

Question#:	1
Topic:	BAR 1
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

**Dr. Michael Walter, BioWatch Program Manager, Office of Health Affairs, U.S.
Department of Homeland Security**

Question: The Department of Homeland Security has asked the National Academies of Science to organize workshops to develop locally-owned jurisdictional response plans for response to BioWatch Actionable Results. Is that an indication that local authorities do not have sufficient guidance for handling a BAR?

Response: DHS did not ask the National Academies of Science to organize workshops to develop jurisdictional response plans. Rather, DHS requested that the National Academies of Science review and assess existing guidance to assist State and local development of response plans, including specific considerations for indoor locations, for the current technology.

The DHS request to the National Academies of Science does not reflect insufficient guidance among local authorities for handling a BAR. To the contrary, guidance documents have been published by the BioWatch Program with the full participation of all BioWatch Jurisdictions and the Federal BioWatch Working Group since 2004. As the BioWatch Program continues to evolve, the Guidance documents are updated to reflect these changes. The current BioWatch Program Guidance document was released on March 18, 2013.

Question: Why has DHS allowed this lack of guidance to occur for so many years?

Response: As discussed above, there has been no gap in DHS guidance for use by the State and Local Jurisdictions. Guidance documents have been published for use by State and Local Jurisdictions since 2004 and are updated periodically.

Question: Is there any discussion inside the Department of Homeland Security to redefine what constitutes a BAR?

Response: There are no DHS plans to redefine a BioWatch Actionable Result (BAR). A BAR is defined as one or more polymerase chain reaction (PCR)-verified positive result(s) from a BioWatch collector that meets the algorithm for one or more specific BioWatch agents. A BAR is one piece of information provided to Federal, State, and local decision-makers as they review findings from other collectors and additional relevant information in order to determine the cause of the BAR and whether there is a risk to public health.

Question#:	2
Topic:	BAR 2
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: The National Academies of Science, in its 2011 report on BioWatch, wrote: “From the wider perspective of public health authorities responsible for determining whether a confirmed positive laboratory test (a BAR) represents a plausible indication of a bioterrorist attack meriting initiation of mass dispensing of prophylaxis, the committee concluded that all BARs to date have been ‘BAR false positives,’ meaning they have signaled the potential occurrence of a terrorist attack when none has occurred.” Do you agree with this statement?

Response: There is common agreement on what a BAR does and does not determine, however the term “false positive” has been used inconsistently. DHS’s use of the term “false positive” refers to a BAR being declared for a specific BioWatch agent, when in fact the DNA from that agent was not actually present. Other groups, including the CDC, consider a “false positive” to refer to a BAR being declared for a specific BioWatch agent, where the DNA is detected for the agent but the specific strain of agent is not a threat to public health. Both DHS and CDC are working to coordinate our use of scientific terminology when communicating with our stakeholders.

As discussed above, the occurrence of a BAR indicates that there is evidence of a *potential* occurrence of a terrorist attack, in that certain DNA has been detected, requiring further investigation. In every case to date, that detection has been accurate. A BAR sets in motion a series of steps to determine whether that potential attack is real. In the case of each BAR to date, the system has successfully and accurately determined that no terrorist attack was under way.

Question#:	3
Topic:	BAR 3
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Even though Dr. Garza said there had never been a false positive, does BioWatch really want to detect near-neighbors or background organisms?

Response: No. DHS’s use of the term “false positive” refers to a BAR being declared for a specific BioWatch agent, when in fact the DNA from that agent was not actually present. Other groups, including the CDC, consider a “false positive” to refer to a BAR being declared for a specific BioWatch agent, where the DNA is detected for the agent but the specific strain of agent is not a threat to public health.

BioWatch detects the actual bioterror agents responsible for causing diseases of concern, and DHS and CDC have worked to minimize the occurrence of BARs due to near-neighbor organisms. BioWatch has also improved its analytical capability to rule out non-pathogenic sub-species of bioterrorism agents.

