examination. When inventorying freezer contents, the participants were flexible about whether inspectors followed host facility rules or inspectors directed host personnel to accomplish tasks. Dr. Nancy Connell, PhD in bacterial genetics; Dr. Barry Kreiswirth, PhD in microbiology; Academic Expert 1, PhD in microbiology, 16 August 2000.

[68] Dr. Barry Kreiswirth articulated this strategy, which struck the rest of the group as a good idea.

[69] "Blood samples could identify agents that have been worked with, what they have been immunized against and exposed to." Dr. Robert Shope, MD and epidemiologist, 16 August 2000. Also on this point: Dr. Nancy Connell, PhD in bacterial genetics; Dr. Corrie Brown, DVM and PhD in comparative pathology. Tests could be prioritized according to the type of research the laboratory was conducting (e.g., viral versus bacterial). Heartily agreeing on the informative nature of blood samples from employees and animals, "that really is great information, especially if they are zero-positive for anthrax and their declaration is saying otherwise. That's a red flag right there, that could be the one determinant thing that put them out of compliance with the treaty: everybody here has been exposed to anthrax." Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company, 28 August 2000.

reverberate through a laboratory if inspectors used this tool.[70] Some laboratories have archived blood samples that might be accessed for this purpose, but in other cases hurdles might have to be cleared prior to sampling.[71] Because of its exculpatory power, several brainstormers also noted that a laboratory ought to be allowed to volunteer blood samples during the first phase of an inspection as a means to avoid the more extensive activities outlined for the second- and third-tier monitoring.[72]

At the conclusion of an inspection, the academic group was extremely wary that the reports prepared at this juncture might be worded to the effect that the inspectors did not see, hear, or detect anything untoward while they were there, but the capability and expertise were present to do bad things nonetheless. The implication of such wording was that the moment the inspectors left, the site reverted to being a weapons facility.[73] For this reason, the group wanted not only the right to review the report, but to have their rebuttals of any of its factual or subjective statements included in the body of the report. The reports should be confidential. In addition, the academic and research institute participants wanted a copy of the report sent to them directly, not just to some point of contact in the government.[74]

As table 3.3 indicates, the group graded all three monitoring activities in the third level as being equally potent. Throughout their discussions, various academic and research institute brainstormers worried that given the dual-use nature of their working environments, the inspectors would never be able to discern what a facility's researchers were really doing. Yet, they gave the preponderance of their recommended inspection techniques moderate or high effectiveness ratings. This seeming contradiction was explained by the group's fundamental belief that with the appropriate expertise, techniques, and care, inspectors could conduct a successful investigation with palpable results. The group's agreed statement was as follows: "The likelihood of these on-site techniques uncovering violations of the BWC by a state in an academic research setting is reasonably high and may deter states from using the academic community to violate the treaty."[75] Moreover, laboratories conducting peaceful research have a vested

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[70] Some staffers are upset about taking a purified protein derivative skin test for tuberculosis, much less one related to exposure to biowarfare agents. Some staffers might object on Constitutional grounds. Dr. Barry Kreiswirth, PhD in microbiology; Dr. Robert Shope, MD and epidemiologist; Dr. Nancy Connell, PhD in bacterial genetics, 16 August 2000.

[71] For example, the institutional review board would have to approve such activity. Moreover, the blood would have to be drawn by a physician, a nurse, or a certified phlebotomist. Academic Expert 1, PhD in microbiology; Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000.

[72] For instance, Academic Expert 1 and Dr. Robert Shope stated they would hand over blood samples early to verify the accuracy of their declarations and the legitimacy of their laboratories.

[73] As in "everything looks okay, but we think he could have hidden everything in the steam tunnel." Such an approach would be a "disaster," "uncalled for and slanderous in some ways." Academic Expert 1 and Dr. Barry Kreiswirth made these statements.

[74] Furthermore, the group wanted the US government to notify an inspected facility formally that it has received a "clean bill of health."

[75] The group's agreed statement continued with: "However, these techniques may not be successful in detecting terrorist activity." Dr. Robert Shope initially made the observation, to roundhouse assent, that regardless of their tangible effectiveness, the inspections would be worthwhile because they might deter laboratories from engaging in offensive research.

Table 3.3: Anticipated Effectiveness of Level 3 Monitoring Activities

Type of Inspection Activity	**Expected Level of Effectiveness**
Inventory, Examine, Sample Freezer Contents	High
Correlate Freezer Contents with Documentation	High
Take Blood Samples from Staff, Animals	High

interest in participating in some sort of regular BWC inspection process, namely to confirm their legitimacy and strengthen the ability of international monitors to pursue suspected cheaters.[76]

[76] "The purpose of the treaty, from an American point of view, is to establish that we have our house in order, that what is being done here is perfectly legitimate. The purpose of the regular inspections is to validate inspections on a challenge basis to look at a lab that *is* suspect. The legitimacy of inspections needs to be established." Dr. Nancy Connell, PhD in bacterial genetics, 16 August 2000. Just as the academic and research institute experts saw reason for some sort of non-challenge inspections in addition to challenge inspections, several defense contractors were adamantly opposed to a protocol built only upon challenge inspections. "That's worse, a worse connotation even if you're found innocent, regardless of the outcome." Defense Contractor 2, principal research scientist, 28 August 2000. Other contractor participants concurred. Still several defense contractors were very anxious about non-challenge inspections as well, underscoring the importance of the screening criteria used to prompt them. They took a strong position that the inspectors would need a reason—a probable cause—to inspect one of their sites. Defense Contractor 5, director of microbiology and special government projects; Defense Contractor 7, president and founder of a small sensor development company; Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company; Defense Contractor 3, senior technical adviser, 28 August 2000. On the benefit of getting a clean bill of health out of this inspection process: Academic Expert 1, PhD in microbiology, 16 August 2000. Also on the reasons for non-challenge inspections: "You want to have a baseline that says, 'this is what should be done, and in some places people are abiding by the treaty, in other places they aren't.'" Dr. Barry Kreiswirth, PhD in microbiology, 16 August 2000.

Box 3.1: Trial Inspection of a Biosafety Level 3 Research Laboratory

On 7 July 2000, the Public Health Research Institute (PHRI) in the heart of New York City hosted a duo of seasoned inspectors whose mission that day was to give the monitoring techniques suggested in the initial meeting of the academic and research institute group a trial run in a high-containment research laboratory setting.[1] The inspectors were Lt.Col. Karen Jansen (USA, ret.) and Dr. David Franz, a team with hard-earned inspection experience in Iraq and the former Soviet Union.[2] As Dr. Barry Kreiswirth, the head of one of the biosafety level 3 laboratories at PHRI, explained during the introductory briefing, PHRI has a venerable history, dating back to the early 1940s. PHRI is home to twenty-two research laboratories working in such fields as microbiology, genomics, virology, immunology, biochemistry, genetics, and cell and structural biology. At the time of the inspection, PHRI was funded by twenty-three National Institutes of Health grants as well as the Centers for Disease Control and Prevention, pharmaceutical and biotechnology companies, private foundations, and other government sources, including the Defense Advanced Research Projects Agency. PHRI also housed a separate biosafety level 3 facility and other laboratory areas that were not the focus of the trial inspection. [3] Collocated in the same multi-story building were the New York City Health Department Bureau of Laboratories, a poison control center, a local university ophthalmology department, a common library, the Diamond AIDS research laboratory, and other clinical and hospital laboratories.

A local epidemic of tuberculosis in 1991 prompted the establishment of Kreiswirth's laboratory. The rise in the number of drug-resistant cases made it apparent to PHRI's management that tuberculosis again represented a public health problem, and money was raised to construct two biosafety level 3 laboratories, which opened in 1992.[4] The larger biosafety level 3 laboratory overseen by Kreiswirth was used mainly by the researchers whose primary task is to genotype or characterize the strains of

[1] The Henry L. Stimson Center is grateful to PHRI for its generous cooperation with this inspection.

[2] Briefly, Lt. Col. Jansen (USA, ret.), a microbiologist and twenty-year veteran of the Army's Chemical Corps, led four United Nations Special Commission on Iraq inspections of biological facilities following the Persian Gulf War. Dr. Franz, who holds a DVM and a PhD, was formerly the commander of the US Army Medical Research Institute of Infectious Diseases and has been to numerous institutes involved in the former Soviet Union's massive biowarfare program. Lengthier resumes for both individuals, who also facilitated each of the brainstorming meetings, can be found in the appendix. In addition, the inspection team included Amy E. Smithson, PhD and senior associate at the Stimson Center, as an observer and note taker.

[3] At the outset, the laboratory was funded locally and conducted research on influenza, hemoglobin, and basic research and development applied to public health until the early 1970s. Among PHRI's long-standing research efforts are programs that explore fundamental aspects of gene expression, deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) replication and recombination, genetic competence, enzyme structure and function, and viral assembly and structure. The other biosafety level 3 laboratory was concentrating on two Centers for Disease Control and Prevention-funded human immunodeficiency virus (HIV) research projects. For more information on PHRI, see http://www.phri.nyu.edu/.

[4] More details about this tuberculosis laboratory can be found at: http://www.phri.nyu.edu/tb.htm/. In keeping with its status as a world-class research institute, the media frequently consults PHRI staff on a variety of topics. See, for example, Constance Holden, "Stalking a Killer in Russia's Prisons," *Science*, 26 November 1999, 1670; Susan Okie, "The Frontiers of Medicine: Science Races to Stem TB's Threat," *Washington Post*, 10 August 1999; Ian Fisher, "Hospitals Uniting to Fight Drug-Resistant Bacteria," *New York Times*, 23 June 1998; Richard Saltus, "Antibiotics: Overused and Misunderstood," *American Health* 14 (October 1995): 50.

tuberculosis. During the briefing, Kreiswirth mentioned that his scientists had developed drug resistant strains of the disease, and his colleague Dr. Nancy Connell, who helped to host the inspection, noted that crossing a gene into tuberculosis strains would be possible. As part of the general characterization of their work, Kreiswirth readily listed several of his laboratory's outside collaborators, naming a few biotechnology companies, nongovernmental and governmental research laboratories in the United States, and other research institutes around the globe (e.g., Russia, Egypt, the Czech Republic). Kreiswirth mentioned that some of the laboratory's collaborators conducted animal research. He said that he had met with Defense Department scientists (e.g., Walter Reed) to discuss collaborative work, but no such relationship had been established. Kreiswirth also volunteered that they had sent control strains to Russia and had received over 1,600 tuberculosis strains from Russia. The Russian aspect of the research was funded by a grant from the Soros Foundation. Aside from the project's scientists, Kreiswirth pointed out that several other PHRI researchers and scientists from collaborating organizations also had access to both biosafety level 3 facilities.[5]

The tour that followed was casual and informative, beginning with an introduction to PHRI's president, Mr. Lewis Weinstein. As the entourage made its way around the building's floors, Kreiswirth explained the general purpose of various laboratories, introducing the inspectors to numerous scientists, including one Chinese and a few Russian researchers.[6] To a person, these widely published scientists were easy to engage in conversation, with a number of them lapsing enthusiastically into lengthy descriptions of their research. They readily discussed their funding sources, their collaborators domestic and foreign, and their travel to places near and far (e.g., Vietnam, Russia, Cuba).[7] After an overall site tour that lasted one and a half hours, the inspectors honed in on the portion of PHRI that was the target of the inspection, namely two biosafety level 3 laboratories, one approximately 250 square feet and another 650 square feet in size.[8] At this point, Kreiswirth handed the inspectors over to his chief laboratory technician, who described procedures for recording the receipt of samples, media preparation, culturing, and moving samples to the fingerprinting laboratories. The chief technician also reviewed the lab's safety protocols and showed them paperwork for various procedures, as well as the computer database used to

[5] The introductory briefing lasted an hour. In a more confrontational setting, Franz and Jansen said that they would have curtailed the briefing earlier, but in this case they allowed a lengthy briefing because in an abbreviated inspection format it gave them a sound basis for where to focus subsequently. In the spring of 2001, PHRI was to move to a new, state-of-the-art facility in Newark, New Jersey, with over twenty biosafety hoods in a biosafety level 3 capacity for pathogen studies, where mice and perhaps pigs will be exposed to aerosols and then moved into biosafety level 3 animal rooms. Kreiswirth also described the features and biosafety protocols for the tuberculosis laboratories.

[6] Not only were several Russians working in the lab, the laboratory chief and several other scientists employed there had traveled to Russia, Cuba, and elsewhere. According to the laboratory chief, most of the Russian contingent in the lab, which was focusing on virulence, preferred to work at night. This information was voluntarily disclosed.

[7] Annually, PHRI's scientists publish in over fifty peer reviewed journals.

[8] Initially, they were testing polymerase chain reaction (PCR) diagnostic kits in the smaller laboratory, but work switched over to macrophage research. The smaller laboratory is still dedicated to tuberculosis work. Inspectors viewed the smaller facility through the observation window.

track samples. The inspectors found that the records for outgoing shipments were not as well organized as those tracking incoming samples, and the chief technician explained that the laboratory was not required to keep such documentation.[9]

Moving to the anteroom of the larger biosafety level 3 laboratory, which doubled as a supply storeroom, the inspectors, following host facility protocols, suited up and entered the laboratory. Coded entry pads safeguard the entrance of both laboratories.[10] The larger facility was equipped with three biosafety cabinets, four double standing incubators, a smaller incubator, a bac-tech machine to detect and diagnose *Mycobacterium tuberculosis* in clinical settings, an electric autoclave, a tabletop centrifuge, a large sink area, two refrigerators, shelving, and a large, low-temperature chest freezer that contained approximately 11,000 frozen strains of tuberculosis.[11] Unbeknownst to Franz and Jansen, Kreiswirth and Connell had planted a few clues that, if noticed, should have cued the inspectors that something wrong was afoot. They put on the shelves inside the laboratory two containers of media used not for tuberculosis (e.g., brain-heart infusion) but rather for *Bacillus subtilis*; placed a strain in the freezer labeled "BA" with a corresponding titillating entry penciled into the logbook; set a blood plate streaked with *Bacillus subtilis* in one of the incubators; and instructed the chief technician to behave nervously.[12] Deliberately making their way around the laboratory, the inspectors looked into the incubators, refrigerators, and the freezer. They asked whether the color of the slant marked "0/19/00" inside the freezer was typical of tuberculosis because the bright yellow color looked unusual to them.[13] Otherwise, it did not appear to Franz and Jansen that anything was out of the ordinary in the freezer because the ice

[9] Logs for incoming samples, the inspectors observed, were kept meticulously. Compared to the number of samples the laboratory received, not that many samples were shipped elsewhere. However, the laboratory had a general policy of sending what was requested.

[10] Note that the other security precautions at PHRI were inconsistent with an expectation that high security would be a signature of a covert military facility. At the main entry, signs said that everyone must wear badges, but such badges were not always visible on personnel entering the building. Two or three security guards were present, but did not check the inspectors' identification. The inspectors were asked to sign in, and Kreiswirth and Connell met the inspection team as they stepped off of the elevator.

[11] Two databases—one written in a logbook, the other computerized—are kept of these isolates. Incoming samples are split, with half going to frozen stock and the other half going to DNA preparation. The freezer has a built-in alarm system that alerts the laboratory chief or a designee of an unauthorized entry and a 24-hour backup carbon-dioxide supply. The larger biosafety level 3 laboratory has twenty-three air exchanges. An outside contractor maintains and certifies the high efficiency particulate air (HEPA) filters every six months. The laboratory is outfitted with ultraviolet lights and HEPA filters at the entrance and above each of the biosafety cabinets. These latter HEPAs are ducted together and feed into a fan, which draws to the rooftop.

[12] *Bacillus subtilis* was selected for the blood plate because its colony morphology is similar to that of *Bacillus anthracis*. The strain record entries in the logbook and the electronic access database are sequentially numbered. The planted strain was number 9717. On that line in the logbook, Kreiswirth wrote "control strain" with "BA" beside it, for *Bacillus anthracis*. In the corresponding empty slot in the freezer, his chief technician placed a normal isolate from Cairo. The planted blood plate in the incubator was marked number 26.

[13] Aside from the chief technician, Kreiswirth did not give any particular instructions to any of his staff members about how to interact with the inspectors. The chief technician's response that she was uncertain of what she should tell them struck Franz and Jansen as somewhat odd. The slant they had identified was not the one planted in the freezer, and since its bright yellow color was indeed typical, a straightforward answer would have sufficed.

crystal dust was evenly distributed across the thousands of vials. They also queried the chief technician about one of the cultures inside an incubator, one that was marked "RIFMIC."[14] Franz saw the different media on the shelf.[15]

Another thing that Franz and Jansen observed was that the exterior filter padding on the ducts leading to the high efficiency particulate air (HEPA) filter was brand new. To hedge against the possibility that the filter had been changed just prior to the inspection in an effort to hide something, they took a notional sample of the filter.[16] When asked about the filter status, the chief technician said there had been some water leaks into the laboratory recently, and they had just replaced and autoclaved the filters on the preceding Friday, 30 June. The day before, the facility had also been repainted. Looking behind equipment, the inspectors noticed only two paint chips, but no other signs of recent repair work.[17] Since the walls did not look freshly painted, this explanation did not sound right to Franz and Jansen, who also saw an atypical entry in the anteroom logbook for 30 June.[18] Upon exiting the laboratory, the inspectors asked to spend more time with the shipping records.

As they would explain to Kreiswirth and Connell during the post-inspection discussion that followed, the inspectors returned to the shipping records instead of other paperwork to try to rule out the possibility that the facility might have been a source of virulent strains for proliferators. Given the laboratory's international connections, its collaboration with institutions that conduct animal studies, its strain manipulation capabilities, and its stellar scientific staff, Franz and Jansen sought and received assurance of their concern through the shipping records and the staff's behavior during interviews.[19] The duo of inspectors also articulated their plans for chasing down other oddities that they had noticed, had time allowed. To sort out the suspicious timing of the maintenance activities just before the inspection, they would have interviewed the biosafety officer(s), maintenance personnel who had repaired the broken freezer compressor, the contractor(s) who changed the filters, and the painter(s). They would have also

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[14] Later, Jansen and Franz said they asked about this culture because they thought that RIFMIC might have stood for Rift Valley Fever, an idea they subsequently dismissed. They also checked the latest entry date for that incubator and noted it as "6/28/00."

[15] Franz thought it was unusual for the media to be inside the laboratory because they had been told that all media preparation was done outside of the laboratory. Franz and Jansen even discussed the utility of various media types for research, but decided not to make an issue of it since preparing media inside the laboratory was not that big of a deal.

[16] The protocol for PCR analysis of the sample was to be negotiated later.

[17] A ledge that ran around the entire laboratory had black sooty dirt, but no paint chips, dust, or other signs of leakage.

[18] This entry was outside of the normal lines and marked with an asterisk, but other standard notations (e.g., name, time) were absent. As for the behavior of the chief technician, Franz and Jansen did not detect anything out of the ordinary other than this one statement. This capable individual was no surrogate, clearly demonstrating during the course of the inspection extensive knowledge of the facility's operations, biosafety protocols, and science.

[19] Earlier, they had pulled at random sample receiving logbooks, biosafety protocol notebooks, and laboratory notebooks inside the larger biosafety level 3 facility. Examining these records, they found nothing out of the ordinary. Ideally, the team would have been larger, including at least one technician assigned to do nothing but review records.

sought documentation of this work.[20] Time permitting, they would have interviewed additional scientists to alleviate their concerns about the laboratory's connections with institutions in countries that the US government publicly names as being of proliferation concern. Both Franz and Jansen explained that while it may be unfair that nationality alone would trigger suspicion, their training was such that inevitably nationality tripped that wire. Interviews can quiet such qualms.

Finally, Jansen and Franz conceded their handicap in carrying out a trial inspection in a facility specializing in tuberculosis research.[21] Neither had the specific expertise necessary to identify the brain-heart infusion media as inappropriate for the laboratory's applications and thus could not pursue the matter further. Having a tuberculosis expert on the inspection team could have made for quite a different inspection outcome. Had they been allotted time to investigate the other ambiguities, both Jansen and Franz agreed that they would have given the facility a clean bill of health, according to the guideline set by the academic and research institute brainstormers: a facility is presumed legitimate unless evidence indicates otherwise. For their part, Kreiswirth and Connell described the inspection as a valuable learning experience, despite its cost.[22]

[20] Kreiswirth and Connell said that it never occurred to them that maintenance work would raise the inspectors' suspicions. Something broke, it needed to be fixed, and the repairs were made without a second thought. They explained that the paint did not look fresh because they had employed several base coats topped by a special, high-sheen epoxy paint to make sure, given the building's porous, cinderblock construction, that the facility was airtight.

[21] Note that both individuals said they would have been more aggressive in a genuine inspection, but they gauged their behavior to the cooperation extended by PHRI for the exercise.

[22] The cost of shutting down the laboratory, Kreiswirth and Connell stated, was offset by the insight they gained into how inspectors do their jobs. Kreiswirth estimated the cost of the exercise to be approximately $5,000. The figure constitutes the cost for temporarily closing the larger biosafety laboratory to PHRI's scientists. Had a real sample been taken of the HEPA filter, he estimated that it would have cost about $2,000 to bring their outside contractor to do that work over the course of two days, including decontamination, sampling, and filter change. Added Connell: "Because we hand nothing to hide, we had a great time. For a whole day, we talked about how cool [PHRI] was. The scientists waxed poetic."

Chapter 4
Industrial Strength Expertise: The Views of Pharmaceutical and Biotechnology Industry Experts on BWC Monitoring

Representing an interesting cross-section of the pharmaceutical and biotechnology industries, a group of specialists graciously rose to the challenge of the Stimson Center's invitation to brainstorm the issues associated with monitoring the Biological and Toxin Weapons Convention (BWC). These industry experts had backgrounds in areas such as vaccine development and manufacturing, antibacterial research, and biotechnology product scale-up and development. Members of this group had vast experience in smaller, niche firms as well as in the large companies of the pharmaceutical and biotechnology industry such as Wyeth-Ayerst Research, DuPont Merck Pharmaceutical Company, Celgene Corp., and Cytec Industries. Cumulatively, the nine experts who composed this group possessed just under 200 years of experience in research and industry. The credentials of the industry brainstormers, four of whom chose to remain anonymous, are recounted in full in the appendix. Stimson facilitators marched the industry participants through the same mental exercise as the academic group, where they addressed the types of questions listed in box 1.1. The pages that follow document this group's pragmatic approach to the vexing questions of monitoring the BWC.

The views of the industry group on how to plan inspections for maximum effectiveness and receive them without compromising sensitive business data came from a deep reservoir of experience, for their facilities had all been involved in countless inspections. To illustrate the point, one participant estimated that his current plant fills out at least fifty reports per year just for state and federal environmental regulators. Also, manufacturing facilities get inspected by the Food and Drug Administration (FDA), the Commerce Department, the Occupational Safety and Health Administration, and state and federal environmental protection agencies. FDA inspectors show up on industry doorsteps without notice. FDA and environmental inspection teams can park on site for weeks, digging through records and examining operations that involve air, water, solids, waste, and emissions of any type. If one kind of inspector finds something wrong, they can call in sister regulatory inspection crews, so the phrase "crawling with inspectors" rang true to this group.[1] This kind of experience functions as a double-edged sword for how the industry approaches the prospect of monitoring under the BWC. "Well, the good news is that we're accustomed to inspections—we're set up for it, we have the people to handle these things.

[1] Dr. Steven Projan gave these examples and other group members agreed. Dr. Steven Projan, Director of Antibacterial Research at Wyeth-Ayerst Research, holds a PhD in molecular genetics and has over twenty years of experience in research and industry. Chemical surety inspectors also oversee some sites, noted one of the participants in the inspection veterans group, who said that the Food and Drug Administration was at his facility for thirty days in 1999. Inspection Veteran 3, trial inspection observer and mock inspection participant, 27 April 2000. Inspection Veteran 3, who holds a DVM and a PhD, observed the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and participated in the mock trilateral inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

The bad news is that the companies are extremely gun-shy. They don't want any more inspections than they are already getting."[2]

In addition to being concerned over the potential loss of confidential business data through inspections under the BWC, the industry group was understandably edgy about anything associated with the phrase "biological weapons."[3] The industry takes the reputation of these companies very seriously because the general public's trust in their products and their credibility with stockholders is at stake. Therefore, the industry group recommended that any possible BWC monitoring activity at corporate facilities be accomplished with the lowest possible profile. The inspectors should come and go in plain clothes without public announcement. This matter was so sensitive that the industry group did not even want the results of an inspection that gave a facility a clean bill of health to be disclosed publicly unless the host company specifically gave the inspectorate permission to do so.[4]

When it came to planning and executing an effective inspection, the industry group mentioned several things time and again. Their foremost mantra was the need for the inspectors to be wary of inconsistencies with the plant's stated purpose. No single incongruity is likely to be sufficient to label a facility "dirty," but an accumulation of them would certainly send up flares to that effect.[5] The industry group's other frequent refrains pertained to the need for the inspectors to be thorough, and to cross-check one thing with another with an eye toward consistency and whether activities at the site made good

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[2] Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000. Dr. Robert Hamilton, holds a PhD in microbiology and cell biology and has over twenty-five years of experience in research and industry.

[3] One participant in the defense contractor group was also terribly worried about adverse publicity. "Just the association . . . . we cannot tolerate that type of notoriety." Defense Contractor 3, senior technical adviser, 28 August 2000. Defense Contractor 3, employed at a large nonprofit research organization, holds a PhD in physics. Another remarked that the cat was already out of the bag, so to speak, due to the inspections they underwent to gain their licenses to work with these agents. Because their community was already aware that they "use these agents, I don't perceive that as a problem." Defense Contractor 2, principal research scientist, 28 August 2000. Defense Contractor 2, a scientist at a medical research facility, is a veterinarian and a PhD microbiologist.

[4] Prior to its Chemical Weapons Convention (CWC) inspection in mid-2000, one US commercial facility engaged in defense research made a "no press" request, which the CWC inspectorate honored although it is under no specific treaty obligation to do so. No publicity resulted from this particular inspection. Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000. Defense Contractor 4 has a PhD in chemical engineering. For that matter, over 275 CWC inspections of industry facilities around the world had been concluded as mid-April 2001 without any press coverage. The general public has little or no idea when the CWC's inspectors are at a nearby chemical plant, the inspection reports are viewed only by corporate and host government officials, and the inspectorate maintains a confidential data system to safeguard all information associated with inspections. Senior official at the Technical Secretariat of the Organization for the Prohibition of Chemical Weapons, telephone interview with author, 19 April 2001.

[5] As one member described it, when inspectors came across something individually suspicious but not conclusive, "another flag goes up, and when there are a certain number of flags at one site, then more inspections would need to be done there and at other locations" to pin down the extent of the program. Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000. Dr. Robert Zagursky holds a PhD in biological science and has eighteen years of experience in industry.

business sense, both operationally and fiscally.[6] Since the inspectors would almost certainly encounter a constant stream of seeming contradictions on the job, the industry group repeatedly observed that fielding a cross-disciplinary team of inspectors would be integral to their ability to unravel these complexities and determine whether a facility was engaged in legitimate commercial work as opposed to illicit weapons research or production activities.

PRE-INSPECTION ACTIVITIES

Prior to an inspection, the industry group recommended that the inspectorate obtain certain information from the site itself and from open data sources. The group suggested keeping the data requested from the sites to the bare minimum, namely what product(s) a plant is making and how much is being manufactured. The industry brainstormers also wanted sites to provide a staff listing, including job titles.[7] Knowing the stated purpose and size of a facility would allow the inspectorate to deploy a team with the appropriate skill sets.[8] These who, what, and how much data points also create a certain set of expectations on the part of the inspectors about the sort of containment, waste treatment, and other operational set-ups they should anticipate seeing once on site, which would prepare them to discern departures from a normal operation.[9]

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[6] Defense contractors also viewed consistency of equipment scale, types, and set-up with a site's declared purpose as a very important point of the inspectors' evaluation. "I would be very shocked to go into a place and not see certain basic equipment around, and I'd be surprised to see other things." Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000. Defense Contractor 7 has a PhD in microbiology. Also on this point: Defense Contractor 5, director of microbiology and special government projects, 28 August 2000. Defense Contractor 5, working at a defense contracting research company, has a PhD in microbiology.

[7] While it is true that this approach would minimize the paperwork burden on industry facilities, it would also avoid flooding the inspectorate with data that would have to be reviewed and, if misinterpreted or if an honest mistake were made, could send inspectors down the wrong path. Since a facility cannot be judged from afar, the purpose of declaration data should be to help set up a successful inspection. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. George Pierce, former manager, technology development and engineering, Cytech Industries; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Dr. Allen I. Laskin, president, Laskin/Lawrence Associates, 23 August 2000. Industry Expert 2 has a PhD in biology and over twenty years of experience in research and industry. Dr. George Pierce has recently become professor of applied and environmental microbiology at Georgia State University where he draws not only on his academic credentials, a PhD in microbiology, but over twenty years of experience in research and industry. Dr. Allen I. Laskin has a PhD in microbiology and has over thirty years of experience in industry.

[8] Different kinds of expertise would be need to inspect a bacterial fermentation plant as opposed to one engaged in viral or cell-culture protein activities. Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[9] Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000. Enthusiastically agreeing that the inspectors should do open-source homework in advance so that they can identify gaps during the opening presentation: Inspection Veteran 3, trial inspection observer and mock inspection participant, 27 April 2000.

Insights 4.1

The defense contracting group was also of the opinion that the inspectors would be well advised to "do a lot of work before they walk in the door," as they put it. The contractors suggested looking for press releases, federal grant and contract announcements, ISO 9000 laboratory qualification data, and records of regulatory violations. With the same phrase that the industry experts often employed, the defense contractors said that the inspectors should make good use of such publicly available sources to "uncover any kind of inconsistencies."

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[1] Continued this individual, "then they can see right off the bat how cooperative a company is going to be." Defense Contractor 5, director of microbiology and special government projects, 28 August 2000. Defense Contractor 5 works at a small defense contracting research company and has a PhD in microbiology. Also speaking out on the utility of careful research before inspecting a production facility, Defense Contractor 3, senior technical adviser; Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000. Defense Contractor 3, employed at a large, nonprofit research organization, holds a PhD in physics. Defense Contractor 7 has a PhD in microbiology. On the utility of regulatory violations (e.g., water standards, pollution) in getting a sense as to whether a facility had previously violated rules: Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company, 28 August 2000. Defense Contractor 6 has over fifteen years of experience in molecular genetics.

Working from the staff listing, the inspectorate should build a more complete picture of a facility from open source data. For instance, the inspectorate should search the scientific literature for publications, resumes that may be on file with professional associations, and other open source reports. Knowing the background of a plant's personnel would be important to understanding what those individuals could accomplish at the facility. Concerns would be raised, for example, if a concentration of personnel at a site had all published or worked on Q fever.[10] Other open source data that could be tapped to learn more about what has been happening at and around the facility include local newspaper stories and obituaries. That disease has broken out or that authorities have been called in to kill off livestock could indicate untoward activities at the facility.[11] The inspectorate should also attempt to assemble from open sources patent estate and intellectual property portfolios for the companies to be inspected.[12] In Insights 4.1, members of the defense contractors group provide additional suggestions for sources that inspectors should consult before heading into the field.

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[10] Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000. Editor's note: Similar worries should arise if a site's personnel had no publication track record for an extended period of time. Scientists are normally eager share their work with colleagues.

[11] In fact, the inspectorate should monitor public news sources regularly, and reports of this type should precipitate an inspection. Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Note that one defense contractor took the suggestion to examine such data a major step further, arguing that the inspectorate should sponsor widespread epidemiological studies around the globe to obtain the appropriate background information to enable detection of unusual outbreaks. Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000.

[12] Such documents can be extremely sensitive because they often contain trade secrets. Also, in some areas of the world where intellectual property laws are weak, these documents may not exist and the plants may be making "knock-off" products. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000. In the defense contracting group, some warned that patent estate and scientific literature searches would not be fruitful for their facilities, since the scientists they employ are often not permitted to publish the results of their research on the job, which is considered the property of their clients. Defense Contractor 7, president and founder of a small sensor development company; Defense Contractor 2, principal research scientist, 28 August 2000.

In addition to newspaper and other database searches, advance knowledge of the regulatory framework in which a plant is operating would be important for the inspectors to do their jobs well. Certainly, regulations differ from country to country, but even if the rules are weak, virtually every country has environmental, food and drug, commerce, and worker safety guidelines. These regulations would help the inspectors understand why processes are set up or done in a certain way.[13] As one brainstormer noted, the inspectorate would be short-sighted not to take advantage of the fact that "there's an amazing amount of information that's easily accessible."[14] Although the group emphasized the value of this data to the inspectors, they argued that the facilities should not be obligated to provide information from such outside sources.

Finally, before the inspectors leave headquarters, the industry group advocated looking at satellite images of the facility taken well in advance of any announced inspection. The operators of a facility can alter maps subtly to create certain impressions, but satellite photographs do not lie. Therefore, the inspectors will be able to get a bearing on the facility's layout and identify areas of interest. Also, it would be useful if the facility were monitored for signs of unusual activity after the inspection was announced .[15]

ON-SITE MONITORING ACTIVITIES: SITE TOUR

The industry brainstormers put a considerable amount of credence in the utility of simply observing what was going on at a facility.[16] Their instincts about the usefulness of a site tour were right on target, according to what an inspection veteran says in Insights 4.2. In a plant that was supposed to be making particular products, it would be noticeable if the facility were not configured and equipped accordingly. Also, the industry group reasoned, it would be conspicuous if the plant workers were ill at ease with or inept at performing tasks they were supposed to do daily.[17] So important was a plant tour in

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[13] In agreement on this point: Inspection Veteran 5, participant in two US trial inspections and a mock inspection; Inspection Veteran 3, trial inspection observer and mock inspection participant; Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 5, a PhD scientist, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico. Even countries that are categorized as "developing" have waste water discharge permits, for instance. Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000.

[14] Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[15] Points made by Dr. Steven Projan, widely supported by the group.

[16] Jokingly, this was tagged the Yogi Berra method, as in "you can observe a lot just by watching." Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000.

[17] "If they're doing what they normally do, they should be able to do it, but if they have to pretend they are doing something else, it's going to be hard." Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

Insights 4.2

One veteran of inspections at former Soviet biowarfare facilities gave support to the argument that just looking around could reveal a great deal. "There was plenty of physical evidence that we saw that showed it was obviously a biological weapons facility. They had removed lots of things, even explosive chambers. Their not admitting to it was what was so frustrating."[1] Seeing proof, in other words, did not necessarily mean that the other aspects of the inspection were a waltz.

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[1] Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico.

their estimation that the industry group argued that the terms of on-site inspections should stipulate that the inspectors be taken on a site tour as soon as they walk through the door, preferably with the plant in operation.[18] Otherwise, the group worried that facility personnel might decrease the potency of this inspection tool by stalling for time with coffee and doughnuts, lengthy introductions, or special training.[19]

Of course, the industry group stated that the inspection ground rules should also specify that the inspectors wear whatever clothing the facility deems appropriate (e.g., gown, boots) and follow all of the facility's procedures to protect product integrity.[20] Inspectors would be accompanied at all times and would be prohibited from touching or picking up any items during the tour.[21] The inspection guidelines should also allow facility managers to see the equipment that the inspectors are carrying (e.g., pens, recorders, computers) and offer them comparable substitutes for use while in the controlled areas of the plant. This option would alleviate industry concerns about surreptitious listening, sampling, or photographic devices.[22] A final precondition for the tour and subsequent access to documents and

[18] Underscoring the importance of touring a facility, seeing cleanliness in a site claiming to make vaccines, as well as a scale and equipment that one would expect in the type of site declared. Defense Contractor 7, president and founder of a small sensor development company; Defense Contractor 3, senior technical adviser, 28 August 2000.

[19] Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000. Assenting to the need to be wary of an unduly lengthy opening briefing, one inspection veteran said of a US full-scale BWC trial: "The introductory briefing seemed to delay the brass tacks of negotiating what we were going to see. We were pandered to in terms of safety and environmental issues. We wanted to know the boundaries of the inspection and when we were going to get there. I learned nothing, even though I was unfamiliar with the site." Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000. Inspection Veteran 9, an MD and a PhD, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. In the opposing corner, pointing out the utility from the host's perspective of consuming valuable inspection time in the conference room with briefings and coffee breaks, Inspection Veteran 3, trial inspection observer and mock inspection participant; Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Finally, it must be noted that in the United States, Occupational Safety and Health Administration and state regulations, as well as legal considerations dictate that operators present appropriate "safety" information to visitors before they enter a plant. Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000.

[20] Agreeing that inspectors must abide by all host facility safety rules, Defense Contractor 2, principal research scientist; Defense Contractor 5, director of microbiology and special government projects, 28 August 2000.

[21] Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[22] Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000.

personnel was that the inspectors sign a confidentiality agreement, just as all site visitors do. This requirement should exist regardless of any confidentiality oath that the inspectors may have taken upon being hired, and it would be needed to elicit anything other than the most begrudging cooperation on the part of industry sites.[23] The industry group also requested that the US government take steps to help protect their intellectual property rights by screening out any inspectors from countries that have not signed the Patent Cooperation Treaty.

Industry experts stated that the effectiveness of a site tour would be significantly affected if the inspectors were not able to conduct it with certain site maps and diagrams in hand. In that regard, they underlined the importance of requiring the plant to give the inspectors the floor layout, the architectural diagram, the as-built engineering diagram, and the piping and instrumentation diagram (PID). Having such diagrams would allow the inspectors to get a feeling for whether the facility made sense for its stated purpose, and whether it flowed meaningfully from place to place.[24] These blueprints would also let the inspectors know whether their hosts were steering them away from certain areas during the tour or taking them to the places they were supposed to see. Additionally, these diagrams would allow inspectors to determine whether equipment was missing and pipes were connected in the right sequence, welded appropriately, and headed where they should.[25] The as-built diagram would facilitate an evaluation of whether the buildings and equipment were constructed as stated or with materials that exceeded the requirements for the kind of production supposedly taking place.[26] Any modifications from the as-built

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[23] "Cooperation is simply not going to happen unless there is a real strong sense on our side that there's going to be strict confidentiality." Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000. Even with such an agreement, industry representatives were skeptical that their companies would have any legal or fiscal recourse should international inspectors break their confidentiality pledges. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000. The inspectors would also be asked to sign a general indemnification waiver that holds the host facility harmless for whatever happens while they are on site. The experts from the defense contractor group also sought confidentiality assurances other than a generic pledge that might be made to a BWC inspectorate. Loss of confidential business data "would be a disaster. All we have is our intellectual property." Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000.

[24] Dr. George Pierce, former manager, technology development and engineering, Cytech Industries; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. The additional utility of these diagrams lies in the fact that making dummy sets of PIDs would be difficult. Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[25] Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000. "In Russia, there was no aerosolization equipment anywhere. It was a glaring omission. Pipes were still coming out of the wall, but there was no equipment." Inspection Veteran 8, trilateral and trial inspector, 27 April 2000.

[26] Like any industry, pharmaceutical manufacturers watch production costs. In other words, it would not make sense financially for a plant to employ glass-lined reactors for a cell production process. Top-of-the-line construction materials could be explained if a facility were used for multiple purposes or another type of product had previously been made there. Such explanations could be documented. Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000.

diagram (e.g., walls around equipment, interior air locks, unusual devices), the group emphasized, should require an explanation.[27]

As they make their way around the facility, the PID and as-built diagrams would enable the inspectors to locate and account for key pieces of equipment (e.g., milling, autoclaves, spray and freeze driers, aerosolizers) ensuring that items were where they were supposed to be and that important pieces were not missing.[28] Some of these items would be out of place for the production of certain products, so the inspectors should question their presence, especially if there was no recovery process upstream.[29] Some industry experts thought that the inspectors should pin down the location of every autoclave in the facility, especially in the purification area.[30] Later, when they are reviewing documents, the inspectors should cross-match what they have seen with the equipment list as a double-check against hidden equipment.[31] With regard to the equipment and piping setup, the inspectors should be attentive to the mobility factor, whether mobile equipment is suitable for the plant's stated purposes and if pipe connections are hard or breakable.[32]

When inspectors come across freezers around the site, the industry brainstormers advised them not to over-react if they found a few unusual microorganisms among the freezer contents. Some strains might be there for research and development as opposed to production purposes, others might be forgotten from previous projects, and still others might have been left there by a staffer who forgot to tell colleagues.[33] Having said that, discovering a super virulent strain at a facility claiming to produce

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[27] Dr. Robert Hamilton and Industry Expert 2 provided the examples, and the group seconded the point.

[28] Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000.

[29] Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[30] Concern should arise, they noted, if autoclaves in that area were being employed to purify recombinant protein. Industry Expert 4; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Industry Expert 4 is president and chief executive officer of a small US biotechnology company and holds a PhD in microbiology.

[31] Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[32] Common wisdom holds that cheaters would stash possibly incriminating pieces of equipment off site during an inspection and re-insert them later. However, a mobile setup would not be unusual for a commercial facility making multiple products. Dr. George Pierce, former manager, technology development and engineering, Cytech Industries; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000. The above-mentioned site diagrams and other documentation should help back up an explanation of legitimate mobile commercial plant. In a multipurpose facility, "everything is an open setup—the same piece of equipment might move around to ten different locations and do ten different things. We don't do anything dedicated anymore." Inspection Veteran 1, facility manager and US trial inspection host, 27 April 2000. Inspection Veteran 1 was a principal host of a US trial inspection held in late March 1996 at three facilities located in Albuquerque, New Mexico.