As technology improves, the BioWatch program is working to increase its specificity and accuracy in detecting target organisms. For example, it has recently improved the specificity of the assays for *Francisella tularensis*, enabling them to detect only the sub-species of the organism that are responsible for causing human disease.

Question: Even if the BioWatch detection of near-neighbors are true-positives, aren’t the Department of Homeland Security and the Centers for Disease Control and Prevention working to minimize the number of BARs for near-neighbors?

Response: Yes. As discussed above, DHS and CDC have worked together with State and local partners to improve detection by continually reviewing and updating the best available assays to screen samples, tightening the analytical criteria for defining a detection, and in the case of *Francisella tularensis*, introducing assays capable of identifying the subtypes that actually cause disease.

Question#:	4
Topic:	cost
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: What was the total cost of Generation-2.5?

Response: The total cost of Generation 2.5 (APDS) was approximately \$27,853,918. Please see chart below for detail.

Fiscal Year	APDS
2003	
2004	
2005	
2006	12,985,852*
2007	
2008	14,868,066
2009	
2010	
2011	
2012	
Total to Date	27,853,918

* \$12,985,852 was spent on APDS prior to the formal transfer of the BioWatch program to the Office of Health Affairs in 2008.

Question#:	5
Topic:	Gen-3
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: How much money has been spent on testing and evaluation of the Gen-3 system to date?

Response: For FY2009 through FY2012, \$77,921,217 was available for obligation by the BioWatch Program for testing and evaluation of the Gen-3 candidate systems. All Gen-3 funding thus far has been for testing and evaluation. In FY 2012, \$24,000,000 was originally appropriated, \$21,600,000 was available for obligation, but only \$4,437,681 has been obligated (the remainder has been placed on hold). Therefore, the total of past allocations plus the FY 2012 obligations is \$61,938,898, a more precise measure of what has been “spent.” No funds have been appropriated for Gen-3 in FY 2013.

Fiscal Year	Gen-3 Available for Obligation	Gen-3 Obligated
2009	34,498,000	34,498,000
2010	10,100,000	10,100,000
2011	12,903,217	12,903,217
2012	20,420,000	4,437,681
Total to Date	\$77,921,217	\$61,938,898

Question: How much money has been spent on R&D by both the Department of Homeland Security’s Science and Technology Directorate and the Office of Health Affairs on the testing and evaluation of Gen-3?

Response: OHA does not have the authority to perform R&D for testing and evaluation of Gen-3 and has not spent any money on R&D related to the testing and evaluation of Gen-3. The OHA funds for testing and evaluation are separate from the funds spent by S&T on R&D testing and evaluation.

S&T has spent \$ 51,893,040 on Research and \$ 12,444,489 on T&E for Gen-3. S&T conducted research and development on a next-generation biodetector from 2004-2008. This program, known as the Bio-Agent Autonomous Networked Detector or BAND, focused on the development of a fully autonomous sampling and analysis instrument capable of detecting a large number of bio-agents (>20 agents) with a higher sensitivity and specificity and lower operating costs than the deployed BioWatch systems. The BAND units were never operationally deployed but the prototype from Microfluidics Systems Inc. (MFSI) was one of the two technologies evaluated for the Gen-3 acquisition. Overall, S&T spent \$145,935,768 on R&D and \$ 14,309,205 on T&E.

Question#:	5
Topic:	Gen-3
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Is the Department of Homeland Security still spending money on Gen-3? If so, how much?

Response: No money for Gen-3 was appropriated for FY13. However, there are ongoing activities, such as an Analysis of Alternatives (AoA) study that have been utilizing FY2012 funds. The AoA will include a comparison of the current operations technology, an autonomous identifier, health surveillance, and a sentinel system. The AoA will summarize benefits and capabilities, as well as cost benefit analysis for the alternatives. Of the \$20.42M provided for Gen-3 in FY2012, only \$4,437,681 has been obligated and the remaining funds are on hold.

Question: How much will it cost for workshops and the study to be conducted by the National Academies of Science on Gen-3?

Response: A public workshop was held by the National Academies of Science Standing Committee on Health Threats and Workforce Resilience on June 25-26, 2013 to explore alternative cost-effective systems that would meet requirements for BioWatch as an automated detection system for aerosolized agents. During this workshop, multiple classes of alternative technologies for autonomous detection were discussed. The final cost for this workshop was \$292,285.

An additional independent study written by an ad hoc committee is focused on determining appropriate standards for the validation and verification of polymerase chain reaction (PCR) tests and assays used in the laboratory. The results of this study will be relevant for all nucleic acid/PCR technology. The cost for this PCR Study is estimated at \$599,469.

Question#:	6
Topic:	certification
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Before making a certification on the science of Gen-3, will the Secretary of DHS rely on information from the study and report by the National Academies of Science that is to be conducted over the next year?

Response: The Department plans to use all available information, including the proceedings of the June workshop referenced in response to question 6 and the Analysis of Alternatives (AoA) as the future of an automated detection acquisition is discussed this fall.

Question#:	7
Topic:	comparison
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: How can an Analysis of Alternatives be done by this fall that includes a cost-benefit comparison between Generation 2 and Generation 3, when the Department of Homeland Security will not have Generation 2 data from Dugway Proving Ground until fall of this year?

Response: The assessment of the Current Operations Program (Gen-2) technology conducted at Dugway Proving Grounds (DPG) is solely intended to generate information regarding the sensitivity of the current collection technology and analytical processes. Gen-2 information has been shared with the AoA study team to compare with the proposed autonomous detection system (Gen-3), and therefore, there should be no need to wait for the DPG data to complete this effort. The costs of the Gen-2 Program have been tracked historically, and that information has also been provided for the AoA.

Question#:	8
Topic:	current plan
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Under the current plan for Gen-3, what is the concept of operations for confirming that a sample is actually a bio-threat once there is a BAR?

Response: Since there is no current Gen-3, there are no local response plans specific to an automated detection system that would be executed at the state or local level in response to a BAR. The decision-making process for what to do in response to a BAR would likely not change substantially from current practices, should the BioWatch program integrate autonomous detection technology; autonomous detection simply provides earlier warning to enable a faster response. It is important to note that guidance for any concept of operations for Gen-3 would be developed in partnership with the local responders in each jurisdiction where the system would be deployed. As a result, there will not be one single concept of operations for autonomous detection, because the guidance developed by BioWatch would be used by each jurisdiction to develop the appropriate response plans for its area of responsibility.

Question#:	9
Topic:	PSAA
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Does the Department of Homeland Security recommend the Public Safety Actionable Assay (PSAA) for Gen-3?

Response: As Generation 3 (Gen-3) is still in the acquisition phase and the performance and concept of operations of deployment has not yet been established, DHS has not formally recommended the PSAA standard for Gen-3 or any future acquisition. The BioWatch program is supportive of any standards that improve the accuracy of our detection capabilities, and DHS and its partners, including the CDC, will continue to review and update standards that can be applied to improve and enhance the specificity of biosecurity technologies.

Both the PSAA standard and Public Health Actionable Assay (PHAA) standard are sufficiently robust to support their respective intended uses though it is important to note that the two standards were developed for different purposes and are used in distinct ways.

The PSAA standard is intended to apply to technologies that would be used in the field by individuals with first responder training to accomplish the initial detection of a biological threat agent. Results from these technologies under this standard are intended to support “immediate” Public Safety Actions that include closure and evaluation of a facility or area, and decontamination of individuals. An additional sample of the suspect material would then be sent to a CDC LRN laboratory for confirmatory testing. The PSAA was developed by DHS S&T in collaboration with other Federal partners to support the commercial/private sector development of technologies and/or assays for use by First Responders and the private sector for screening of suspicious materials (environmental samples only) for biological threat agents.