[33] Like their counterparts in other fields who have masses of outdated files, it would appear that pharmaceutical workers do not clean their freezers regularly. Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Note that it may be difficult to cross-check explanations for all

vaccine should raise eyebrows.[34] The level of containment present may provide clues to a facility's intent for questionable strains.[35] Also, plant managers should be able to describe why they had such strains and provide supporting documentation, such as the grant information and batch records that show that the number and size of lots is consistent with that scope of work.[36]

After some discussion, the group concluded that inspectors should not be disturbed by large scale capacity, even if such capacity were in a high-level containment setting. Capacity per se was not the issue, but rather whether that capacity made sense for what the facility claimed to be doing.[37] Other matters that deserved to catch the attention of inspectors included the partitioning of reactors, air-handling systems, water cooling systems, and the like when the product(s) being made did not call for such measures.[38] Another sure-fire attention-grabber would be excessive containment.[39] Also in the look closely category would be a purification capability appropriate for the declared product(s). Missing tests

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questionable strains with outside organizations like the American Type Culture Collection or the National Collection of Type Cultures because personnel may have gotten a strain informally from a colleague. Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[34] In that setting, one would expect to find an attenuated strain, but one participant noted that something like an E-coli O1H5787 strain should be questioned. Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[35] Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[36] An example of an explanation might be that pandemic strains of influenza were present due to vaccine work for the World Health Organization. Documentation would be redacted to protect confidential business information. Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Agreeing that records can be redacted and pointing out that many facilities are used to having their records reviewed, Inspection Veteran 5, participant in two US trial inspections and a mock inspection, 27 April 2000. According to Inspection Veteran 3, US regulatory inspectors retrieve "every piece of documentation they can possibly get at." On the need to redact carefully, lest a biodefense site reveal unthinkingly crucial national security information: Inspection Veteran 8, trilateral and trial inspector; Inspection Veteran 2, trial inspection observer and mock inspection participant, 27 April 2000. Inspection Veteran 2 participated in inspections under the 1992 trilateral agreement, took part in a series of round robin mock inspections at military facilities in the western United States, and engaged in background planning for the mock visit to the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[37] One participant called this "the Goldilocks phenomenon. It's got to be just right." Industry Expert 4, president and chief executive officer, small US biotechnology company, 23 August 2000. Industry Expert 2 made a similar statement and the group concurred.

[38] As one brainstormer put it, "If they start to partition too much stuff, they had better have a good story for that." Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000. Operators for a single-use manufacturing plant, for instance, would not ordinarily partition multiple reactors. Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[39] Constructing high-level containment capacity is an expensive endeavor, so businesses would not do so unless product manufacturing requirements mandated it. Members of the industry group also observed that since some governments (e.g., Iraq) have conducted biowarfare research and production activities without the benefit of stringent containment, lack of high-level containment or a level of containment consistent with a facility's stated purposes would not automatically indicate an above-board operation. If the inspectors suspect that higher containment work is being done in a site that may appear to have that capability, one defense contractor recommended going to the roof to check for high efficiency particulate air (HEPA) filtration ducts. Defense Contractor 1, staff scientist in biotechnology, 28 August 2000. Defense Contractor 1, a scientist at a large research contractor, has an MA in cellular and molecular biology.

and purification steps would be peculiar, to say the least, for an industry facility supposedly concerned about product integrity and quality.[40] In the purification area, inspectors would want to check whether the containment setting was markedly out of step for the product(s)—unusually high containment for an animal vaccine or oddly low containment for a pharmaceutical for human consumption.[41]

Things to watch for in the warehouse and other storage areas would include unlabelled supplies, unusual supplies, or large inventories of certain supplies (e.g., antibiotics). Stocks of high efficiency particulate air (HEPA) filters, gowns, and disinfectant should be in line with the facility's declared activities and operational status.[42] With regard to media, the inspectors should be attuned not just to surplus quantities, but to the presence of media that was out of place, such as specialty media (e.g., oxide beef broth) not called for by the stated product(s).[43] The group explained that whereas the inspectors would probably see smaller inventories because of a just-in-time supply philosophy in Western, European, and Asian countries, in other parts of the globe they could see huge supply backlogs.

One of the areas not to be missed during the tour would be the waste handling system, the design, construction, and operation of which should fit with what was needed to inactivate and treat the organism(s) and other wastes supposedly generated at the facility. Inspectors should be puzzled if a plant that declared it was making nontoxic waste with no biologic activity had procedures, equipment, and chemicals in place to treat hazardous wastes.[44] Inspectors should also consider what wastes were being funneled into the treatment system. For instance, it would be odd if liquid waste from all phases of the production process were sent there, particularly from purification and formulation areas.[45]

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[40] Purification processes are costly and not needed for weapons manufacture, so some industry experts felt that cheaters could be tripped up in this area. Dr. George Pierce, former manager, technology development and engineering, Cytech Industries; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000. Or, as another brainstormer noted, a smart proliferator could spend the extra money to purify a biological agent. Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[41] Note that to safeguard against contamination, the downstream processing of some products is accomplished under high containment. The regulatory requirements can help inspectors determine whether the containment is excessive. In some countries, however, containment standards may not be uniformly maintained. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[42] Inventories would be larger for a three-shift operation than for a day-only operation. Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[43] Specialty media is expensive, so a cost-conscious manufacturer would not use it unless necessary. Eggs were singled out as possibly of concern if they were being employed in a complete containment setting as opposed to clean, class 100 conditions. Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[44] To illustrate, a large inventory of an expensive chemical like sodium hydroxide would be superfluous under these circumstances and could betray an effort to mask trace waste. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000.

[45] Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Robert Zagursky, distinguished

If present, another area that should receive close scrutiny would be an animal facility. The higher the species of animal and the more animals present, the harder the inspectors should look, especially if the animals are being kept isolated in individual, negative air flow chambers. Justification for a primate facility, the industry group agreed, would have to be crystal clear. "There's no reason why they should have a primate facility there unless they can prove that they're using it for some downstream testing of the product. And only then, the number of animals there would have to be consistent with the protocol."[46] Industry group members agreed that deciphering the real purpose of an animal facility might be difficult for inspectors because they would be highly unlikely to allow outsiders into that area, given the risk of contamination.[47] If this sector of the plant had video surveillance, inspectors may be able to view certain parts of it remotely. Or, one or two inspectors as opposed to the entire contingent might be allowed in some rooms. If these options were not acceptable, the inspectors could answer some questions through documentation (e.g., animal pathology records) and supplemental interviews with the personnel from the organizations that would certify the facility for animal work, the American Association for the Advancement of Laboratory Animal Care. Should such activities prove inconclusive, a complete tour of this area might be scheduled for a time when there is a break in the testing process.[48]

The industry group identified a few other types of activities that, if observed, would alert them to possible foul play. For instance, they would be wary if while on the premises they saw:

- an inordinately high number of paper shredders or controlled copy machines;[49]
- evidence of recent demolition activity;[50]

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research scientist, Wyeth-Lederle Vaccines, 23 August 2000.

[46] Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000. Also, Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000. Note that commercial plants would try to keep the number of primates involved to a minimum because they are very expensive. Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000. Large animal facilities are more frequently located near production facilities overseas than they are in the United States. Also, the quality of animals may vary significantly from country to country.

[47] Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000.

[48] Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000. Industry group members were willing to release some animal modeling data, of course redacted to protect trade secrets, to answer inspectors general questions about their animal facilities. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Industry Expert 4, president and chief executive officer, small US biotechnology company, 23 August 2000.

[49] While it is normal for a commercial facility to have a few shredders and controlled copiers around to safeguard its proprietary data, a swarm of such machines would be out of place and perhaps indicative of very strong precautions in place to prevent people from sneaking data out of a covert military site. Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000.

[50] Recently destroyed buildings or bulldozed ground could indicate an effort to bury contaminated evidence. Plant

- on-site housing and a preponderance of unmarried workers;[51]
- strange or excessive food and waste handling procedures in the cafeteria; [52]or,
- a medical facility that was unusually large, had isolation capacity, was stocked with certain medications (e.g., a specific immunoglobulin), or had a morgue attached to it.[53]

Such capabilities or activities would appear even more suspect if security measures were being taken that seemed excessive for a commercial enterprise.[54] Heightened security is one of the hallmarks of military facilities.

Facility layout, capabilities, and equipment should not be the only matters to come under the watchful eye of inspectors during the tour. According to the industry group, it would be very telling to view the plant's staff performing their daily activities. Were they to see personnel use stringent precautions while working with a nonpathogenic, bacterial agent, it could indicate that they were more accustomed to tissue culture or other high-level containment work. Another telltale sign of personnel quickly pulled from high-level containment to lower precaution work would be dermatitis on the hands, a skin condition that can be caused by wearing protective gloves. Observing the staff go through their degowning procedures could also reveal some peculiarities for the type of product supposedly being

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managers should be able to explain any demolition activity and back that up with documentation that it was planned. Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[51] Note that in some countries, on-site housing could be a benefit of employment. However, pharmaceutical and biotechnology workers are usually very well paid and could afford off-site housing. Therefore, such arrangements could be precautions against the spread of infectious disease to spouses or children or others outside of the compound. Industry Expert 2, senior vice president, US biopharmaceutical company; Industry Expert 4, president and chief executive officer, small US biotechnology company, 23 August 2000.

[52] Note that an examination of operational documents might also uncover such procedures if the cafeteria were not in operation. Dr. George Pierce, former manager, technology development and engineering, Cytech Industries; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[53] Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000.

[54] Aside from an unusually high number or guards, extra security around product or ingredient materials should be noted. Such measures would exceed normal security at a site manufacturing ethical pharmaceuticals or at a containment or animal facility. Dr. George Pierce, former manager, technology development and engineering, Cytech Industries; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000. Prior to the inspection, satellite imagery could also reveal unusual external security measures, such as double fences and clear zones. Such imagery would also show whether a military installation was located nearby, which might also raise suspicion. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. George Pierce, former manager, technology development and engineering, Cytech Industries; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000. Security for many Western plants is handled by third party contractors, so facility managers may have to forward some inspectors' inquiries about these matters to their contractors.

made.[55] In all sectors of the plant, personnel would be executing their tasks and standard operating procedures (SOPs) smoothly if they are doing what they are accustomed to instead of putting on some type of masquerade. Should the inspectors note awkwardness, they might ask later to see staff perform certain SOPs. As one industry brainstormer stated, "it can become very apparent very fast that these people are not trained, that they are not used to doing this operation."[56] For this reason, the industry group widely endorsed the idea of just observing the staff go through their paces.

As for their reaction were they on the receiving end of this type of inspection, members of the industry group stated that they would willingly show inspectors practically all of their facilities. However, they could think of a few justifiable reasons not to take inspectors into each and every building or room.[57] For instance, a room may contain proprietary processes or a dilapidated building may be closed for safety reasons, prior to demolition. In some areas, they would opt to shroud sensitive equipment and the attached piping but leave the rest of the room open to view.[58] Defense contractors would take similar steps, as Insights 4.3 describes. For areas where they would not be able to provide visual access, the industry group

Insights 4.3

Although edgy about having international inspectors in their midst, defense contractors said they would shroud extensively to shield equipment under development and that for proprietary reasons would deny any access at all to certain areas of their sites.[1] One of the contractors had hosted a Chemical Weapons Convention inspection and stated that the inspectors accepted it when his company declined to let them to look in certain biosafety hoods because proprietary items were inside. He doubted, however, that denial of access to an entire building would fly with inspectors.[2]

NOTES

[1] Defense Contractor 1, staff scientist in biotechnology; Defense Contractor 7, president and founder of a small sensor development company; Defense Contractor 2, principal research scientist, 28 August 2000. Defense Contractor 1, a scientist at a large research contractor, has an MA in cellular and molecular biology. Defense Contractor 7 has a PhD in microbiology. Defense Contractor 2, a scientist at a medical research facility, is a veterinarian and a PhD microbiologist. For one defense contractor, however, the thought of taking inspectors anywhere other than a conference room was very unsettling. Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company, 28 August 2000. Defense Contractor 6 has over fifteen years of experience in molecular genetics.

[2] Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000. Defense Contractor 4 has a PhD in chemical engineering.

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[55] For example, the disinfectants used might be incongruous for the declared setting. A large number of workers sporting bleached hair might also indicate something was amiss. Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000.

[56] Continued this individual, running through SOPs is "just like any other physical thing. The more someone does it, the better they get at it," so lack of skills would be evident. Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. A defense contractor was also of the opinion that a laboratory technician should be comfortable answering a question about why, for example, a huge jar of cystine is sitting over there. "They're the ones who should know, and if they prevaricate," then it should be noted. Defense Contractor 1, staff scientist in biotechnology, 28 August 2000.

[57] In the same vein, on showing the inspectors what they came to see, but not everything: Inspection Veteran 5, participant in two US trial inspections and a mock inspection, 27 April 2000.

[58] Industry Expert 2 made this statement, and the group nodded in agreement. During a Chemical Weapons Convention inspection of an industry site that performs defense research under contract, the laboratory's managers shrouded proprietary and sensitive equipment, a practice that the inspectors did not challenge. Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000. The Chemical Weapons Convention specifically permits inspected facilities to

members were confident that they could explain the reasons and give sufficient documentation to allay suspicions. Following the tour or any other entrances into controlled areas of the plant, the industry group sought the right for the facility managers to inspect the inspectors to ensure they had not unintentionally or purposefully acquired proprietary data, including testing residues on shoes and clothing.[59]

While the industry group advocated visual observation as an effective inspection tool, they also pointed out its limitations. Grates could lead to an air drop instead of HEPA filters and pipes through the ceiling could be channeled to a hidden filter. While inspectors can take certain steps to visually ascertain what is going on—going to the roof and counting exhaust stacks in this instance—that would only take them so far.[60] Therefore, the inspectors would have to bolster their visual observations with document reviews and interviews with facility personnel.

ON-SITE MONITORING ACTIVITY: REVIEW OF DOCUMENTS AND RECORDS

One of the fundamental activities that inspectors should undertake to investigate what they saw during the site tour is to review documents and records. The reason that the industry group had strong faith in the utility of a thorough document review was summed up by one participant in the following way: "I personally have believed all along that one of the best things the inspectors can do is detailed auditing of paperwork because if someone's dirty and trying to hide, they can't. No one's that good."[61] When it comes to paperwork, the military and legitimate pharmaceutical companies both document their activities voluminously. Inspectors can take advantage of that fact. Everyone agreed that somewhere along the line, the inconsistencies in paperwork would belie a cheater. Conversely, a paperwork trail that cross-checks well would buttress a legitimate plant's case for a clean bill of health.[62] In box 4.1, the inspection veterans draw upon their experience reviewing records to show why the industry group's faith in this monitoring tool was well placed.

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shroud.

[59] Dr. Robert Hamilton articulated this point to a chorus of agreement from the group.

[60] Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000.

[61] Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Agreeing that it is "harder to hide inconsistencies" in documents and records: Defense Contractor 1, staff scientist in biotechnology, 28 August 2000.

[62] Concurring that a complete absence of records flags a problem, a veteran of visits to former Soviet biowarfare institutes said that there were virtually "no records" there, nothing. Inspection Veteran 8, trilateral and trial inspector; Inspection Veteran 2, trilateral and mock inspection participant, 27 April 2000.

Box 4.1: Veteran Voices on the Examination of Site Records

As one inspection veteran put it, "Records are a very important part of the archaeological dig. They provide an audit trail for people, material, and equipment. Sometimes there will clearly be a mass balance problem."[1] In addition, records can substantiate explanations, as was the case during a 1991 Russian inspection of a US defense facility under the trilateral agreement.[2] At the same time, cautioned another inspection veteran, "records can also be very disorienting" because different facilities and inspectors, depending on their discipline, ascribe different meanings to the terminology in the records.[3] Moreover, a large, multipurpose facility will order all types of supplies for different purposes, so inspectors could come to erroneous conclusions about whether those supplies are being channeled to a covert program or used in legitimate, separate projects.[4] Even though it may take a while to sort them out, one veteran advocated going after the records—especially the shipping and receiving documents—up front during an inspection, instead of at a later point as the United Nations did during the series of inspections at Iraqi biological facilities.[5] Finally, given the increasing tendency of records to be placed in electronic databases, the veterans group urged that the pluses and minuses of that reality be taken into account.[6]

NOTES

[1] Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico.

[2] Sometimes cultural and regulatory differences in the way countries conduct research, development, and testing can be the source of suspicions. The Russians, for example, had a different approach to laboratory animal medicine. "The Russians were convinced that the large number of veterinarians [at this site] indicated a hidden command and control for the institution and that everything else was a front. We used records to prove that regulations require US facilities to have lots of vets." Also on this inspection, host officials were able to use construction and regulatory records to explain why a room at the facility was constructed in a certain manner and salvage and demolition records to document the destruction of a capability shown in an old facility brochure. Inspection Veteran 5, participant in two US trial inspections and a mock inspection, 27 April 2000. Inspection Veteran 5, a PhD scientist, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[3] Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000. Inspection Veteran 9, who has an MD and a PhD, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[4] Inspection Veteran 1, facility manager and US trial inspection host, 27 April 2000. Inspection Veteran 1, a facility manager, was a principal host of a US trial inspection held in late March 1996 at three facilities located in Albuquerque, New Mexico.

[5] Inspection Veteran 7, United Nations Special Commission on Iraq inspector and mock inspection participant, 27 April 2000. Inspection Veteran 7, a PhD scientist, served on several United Nations Special Commission on Iraq missions, was on the host team during the mock inspection at Dugway Proving Ground, Utah, and took part in a follow-on round robin exercise. Shipping and receiving documents enabled the inspectors to piece together the fact that Iraq had imported media far beyond the stated needs of the facilities inspected. United Nations, *Report of the Executive Chairman on the Activities of the Special Commission Established by the Secretary-General Pursuant to Paragraph 9(b)(i) of Resolution 687 (1991*), S/1998/920 (New York: United Nations, 6 October 1998); United Nations, *Report of the Executive Chairman on the Activities of the Special Commission Established by the Secretary-General Pursuant to Paragraph 9(b)(i) of Resolution 687 (1991*), S/1998/920 (New York: United Nations, 16 April 1998); Barton Gellman, "A Futile Game of Hide and Seek; Ritter, UNSCOM Foiled by Saddam's Concealment Strategy," *Washington Post*, 11 October 1998; William Broad and Judith Miller, "The Hunt for the Germs of War—Iraq's Deadliest Arms: Puzzles Breed Fears," *New York Times*, 26 February 1998.

[6] For example, a word search could possibly enable inspectors to locate desired data within seconds. Site managers, however, will have to make careful decisions about how and if to provide inspectors access to such databases, which are likely to contain sensitive information. Host officials could perform the search themselves, providing thereafter appropriately redacted records. Inspection Veteran 3, Inspection Veteran 6, and Inspection Veteran 9 raised these points during discussion. Inspection Veteran 3, who holds a DVM and a PhD, observed the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and participated in the mock trilateral inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. Inspection Veteran 6, a PhD scientist, was on the host team during the mock inspection at the Dugway Proving Ground, Utah, and on the inspection team during the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

Accustomed as they were to having inspectors pore over their records, the industry group did not have much of a problem with handling this aspect of a possible BWC inspection, provided facility-specific confidentiality agreements were in effect. The industry group members said they would adopt a strategy of trying to predict the main questions that the inspectors would ask and have the supporting documentation pulled and ready for review. If the inspectors chose other lines of inquiry, they would do their best to satisfy the requests and in most instances their regulatory affairs staffs could do so quickly. However, some documents may take time to locate and prepare for review. To protect proprietary data, they would redact some documents, heavily if need be.[63] Also, the industry group would show the inspectors just the information that answered their specific questions, putting the onus on the inspectors to ask for additional documentation. Finally, documents given to inspectors should be read only. Unless facility managers gave explicit permission for a specific document to be copied, no plant records should leave the site.[64]

Retrieving documents would be one of the more expensive aspects of hosting an inspection. The industry group members stated that when a trio of Food and Drug Administration inspectors show up, escorting them, finding requested documents, and otherwise answering their inquiries can swallow the time of eight to ten staffers. They estimated that the price tag for preparing for a BWC inspection would be roughly $500,000. They put the manpower costs to host a five-day inspection at $125,000. Therefore, hosting a larger inspection team would be difficult for smaller firms to handle. The industry group would want the US government to cover companies' costs to host BWC inspections.

A genuine manufacturing facility will have a paperwork trail that stretches from beginning to end, with several types of overlapping records. The industry group devised a lengthy roster of documents that inspectors should consult, as shown in table 4.1. All inspectors, it was observed, work from some type of a checklist. The savvy ones keep facility managers guessing to a certain extent, however, by mixing it up, varying the emphasis of their inquiry each time they come through the door.[65]

At the outset, inspectors can survey the ingredients coming into a facility via documents such as purchasing requisitions, receiving documents, disposition and warehousing records, and the bill of materials, which lists every ingredient used to manufacture product(s) at the facility. Comparing these documents, the inspectors can tell what kinds and amounts of materials the facility is regularly receiving

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[63] At defense facilities, one of the true difficulties about parsing the records is the classification level. Inspection Veteran 8, trilateral and trial inspector, 27 April 2000.

[64] Dr. Steven Projan, Dr. Robert Zagursky, and Industry Expert 2 voiced this strategy and the group as a whole concurred.

[65] The group chuckled at the common practice of telephoning each other to find out what inspectors had been focusing on in the last go-around. With so much to examine, the inspectors could keep them on their toes just by shifting their focus from one area to another.

and whether items are being ordered in types and quantities other than what is needed to make the stated product(s).[66] The inspectors might want to look especially closely at the numbers of personal protective equipment and other biosafety items that the site is consuming.[67] More detailed paperwork on the media, namely the material safety data sheets and the paperwork that certifies the media being used, should also be available in plants operating in many countries.[68]

Table 4.1: Documents for Inspectors to Review

bills of materials	billing documents
purchasing requisitions	sales/shipping records
receiving documents	site map
disposition information	piping and instrumentation diagrams
patents	as-built diagrams
strain list	airflow diagrams
material safety data sheets or equivalent	visitor logs
media qualification paperwork	equipment list
logs (equipment, activity, cleaning)	equipment calibration records
quality control paperwork (material lists/SOPs)	staff list with job titles/organizational chart
batch records	product release tests
timesheets	gate records

Another set of records that the industry group believed would be very important for the inspectors to look into would be the logbooks that record who is coming and going from the site. A legitimate business would receive a certain number of outsiders. Visitor logs, however, might reveal oddly low levels of traffic at the site, callers from the military or who had expertise that might be of concern, or more routine traffic from maintenance contractors, business partners, and regulatory inspectors. Such data points could be quite helpful in facilitating inspectors' efforts to determine what is happening at a site.[69] For instance, a site engaged in covert activity would probably do its maintenance work in-house, but

[66] Indeed, these records can reveal a lot, such as "what kind of reagents they're ordering, how much. So if they are a small facility that is ordering thousands of trypticase soy agar plates and huge quantities of growth media, then what is that all about?" Defense Contractor 2 to widespread agreement from the other contractors.

[67] Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Note that some participants had no problem revealing the ingredients that they use for their product, of course leaving formulas and specific amounts off limits. Since their processes were not patent protected, others would have to redact the bill of materials and receiving documents to hide the identity of the companies that ship them goods as well as the type of media used. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[68] This point was brought up by Dr. Steven Projan and agreed by the whole group.

[69] Dr. George Pierce, Dr. Robert Hamilton, and Industry Expert 2 articulated these points, which the whole group then acknowledged as important. A couple of the participants observed that a few log entries might need to be redacted to mask the identities of possible joint venture partners. Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Also, it was noted that some contractors did not make routine visits because they worked on an as-needed basis. Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

many commercial plants employ outside contractors for all manner of maintenance and other tasks (e.g., site security).[70]

The pace of the facility's manufacturing activities can be traced through activity, equipment, and cleaning logs. Batch records, for instance, will show how much product was processed within certain time periods, which can be checked against ingredient inventory levels and the list of products that a facility manufactures at every step.[71] Since normal plants do not operate perfectly, inspectors should see records of deviations as well as investigations at the plant.[72] In a similar vein, inspectors can learn about the tempo of plant operations by looking through the engineering control records for biosafety cabinets, high efficiency particulate air filters, autoclaves, and decontamination operations as well as the hazards operations evaluation documents.[73] Moreover, equipment in certain areas of the facility will generate pressure and temperature data, which inspectors should review to see that trends correspond to the manufacture of the stated product(s).[74] A site's operations can also be explored through equipment validation and calibration records. For instance, equipment is routinely calibrated, but inspectors should be sensitive to the possibility that plant managers trying to rig an inspection would recalibrate equipment to give false readings just before the arrival of the inspection team.[75]

Another area of documentation rich with helpful data would be the records related to personnel management. A review of the organizational charts would show whether staff ratios in different departments were reasonable for a facility's stated activity. To see one quality control staffer for every thirty individuals in manufacturing would be a peculiar ratio in the West.[76] Training records should

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[70] Although reliance on contractors is quite prevalent in the West, this may not necessarily be the case in the developing world. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[71] Also, note that overseas, some companies generate extensive analyses of their processes to compare them with manufacturers in other countries using different raw materials. Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[72] Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[73] Note that documentation related to HEPA filter changes would help the inspectors understand some things they may not be able to observe. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Allen I. Laskin, president, Laskin/Lawrence Associates; Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000.

[74] Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[75] If records showed recent calibration, inspectors should examine the nature of the changes carefully. The group as a whole emphasized the importance of calibration records. Standards requiring equipment validation would differ from country to country, but normally some type of document would indicate whether equipment had passed negative pressure tests, which would be strange if there was no apparent need for negative pressure operation. Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[76] Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Note that organizational charts can be highly confidential because job titles and organizational set ups and titles can tell outsiders a lot about what a

conform with the facility's stated activities, and personnel turnover rates should be within the expected range for the industry in that country.[77]

A manufacturing plant will have a raft of SOPs that inspectors can peruse for consistency or lack thereof with a plant's stated activities. A facility purportedly working with innocuous microorganisms would need to explain why it was employing SOPs that would require seed cultures to be handled under high-containment conditions.[78] Looking through the SOPs for a manufacturing process that ordinarily requires a "kill step" after fermentation (e.g., bacterial vaccines), inspectors should wonder if those SOPs do not show one. In the biosafety arena, SOPs for emergency response should match the kind of microorganisms the plant has declared.

The industry group underscored that SOPs for quality control testing should be examined to see whether the tests being run make sense for the product(s) the plant is supposed to manufacture. Products using bacteria, for example, should be tested for endotoxins (i.e., lipopolysaccharide) and pyrogens. If something appears out of order to the inspectors, these SOPs should be cross-matched against the list of quality control supplies and raw test data, which in and of itself constitutes a huge paper trail. The lot release test records would also contain lot numbers that can be put side by side with batch records as well as product specifications. Faking this cross-cutting documentation would be no easy task.[79] Should the inspectors have reason to believe commercial goods are not normally coming off the line, they can study the product billing, sales, and shipping records.[80]

Again, the beauty of having a wealth of documentation is that inspectors worried that something may be awry can compare various items against each other. Should the inspectors sense that a plant is really working around the clock instead of fielding just a day shift, they can pull gate records and timesheets.[81] These items can be checked against utility expenditure documents (e.g., energy, water),

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facility is doing. Therefore, industry group members indicated they would alter these documents would to only contain generalized titles and redact them in some areas. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Dr. George Pierce, former manager, technology development and engineering, Cytech Industries; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[77] A controlled workforce would have abnormally low or no turnover. The first point was made by Industry Expert 2, the second by Dr. Steven Projan.

[78] Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[79] Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000.

[80] Sales and shipping records are highly sensitive, so the industry group suggested the inspectors not ask for them unless necessary. If they were requested, plant managers would respond best to a specific inquiry that would enable them to provide a slice of data. Industry Expert 2, senior vice president, US biopharmaceutical company; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[81] Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000.

airflow diagrams, and heating, ventilation and air conditioning maintenance records, among other things. Utility bills and filter changes would need to be in line with the number of shifts the plant says it is running.[82] Inspectors could cross-check visitor logs with service contracts, and if need be, subsequently interview contract personnel to confirm the nature of their activity on site. Inspectors that believe they have been fed a cover story can request project proposals and reports, service contracts, Institutional Animal Care and Use Committee documents, and records from internal review committees that govern project approval, biosafety, and waste management.

ON-SITE MONITORING ACTIVITIES: INTERVIEWS

Following a site tour and a thorough review of documents, inspectors should have a good idea of what questions, if any, they would like to pose to the facility's personnel. Ideally, key people in each division would be made available for interviews, and the industry group noted that it would be a bad omen if all of the key people at a site were conveniently out of town on vacation or "business" when the inspectors arrived.[83] Aside from senior personnel, the industry group strongly encouraged the inspectors to speak with the rank and file. The thrust of those interviews would be to find out whether the worker bees really know how to operate the facility, to have them run through their own SOPs if inspectors believe something is amiss. Personnel at a *bona fide* facility would have a solid understanding of their own processes and SOPs. If not, that knowledge gap should be patently clear to inspectors experienced in commercial operations.[84] Or, as another industry group member said, "It always helps an inspector if basically the person convicts themselves" by contradicting during an interview what is in a plant's SOPs, historical production records, or open source data about the facility.[85] Nervousness could account for a fumble or two during interviews, but if individuals in the waste management, post-production, biosafety, and other divisions cannot confidently and comfortably relay information about the tasks they are supposed to perform regularly, then the inspectors would have sound grounds to believe something suspect was happening. For this reason, the industry group as a whole stated that staff interviews would allow the inspectors to gain significant insight into a facility's true status.

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[82] "If they're pumping a lot of air and have a lot of water flow, that will tell you something." Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000. Note that inspectors would also need to calculate what effect local climatic conditions would have on energy usage. Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000. Seconding the idea that looking at power consumption would be a sound investigative course, but warning that the inspectors would need to be well-versed in the energy use requirements of industry versus weapons production sites: Defense Contractor 3, senior technical adviser, 28 August 2000.

[83] Dr. George Pierce made this comment, which the group followed with a chorus of groans and assents.

[84] Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[85] Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000.

When it came to the prospect of having BWC inspectors interview their personnel, aside from the time sink involved, members of the industry group were quite nonplussed. Some companies have formal training to teach staffers how to respond to inspectors' questions. If that were not the case, a facility's managers would probably talk to staff beforehand to acquaint them with the context of the inspection and let them know the types of questions that they should and should not answer. In the latter category, personnel would be instructed to follow standard house rules not to reveal propriety data.[86] The major guideline that the industry group wanted in place for interviews was that a senior plant manager be present during all interviews to guard against improper fishing expeditions on the part of the inspectors. The inspectors would be welcome to ask about SOPs and other operational issues pertinent to plant operations, but pressing for confidential business data would be out of bounds and the manager would have the right to intervene should inspectors do so.[87]

If the inspectors are getting mixed signals from interviews, documents, and visual observation, they could opt to pursue matters further by seeking out and interviewing ex-employees, contractors, neighbors, and other entities that supposedly work with the facility in question (e.g., Institutional Animal Care and Use Committees, American Type Culture Collection). Unless they volunteer to locate such individuals, the facility's managers should be under no obligation to help the inspectors with outside interviews. Also, the inspectors should be conscious of the possibility that ex-employees might hold a grudge and neighbors might simply speculate about activities behind the fence. Inspectors would need to consider such factors when they evaluate what outsiders and ex-employees had to say about the site.[88] Although seeking out such outside interviews would be a logistical burden and some interviews could be tainted, the industry group believed that inspectors grappling with ambiguities about a site's status should not pass up opportunities to gain additional perspective on a questionable facility.

ON-SITE MONITORING ACTIVITIES: SAMPLING AND IDENTIFICATION

Sampling is often thought of as an ace in the inspector's toolkit.[89] This viewpoint certainly came out in the course of the industry group's discussion. To that effect, one industry brainstormer simply said: "If the inspectors can get a sample—any kind—they should take it."[90] Theoretically, all manner of

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[86] Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[87] Industry Expert 2 stated this ground rule, to which the rest of the group heartily agreed.

[88] Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[89] "Data can still be picked up after a room is decontaminated. Studies have been done to that effect." Inspection Veteran 6, member of host and inspection teams during two mock inspections, 27 April 2000. Inspection Veteran 6, a PhD scientist, was on the host team during the mock inspection at the Dugway Proving Ground, Utah, and on the inspection team during the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[90] Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

samples could be taken at a site to enable inspectors to pinpoint whether microorganisms of concern are present.[91] In practice, however, the industry brainstormers expected commercial firms to give only one type of sample without much, if any, hesitation, namely a final product sample. As one participant said, "every ethical company will happily give inspectors a sample of their final product that can be tested to specifications to verify" legitimacy in an appropriate laboratory.[92] A final product sample would be the only type of sample that does not raise the specter of losing proprietary, extremely valuable business data. Understandably, therefore, the industry group approached the prospect of other types of sampling with considerable trepidation. Despite their concerns, their discussion of this topic also showed creativity and willingness to craft sampling and analysis ground rules that would satisfy the needs of inspectors and host facilities alike.

As a matter of fact, the industry brainstormers proposed a set of ground rules for sampling and analysis that they believed was feasible and should be acceptable to their colleagues in industry. Their ground rules and rationale are summarized below, and the meat of their discussion on this tough topic is presented verbatim in box 4.2 at the end of this chapter. The first governing principle would be that due to its intrusiveness, sampling should be a tool of challenge inspections unless the industry facility volunteered a sample under other circumstances. Second, the inspectors should have the right to request samples, and the host facility the right to refuse that request. Members of the group differed on what factors would influence a company's decision to accept or reject a sample request.[93] Insights 4.4 relates the factors that one of the inspection veterans considered when faced with this decision. Third, if samples were in order, they should be taken by facility staff or a third party with proven skills on the first day of the inspection.[94] The sampling techniques would be pre-stated with protocols that are based on accepted practice for different sample types (e.g., air, water, wipe, other medium).[95] The sample should be split

[91] Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000.

[92] Quote from Industry Expert 2, and the group agreed to this principle.

[93] During the 23 August 2000 meeting, Dr. Robert Hamilton thought that a company's decision would "probably depend on how serious they thought the allegations were and whether they thought the inspectors had the wrong image [about their plant] for some reason." Industry Expert 2 believed that large companies with decades of ethical behavior would reject a sample request because they would bet that their company's stock would not plummet due to an unsubstantiated allegation concerning bioweapons work. Such an allegation would torpedo the stock of a small biotech firm, however, so a smaller company would take the risk to try to clear its name. Dr. Robert Zagursky stated that the size of the company involved would not matter because even the big companies are sensitive to bad press.

[94] Otherwise, as Dr. Steven Projan stated, the industry group believed that a weapons producer would flush their system and get rid of evidence. Though defense contractors viewed sampling as being of particularly low utility on their sites, one contractor said that if samples were taken he would also want to conduct their own analysis. Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000.

[95] "Appropriate steps have to be taken to preserve the samples. Part of the puzzle has been solved, such as how to provide a sterile environment and temperature guidelines, but there is still work to be done. Refrigeration would help maximize the sample. More research and testing is definitely needed, confirmed in various field conditions." Inspection Veteran 6, member of host and inspection teams during two mock inspections, 27 April 2000. The industry group suggested that several accepted sampling practices might be the basis for these protocols, including the Environmental Protection Agency's certified

into blind or double blind sets for the inspectors and the host site and subsequently held in a lock box on site.

If the inspectors were able to conclude their work and resolve their concerns without analysis of the samples, then the host facility would have the right to destroy the samples. In the event that the investigation needed to proceed to analysis to resolve ambiguities, the analytical test(s) performed on the sample(s) would have to be prevalidated, with false positive rates articulated.[96] One industry group member noted that the inspectors might be able to employ a portable riboprinter that can speciate bacterial strains within eight hours.[97] Preparing the assays for other samples would be a lengthy process, but the industry group reasoned that running unvalidated assays would not be scientifically credible and might not even catch a cheater. Once validated assays were available, the samples would be taken from the dual key lock box and preferably analyzed on site under the watchful eye of inspectors.[98] Another, less desirable option would be to ship the samples under pre-agreed chain of custody procedures to certified third-party laboratories that are routinely tested for competency. In that case, the plant would have the right to have its personnel observe the analytical work from start to finish.[99]

Insights 4.4

The decision to allow samples to be taken is not easily made. One individual who hosted a US BWC trial described his deliberations in the following terms: "I was torn because sampling was the only way I could prove I was clean and wasn't using all of that [equipment] for biowarfare purposes. In theory, it might give me a clean bill of health. I weighed that against the possibility of them finding one little organism, in which case I'm probably worse off than before they sampled. In the best of all worlds, sampling would prove guilt or innocence."[1]

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[1] Inspection Veteran 1, facility manager and US trial inspection host, 27 April 2000. Inspection Veteran 1, a facility manager, was a principal host of a US trial inspection held in late March 1996 at three facilities located in Albuquerque, New Mexico.

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samples for environmental chemicals, US Pharmacopoeia, the Association of Official Analytical Chemists, the American Society for Testing Materials, and Standard Methods for Water and Wastewater Analysis.

[96] The industry group estimated that four or five years would be needed to develop, test, and validate the assays to be used. The assay could probably be 75 percent validated based on laboratory studies, with the remaining 25 percent of the validation pertaining to ruggedness and reproducibility. Both the inspectorate and the host company should accept the data, which would be subsequently tested. If the BWC protocol was activated prior to the validation of assays, samples would be stored according to a pre-stated storage protocol until the validated tests were available.

[97] Dupont makes a riboprinter, which performs automated southern blotting to break down and identify a sample. Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000.

[98] In the interim until the assays were ready, the industry group also considered the possibility that an agreed third party could store the samples, using the appropriate chain of custody and storage protocols.

[99] "Without a doubt, whether it is done on site or at a contract laboratory, I'm going to have one of my technical experts in that lab watching exactly how the samples are handled, making sure that all the necessary positive and negative controls are run, and that the tests are being run appropriately because it's too sensitive of an issue." Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Also, the group stated that a set of samples should always be archived at an agreed central repository in case a re-test was needed. The company could request another test if the wrong assay was used. Also, the company could generate its own test in an effort to clear itself of any allegations.

Aside from a final product sample, the other types of samples that might be taken at a manufacturing plant include samples from points along the production process, from the waste treatment system, from personnel or test animals, and from the other general surface locations inside or outside the fence. Ordinarily, many of the pieces of equipment along the production cycle are equipped with sampling ports.[100] Indeed, a plant that claims to be making vaccine or biopharmaceuticals but does not have multiple sampling access points within its production process should automatically provoke questions from the inspectors.[101]

Unanimously, the industry group agreed that the waste treatment system would be an ideal location if samples were needed to unscramble a facility's true nature. A sample of waste, as one industry brainstormer observed, "tells all lies right there. Just because something doesn't grow doesn't mean that the telltale signs of that organism are not still present, and the best way to figure that out is to sample the waste."[102] The filters in the waste handling system, everyone agreed, would be truly revealing, and taking a sample from those filters would be an extremely sensitive matter for that very reason.[103] As for whether companies would grant permission for such samples, one industry group participant did not think that his facility would have a problem providing a waste sample. Even before doing so, however, this individual would still try to answer the inspectors' questions by showing them documentation that outside organizations had certified the waste to be clean.[104] Other industry group members objected to any sample other than from a final product unless validated tests and other guidelines discussed above were in force. Their concerns stemmed from the possible damage to their company's public image if a false positive indicating bioweapons manufacture resulted from an unvalidated test.

Even though the group considered sampling as a possibly definitive inspection strategy, the prospect of taking blood or other fluid samples from animals or personnel at a facility was truly unsettling for the industry group. Prevailing opinion held that commercial firms would flatly refuse animal samples because of the potential to compromise proprietary data.[105] Samples from personnel run up against the same dilemma—powerful investigation tool versus powerful potential to reveal proprietary data. Because of the latter circumstance, they argued that such samples be considered a tool of "last resort," to be

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[100] In some plants, some of these sampling processes are automated. Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm, 23 August 2000.

[101] Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[102] Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000.

[103] Aside from waste treatment and high efficiency particulate air filters, the industry group identified drains, sewage, garbage, and gloves as possible sampling locations.

[104] Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines, 23 August 2000.

[105] In addition to blood samples, the industry group discussed sampling fecal matter and concluded such sampling for antibodies there would be similarly problematic.

employed only when there were really serious concerns of illegal activity.[106] Members of the industry group suggested that as an alternative some medical records might be made available to inspectors, but that would depend on company policy and whether the individual(s) involved viewed the release of such data as infringing on their civil and legal rights.[107] The same provisos applied to permitting blood samples, where some complications might be avoided by masking the identity of the employees giving the samples.

As for the possibility that inspectors would request samples from various surfaces around the plant or from garbage, the industry group stated that even with the precautions that manufacturers use to control the environment, the fact of the matter is that workers or visitors can track or bring anything inside a building. Therefore, such environmental samples could hardly be considered conclusive. General samples from outside of buildings or the fence line would be a similarly unattractive basis for any assessment of a facility's nature.[108]

ON-SITE MONITORING ACTIVITIES: PHOTOGRAPHS, VIDEOTAPES, AND REPORT PREPARATION

The industry experts recognized that inspectors would find it quite useful to document certain things with photographs or videotapes.[109] Not only would photographs and videos provide a record of the inspection that would be difficult to refute, it would allow inspectors to tap into additional expertise within the inspectorate to help determine what a certain setup might represent.[110] The industry group argued that it would be far preferable to host a larger team that incorporated the needed expertise than to permit the inspectors to take photos or videos. The industry group was adamantly opposed to the idea that treaty ground rules would stipulate that inspectors automatically be allowed to take visual records from the premises. The inspection team should have the right to ask if they could take photographs or

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[106] Industry Expert 4 stated this point, and the rest of the group readily agreed. Note that if such blood samples were necessary, the group recommended that they be taken from operational and maintenance workers as opposed to the managers whose duties would make them less likely to have developed antibodies. These samples could also be analyzed to determine if workers had been vaccinated against a disease of concern. Dr. Robert Zagursky, distinguished research scientist, Wyeth-Lederle Vaccines; Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Industry Expert 2, senior vice president, US biopharmaceutical company; Industry Expert 4, president and chief executive officer, small US biotechnology company, 23 August 2000.