The final verification test panel necessary for a BioWatch Actionable Result (BAR) to be declared is done using CDC LRN assays which use the Public Health Actionable Assay (PHAA) standard. Also developed by DHS S&T in collaboration with other Federal partners, PHAAs are required to have the specificity, sensitivity, and robustness to provide critical information on agent-specific detection to support public health actions and decisions such as initiating a national or local health alert warning, initiating a public health investigation, conducting risk assessments to support distribution of post exposure prophylaxis, and initiating public health risk communications.

Question: During his interview with Committee staff, a prior BioWatch program

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Topic:	PSAA
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

manager, Dr. Jeffrey Stiefel, said that he unequivocally supported the PHAA standard for Gen-3. He took the same position publicly when he was BioWatch program manager in 2005 in a lecture before the NIH. Why don't you agree with Dr. Stiefel?

Response: The BioWatch program is supportive of any standards that improve the accuracy of our detection capabilities. However, the PHAA standard referenced by Dr. Stiefel in 2005 is not the PHAA standard currently being proposed and utilized in certain LRN laboratories, which began development in 2008. DHS and its partners, including the CDC, will continue to review and update standards that can be applied to improve and enhance the specificity of biosecurity technologies.

Question: Why won't the Department of Homeland Security accept the Public Health Actionable Assay (PHAA) for Gen-3?

Response: The BioWatch program is supportive of any standards that improve the accuracy of our detection capabilities. As Gen-3 is still in the acquisition phase and the performance and concept of operations of deployment has not yet been established, it cannot be said that DHS will not accept the PHAA standard for Gen-3. DHS and its partners, including the CDC, will continue to review and update standards that can be applied to improve and enhance the specificity of biosecurity technologies.

Question: If the National Academies study recommends the PHAA standard, would that standard be too rigorous for Gen-3 to meet the requirements for certification by the Secretary?

Response: If the National Academies recommends the PHAA standard for any future acquisitions, the BioWatch Program would determine cost and schedule impacts in order to utilize PHAA and provide this information to DHS leadership.

Question: Which testing standard would give the public health community and the public the most confidence in Gen-3?

Response: Both the PSAA standard and PHAA standard are sufficiently robust to give the public health community and the public confidence in the BioWatch program, however, it is important to note that the two standards were developed for different purposes and are used in distinct ways.

Currently, the PSAA standard is intended to apply to technologies that would be used in the field by individuals with first responder training to accomplish the initial

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Topic:	PSAA
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Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

detection of a biological threat agent. Results from these technologies under this standard are intended to support “immediate” Public Safety Actions that include closure and evaluation of a facility or area, and decontamination of individuals. The final verification test panel necessary for a BioWatch Actionable Result (BAR) to be declared is done using CDC LRN assays which use the PHAA standard.

Therefore, the PHAA, as a verification of the initial results, gives public health officials more information, because the PSAA standard is an initial indicator meant to detect potential threats to public health. However, as Gen-3 is still in the acquisition phase and the performance and concept of operations of deployment has not yet been established, DHS has not recommended either standard for Gen-3 or any future acquisition.

Question: Do you believe that with a PSAA standard, you would need to have confirmatory testing?

Response: In BioWatch current operations, the results of PCR analysis always include initial screening and verification testing. In the event of a BAR, jurisdictional response plans would guide local public health officials in determining the appropriate response including, but not limited to, the decision to conduct additional testing.

Question#:	10
Topic:	drawbacks
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: What are the drawbacks for having a largely outdoor detection system?

Response: There are identified exposure vulnerabilities to the American public in indoor and outdoor venues, and detection systems are valuable for both outdoor and indoor applications. A largely outdoor detection system provides less capacity to cover vulnerable locations with a large concentration of people, i.e., high-throughput transportation nodes, such as mass transit systems and international airports. The largest of these indoor facilities accommodates the passage of several hundred thousand passengers per day, making them the highest density target where a bad actor could inflict the greatest amount of harm with the smallest amount of biological agent.