[107] Dr. Robert Hamilton, senior scientist and group leader, US biotechnology firm; Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000. Stating that providing medical records would definitely not be allowed at his facility: Inspection Veteran 2, trilateral and mock inspection participant, 27 April 2000.

[108] Dr. George Pierce laid out this reasoning, to the agreement of the rest of the group.

[109] Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research; Industry Expert 4, president and chief executive officer, small US biotechnology company, 23 August 2000.

[110] If the needed expertise was not on the inspection team, transmittal of such data and subsequent discussion could be very helpful to the team on site. Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000.

Insights 4.5

An inspector who had been inside former Soviet biowarfare facilities agreed that "photos are a very important piece of the documentary evidence, especially for such things as scale. Two rows of eight three-story fermenters—that says it all right there."[1] Regular photographs and videotapes were a standard part of trilateral inspections in the United States and Russia, United Nations inspections in Iraq, and US trial and mock inspections, [2] but the inspection veterans were leery of digital photographs that could be manipulated. This group advised that site operators always be the ones looking through the viewfinder and pushing the shutter button. Copies of any visual records, they said, should be made for host and inspectors alike.

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[1] Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico.

[2] For instance, the Russians walked through two US defense facilities with videos in hand. No photographs were allowed en route to any US sites, and at other locations host officials took photographs for the Russians on a case by case basis. In Russia, some items were shrouded, but otherwise photographs were allowed. Photographs were allowed inside Iraqi sites, but not outside, where the cameras might capture security. Two sites involved in a US BWC trial refused all photographs fearing bad publicity and subsequent protests from animal rights activists, but another site allowed photos in all but a few locations. Inspection Veteran 1, facility manager and US trial inspection host; Inspection Veteran 3, trial inspection observer and mock inspection participant; Inspection Veteran 5, participant in two US trial inspections and a mock inspection; Inspection Veteran 6, member of host and inspection teams during two mock inspections; Inspection Veteran 7, United Nations Special Commission on Iraq inspector and mock inspection participant; Inspection Veteran 8, trilateral and trial inspector; Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000.

videos, but the host facility should have an equal right to decline such requests. Industry brainstormers projected that few, if any, commercial plants would give permission for photographs and videos. As Insights 4.5 relates, the inspection veterans group recalled that in the past inspectors have often pulled out cameras.

At the conclusion of the inspection, the industry group expected commercial companies to have certain rights pertaining to the preparation of draft and final inspection reports. The experience of a defense contractor whose firm had been inspected under the CWC, described in Insights 4.6, indicates that perseverance would serve industry officials well during the drafting of an actual inspection report, as would ironing out in the protocol text host site rights vis-à-vis the report drafting process. First, the industry would want to obviate the chances that an arms control inspection could place them in double jeopardy with US regulatory agencies. Therefore, draft and final reports should not contain any information that could get a commercial facility in trouble with US regulators.[111] Also, the industry group stated that companies would want a right of response or rebuttal to the draft and final reports in the event that company representatives believed that they had been misquoted or data had been misinterpreted. Ideally, the company's response would be incorporated as a formal part of the inspection record.[112] A copy of the final report and any other

[111] In fact, the entire group asked that the official US escorts for the inspectors come from a non-regulatory organization, such as the State Department or Commerce Department. "This is an arms control inspection, and when all is said and done, there is no reason for cooperation with that type of inspection to bring any US regulators through the door." Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

[112] The company should be allowed sufficient time to prepare this response. Dr. Robert Hamilton, senior scientist and

associated documentation should remain with the inspected company.[113] Finally, the industry group suggested that the facilities hosting inspections should have the right to file their own reports about the competency of the inspectors.

INDUSTRY GROUP ASSESSMENT OF MONITORING TECHNIQUES

Since a treaty monitoring regime is often judged primarily by its effectiveness, the Stimson facilitators asked the industry group to flesh out what effectiveness meant in the context of their proposed BWC inspection tools and strategies. They defined effectiveness as the ability of monitoring techniques to help determine whether a facility was intentionally violating or was compliant with the BWC's provisions. Having said that, the industry group stated that no single monitoring tool in and of itself would necessarily get to the "truth." They stressed that the monitoring tools would only be as good as the inspectors and that intentional violations would be difficult to prove. Still, if the BWC inspections were focused on inconsistencies with expected legitimate practice, then the industry group believed that visual observation, document review, interviews, and, as a last resort, sampling and analysis would lend clarity and confirm compliance or noncompliance. In some cases, they expected that the results of using these tools would have to be somewhat qualified or graded. Their predictions for the effectiveness of their monitoring approaches to evaluate the status of a manufacturing facility can be found in table 4.2. They projected that monitoring effectiveness would be very high in one area, high in five areas, medium in four areas, and low in one. In two other areas, their assessment differed depending upon whether samples were involved.

Insights 4.6

According to a defense contractor who had hosted a Chemical Weapons Convention inspection, settling the details of the report was one of the most tedious parts of the inspection. While the inspectors tabled a draft report that was factual in nature and eschewed subjective judgments, the facility's managers still had to pay careful attention to the report's wording. This facility, which had government and commercial clients, wanted to ensure that the report did not compromise its customers and thereby its business. Part of the problem encountered was that the various individuals drafting the report were from a variety of organizations and backgrounds and ascribed different meanings to the same words. After "long hours" of haggling over the wording, this defense facility "got a positive report from the inspectors. They didn't really find anything that they were concerned about in terms of production of offensive chemicals, activities, or anything like that."

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[1] Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000. Defense Contractor 4 has a PhD in chemical engineering.

group leader, US biotechnology firm, 23 August 2000.

[113] Industry group members explained that such reports would possibly be needed for patent application.

Table 4.2: Expected Effectiveness of BWC Monitoring Techniques

Area of Inconsistency with Site's Stated Purpose	Expected Level of Effectiveness of Monitoring Techniques Used in Combination
Level of Containment	High
Supplies	High
Equipment and Materials of Construction	Medium
Medical Facilities	High
Facilities (e.g., air filtration, cooling)	High
Waste Handling and Treatment Systems	Low to Medium without Sample High with Sample
Procedures	Low
Management Program	Medium to High
Downstream Processing	Very High
Degree of Concern with Product Integrity/Quality	High for Human Products Medium to High for Animal Products
Microorganisms on Site	Medium with Sample Low without Sample
Animal Facilities and Numbers	Medium to High

The industry group characterized their overall expectation of how these monitoring techniques would perform in the field by stating that good inspectors employing them would find careless bioweapons makers and very large offensive programs. In other words, these techniques would unmask the type of bioweapons program run by the former Soviet Union. Therefore, the industry experts reasoned that initiating such inspections would make it more difficult for proliferators to hide their activities at industry facilities and would certainly increase the risk that cheaters would be caught.

Even though they estimated that these monitoring tools would be reasonably effective in identifying and parsing the nature of inconsistencies, the industry group pointed out that their inconsistency inspection strategy is one that could cut both ways. The inspectors will find inconsistencies at real commercial plants for the simple reasons that humans make mistakes. "An erroneous assumption that is sometimes made is that a credible operation will always do a very good job," but genuine commercial sites do not run perfectly, explained one industry expert.[114] Picking up that same train of thought, another industry group member turned it the other way:

> For many of processes that we've developed, we never get it right the first time. There's trial and error that goes into these things and it takes a long time to work out all the kinks. If they're trying

[114] Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000. Another industry participant also voiced this sentiment: "I think it's going to be almost impossible for even an ethical manufacturer to have one of these inspections, and not have a couple of flags." Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

> to cloak a weapons facility inside a legitimate manufacturing plant, to do a phony process at the same time as doing a valid process, it's going to be very tough to get it all working right. It's going to smell to high heaven unless they practice it *ad infinitum*.[115]

Sorting through the inconsistencies at some facilities could be a monumental challenge, however. To wit, a couple of the group's members described an animal or poultry vaccine manufacturing facility as optimal cover for a bioweapons facility because they operate at scale, produce in bulk, have a sound rational for having aerosol chambers and other key equipment.[116] In short, should a protocol be concluded and BWC inspections become a reality, the industry group believed that the inspectors would have their work cut out for them. They hoped that negotiators of the protocol would give those inspectors a fighting chance by adopting their recommendations for the design of such a monitoring regime.

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[115] Dr. Steven Projan, director of antibacterial research, Wyeth-Ayerst Research, 23 August 2000. Another industry expert made a similar remark: A cheating facility "is probably going to try to cover it up, but that is going to be very, very hard for someone to do across all the bases. All that is needed is to have them slip up on one or two things—they don't even have to be major slip-ups—and that can be enough to get the inspectors started on the track." Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000.

[116] In the West, animal vaccine facilities are almost as heavily regulated as those that produce human medications, but in other countries, that may not be the case. Dr. George Pierce, former manager, technology development and engineering, Cytech Industries, 23 August 2000. Seconded by Industry Expert 2, senior vice president, US biopharmaceutical company, 23 August 2000.

Box 4.2: The Industry Brainstorming Group on Sampling and Analysis[*] [†]

Dr. Steve Projan: Forget about getting wastewater samples.

Industry Expert 2: That's right. I'm licensed to manufacture a pediatric vaccine. I'm not sure how the FDA is going react to that. Their number one charter when all is said and done is to assure the safety of the pharmaceuticals and vaccines that are put on the market. If someone's got even a whiff of doubt about anthrax coming out of my plant, I couldn't in good conscience keep the facility open while that allegation is out there, even if it's just a bad idea that the inspectors had. I'd tell them to shut the plant down until it was resolved.

Dr. Robert Hamilton: We're not even talking yet about the way the investors would react to that kind of a charge.

Dr. George Pierce: I understand where he's coming from, but, basically, this is the exact same argument the American chemical industry took twenty years ago with the EPA. It got nowhere. People are worried about possible exposure to hazardous chemicals, about whether living near a chemical plant causes illnesses or learning disabilities with their children. Now, the samples are taken. Every year, they take more samples than they took the year before.

Industry Expert 2: You want to believe the chemical industry is working in good faith, that any hazardous chemical problems are being identified and will eventually be resolved. If somebody's making a biological weapon, they're dirty from the start. They're not ethical. They're not trustworthy. There's a completely different connotation between failing a BWC sampling test and failing an EPA hazardous emissions test.

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[*] Several members of the industry brainstorming group chipped into this discussion which took place on 23 August 2000. In order of appearance, the participants were: Dr. Steven Projan, Industry Expert 2, Dr. Robert Hamilton, Dr. George Pierce, Dr. Robert Zagursky, and Dr. Allen Laskin. Dr. Steven J. Projan, director of antibacterial research at Wyeth-Ayerst Research, holds a PhD in molecular genetics and has over twenty years of experience in research and industry. Industry Expert 2, a senior vice president at a US biopharmaceutical company, has a PhD in biology and over twenty years of experience in research and industry. Dr. Robert Hamilton, senior scientist and group leader at a major biotechnology firm, holds a PhD in microbiology and cell biology and has over twenty-two years of experience in research and industry. Dr. George Pierce, manager of technology development and engineering, Cytech Industries on 23 August 2000, has since become professor of applied and environmental microbiology at Georgia State University where he draws not only on his academic credentials, a PhD in microbiology, but over twenty years of experience in research and industry. Dr. Robert Zagursky, distinguished research scientist at Wyeth-Lederle Vaccines, holds a PhD in biological science and has eighteen years of experience in industry. Dr. Allen I. Laskin, President of Laskin/Lawrence Associates, has a PhD in microbiology and has over thirty years of experience in industry. Amy E. Smithson, PhD, senior associate at the Henry L. Stimson Center facilitated this exchange.

[†] The brainstormers use several acronyms in this discussion. As they appear in the conversation, they are: Food and Drug Administration (FDA); Environmental Protection Agency (EPA); Biological and Toxin Weapons Convention (BWC); PCR (polymerase chain reaction); DNA (deoxyribonucleic acid); and CBI (confidential business information).

Hamilton: A BWC inspection could turn into an adversarial relationship. Somebody is coming in to see whether or not you're dirty. You're not going to readily want to give them anything more than you have to, whether or not you're clean.

Dr. Robert Zagursky: If they wanted to poke into our waste treatment, to sample waste, I don't think my company would have a problem giving a sample. Probably, though, we would first show them all of the documentation that the waste had already been certified from outside to be clean. After that, it they want to sample, we would offer to send a sample to the same lab because we know that it's certified. They can look in on that and get the results.

Projan: Yeah. Except the certified places don't do PCR, which is sensitive enough but produces false positives at an alarming rate.

Hamilton: Whoa! If this is a biotech site, a proprietary part of their DNA might be in there.

Projan: But the inspectors aren't going to be looking for the DNA—your proprietary stuff. They're going to be testing for smallpox or some other warfare virus, and that won't be in there.

Industry Expert 2: Well, no, this gets into a CBI issue if they do testing of some sort. So, I think industry as a whole would only agree if the samples are taken on the plant site, processed on the plant site, and nothing is removed from the plant site.

Projan: Okay. That's fine.

Pierce: Yes, but what if they also developed a truly validated assay? That would get around the concern that they're coming in to test for something but they're stealing trade secrets.

Hamilton: Right. But whatever comes out of that test, you want to be able to discuss the results before it gets out in the public.

Projan: Absolutely. That's got to be done.

Pierce: At the same point, nothing can stop them from taking a sample outside the fence.

Industry Expert 2: Yeah, they might try to use the results of that kind of sample as a lever to get into the plant. But the company would say that the sample was from an area outside of their control, so they can't be pinpointed as the source.

Pierce: Well, again, if a chemical plant wouldn't let them sample the effluence and the inspectors took a perimeter sample and found sarin or something, their stock prices would dive.

Industry Expert 2: I know, but we're talking about anthrax, okay? If inspectors sampled at the perimeter of my plant and it turned up positive, I'd just point five miles in that direction to a big farm and tell them to go check their land for anthrax. It's not the testing per se, it's the connotation and the result.

Pierce: Having dealt with the inspectors on the EPA side and worked at some contaminated sites, when you balk at samples or sample analysis by responsible parties, it shows a real lack of compliance and a real lack of transparency. Basically, the flags go up all over the place, and the inspectors start turning really aggressive.

Industry Expert 2: No argument there. Listen, the key to this whole thing is responsible parties and validated assays. If you've got those two things, then I think the answer can be found.

Zagursky: Okay, if we're letting them analyze on the site, how do we know their assay is validated? We've never done that kind of test before. They're going to be testing for anthrax, and we're going to take their word for it?

Projan: Hey, keep in mind that for the inspectors to really do it right, they can't really identify what probes they're using or else people can engineer to avoid the probes.

Zagursky: I don't like that idea of analysis on site. The sample should go to a certified third party to test it. Well, I know I'm clean, so I okay the inspectors to send it out, but I want to see that certification and know their frequency of false positives.

Hamilton: Yes, but we had a certified laboratory that did validated assays on a lot of our things until they got sloppy. We had to drop them. So, how do I know that a third party is better than analysis on site? There might still be concern with third party labs.

Pierce: For most things, laboratories do a number of qualifications with the EPA, and they do audits. They're tested on a periodic basis to show that they can do these assays to a certain degree of confidence.

Dr. Amy E. Smithson: Okay. Are you advocating third party laboratories, routinely tested for competency?

Pierce: Right.

Industry Expert 2: Yep.

Smithson: Could a network of laboratories be certified?

Hamilton: Actually, in this case I might like a multinational approach. There would be an advantage to having more than one laboratory run the assays, with all of them equally qualified and certified.

Industry Expert 2: Okay, I think there's ways around the certification and validation issues. Still, whether it is done on site or at a contract laboratory, I'm going to have one of my technical experts in that lab watching exactly how the samples are handled, making sure that all the necessary positive and negative controls are run, that the tests are done appropriately, because it's too sensitive of an issue. This is not the same as seeing something in your ground water.

Zagursky: We would probably want the assay duplicated in our own labs.

Pierce: No, it's not the same degree of sensitivity. Chemical plants have been fined or shut down for such findings.

Industry Expert 2: Yeah, but we're talking about finding a biological warfare agent. A plant shut down because they made a mistake or they did something—hopefully, it wasn't unethical—is not the same thing as putting together a weapon of mass destruction.

Pierce: No, it is the same thing because we're also talking about how an ethical company does not get tagged as a biological weapons producer. A positive sample of anthrax would be a huge flag, but there would have to be more than one indicator to nail a biological weapons producer.

Industry Expert 2: Alright. Now, say a sample is requested. All of this isn't going to be resolved in a few days. It could take months.

Projan: The methodology can be done in two hours.

Industry Expert 2: Sure, but you're going to want to be convinced that it works with reproducibility, to know the false positive rate and the background. You're going to want a lot of data before saying run the test.

Zagursky: Also, the laboratory that normally runs your samples is probably not trained and certified to test for anthrax or any of these other warfare agents.

Projan: Whether it's a third party or the inspectors themselves, I've got to have confidence in the people running the assays. The scientific rigor that this assay is subjected to is probably not going to be a matter of public record or in a peer-reviewed journal. That's why getting that confidence is going to be very tough.

Hamilton: Any negative information that gets out does the company irreparable harm and can't be reversed. That's what the industry worries about.

Projan: Right. Developing the methodology is probably going to be straightforward, but this is about a possible lack of confidence in who is doing the testing. We surrender samples all the time, so what we're

really objecting to, when all is said and done, are the reasons these samples would be taken and who we're giving them to.

Smithson: If there were a way to do so, how would you arrange this to make you comfortable?

Projan: Test everybody everywhere. That means everybody has false positives.

Hamilton: There's actually something to that. One of the other concerns is that no one wants to look like they're being singled out for some reason.

Projan: Have the same standard, not a different standard.

Industry Expert 2: What would be acceptable to us in the end may not be acceptable to an inspectorate. Say, for example, things are pointing to "it's dirty," and the inspectors need a sample. Then I'll say, okay, take the sample, but now initiate a validation program. The inspectors have to convince me before the sample was tested that the assay was completely validated. I've got to know the false positive rate in a similar background, which could take months. Only then could they run the assay.

Pierce: I would even take one step back from that. The inspectors don't take a sample until they have the protocol validated for how to take it.

Projan: I disagree with that because you don't want to give a cheater a chance to flush their system. Take the sample on day one. It's the testing that may have to wait for a validated assay.

Pierce: These inspectors should have a protocol for how to take samples of anthrax before they go in the field. In most sampling programs, most mistakes are made in how the sample is taken, stored, and transported before it even gets to a lab for analysis.

Industry Expert 2: I agree. Have the sampling protocols up front and procedures in place to assure that these things are kept under lock and key by some sort of approved third party. The assay could be probably 75 percent validated just based on laboratory studies. The last 25 percent is the ruggedness and reproducibility in the specific area. Then, the data is reviewed so that everybody is happy with the data. Then, the test is run. But, still, all of this has to be the last recourse for the inspectors. There have to be other indicators that someone is dirty.

Pierce: Maybe have a precondition that previously validated tests of this method are good.

Industry Expert 2: Well, again, previously validated means it's validated in some milieu that could be very different from yours. So you still have that piece that's got to be handled.

Projan: The only trouble with that is that you can't take waste water and assume its negative. If it's positive, it's positive. So it's very hard to validate in that.

Industry Expert 2: Yep. Yep. It is.

Projan: I mean, you can spike and quantitate, but it's got some problems.

Industry Expert 2: That can't be helped, but under certain circumstances there's no waiting to take that sample. If I'm industry, and I've answered 95 percent of the inspectors' questions during the course of the inspection and all of a sudden they start asking for samples, then I'm going to interpret that as a fishing expedition. Okay? We're clean and it's ridiculous that they're going down this road. Now, it would be different if I'm at a 50 percent level on their questions and the inspectors are getting nervous. Heck, our own federal government is getting nervous. Then, I might say it's okay to sample. So there's a decision path that must lead up to this. Sampling should not just be a kneejerk, that they walk through the door and start asking for samples from all these places.

Projan: Well, you do have to obtain the sample on day one. You don't give somebody time to clean up their stuff. Take that sample and hold it in a lock box. Nothing is done with it unless there are sound reasons to proceed to analysis.

Zagursky: If it is positive, sampling really puts up the biggest flag.

Projan: You know, on the false positive problem, there are still ways of getting better data. What if after doing a second PCR, they actually do a sequence to make sure what they've got is really an amplification of variola, or anthrax, or whatever? The technology exists to get a reasonable level of assurance that what they found was actually there. Of course, there are potentially innocent explanations of some stuff being there. Anthrax is possible in the environment, but there's no legitimate explanation for variola.

Hamilton: I'd be more comfortable if we retained our own portion of that sample.

Industry Expert 2: Right. I've gotten a positive on this sample that's been handled by someone else. I want it retested under my control. But again, analysis is the last recourse because this is the biggest hot button there is.

Smithson: To clarify, did I hear say you'd walk in the door and take that sample?

Projan: Absolutely.

Smithson: What is thought about that suggestion around the table?

Hamilton: I wouldn't have a problem with that.

Dr. Allen Laskin: That approach is desirable from both sides—from the perspective of the inspector and the host facility.

Industry Expert 2: The fate of your company depends on this sample, so the control of that sample is going to be critical.

Zagursky: Right, but they're only going to test that sample it if there's a real reason.

Industry Expert 2: Only test if there’s a real reason.

Chapter 5
Concluding Observations and Recommendations

After major violations of the Biological and Toxin Weapons Convention (BWC) came to light in the early 1990s,[1] the international community inaugurated Ad Hoc Group negotiations to strengthen this 1972 treaty with a compliance monitoring protocol. Given the difficulties inherent in monitoring this treaty's sweeping prohibitions on offensive germ weapons activities, the negotiators have had to fight their way forward. They have produced a labyrinthine draft BWC protocol text overflowing with technical detail. Quantity, however, does not always equate to quality.

Few outside of a relatively small community of diplomats, policy makers, and government arms control and national security analysts have waded through this tome, much less penetrated the rather closed process of Ad Hoc Group negotiations with policy or technical input. Operating on the more-heads-are-better principle, the Henry L. Stimson Center's Chemical and Biological Weapons Nonproliferation Project decided to dip into reservoirs of nongovernmental technical expertise in search of fresh thoughts and recommendations about the prospects and problems of BWC monitoring. The Stimson Center recruited technical experts from three types of facilities likely to fall under the monitoring umbrella of a BWC protocol, namely research institutes and universities, pharmaceutical and biotechnology companies, and defense contracting firms. The Stimson Center asked these groups to brainstorm the technical aspects of BWC monitoring, showering them with questions to facilitate their discussions. A fourth group was composed of inspection veterans, who imparted the lessons they learned from US BWC trial and mock inspections, visits under the 1992 trilateral agreement to confirm the closure of the former Soviet biowarfare program, and United Nations Special Commission on Iraq inspections.

This chapter presents the observations and recommendations of these four expert panels. The following section briefly captures their thoughts about such matters as BWC monitoring tools, strategies, costs, and effectiveness. On these issues, the brainstormers came out mostly in alignment with the technical substance and monitoring concepts in the draft BWC protocol. Next, the chapter reviews key points where the brainstormers disagree with some of the technical parameters that the Ad Hoc Group has proposed to govern inspections. The discussion then moves to matters where related inspection experience can offer insights about such intricate BWC monitoring issues as the protection of confidential business information and the management of inspectors' access on site. Functioning solely as an "honest broker" facilitator for these brainstorming meetings, the Stimson Center takes no credit for and does not necessarily endorse the views and conclusions that these technical experts espoused. The bottom line,

[1] At this time, long-held suspicions that the Soviet Union had a huge covert biowarfare program were publicly confirmed by high-level defectors from this effort. Also, the United Nations sent inspectors into Iraq after the Gulf War to verify the elimination of Iraqi missile and weapons of mass destruction capacities. Those inspections revealed Iraq's germ warfare program. A first-hand account of the USSR program can be found in Ken Alibek with Stephen Handelman, *Biohazard* (New York: Random House, 1999). Briefly, on the Iraqi program, R. Jeffrey Smith, "Iraq's Drive for a Biological Arsenal: U.N. Pursuing 25 Germ Warheads It Believes Are Still Loaded With Deadly Toxin," *Washington Post*, 21 November 1997.

according to the brainstormers, is that the Ad Hoc Group negotiators have much more work ahead of them if they are to achieve a meaningful, feasible BWC monitoring protocol.

POINTS OF ALIGNMENT BETWEEN THE BRAINSTORMERS AND THE BWC PROTOCOL NEGOTIATORS

Both the industry and academic experts turned to the same monitoring tools—such as advance research on facilities to be inspected, visual observation, documentation review, interviews, and sampling and analysis—that those involved in efforts to strengthen the BWC have been contemplating since the early 1990s.[2] With regard to the use of sampling and analysis, they observed that a great deal remains up in the air regarding the procedures for this important inspection tool. Without validated sampling and analysis protocols, many pharmaceutical and biotechnology industry companies would have reason to shy away from, if not outright resist, the imposition of a BWC monitoring regime. Both industry and academic experts called for technical research in the area of sampling and analysis.

The academic and industry groups unfolded their own strategies for applying the aforementioned monitoring tools on site. Their strategies share common threads with what is known in arms control circles as "managed access" inspections, wherein inspectors and host officials work out compromises on the spot to satisfy inspection and host site needs. Both groups specified ways for the inspectors to ratchet up the intensity of monitoring activities so that the inspectors could determine a site's status. The academic group would have inspectors square ambiguities with a three-tiered inspection approach. Inspectors would curtail their activities after the first level of inspection if they did not find evidence of noncompliance, but if compliance concerns arose inspectors would proceed to the more intrusive tactics of a second tier inspection. The academic group designed a third level of inspection that could be used if necessary to pinpoint a suspected violation. In their monitoring formula, the industry experts direct inspectors to focus on any inconsistencies that did not fit with a facility's stated activities. This group recommended that the inspectors make use of monitoring tools in various combinations. For example, inspectors could cross-check stacks of documentation exhaustively against interviews and visual observations. Chapters 3 and 4 of the report relate fully the inspection strategies of these two groups.

Having created their own BWC monitoring strategies, the academic and industry experts then estimated how effectively their techniques would work in their respective settings. Academic and research institute experts assigned moderate or high effectiveness ratings to the monitoring activities in the first two levels of inspection at laboratory facilities, while predicting that a level three inspection

[2] Note that the industry group discussed the use of photography and videotapes, but the academic and research institute group did not. Chapter 2 contains an overview of international efforts to craft a monitoring regime for the BWC, including a discussion of the Ad Hoc Group of Verification Experts, which met in 1992 and 1993 to evaluate monitoring technologies and strategies.

would be highly effective.[3] A bit more circumspect, industry experts graded the effectiveness of monitoring to discern legitimacy or weapons-related work at a manufacturing facility according to the area in which the tools were applied. They handed out one low effectiveness rating, four medium ratings, five high ratings, and one very high effectiveness rating.[4]

In contrast, the members of the defense contractors group were quite dubious about the possible utility of BWC inspections at their facilities. In their discussions, the defense contractors had difficulty escaping the obvious Achilles heel of attempting to monitor this treaty: A lethal seed culture could be placed in any vat, anywhere, to kick off an offensive program. The inspectors, they said, would probably never come across that hidden collection of "nasties" at defense facilities, but those sites would nonetheless incur the burden of inspections.[5] Accordingly, the defense contractors had very meager expectations for the effectiveness of BWC inspections at defense sites awash in capacities and biological agents. "They might find a few rare smoking guns, but all of the other defense sites are going to fall in a "maybe" category."[6] In the view of another contractor, however, just being able to "determine that a facility was in the middle ground" would constitute an effective BWC inspection and therefore be something of a positive step, as long as the inspectors could rule out that a facility had crossed the line into offensive activities.[7]

Although opinion was somewhat divided among defense contractors about the desirability of instituting a BWC monitoring regime, they unanimously recognized that the activation of a BWC protocol would bring them to a crucial decision point, namely whether their companies should forsake defense contract work entirely.[8] The burdens that they predicted would result from regular BWC inspections could well jeopardize their relationships with commercial firms, making the costs of

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[3] For more detail, see tables 3.1, 3.2, and 3.3 and the discussion on pages 34, 40, and 43, respectively.

[4] Note that the industry group pegged a few ratings variably, giving low to medium effectiveness grades or other variations according to whether a sample was taken and the area in which the monitoring tools were applied. See table 4.2 and discussion on page 76.

[5] Defense Contractor 6 made the strongest statement in this regard: "They're not preventing people from doing it, they're not effectively being able to detect whether they're doing it, but they're putting legitimate companies out of business with their monitoring." Defense Contractor 6, the senior vice president and co-founder of a biotechnology research contracting company, has over fifteen years of experience in molecular genetics. In concurrence: Defense Contractor 5, director of microbiology and special government projects; and Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000. Defense Contractor 5, working at a small defense contracting research company, has a PhD in microbiology. Defense Contractor 7 has a PhD in microbiology.

[6] Defense Contractor 2, principal research scientist, 28 August 2000. Defense Contractor 2, a scientist at a medical research facility, is a veterinarian and a PhD microbiologist. Defense Contractor 6 used the same phrase, "the maybe category," to describe where just most defense companies' capabilities, much less the presence of agents, would place them.

[7] Defense Contractor 1, staff scientist in biotechnology, 28 August 2000. Defense Contractor 1, a scientist at a large research contractor, has an MA in cellular and molecular biology.

[8] This group fully appreciated that countries (e.g., Iraq, the Soviet Union) had violated the BWC and that it was important to detect and halt cheating, they were just extremely skeptical that desirable monitoring and compliance outcomes were within the realm of possibility.

continuing as a defense contractor outweigh the benefits.[9] The inspection veterans group, which was similarly skeptical about the effectiveness of BWC inspections, agreed that BWC monitoring could create an atmosphere that was not conducive to legitimate defense work (e.g., development of new vaccines, testing of protective gear).[10] The costs of BWC monitoring (e.g., lost productivity) were also an issue for the academic and industry groups, which, like the defense contractors, argued that inspected sites should be reimbursed for such costs.[11]

Despite the burdens accompanying inspections, the academic, industry, and defense contractor groups saw reason for some sort of non-challenge inspection activity, not just a monitoring protocol dependent on challenge inspections alone. The tendency for those evaluating arms control verification activities is to dwell on an inspection regime's ability to nab cheaters, but from the perspective of the academic and industry experts, a major purpose of BWC monitoring should be to demonstrate that legitimate facilities are just that: lawful. Non-challenge monitoring, in their view, would establish the legitimacy of inspections and provide a baseline from which to identify cheating. Also important, non-challenge inspections would allow the inspectors to become as adept as possible with their tools and strategies, decreasing the potential for critical fumbles on challenge inspections. Of a BWC protocol built solely on challenge inspections, one defense contractor said, "That's worse, a worse connotation even if you're found innocent."[12] In other words, the brainstormers' support of non-challenge monitoring rested on the ability of such inspections to avoid erroneously tarring all university laboratories, research

[9] Some said they fully expected the losses to be greater than what they make in their defense work. Defense Contractor 3, senior technical adviser; Defense Contractor 5, director of microbiology and special government projects, 28 August 2000. Defense Contractor 3, employed at a large, nonprofit research organization, holds a PhD in physics. Also worrying that inspections would delay contract work, possibly bringing penalties from clients: Defense Contractor 1, staff scientist in biotechnology, 28 August 2000.

[10] Inspection Veteran 8 stated that inspections could foster a backlash against biodefense work as being controversial or politically unpopular, a possibility that other veterans also thought could occur. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico.

[11] According to one contractor, the US government should indemnify companies "for all costs of the inspection because basically companies would be sticking their necks out for their country by receiving these inspections, putting their investors' money, their time, even their careers on the line." Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company, 28 August 2000. While seconding the idea of reimbursement, other members of the defense contracting group that it would not occur because the tab would be too high. Defense Contractor 1, staff scientist in biotechnology; Defense Contractor 2, principal research scientist; Defense Contractor 3, senior technical adviser; and Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000. One contractor, for instance, ran up a bill of approximately $100,000 to prepare for and host a Chemical Weapons Convention inspection. Defense Contractor 4, president of a defense and commercial contracting firm, 28 August 2000. Defense Contractor 4 has a PhD in chemical engineering.

[12] Defense Contractor 2, with others concurring. People are much more likely to recall the accusation than the outcome of the trial, so this group worried that even an "innocent" verdict from a challenge inspection would damage their reputation. Several defense contractors were anxious about non-challenge inspections as well, underscoring the importance of probable cause for a non-challenge inspection at one of their sites. Defense Contractor 3, senior technical adviser; Defense Contractor 5, director of microbiology and special government projects; Defense Contractor 6, senior vice president and co-founder of a biotechnology research contracting company; Defense Contractor 7, president and founder of a small sensor development company, 28 August 2000.

institutes, pharmaceutical, biotechnology, and defense contractor facilities with suspicion that they are somehow operating outside of the law when inspectors are not present.

POINTS OF DISAGREEMENT BETWEEN THE BRAINSTORMERS AND THE BWC PROTOCOL NEGOTIATORS

Of note, the academic and industry groups caveated their effectiveness assessments to their stipulations about the timeframes governing inspections and the number and caliber of the inspectors deployed. On several important inspection parameters, these experts therefore differed with what the BWC's negotiators have envisioned.[13] One area of divergence concerns the draft protocol provision that two weeks advance notice be given for one type of non-challenge visits that would last no longer than two days. Another timeframe in the draft text that drew objections was the twelve hours notice prior to the arrival of a challenge inspection team in the host country. A second major difference of opinion concerns the number of inspectors to be deployed. The draft text states that non-challenge teams will consist of no more than four members. As for the qualifications of the inspectors, the brainstormers found the draft text short on specificity.[14]

The academic experts thought that two weeks advance notice should be required for a non-challenge inspection, but the industry group took issue with such a long period of notice. While such a long advance notice appealed to them as corporate hosts of an inspection, they recommended that inspectors give a week's advance notice, thereby decreasing the time that a dirty facility would have to put its house in order. As for notice of a challenge inspection, the industry experts stated that two days advance notice was about right from the inspectors' viewpoint. The pharmaceutical and biotechnology industries would be uncomfortable with such a short lead-time but might come to accept it, they thought, if challenge inspection terms were well framed. The Food and Drug Administration conducts no-notice

[13] In the last topic broached with the academic and industry experts, Stimson facilitators solicited their views on the monitoring provisions in the draft BWC protocol by showing them tables summarizing the key features of the April 2000 rolling text. See United Nations, *Procedural Report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, BWC/Ad Hoc Group/51, 6 April 2000. The facets of the text that drew their attention remained substantially the same in the March 2001 draft protocol, segments of which are cited in this paragraph.

[14] One category of non-challenge visits, randomly-selected transparency visits, would proceed from two weeks advance notice, while voluntary clarification visits, another group of non-challenge visits, require only seven days notification. Both types of non-challenge visits shall not exceed two days. For provisions about advance notice and inspection team size for randomly-selected transparency visits, see United Nations, *Draft Composite Text*, Article 6(B), paragraphs 22 and 26. The guidelines for voluntary clarification visits can be found at United Nations, *Draft Composite Text*, Article 6(C), paragraphs 82 and 85. Generally speaking, the draft text stipulates that a BWC inspectorate would be staffed by "such scientific [and] technical. . . as may be required." See United Nations, *Draft Composite Text: Protocol to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*, BWC/Ad Hoc Group/CRP.8 (Future), 30 March 2001, Article 16, paragraph 41. Specifically regarding investigations, the draft notes that investigation personnel shall be recruited "on the basis of their expertise and experience relevant to the purpose of investigations of non-compliance concerns." United Nations, *Draft Composite Text*, Annex on Investigations (Annex B), paragraphs 1 and 2. The draft text contains no further requirements for inspector qualifications.

inspections, so the concept is not unheard of in industry. The industry experts also worried that the challenge inspection framework might be worded in such a way as to make it less effective than a routine inspection.[15] Should the guidelines for challenge inspections allow host officials to decline inspectors' requests for access and information, they believed that the endeavor would be stripped of any teeth that it otherwise might have had.

While no one envied the inspectors of the Chemical Weapons Convention (CWC) their jobs, everyone agreed that the tasks before the BWC inspectors would be more demanding. Chemical warfare agents and the ingredients that go into them are known, as are their degradation by-products. Analytical chemists and chemical engineers can go to a plant site and reliably identify these substances. Moreover, the brainstormers described the pace of technical developments in the chemical manufacturing arena as relatively static in comparison to the speed with which technical advances are transforming pharmaceutical and biotechnology research, testing, and manufacturing facilities. Not only would BWC inspectors have trouble keeping abreast of such technical advances, the range of specialties necessary to clarify what is truly going on at research and development laboratories, pilot plants, and manufacturing facilities is much wider. These sites encompass many types of technologies and products. For these reasons, the academic and industry brainstormers had very strong views about the quality and number of inspectors needed to unravel the complexities they would undoubtedly encounter in the field.

The academic and research institute experts argued that the skills and experience of the inspectors would be paramount to their ability to detect when the fine line from legitimate research to offensive bioweapons work was being crossed in a laboratory setting. As one participant stated, one in a thousand such sites inspected might be the tip of an offensive bioweapons program, "and these are the people who are going to have to be able to tell that."[16] Due to the need to avoid false accusations and also to catch BWC violators, the individuals selected for these jobs, they felt, should be true experts in their fields. The basic credentials for inspectors should be a professional degree in a pertinent field or noteworthy, extensive experience in research or as an independent investigator at a research institute. The academic brainstormers believed that a team of five to seven inspectors would be needed to inspect university and research institute facilities. The core of this team should be individuals with skills in biosafety engineering, aerobiology, molecular biology, and computers. Someone in this core group should be a

[15] In the April 2000 rolling text, the phrase that concerned the industry group was that inspection activities would proceed "with appropriate consent by the receiving State Party." Similar wording, intended to create a balance between inspection and host state rights is found in the March 2001 text in several places, for example with a requirement in paragraph 152 that inspectors show host state officials their inspection plan before beginning any investigatory activities and consider host comments on that plan. Interviews are to be conducted with the "explicit consent of" interviewees "in the presence of [host] representatives" and records are to be examined "only when required to fulfill" the inspection mandate. Similarly, the terms that frame the launch of challenge investigations at facilities would also sap such inspections of their potency because they can proceed only if approved by a simple majority of the Executive Council. See United Nations, *Draft Composite Text*, BWC/Ad Hoc Group/CRP.8 (Future), Annex B, Section C, paragraphs 152, 155, and 162; Article 9 (F)(e).

[16] Academic Expert 1, PhD in microbiology, 16 August 2000. Academic Expert 1 is a virology professor in the Department of Microbiology and Immunology of a major US university.

highly experienced inspector. Depending on the site being inspected, additional skill sets should be added. For example, someone with expertise in tuberculosis, alpha virus, or fungal research should be on any inspection team going to sites concentrating in these research areas. The need for specialized expertise on an inspection was driven home during the trial inspection that the Stimson Center conducted at a biosafety 3 level research laboratory to test the academic group's proposed monitoring tools and strategies. During this trial, which is fully described in box 3.1 at the end of chapter 3, two experienced inspectors resolved a few issues of monitoring concern but, lacking expertise in this laboratory's area of research concentration, did not pick up on the significance of clues that the laboratory's operators had planted to indicate possible foul play.[17]

Similarly, industry brainstormers believed that highly skilled, well-trained inspectors would be key if inspectors were to figure out whether an unusual strain was a "smoking gun" at a manufacturing plant collocated with interesting research and development capacities. This job, they said, was not for bean counters. When considering candidate inspectors, the BWC inspectorate should emphasize experience over education. Inspectors should have at least a bachelor's degree in a pertinent scientific area. More importantly, inspectors should have a minimum of eight to ten years experience in scale-up activities, operations management, activities along the chain from research and development to commercialization, or multi-purpose industry consulting. As a rule, the industry group agreed that all team members should receive auditing training.

According to the industry group, the teams headed for manufacturing sites should be large enough to span multiple disciplines well, not just superficially. The composition of an inspection team should be tailored to what is known in advance about a site's activities, but the team should at a minimum encompass the following areas of expertise: biochemical engineering; industrial microbiology; heating, ventilating, and air conditioning operations; infectious disease research; regulatory and quality control operations; and support/process/instrumentation/civil engineering. At least five or six individuals, but ideally six to eight inspectors should comprise a team because additional site-specific functional expertise would probably have to be added. Also, even though the industry group recommended that legal and administrative support staff remain on-call at inspectorate headquarters, someone on the team should have a working knowledge of service contracts and other routine legal matters.

Even without legal or administrative field staff, both the academic and industry experts clearly thought that non-challenge inspections required more than four inspectors. A non-challenge inspection team would expand even more if one heeded the counsel of the inspection veterans group. These experts

[17] Briefly, Lt.Col. Karen Jansen (USA, ret.) and Dr. David Franz, former commander of the US Army Medical Research Institute of Infectious Diseases, mounted a one-day inspection of the Tuberculosis Center at the Public Health Research Institute in New York City. The planted clues included media not used for tuberculosis, a suspiciously mislabeled strain in the freezer holding the culture collection and a corresponding entry in the logbook, and a blood plate in an incubator streaked with *Bacillus subtilis*, a bacteria in the same genus as *Bacillus anthracis*.

pointed out that the effectiveness of an inspection team can be punctured by the failure to include enough interpreters and translators, leaving the inspectors at the mercy of local interpreters or handicapped in front of a mound of records that they cannot read.[18] Accordingly, non-challenge inspection teams should also include a sufficient number of translators and interpreters to facilitate the inspectors' work.