Question: What are the drawbacks for having a largely indoor detections system?

Response: There are identified exposure vulnerabilities to the American public in indoor and outdoor venues, and detection systems are valuable for both outdoor and indoor applications. While indoor detection systems enable early detection of an attack against our highest density targets (such as mass transit systems and international airports), it is unlikely that an indoor system will be able to detect a large outdoor attack without a significant passage of time.

Question: What are the advantages for an indoor detection system?

Response: An indoor detection system enables early detection of an attack against our highest density targets (such as mass transit systems and international airports). Indoor detection systems can help reduce the number of exposures by closing or limiting access to contaminated facilities.

Question: Are you aware that Dr. Stiefel favors only deploying Gen-3 indoors? Do you agree with this?

Response: Dr. Stiefel has stated that, with limited budget and resources, an automated system should be at a minimum deployed indoors. OHA, through the Analysis of Alternatives, continues to evaluate whether the indoor requires the same specifications as requirements in Gen3 for outdoor environments, or whether tailoring detectors to the indoor environment could result in more cost-efficient and cost-effective options.

Question#:	11
Topic:	President's directive
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Has DHS produced a strategic implementation plan in response to the President's directive last July when he released the National Strategy for Biosurveillance?

Response: The National Strategy for Biosurveillance included the Presidential Directive to complete a National Implementation Plan. Individual Departmental plans were not directed in the Strategy, but specific Departmental actions are likely to be part of the National Implementation Plan once it is finalized. The DHS Office of Health Affairs is involved in the interagency process led by the National Security Staff to write the National Implementation Plan. As active participants in the process, the National Biosurveillance Integration Center (NBIC) is also working to align implementation of its Strategic Plan to the National Implementation Plan. In the year since the NBIC Strategic Plan was finalized and released, the Center continues to undergo a transformation in its processes and products. Specifically, among a number of activities, NBIC is: 1) improving the data and analytics it uses for biosurveillance based on new capabilities developed in its Innovation Section; 2) conducting an independent stakeholder and customer analysis to identify ways to improve our operational products; and 3) preparing new processes and product lines for evaluation starting this fall. These and other activities form the core of NBIC's implementation actions following the Strategic Plan's release last year.

Question: If so, what are the projected costs of this plan?

Response: Since NBIC's mission in statute is to support and serve the Interagency regarding biosurveillance, we consider our contributions to the NSS in developing its plan as part of our staff responsibilities covered by base salaries and expenses. NBIC's Strategic Plan, which aligns with the National Implementation Plan, is designed to be successfully executed within our anticipated appropriated resources.

Question#:	12
Topic:	BioWatch cost
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Steve Scalise
Committee:	ENERGY & COMMERCE (HOUSE)

Question: How much money has been spent on BioWatch?

Response: Since formal transfer of the BioWatch program to the Office of Health Affairs in 2008 and as of July 31, 2013, \$566,129,697 was allocated and available for obligation, and \$547,432,959 has been obligated (“spent”) or committed (Purchase Request submitted to spend). These totals are for the entire BioWatch Program to include Current Operations (Gen-1/ 2), APDS (Gen-2.5), and Gen-3. The difference between what was available and what has been obligated is primarily the FY 2012 Gen-3 funds that the Program has put on hold.

In addition to OHA’s expenditures, S&T has spent a total of \$145,935,768 on research and development and \$ 14,309,205 on testing and evaluation.

Question#:	13
Topic:	update
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Gus M. Bilirakis
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Once the analysis of alternatives report comes out, please give us an update on any efforts to measure the cost-effectiveness of the BioWatch program.

Response: As part of the analysis of alternatives, OHA requested that a cost benefit analysis also be conducted. OHA expects to receive a draft report by the end of September 2013, which will be shared with Federal stakeholders for review and comment. These comments will be incorporated into the final report, which OHA expects to be completed this fall.