The error of deploying undermanned inspection teams would be compounded, both academic and industry experts agreed, if the non-challenge inspection terms did not allow the inspectors enough time on site to determine much of anything. Again, from their vantage points, a non-routine inspection was as much about establishing compliance as it was about trying to determine noncompliance. Compliant facilities should get a clean bill of health, not have the inspectors leave a question mark hanging over their heads. The academic group believed that three days would probably be needed for large research laboratories, while for commercial sites, the industry group judged the time required for non-challenge inspections to be five days.[19] The industry group also objected to the times allotted in the draft protocol for certain non-challenge inspection activities. For example, the draft BWC protocol terms state that an introductory briefing could stretch to three hours and the site tour that followed must not exceed two hours.[20] In contrast, the industry group's monitoring strategies centered on getting the inspectors off the mark quickly and more aggressively. In their approach to non-challenge inspections, as chapter 4 describes, an interactive facility tour should begin right after perfunctory introductions and last at least a day, if not longer. In the words of one industry expert, "two hours is a high school tour," not worth anything in terms of monitoring assurance.[21] Likewise, the industry experts advocated getting down to brass tacks during a challenge inspection faster than the draft BWC protocol.[22] In a challenge inspection,

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[18] In Iraq, United Nations inspectors found translating the financial, technical, and personnel records to be an overwhelming task, requiring them to copy all documents and carry them back to headquarters for translation. Note that interpreters who are well-versed in local customs can also cue inspectors to more subtle meanings, not to mention save them from making unintentional cultural missteps. "An interpreter that can give inspectors the feeling of what people are saying, not just the words, makes a huge difference." Inspection Veteran 7, United Nations Special Commission on Iraq inspector and mock inspection participant. Inspection Veteran 7, a PhD scientist, served on several United Nations Special Commission on Iraq missions, was on the host team during the mock inspection at Dugway Proving Ground, Utah, and took part in a follow-on round robin exercise.

[19] Several members of the industry group indicated that if inspectors at their site needed even more time in a regular type of inspection, their plants would probably grant permission for them to stay longer to get questions answered.

[20] *Procedural Report of the Ad Hoc Group of the States Parties* BWC/Ad Hoc Group/51, 6 April 2000, Article III(D)(II)(A), paragraphs 34 and 36. The provision for on-site briefings was bracketed, while the tour time limit was not. In the March 2001 chairman's text, the briefing and tour durations for randomly-selected transparency visits can be found at Article 6(B), paragraphs 33 and 35. United Nations, *Draft Composite Text*, BWC/Ad Hoc Group/CRP.8 (Future), 30 March 2001.

[21] Dr. George Pierce, manager of technology development and engineering, Cytec Industries, 23 August 2000. Dr. Pierce has since become professor of applied and environmental microbiology at Georgia State University where he draws not only on his academic credentials, a PhD in microbiology, but also over twenty years of experience in research and industry. See chapter 4, which describes the interactive nature of industry group's tour strategy, with inspectors working from key site diagrams and asking questions along the way. This chapter also lays out the group's strategy for sampling and analysis.

[22] As set forth in the April 2000 rolling text, facility investigations could last no longer than eighty-four consecutive hours. In a facility investigation, the rolling text envisioned sampling as a tool of last resort, introduced only when the inspection team concluded that sampling was necessary to fulfill the investigation mandate. However, the draft did allow the host to volunteer a sample at any time during the investigation in order to clear up any lingering non-compliance concerns. The

the industry group called for samples to be taken at various locations around a facility early on, stored thereafter in a lock box for possible analysis later, if needed. So, while the academic and industry brainstormers agreed with the BWC negotiators on the basic monitoring tools to be used, they differed markedly on important quantitative and qualitative aspects of the inspections.

Consequently, after reviewing summaries of the draft inspection terms in the BWC rolling text, the following exchange occurred as the industry group gave their overall assessment:

> Dr. Amy E. Smithson:[23] "So, how did the negotiators do? Would you like to give them a grade, professors?"
>
> Dr. Allen Laskin:[24] "That's about a 'D.'"
>
> Smithson: "Why a 'D'?"
>
> Dr. Robert Hamilton:[25] "Well, they did have an outline. I guess that's something."
>
> Smithson: "Would anybody go higher or lower than a 'D'?"
>
> Dr. George Pierce:[26] "I think a 'D' is a good grade because that's really about the worst grade you can get. Sometimes an 'F' shows a little innovation."

The industry group observed that the private sector would not want to participate in an empty exercise, so putting together inspection terms that would actually provide ways to differentiate between the good guys and the bad guys would be a pre-requisite for industry's willing cooperation with BWC monitoring. In their view, such inspection terms were possible, but significant revisions of some of the draft protocol's technical nuts and bolts were in order: Even the best inspection tools in the world will be of marginal utility if the inspectors are not true experts in their fields and are not given sufficient time to do their jobs.

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investigation sampling provisions went on to state that whenever possible, samples were to be analyzed on-site. If on-site analysis were impossible, the rolling text permitted samples to be analyzed at certified off-site laboratories, with duplicate samples staying in the host's possession. *Procedural Report of the Ad Hoc Group of the States*, BWC/Ad Hoc Group/51, 6 April 2000, Article III(G), paragraphs 50–61. The April 2000 provisions are largely unchanged in the March 2001 draft composite text.

[23] Smithson, a senior associate at the Henry L. Stimson Center with a PhD in political science, facilitated this exchange, which took place during the 23 August 2000 meeting.

[24] Dr. Allen I. Laskin, president of Laskin/Lawrence Associates, has a PhD in microbiology and over thirty years of experience in industry.

[25] Dr. Robert Hamilton, senior scientist and group leader at a US biotechnology firm, holds a PhD in microbiology and cell biology and has over twenty-five years of experience in research and industry.

[26] Dr. George Pierce, former manager of technology development and engineering, Cytec Industries.

FACTORING PERTINENT INSPECTION EXPERIENCE INTO THE BWC PROTOCOL

One of the hot-button issues for the industry, academic, and defense contractor groups was the possibility that confidential business information would be lost during the course of an inspection or via the inspection report. Experience, however, does not indicate that such losses have occurred in other arms control treaty inspections. Asked point blank whether his firm had lost proprietary business data as a result of a CWC inspection, one of the defense contractors who participated in that brainstorming group stated simply, "No."[27] A similar question was posed to a staff member at the US chemical industry's main trade association, the American Chemical Council. By mid-April 2001, over twenty US chemical plants had been inspected under the CWC with US firms registering nary a complaint about loss of confidential business data.[28] Another US chemical industry representative reiterated this point by saying, "Trade secrets are staying that way, the way they should."[29] Nor were problems with loss of confidential business information arising as a result of CWC inspections elsewhere in the world. As of mid-April 2001, the Technical Secretariat, the CWC's international inspection agency, had conducted over 275 inspections at chemical industry plants worldwide. According to a senior Technical Secretariat official, none of these inspections resulted in either industry officials or host state governments lodging a complaint that inspections had compromised confidential business data.[30]

These circumstances should not be taken to mean that implementation of the CWC has been a cakewalk for the chemical industry. Problems were bound to crop up during the global inauguration of a declaration and inspection regime of the CWC's intricacy and intrusiveness.[31] For the most part, however, both industry and Technical Secretariat insiders say that CWC inspections have gone smoothly

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[27] Defense Contractor 4, 28 August 2000. Defense Contractor 4 is president of a company that provides consultant, technical, and materials evaluation support to government agencies and commercial clients. This individual received a PhD in chemical engineering but is also trained in physics and previously worked for almost a decade in the aerospace industry. More of this individual's observations about hosting a CWC inspection in 2000 can be found in chapters 3 and 4.

[28] American Chemical Council representative, interview with author, Washington, DC, 9 April 2001. Also, US government official, telephone interview with author, Washington, DC, 1 May 2001.

[29] Richard H. Burgess, who was with E.I. DuPont de Nemours & Company during the CWC's formative years, at a 26 April 2001 report release meeting in Washington, DC. Burgess addresses trade secret protection issues on page 42 in his essay, "Chemical Industry and the CWC," in *The Chemical Weapons Convention: Implementation Challenges and Solutions*, Jonathan B. Tucker, ed. (Washington, DC: Monterey Institute of International Studies, April 2001). See also, Frederick L. Webber, "A US Industry Perspective on Implementation of the Chemical Weapons Convention," *OPCW Synthesis* (November 2000): 16–19. *Synthesis* is the quarterly publication of the Organization for the Prohibition of Chemical Weapons.

[30] Senior official at the Technical Secretariat of the Organization for the Prohibition of Chemical Weapons, telephone interview with author, 19 April 2001. Not long after the CWC's activation on 29 April 1997, the Technical Secretariat began inspecting industrial facilities that manufacture, process, or consume certain proliferation-risk chemicals in above-threshold quantities. The tally of inspections at Schedule 2, 3, and discrete organic chemical/phosphorous-sulfur-fluorine plants stood at 278 in mid-April 2001. For the CWC's provisions governing industry inspections, see the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction. More about the treaty's status can be found at: www.opcw.org.

[31] For several industry perspectives on the CWC's early years, see the November 2000 issue of *OPCW Synthesis*.

at industry sites. Roughly 20 percent of the time, according to one insider's estimate, the inspectors and host officials have used negotiations and managed access techniques to address industry concerns to demarcate inspectors' access to sensitive areas or records, resulting in all instances in resolutions acceptable to both industry hosts and inspectors.[32] The chemical industry's experience with the CWC is indicative that with the designation of appropriate precautions and concerted efforts on the part of inspectors and host officials, loss of proprietary data in a BWC monitoring context is not the unavoidable catastrophe that some have made it out to be. Certainly, that was the conclusion reached by the academic and industry brainstormers, who saw ways to use planning, training, redaction of documents, shrouding, negotiation, and other techniques to steer clear of revealing proprietary data while still allowing the inspectors to go about their tasks.

Other field inspection experience appears to bode less well for a BWC monitoring regime. According to the inspection veterans group, the degree of access granted during an inspection can be an unreliable barometer of dirtiness or legitimacy. Policy makers and negotiators, the inspection veterans argued, have all too little appreciation for how managed access works in practice. To illustrate the convoluted situations that can arise, veterans of trilateral inspections in the former Soviet Union observed that as their Russian hosts became accustomed to the inspection process, they allowed fairly comprehensive access to facilities that had been deeply involved in biological warfare research, development, testing, and production. "I saw plenty in Russia and had the pictures to prove it. You don't need to be denied access to be uncomfortable."[33] Likewise, a former United Nations Special Commission on Iraq inspector said, "I had the same reaction at Al Hakem. The Iraqis kept insisting it was a single-cell protein plant, but it obviously wasn't."[34] While the Iraqis at first gave United Nations inspectors access to the facilities at the heart of their biowarfare program, they became increasingly obstructionist as the inspectors began tightening the noose on this program.[35] Had the trilateral inspection process not been

[32] Senior official at the Technical Secretariat of the Organization for the Prohibition of Chemical Weapons, telephone interview with author, 19 April 2001.

[33] Continued this individual, "They would take us where we wanted to go and we could figure it out, but they never admitted to anything." Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 8, a PhD scientist, went on several trilateral visits to former Soviet biowarfare facilities and was an inspector during the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico. Also having the same experience at another Russian facility, Inspection Veteran 5, participant in two US trial inspections and a mock inspection. Inspection Veteran 5, a PhD scientist, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. As chapter 2 explains, a 1992 agreement between the United States, Russia, and the United Kingdom touched off a series of inspections, later curtailed, to ascertain whether the former Soviet biowarfare program had indeed ended.

[34] Inspection Veteran 7, United Nations Special Commission on Iraq inspector and mock inspection participant, 27 April 2000.

[35] "Occasionally, we had to break down a few doors, cut off locks when they lost keys. What really got sticky was when we did no-notice inspections at undeclared facilities. It got ugly at Ministry of Defense facilities. We weren't allowed into presidential palaces or military facilities." Ibid.

aborted, the inspection veterans believed that the Russians may well have embraced the on-again, off-again approach that the Iraqis took, drawing the line at access to their core military facilities.[36]

Adding complications to how inspections might unfurl at possibly noncompliant sites, veterans of mock inspections in the United States said that things can go wrong (e.g., lost keys, equipment being moved) even at sites that have a cooperative outlook and have practiced receiving inspections. Such gaffes made the operators of these facilities look like they were attempting to hinder the inspectors.[37] Moreover, denial of access to areas of concern during one of the two major US trials played into the inconsistencies that the inspectors had uncovered during review of the site's records. Unable to understand the materials flow and the purpose of the facility's large capacity, "the team could not determine with *high* confidence what was going on in the site."[38] Inspection veterans had seen both BWC violators and legitimate facilities go all over the map on access, with dirty sites opening doors and legitimate facilities closing them because of logistic clumsiness or their inability to figure out how to allow access yet protect sensitive data.

With a cynicism borne perhaps from experience, the veteran inspectors did not necessarily view managed access techniques as the answer. Policy makers, said one of the participants in the inspection veterans group, tended to portray managed access as "wonderful; it will be your salvation." However, said this individual, "I don't believe it. Because of the dual-use nature of biologicals, equipment, and facilities, any time access is denied, the suspicion alarm goes off. "[39] Another inspection veteran chimed in with: "Managed access is the fourth great lie, right after 'the check is in the mail.'"[40] By their own

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[36] "We were not in their core capabilities. We were in a Russian quark environment, in their mobilization centers, which they considered giveaways. These weren't the military facilities that they were really trying to protect." Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Four facilities—Sergiyev Posad, Kirov, Yekaterinburg, and Strizhi—have been named as being the center of the former Soviet biowarfare program. To date, the Russian government has not permitted outsiders into these sites, although via the International Science and Technology Center, Initiatives for Proliferation Prevention, and the Civilian Research and Development Foundation collaborative grant programs, Western government officials and scientists have had fairly liberal access at the dozens of other facilities that were involved in the biowarfare program. For more on these collaborative grant efforts, see Amy E. Smithson, *Toxic Archipelago: Preventing Proliferation from the Former Soviet Chemical and Biological Weapons Complexes* (Washington, DC: Henry L. Stimson Center, December 1999). As chapter 2 explains, the trilateral inspections were abandoned in 1994.

[37] Inspection Veteran 2, trilateral and mock inspection participant; and Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Inspection Veteran 2 participated in inspections under the 1992 trilateral agreement, took part in a series of round robin mock inspections at military facilities in the western United States, and engaged in background planning for the mock visit to the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[38] Emphasis added. The host facility cited proprietary data and the inspectors' lack of proper vaccinations as reasons for refusing access to requested areas. Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000. Inspection Veteran 9, who has an MD and a PhD, took part in the trial inspection at US vaccine production plant in late October 1995, the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and the mock inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland. Confirming this account: Inspection Veteran 5, participant in two US trial inspections and a mock inspection.

[39] Inspection Veteran 5, participant in two US trial inspections and a mock inspection, 27 April 2000.

[40] Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Similarly, Inspection Veteran 3 described managed access as automatically "setting up a confrontation. Something is not going to be shown, which defeats the purpose of being as

admission, the inspection veterans' scorching assessment of the potential of managed access to resolve inspectors' concerns was influenced in no small part by the trilateral experience, where giving the Russians unfettered access at US sites made no noticeable difference in the outcome.[41] Still, other recollections that the inspection veterans offered tended to undercut their strong criticism of managed access. "In many cases," said one veteran stated, "you can readily give the explanation and provide an alternative."[42]

While the inspection veterans as a whole remained to be convinced of the technical feasibility of monitoring the BWC, this group did coalesce around a couple of conclusions concerning managed access. First, no amount of access can convince inspectors who have already made up their minds, so what managed access boils down to is how open-minded and reasonable the inspectors and hosts are. Second, managed access, no matter how skillfully wielded, may still leave some questions unanswered.

In a perfect world, all situations would be clear-cut and managed access would provide explicit answers to all questions. Those who would endeavor to monitor the BWC must contend with the real and mercurial nature of modern laboratories and pharmaceutical facilities, where virulent characteristics can be spliced into genes and, in a matter of moments, manufacturing plants can be flushed of incriminating evidence.[43] Add to that reality the dishonesty and determination typical of treaty violators and the odds against successful monitoring of the BWC get even longer. In the face of such odds, those drafting the BWC protocol would be imprudent to dismiss the insights gained from field inspection experience.

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open as possible." Inspection Veteran 3, trial inspection observer and mock inspection participant. Inspection Veteran 3, who holds a DVM and a PhD, observed the late March 1996 trial inspection at three facilities located in Albuquerque, New Mexico, and participated in the mock trilateral inspection at the Edgewood Arsenal, Aberdeen Proving Ground, Maryland.

[41] Russian visits to US pharmaceutical and biodefense sites resulted in accusations of cheating on the BWC. According to the veterans, the Russians, having had their own offensive biowarfare program unmasked, came in determined to make mountains of molehills at US sites. "In the trilats, it wasn't possible to satisfy the Russians. The chief Russian inspector always came in with a list of questions or a piece of data—sometimes laughably old—to try to nail the site. We gave them an explanation, and it didn't matter, they said we were guilty. They said smoke bombs were bio munitions!" Inspection Veteran 8, trilateral and trial inspector, 27 April 2000. Other trilateral inspection veterans gave similar accounts.

[42] Inspection Veteran 5, participant in two US trial inspections and a mock inspection, 27 April 2000. This same individual was very critical of managed access, yet gave several examples, described in box 4.1, where alternative means were found. Another veteran described how Occupational Health and Safety Administration records were shown to back up the host officials' explanation that an area was closed to inspectors because it had been contaminated with beta emitters. Inspection Veteran 9, participant in trial and one mock inspection, 27 April 2000.

[43] Whereas years ago, cleaning a manufacturing facility was a labor-intensive endeavor consuming roughly a workday, experts from the industry group stated that clean-in-place technology now enables the sterilization of an entire production system with the push of a button.

FINAL THOUGHTS ABOUT THE COURSE AHEAD

Some would argue that the draft BWC protocol text is built upon just such experience. Commendably, several nations participating in the negotiations have staged BWC trial inspections.[44] The brainstormers pointed out, however, that a test is only as good as the strength of the criteria governing it. To the extent that the individuals assuming the role of inspectors in these trials already knew their way around the inspected facilities or were well-acquainted with those hosting the trials, then the results of these exercises can be questioned. In such situations, the "inspectors" have difficulty conjuring suspicions that their colleagues or a familiar facility could be misbehaving, so factors are glossed over that might cause uncertainty and friction in more authentic circumstances. However, if trials are held at sites unfamiliar to the inspectors and all of the participants are strangers with varied technical backgrounds, then the trial begins to approach the dynamics of an actual inspection. The nuances of an international inspection could be further mimicked if the trial participants were native speakers of several different languages.[45] Trials set up in this fashion force the inspectors and the hosts to contend with multiple challenges as the facility's status is being examined. Valuable lessons can be gleaned as inspectors maneuver to clarify ambiguities and host officials endeavor to protect data unrelated to treaty compliance.

To a person, all of the technical experts that participated in the brainstorming series believed that additional technical research and field trials, if well designed, would greatly serve the purposes of an eventual BWC protocol. These experts were not assured that the terms on the table as of April 2000 would work well for either inspectors or host facilities. The draft protocol appears to have bent over backward to minimize the inconvenience and intrusiveness of inspections to host facilities. While it is important to hold down the burden of inspections, skimping on inspection manpower and time on site could yield poor results that inspected facilities might find more offensive than full-blown inspections. Additional research and tests would take time to mount, and time would also be needed to refine the protocol text according to the lessons learned. Unless negotiating coups of the like rarely seen in Geneva occur, these further activities would mean that a monitoring protocol would not be completed in time for the November 2001 BWC Review Conference. Some have forecast that failure to conclude a protocol by then would jeopardize the negotiations.[46]

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[44] The United Kingdom, Canada, Spain, Germany, Switzerland, Denmark, Finland, Iceland, Norway, Sweden, Austria, and Iran held trials at a variety of sites, including pharmaceutical research and production, biodefense, and vaccine production facilities.

[45] Inspection Veteran 9 offered this critique of some of the BWC trials that have been held, as well as recommendations for more rigorous exercises. Several other veterans strongly seconded these remarks. For the difficulties that can crop up because of language barriers and varying technical backgrounds, see box 4.1.

[46] As one analyst noted, "It is simply a display of political will that is needed to go the final distance, and the window of opportunity for completion is indeed now." Graham Pearson, "The Protocol to the Biological Weapons Convention Is Within Reach," *Arms Control Today* (June 2000). Also, "Political Decisions Needed Soon on Germ-Warfare Treaty: Chairman,"

Such breathless predictions are overly pessimistic. Longtime observers of the Geneva negotiation process are accustomed to deadlines that slip. While no one aspires to duplicate the two-decades plus marathon that generated the CWC, a fully developed, technically sound product that has widespread political support is far preferable to an immature one viewed tepidly in various capitals.

Moreover, delays are not always detrimental. A delay that stimulates technical improvements in the draft protocol and augmented political support from governments and the private sector would be a delay well worthwhile. BWC monitoring procedures need to work effectively and dependably in the field. International security and the viability of an industry essential to global health will rest partly on this protocol's performance. Surely, those stakes are important enough to warrant an all-out effort to secure technically sound BWC monitoring procedures that enable inspectors to differentiate reliably between legitimate and illicit facilities and inspected sites to safeguard sensitive data unrelated to treaty compliance during that process.

Over the years, the US government has spoken perhaps loudest about the seriousness of the biological warfare threat. For instance, Secretary of State Colin Powell said while serving as the Chairman of the Joint Chiefs of Staff that "Of all the various weapons of mass destruction, biological weapons are of the greatest concern to me."[47] Therefore, the United States bears a special responsibility to see that all possible efforts are made to secure a technically sound BWC monitoring protocol. For the past several years, the US role in the BWC protocol negotiations has been anything but distinguished, not approaching the technical prowess and political determination that the United States displayed in the latter stages of the CWC's negotiations. During those talks, the US government forged a constructive partnership with the US chemical industry and held demanding field trials at a variety of locations. Along with research from other countries, the US trials provided the necessary technical input for meaningful, workable verification procedures. Through the inevitably bumpy opening years of the CWC's implementation, the technical sturdiness of the CWC's verification procedures has been demonstrated repeatedly. Common sense requires that key technical details of a BWC protocol be worked out before party plans are made for the treaty signing ceremony.

The time has come for the US government to put resources behind its rhetoric. The administration of President George W. Bush needs to do more than just carry out an interagency review of the draft BWC protocol text. What is called for is a technical research and field testing program worthy of the momentous proliferation problem that is being addressed. Nor can the US pharmaceutical and biotechnology industries continue to hide behind rhetoric. The Pharmaceutical Research and

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Associated Press, 31 March 2000.

[47] General Powell made this statement at a 15 March 1993 hearing of the Base Realignment and Closure Commission. For more on the threat of biological warfare, see US Department of Defense, *Proliferation: Threat and Response* (Washington, DC: US Government Printing Office, January 2001); and US Congress, Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks* (Washington, DC: Government Printing Office, August 1993).

Manufacturers of America long ago declared its willingness to "offer expert assistance to the US Government to help ensure that any Compliance Protocol to the Biological Weapons Convention is scientifically and technically sound."[48] Years later, this statement rings empty since there have been no industry field trials of prospective monitoring procedures. In this report, technical experts from the pharmaceutical and biotechnology industries charted a course for BWC monitoring that they believe could earn industry-wide support. Therefore, it is incumbent upon both US industry and the US government to mount good faith efforts to test fully the assorted permutations of BWC monitoring technologies and strategies.

After more than five years at the negotiating table, the effort to reach a BWC compliance protocol appears to be at the proverbial crossroads. Some participating governments seem poised to drive for the approval of a technically weak agreement. Others seem content to make such a superficial show of participation in the talks that the process could wander fruitlessly for years on end. Either outcome risks consigning the BWC to a house of cards existence. An impotent monitoring protocol would implode sooner or later, and absent the political will to conduct the requisite research, field trials, and tough negotiation, the BWC would remain a nice international behavioral norm, violated at will and possibly with impunity. One need only scan international newspapers and official government reports worldwide to see germ weapons repeatedly depicted as one of the most colossal threats facing mankind now and in the future. If that is indeed so, then the governments negotiating a BWC monitoring protocol surely owe their citizens better outcomes than those that destine the international community's principal mechanism for biological weapons nonproliferation and arms control for insolvency.

[48] Note also that this organization stands in opposition to "any Compliance Protocol that does not fully protect the confidential business information of its member companies." Pharmaceutical Research and Manufacturers of America, "PhRMA Position on a Compliance Protocol to the Biological Weapons Convention," 9 January 1997. Available online at http://srpub.phrma.org/phrma/01.09.97.phrma.bwc.html.

Appendix: Participant Biographies

Corrie Brown has worked at the University of Georgia College of Veterinary Medicine as professor and head of the department of veterinary pathology since 1996. She received her DVM from Ontario Veterinary College at the University of Guelph. After practicing for a short period in western New York, she did a combined residency/PhD in comparative pathology at the University of California at Davis. Board certification (ACVP) and PhD were both attained in 1986. She was an assistant professor of pathology at Louisiana State University briefly before joining the US Department of Agriculture at Plum Island, where, as head of the pathology section, she specialized in the diagnosis and pathogenesis of foreign animal diseases. Her professional interests are in infectious diseases of food-producing animals, emerging diseases, agroterror and international veterinary medicine. She has over 250 scientific publications and presentations. She currently serves as coordinator of international veterinary medicine for the College of Veterinary Medicine.

Nancy Connell earned her PhD in bacterial genetics from Harvard Medical School, where she studied gene expression during the stationary phase of growth in *Eschrichia coli*. She then held a postdoctoral position at Albert Einstein College of Medicine where she developed live recombinant vaccines. In 1992 Dr. Connell joined the Department of Microbiology and Molecular Genetics in the medical school at the University of Medicine and Dentistry of New Jersey. Using genetic and cell biological approaches, her laboratory focuses on intracellular metabolism of *Mycobacterium tuberculosis*, a bacterium that infects and replicates in macrophages. She has a joint appointment in the department of medicine and is the director of molecular mycobacteriology at the New Jersey Medical School National Tuberculosis Center. In addition to mycobacterial metabolism, her laboratory has been examining the molecular basis of resistance in multidrug-resistant clinical strains of *M. tuberculosis*. Finally, Dr. Connell has been working for many years in the area of the control of proliferation of biological weapons.

David R. Franz has been the vice president of the Chemical and Biological Defense Division of Southern Research Institute since 1998. He retired from the US Army at the rank of colonel, having served as commander of the US Army Medical Research Institute of Infectious Diseases. During over twenty years on active duty, Franz was a group veterinarian for the 10th Special Forces Group before going on to assignments at four of the Medical Research and Development Command's laboratories. Armed with a DVM from Kansas State University and a PhD in physiology from Baylor College of Medicine, Franz conducted research and published in the areas of frostbite pathogenesis, organophosphate chemical warfare agent effects on pulmonary and upper airways function, the role of cell-mediated small vessel dysfunction in cerebral malaria, and most recently, medical countermeasures to the biological toxins. Franz was the chief inspector on two United Nations Special Commission on Iraq biological warfare inspection missions to Iraq and was technical advisor on long-term monitoring. He was also a member of the first two US/British teams to visit Russia in support of the Trilateral Joint Statement on Biological Weapons.

Jerry Goldstein is a professor of microbiology and chairman of the Botany/Microbiology Department at Ohio Wesleyan University. Dr. Goldstein earned a PhD in microbiology from the University of Wisconsin-Milwaukee where he began research on the effectiveness of antiviral drugs on polio, vaccinia, herpes and adenovirus-infected cells. Currently his laboratory is involved with cloning, sequencing, and expressing a variety of bacterial protease genes in various expression vectors.

Robert Hamilton is a senior scientist and group leader at a large biotechnology company that has sales approaching $2 billion annually. A PhD microbiologist with more than seventeen years of experience in industrial biotechnology including yeast, E. coli, and mammalian cell culture process development and manufacturing process improvement. Among his proficiencies are troubleshooting at large scale, project management, directing research and development laboratories, Good Manufacturing Process regulations, regulatory filings for chemistry, manufacturing, and control sections at the IND and NDA (BLA) stages as well as validation and regulatory aspects involved in process change implementation. Prior to joining industry, Hamilton spent five years as a postdoctoral research fellow at the Department of Biological Chemistry at the Pennsylvania State University College of Medicine. He holds a US patent and has had a dozen articles published in key peer-reviewed journals.

Jennie Hunter-Cevera is president of the University of Maryland Biotechnology Institute. Hunter-Cevera received her doctoral degree in microbiology from Rutgers University in New Jersey in 1978. Dr. Hunter-Cevera began her career at E.R. Squibb in Princeton, NJ as a researcher and later moved to Cetus Corporation. In 1990, she started a consulting company specializing in biotechnology, agricultural and industrial microbiology, bioremediation and pharmaceuticals. Hunter-Cevera then went on to direct the Department of Environmental Biology and Biochemistry for the Lawrence Berkeley National Laboratory, which is operated by the University of California as part of the Department of Energy's national laboratory system. There she started the Center for Environmental Biotechnology where she remained until becoming president of the University of Maryland Biotechnology Institute in 1999. Hunter-Cevera is also a principal investigator of two cooperative programs sponsored by the Department of Energy with Ukrainian institutes to screen rare botanical and microbial extracts throughout the former Soviet Union. She has also worked on *Bacillus anthracis* biomarkers, specifically saspB which is now a classified assay.

Karen Jansen (Lt.Col., ret.) served as a US Army Chemical Corps officer from 1978 in a variety of command and staff positions that included assignments in Germany, Saudi Arabia, and South Korea. With a background in microbiology and immunology, she made contributions to US chemical and biological weapons defenses. From 1991 to 1992, Jansen was a chemical and biological weapons inspection operations officer for the United Nations Special Commission on Iraq (1991-1992), having participated in six and led four inspection missions. She was subsequently posted as a chemical inspection team chief to the US On-Site Inspection Agency. Jansen has an MS in microbiology from North Carolina State University.

Barry Kreiswirth has more than twenty years of microbiology research experience. For nearly ten years, Kreiswirth has directed the Tuberculosis Center at the Public Health Research Institute (PHRI) in New York City. With the burgeoning tuberculosis epidemic in Russia, the program's most recent work has focused on efforts to develop demonstration tuberculosis control projects that could form a model for replication throughout Russia. Prior to his current role, Kreiswirth headed the New York City Department of Health Phage Typing and Antibiotic Susceptibility Testing Laboratory. He had previously spent four years as a research scientist and postdoctoral fellow at PHRI. A PhD in microbiology, he has had dozens of articles published in such journals as *Emerging Infectious Diseases*, *Journal of the American Medical Association*, *Clinical Microbiology*, and *Journal of Infectious Diseases*, and is a member of the American Association for the Advancement of Science, American Society for Microbiology, and the New York Academy of Sciences.

Allen I. Laskin is president of Laskin/Lawrence Associates and serves as an independent consultant in microbiology and biotechnology. For fourteen years, Laskin was assistant director of microbiology at the Squibb Institute for Medical Research. He subsequently spent fifteen years as head of biosciences research at Exxon Research and Engineering Company. Later, he was instrumental in developing the New Jersey Center for Advanced Biotechnology and Medicine and became its first associate director. He then spent three years as president of Matrix Laboratories, a small start-up biotechnology company, before starting his current consulting activities. Laskin, who holds a PhD in microbiology, has received several awards and honors. He is a fellow of the American Academy of Microbiology, the American Association for the Advancement of Sciences, the Society for Industrial Microbiology, and the New York Academy of Sciences. He has authored numerous scientific papers and US patents, is the editor or co-editor of many books and book series, and is a senior editor of the *Journal of Industrial Microbiology and Biotechnology*.

Theodore Myatt is a doctoral candidate at the Harvard School of Public Health in the where he is studying the airborne transmission of common cold pathogens and their relation to building management. Mr. Myatt earned his master's degree in environmental management from Duke University and interned at the Centers for Disease Control and Prevention in Atlanta. Subsequently, he was a biological safety officer at UCLA's Office of Environment, Health, and Safety. In addition, Mr. Myatt now serves in the Division of Epidemiology and Immunization at the Massachusetts Department of Public Health.

George Pierce became a professor of applied and environmental microbiology at Georgia State University in late 2000. Prior to his transition to academia, Pierce worked for nearly ten years at Cytec Industries, formerly American Cynamid, where his last position was manager of technology development and engineering. He has also held senior research posts with Battelle Memorial Institute and at Celgene Corp., where he was the director of research and development. His research interests include development and scale-up of microbial processes for pollution prevention, site remediation and restoration at Superfund and Resource Conservation and Recovery Act sites, scale-up and development of

commercial biotechnology products, development of enzyme based and fermentation based products, and regulatory affairs and compliance in the area of environmental and industrial microbiology. A PhD in microbiology, Pierce has also been an adjunct profession at Ohio State University and at the Rensselaer Polytechnic Institute. He has numerous publications and patents in biotechnology and has served in several professional organizations, including a stint as the director of the Society for Industrial Microbiology.

Steven J. Projan is the director of antibacterial research at Wyeth-Ayerst Research, which is the research and development division of American Home Products Corporation. He has a PhD in molecular genetics and over twenty years of experience in research and industry, having begun his career as a postdoctoral fellow at the Public Health Research Institute in New York City, where he studied plasmid replication and virulence in *Staphylococcus aureus*. After becoming an associate at the Public Health Research Institute, Projan continued his work on plasmid replication, antibiotic resistance and staphylococcal virulence though 1994. In 1987 Projan became a senior scientist and then group leader at Applied Microbiology, Inc.—then an in-house biotechnology company at the Public Health Research Institute—working on antimicrobial peptides and bacteriocins. In 1993, Projan moved to Lederle Laboratories, which Wyeth-Ayerst Research absorbed, as a group leader in anti-infectives research. Four years later, Projan became an associate director in bacterial genetics and subsequently moved to his current position. The author of over fifty papers and book chapters, Dr. Projan is a past chair of the Gordon Research Conference on Staphylococcal Diseases, a member of the Bacteriology and Mycology I National Institutes of Health Study Section, and serves on four editorial boards.

Robert Shope is a professor of pathology in the Center for Tropical Diseases at the University of Texas Medical Branch at Galveston. He graduated with a BA in zoology and went on to earn an MD from Cornell University Medical College. Before joining the University of Texas he was a professor of epidemiology and head of the Division of Infectious Disease Epidemiology at Yale University's Department of Epidemiology and Public Health. Dr. Shope's research activities are mainly in the epidemiology of arboviruses and rodent-associated viruses, anti-viral compounds, vaccines and emerging infectious diseases. His career also includes a stint as a Captain in the US Army Medical Research Corps during which he was stationed at the US Army Medical Research Institute for Infectious Diseases. Dr. Shope is a member of numerous committees and programs including the International Committee on Taxonomy of Viruses, the Defense Department's Biomedical Technology Area Review and Assessment, and the Institute of Medicine's Committee on Research and Development Needs for Improving Civilian Medical Response to Chemical and Biological Terrorism Incidents.

Amy E. Smithson has been a senior associate at the Henry L. Stimson Center since 1990. In January 1993, she initiated the Chemical and Biological Weapons Nonproliferation Project, which conducts analytical research across the spectrum of complex topics associated with the control and elimination of chemical and biological weapons. She has published widely in journals, testified before Congress, and is

frequently consulted by the media. Before her tenure at the Stimson Center, she worked at Pacific-Sierra Research Corporation and the Center for Naval Analyses. She holds a PhD in political science from George Washington University.

Anne Vidaver is head of the Department of Plant Pathology at the University of Nebraska-Lincoln. She received her PhD in bacteriology with a minor in plant physiology from Indiana University in Bloomington. Vidaver has more than thirty-five years of teaching experience, as well as research in phytopathogenic bacteria and bacteria associated with plants. Her work has included systematics, epidemiology and control, plasmid, bacteriophage and bacteriocin characterization and genetics. She has served as an advisor or consultant to several companies and federal agencies. She has authored or co-authored over 180 scientific articles and a book. In collaboration with colleagues, she also holds two patents.

Robert Zagursky is a distinguished research scientist for research and development at Wyeth-Lederle Vaccines, a business unit of Wyeth-Ayerst Research, which is a division of American Home Products Corporation. Zagursky has eighteen years of experience in industry: seven years in research and development of bacterial vaccines at Wyeth-Lederle Vaccines; three years in research and development of eukaryotic expression and HIV research at DuPont Merck Pharmaceutical Company; and nine years in corporate research and development studying fluorescent DNA detection and PseudoRabies viral recombination at E.I. DuPont de Nemours & Co. Zagursky, who holds a PhD in biological science, also has two years postdoctoral experience in bacterial research at the US Army Medical Research Institute for Infectious Diseases. He is a recent recipient of American Home Products' Exceptional Achievement Award and Team of the Year Award, a member of the American Society for Microbiology, and a member of the editorial board for *BioTechniques*.

Academic Expert 1 is a PhD microbiologist and a virology professor in a major US university's microbiology and immunology department. This expert's research has focused on the molecular genetics of alphavirus pathogenesis, the design of molecularly cloned vaccines, and the development of alphaviruses as in vivo and in vitro expression systems. This individual is also a founding scientist of a commercial enterprise for applications of an innovative vaccine delivery technology.

Academic Expert 2 is a pathology professor at a top-ten US medical school. The director of a tissue typing laboratory, this physician's research is in the area of autoimmune endocrine disease, having helped define the basis of the autoimmune response to thyroid autoantigens. In particular, this person's recent work has focused on epitope mapping of thyroid peroxidase, a major autoantigen in autoimmune thyroid disease. His laboratory has used molecular biologic techniques to identify the specific epitopes recognized in thyroid peroxidase and shown that the recognition of this autoantigen is heterogeneous in different individuals. This expert, who has published numerous articles, has also served on the editorial boards and as a review for several professional journals.

Defense Contractor 1 is a staff scientist in the biotechnology sector of a large contract research organization that handles both governmental and private clients. This individual holds an MA in cellular and molecular biology and concentrates on method development and validation in molecular biology.

Defense Contractor 2 is a principal research scientist at a medical research facility that works primarily under government contracts and is part of a large global technology development company. A PhD microbiologist and veterinarian, this individual is an anatomic pathologist with in-depth experience in veterinary medicine and research.

Defense Contractor 3 is a senior technical adviser at a large a nonprofit organization focusing on basic and applied research, product development and policy studies in a range of fields of science. A PhD in physics, this individual has over thirty-five years of instrumentation development experience, over twenty years of direct experience working on several government and industry committees concerning weapons of mass destruction.

Defense Contractor 4 is president of a company that provides consultant, technical, and materials evaluation support to government agencies and commercial clients. This individual received a PhD in chemical engineering but is also trained in physics and previously worked for almost a decade in the aerospace industry.

Defense Contractor 5 is the director of microbiology and special government projects for a small defense contracting research firm. The recipient of a PhD in microbiology and an MS in human genetics, this individual is a board-certified medical technologist who has co-authored numerous peer-reviewed journal articles. Previously, this person served in the US Air Force as chief of molecular biology in a clinical investigation facility.

Defense Contractor 6 is senior vice president, director, and co-founder of a biotechnology research contracting firm. Previously, this individual managed a research laboratory in a cancer center in the microbiology, biology, and immunology department of a university. With over fifteen years in molecular genetics, this individual is the co-inventor of US patents and co-author of over peer-reviewed journal articles and book chapters.

Industry Expert 1 is the associate director for fermentation development at a US vaccine company that specializes in the development and manufacture of bacterial and viral vaccines and is a division of a Fortune 100 pharmaceutical firm. He holds a PhD in microbiology and has thirteen years experience in process development and scale up for the production of new and licensed vaccines for infants and adults. He also has extensive background working with biosafety level 2 and 3 microorganisms and designing facilities for large scale biosafety level 2 and 3 operation.

Industry Expert 2 is a senior vice president at a US biopharmaceutical company overseeing operations, product development and manufacturing. Prior to joining this firm, this expert served as vice president of manufacturing operations and process development at a US vaccine manufacturer, where he was responsible for all phases of vaccine manufacturing, including bulk manufacturing, filling, and packaging. Previously, this expert, who holds a PhD in biology, was the senior director for biological manufacturing at a US pharmaceutical company with roughly $40 billion in annual sales. In this capacity, he was responsible for manufacturing licensed bulk biologicals, including several vaccines. Earlier, this individual served as the director of the department of gene expression sciences and as the associate director of the biological process sciences department in one of the largest drug companies globally. This expert was previously the president of the Society for Industrial Microbiology and is a member of other professional organizations.

Industry Expert 3 is a senior research scientist at a small US biotechnology company that is a subsidiary of a larger firm that specializes in the discovery, analysis, and manufacture of proteins to be used in new applications. After receiving a PhD in biochemistry, this individual began a career in industry and research that has stretched over twenty-five years. This expert has worked in several research positions at a large US chemical corporation with well over a billion dollars in annual sales where his research concentrated in the field of polymers for biomedical applications. Prior to joining industry, he held research positions in two different research institutes of the National Institutes of Health. His bibliography contains more than eighty published pieces, he holds over ten patents, and he is a member of several professional associations.

Industry Expert 4 is president and chief executive officer of a small US biotechnology company focusing on novel therapeutics for the pharmaceutical and dietary supplement industry. The firm is a wholly-owned subsidiary of a privately held international company that sells cosmetics and supplements overseas. This individual holds a PhD in microbiology.